

THE STATE OF SOUTH CAROLINA
In The Supreme Court

APPEAL FROM SPARTANBURG COUNTY
Court of Common Pleas

Roger L. Couch, Circuit Court Judge

Case No. 2007-CP-42-1438

State of South Carolina ex. rel. Alan Wilson in his
capacity as Attorney General of the State of South
Carolina, ... Respondent,

v.

Ortho-McNeill-Janssen Pharmaceuticals, Inc., f/k/a
Janssen Pharmaceutica, Inc., and/or Janssen, L.P., and
Johnson & Johnson, Inc., ... Defendants.

Of whom Ortho-McNeill-Janssen Pharmaceuticals, Inc.
is Appellant.

RECORD ON APPEAL – VOLUME X

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Committee which has approved the protocol unless otherwise required and documented by the Ethics Committee.

If the subjects are not under 24-hour supervision of the investigator or his/her staff (out-patients, volunteers), they (or their designee, if appropriate) must be provided with a "trial card" indicating the name of the investigational product, the trial number, the investigator's name and a 24-hour emergency contact number.

7. TRIAL CLOSURE CONSIDERATIONS

The JRF reserves the right to close the investigational site or terminate the trial at any time.

Reasons for such action include, but are not limited to:

1. Safety concerns;
2. Sufficient data suggesting lack of efficacy;
3. Inadequate recruitment of subjects by the investigator;
4. The required number of subjects for the trial has been recruited;
5. Failure of the investigator to comply with the protocol, JRF procedures or Good Clinical Practice (GCP) guidelines.

8. TRIAL MATERIALS

8.A. Investigational drugs

The investigator acknowledges that the drug supplies are investigational and as such must be handled strictly in accordance with the protocol and the container label. Supplies must be retained in a safe, secure location and stored under the appropriate conditions as specified on delivery. Supplies should be dispensed under the supervision of the investigator or the assistant investigator, or by a hospital pharmacist.

It is the investigator's responsibility to ensure that subjects or those held to be responsible for subjects, return their medication. Returned supplies must not be dispensed again, even to the same subject. Unused medication and medication returned by the subject must be available for verification by the trial monitor.

8.B. Trial documents

The following documents must be provided to the Janssen Research Foundation:
a signed protocol and Trial Agreement;

the curriculum vitae of the investigator and all persons listed on the Trial Agreement;

1. a copy of the dated and signed approval notice from the ethics committee, clearly identifying the trial by title and number;
2. the names of the current members or composition of the ethics committee and their position in the health-care institution or their credentials;
3. a copy of the subject information and informed consent form approved by the ethics committee or institutional review board;
4. evidence of laboratory certification and institutional accreditation, if applicable;
5. a list of reference ranges and appropriate units for all laboratory tests to be performed at the institution, if applicable.

8.C. Case report forms

CRFs are provided for each subject. All forms must be filled in legibly in durable black ball-point pen.

All data relating to the trial must be recorded on CRFs prepared by the JRF. These CRFs are to be completed at the time of the subject's visit, with the exception of results of tests performed outside the investigator's office, so that they always reflect the latest observations on the subjects participating in the trial. Every effort should be made to ensure that all efficacy evaluations are completed by the same individual who made the initial baseline determinations. The investigator must verify that all data entries in the CRFs are accurate and correct. If certain information is not done, not available or not applicable, the investigator must enter "N.D." or "N.A.V." or "N.A.P.", respectively in the appropriate space.

During monitoring visits, the monitor will review the CRF, evaluate them for completeness and give back the forms with missing information and/or errors to the investigator for correction. All entries, corrections and alterations are to be made by the responsible investigator or his/her designee. Corrections must be made in such a way that the original entry is not obscured. Correction fluid must NOT be used. The correct data must be inserted, dated and initialed by the investigator or his/her designee.

A CRF must be completed and in the case of a CRF printed on No Carbon Required (NCR) paper, the original must be returned to the JRF. One copy is to be retained in the archives of the sponsor from the country in which the trial is performed. A second copy will be provided for the investigator's convenience.

8.D. Subject identification register

In order to permit easy identification of the individual subject during and after the trial, the Investigator is responsible for keeping an up-dated "Subject Identification Register".

This document will be reviewed by the monitor for completeness. However, in order to ensure subject confidentiality, no copy will be made.

8.E. Archiving

The investigator shall arrange for the retention of the Subject Identification Register for at least fifteen years after the Final Trial Report has been signed. All other documentation relating to this trial (source documents, informed consent forms, approvals) shall be kept for the maximum period of time permitted by the hospital, institution or private practice.

Under no circumstance shall the investigator re-locate or dispose of any trial documents before having obtained the Janssen Research Foundation's written approval.

If it becomes necessary for the JRF or the appropriate Regulatory Authority to review any documentation relating to this trial, the investigator must permit, with the approval of the subject, access to such reports.

Any difficulty in storing original documents must be discussed with the monitor prior to the initiation of the trial.

9. REPORTING AND PUBLICATION

Trial conduct and results will be described in a Clinical Trial Report, prepared according to the existing Standard Operating Procedures.

Publication of the results by the investigator must be subject to mutual agreement between the investigator and the JRF. Manuscripts and abstracts should be sent to the JRF at least one month prior to submission for publication or presentation.

10. ETHICS

10.A. Ethics Committee or institutional review board (IRB)

This trial will be undertaken only after full approval of the protocol and addenda has been obtained from the local Ethics Committee and a copy of the approval has been received by the JRF.

The Ethics Committee must be informed of all subsequent protocol amendments proposed by either the investigator or the JRF and should be asked for its opinion if a re-evaluation of the ethical aspects of the trial appears to be called for.

Reports on, and reviews of, the trial and its progress will be submitted to Ethics Committees or IRB by the investigator at intervals stipulated in their guidelines.

10.B. Declaration of Helsinki

This trial will be conducted in accordance with the current version of the Declaration of Helsinki.

10.C. Subject information and informed consent

Prior to entry in the trial, the investigator must explain to potential subjects or their legal representatives the aims, methods, reasonably anticipated benefits and potential hazards of the trial and any discomfort it may entail. Subjects will be informed that they are free not to participate in the trial and that they may withdraw consent to participate at any time. They will be told which alternative treatments are available if they refuse to take part and that such refusal will not prejudice future treatment. Finally, they will be told that their records may be examined by competent authorities and authorized persons but that personal information will be treated as strictly confidential and will not be publicly available. Subjects must be given the opportunity to ask questions. After this explanation and before entry to the trial, consent should be appropriately recorded by means of either the subject's or his/her legal representative's dated signature or the signature of an independent witness who certifies the subject's consent in writing.

If neither signed informed consent nor witnessed verbal consent can be obtained, the reason must be documented by the investigator.

11. REGULATORY APPROVAL

This trial must be submitted to the Regulatory Authority for approval under the requirement/scheme. The trial will only be undertaken following receipt by the JRF of (written) approval from the Regulatory Authority.

12. INDEMNITY INSURANCE

For subjects treated according to the protocol, injury possibly arising from the test treatment is covered by the Janssen product liability insurance.

13. MONITORING

The trial will be monitored according to the current JRF Standard Operating Procedure (SOP) for the Monitoring of Clinical Trials.

The trial monitor will meet with the investigator and all staff involved in the trial shortly before the trial starts to review the procedures to be followed in conducting it and recording the findings in the CRF. During the trial, the investigator shall permit the trial monitor to verify the progress of the trial on site as frequently as necessary. The investigator shall make the CRF available, provide missing or corrected data and sign the CRFs. Key data transcribed onto the CRFs, such as the subject's sex, date of birth, assessment dates, test results etc, will be reviewed against source documents. Personal information will be treated as strictly confidential and will not be publicly available. The CRF must be amended, after any inconsistencies found at this review have been resolved.

14. INSPECTION OF THE TRIAL

This trial may be reviewed by an independent QA department and/or regulatory authorities. This implies that auditors/inspectors will have the right to inspect the trial center(s) at any time during and/or after completion of the trial and will have access to source documents, including the subject's file. By participating in this trial, investigators agree to this requirement.

Measures will be undertaken to protect subject data handed over by the investigator to the JRF and to inspections against disclosure to unauthorized third parties and subject confidentiality will be maintained at all times.

15. INVESTIGATOR SIGNATURE PAGE

I have reviewed the above protocol (RIS-USA-113) and agree to execute the study as written.

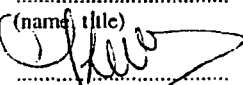
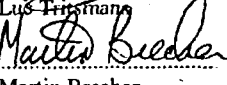
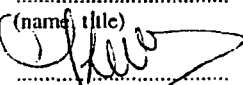
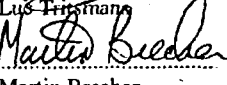
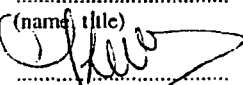
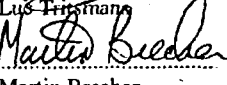
Signature of Primary Investigator

Date

Risperidone vs. Olanzapine RIS-USA-113

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JANSSEN RESEARCH FOUNDATION

International Clinical Research & Development															
CLINICAL TRIAL PROTOCOL AMENDMENT															
Number and final version date: 104-May, 1998	Drug number: R064766														
Trial number: RIS-USA-113	Clinical Phase: IV														
Title:	Risperidone vs. olanzapine in the treatment of schizophrenia														
Summary:	A multicenter, randomized, double blind, parallel group trial comparing the safety and efficacy of risperidone and olanzapine in the treatment of psychosis in patients with schizophrenia and schizoaffective disorder.														
Approvals:	March 5, 1997 #030597005														
Investigator:	<table border="0"> <tr> <td>(name, title)</td> <td>(date)</td> </tr> <tr> <td></td> <td>6/12/1998</td> </tr> <tr> <td>Development Project Leader: Janssen Research Foundation</td> <td>Philippe Lemmens (date)</td> </tr> <tr> <td></td> <td>Oct. 8, 1998</td> </tr> <tr> <td>Clinical Development Director: Janssen Research Foundation</td> <td>Luc Trisman (date)</td> </tr> <tr> <td></td> <td>6/18/98</td> </tr> <tr> <td>Clinical Research Director: Janssen Research Foundation</td> <td>Martin Brecher (date)</td> </tr> </table>	(name, title)	(date)		6/12/1998	Development Project Leader: Janssen Research Foundation	Philippe Lemmens (date)		Oct. 8, 1998	Clinical Development Director: Janssen Research Foundation	Luc Trisman (date)		6/18/98	Clinical Research Director: Janssen Research Foundation	Martin Brecher (date)
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This amendment has a minor impact on the original protocol and must be submitted to the Ethics Committee.															
This protocol amendment contains confidential information that should only be disclosed to those persons responsible for execution and organization of the trial and on condition that all such persons agree not to further disseminate it															

Clinical Trial Protocol Amendment I (final version, 4 May 1998) Janssen Research Foundation

PROTOCOL AMENDMENT

The protocol dated 19-Jun-1997 for the above trial will be amended as follows:

The following paragraph will be added to Section 3 (Assessments) of the protocol:

3.D.4. GENETIC TYPING OF DISEASE

For the genotyping amendment to the protocol the subject will be requested to donate an additional amount of blood (5-10 ml) from which DNA will be extracted. Blood samples will be taken from those subjects who did not donate a sample in RIS-USA-112 and wish to do so or from those subjects who did donate a sample in RIS-USA-112, but the sample was either inadequate or damaged. This sample will be taken only once during the trial and may be taken in conjunction with the other scheduled laboratory samples.

A 5-10 ml blood sample has to be obtained in a separate EDTA coated vacutainer tube. The tube should be mixed gently approximately 10-15 times in order to prevent coagulation of the blood. The sample will then be transferred into a plastic screw top vial. The vial will be labeled with the trial identification number and the CRF number of the subject. Tubes, vials and labels will be provided by the central laboratory, SBCL. Within 8 hours after sampling, the vial should be frozen at -20 C to -80 C (spinning or any other manipulation is not necessary). Repeated freezing and thawing should absolutely be avoided.

The vials will remain in the frozen storage at the site until every subject who gave consent for genotyping is sampled. A courier service will pick up the samples for transport to Janssen facilities. Site personnel will be notified at least 1 week in advance when the samples will be picked up.

Subjects must give their separate informed consent to the collection, storage and possible analysis of these samples. Subjects may still enter or continue the trial without giving their informed consent for this procedure.

The following will be added to Section 5 as addendum 2:

Rationale for taking DNA samples in trial RIS-USA-113.

Family, adoption, and twin studies suggest a significant genetic component in the etiology of schizophrenia (Gottesman and Shields, 1982). The heritability of schizophrenia has been estimated at 71% (Rao et al., 1981). Both the nature and the magnitude of the results have been reproduced and are robust to re-evaluation with newer, more powerful analytical methodologies. On the other hand, the precise mode of inheritance, as well as the nature of the genetic factors involved, are unknown. It becomes clear that monogenic forms of inheritance may not explain the observed familial aggregation adequately, and a polygenic/multifactorial threshold model becomes more and more accepted. As a result, it is the combination of genetic and environmental factors which are important in the etiology of schizophrenia. Furthermore, although the clinical efficacy of a number of antipsychotic drugs for patients with schizophrenia are well established, a significant minority of patients fail to respond satisfactorily (Kolakowska et al., 1995). The factors associated with inadequate response are unclear and might be genetic (Csernansky et al., 1985).

Clinical Trial Protocol Amendment 1 (final version, 04-May, 1998) Janssen Research Foundation

Risperidone vs Olanzapine RIS-USA-113

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Several investigators are currently trying to map, clone and identify the predisposing genes and the genes which are modulating drug response. A large number of attractive candidate genes implicated in several neurotransmitter systems are currently investigated for their involvement in schizophrenia. For example, it has been hypothesized that variations in the genes coding for dopamine and serotonin receptors and transporters are associated with schizophrenia (Crocq et al., 1992, Williams et al., 1996). It was also reported that in case-control studies, association to the dopamine D3 receptor is mainly limited to patients demonstrating a positive clinical response to antipsychotic drugs (Owen et al., 1993, Nimgaonkar et al., 1996a). Similarly, association as well as treatment refractoriness at the 5-HT₂ locus have been reported (Arranz et al., 1995, Nimgaonkar et al., 1996b, Williams et al., 1996). These results are currently waiting for further replication and confirmation.

Usually case-control association studies are used to identify disease susceptibility genes for complex genetic disorders (Cooper and Clayton, 1988). However, these studies are seriously influenced by population stratification and thus the selection of properly matched control populations is indispensable. An alternative to case-control association studies is the haplotype relative risk method (HRR) (Terwilliger and Ott, 1992). In HRR, the non-segregating alleles from the patients' parents are used as internal control alleles, leaving out the necessity to sample an ethnically matched control population.

There are two roles that DNA testing play in trial RIS-USA-113, a study will be set up to study drug response, and separately, we will be searching for disease causing markers. Firstly, DNA samples from subjects are necessary to identify variations in the genes involved in neurotransmission which affect treatment response to risperdal. Efficacy data may be analyzed according to genotype to determine whether genetically-defined subgroups may respond differentially to drug treatment. Secondly, to follow up and identify the relevance of variations in the etiology of the disorder, we need to compare the frequency distribution of these variants in a patient and a control population. If successful, both approaches could allow for greater future prognostic or diagnostic accuracy: the presence of specific marker alleles could be used as an inclusion criterion, allowing the conduct of clinical trials in more homogeneous populations, or as a stratification factor. Secondly, identification of new predisposing genes would enlarge the number of drug development targets.

There are a number of ethical issues associated with DNA testing: in the context of prospective use in clinical trials, all subjects must give informed consent. Subjects retain the right to withdraw consent at all times, without jeopardizing participation in the trial. As a result, the subject is the "owner" of the sample. If the donor wishes to withdraw, his/her sample will be taken out of the study and destroyed.

The expected results will only be relevant on a statistical basis. Together with the concern that communication of data from early research may cause subjects to take inappropriate actions or have psychological ramifications that may result in harm to the subjects, results on an individual basis, will not be forwarded to either the patient or his/her relatives.

The blood for DNA extraction will completely and only be used for this purpose, no cells or other derivatives will be stored from this sample. The DNA samples will be prepared at BARC, the genetic tests will be performed at the Laboratory for Molecular Genetics at the Janssen Pharmaceutica Headquarters in Beerse (Belgium). The DNA samples will be used for research only in the context of the disease under study. Samples will only be taken in trials of adults.

The confidentiality of the donor subject is safeguarded similarly as the subject's clinical history and personal information in the trials. The DNA samples will be coded by the laboratory which receives the blood samples. This will be the central lab (BARC in this trial), which will also carry out all biochemical analyses. The DNA laboratory at Janssen Pharmaceutica Headquarters will genotype all samples blindly, but triplets of subjects will be grouped to facilitate data reading. As a result the DNA genotyping laboratory (which is

Clinical Trial Protocol Amendment I (final version, 04-May, 1998) Janssen Research Foundation

Risperidone vs Olanzapine RIS-USA-113

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different from the laboratory which receives the blood sample) will never have access to sensitive personal information, like names, addresses, etc. Statistical analysis of genotype vs. drug response will be performed together with and similarly to the efficacy and statistical analyses.

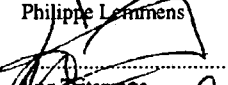
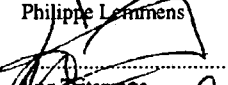
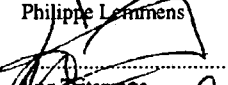
References.

- Arranz et al., *Psychiatric Genetics*, 5, 45 (1995).
Csernansky et al., *Journal of Nervous and Mental Diseases*, 173, 299-312 (1985).
Croq et al., *Journal of Medical Genetics*, 29, 858-860 (1992).
Gottesman and Shields, "Schizophrenia, the epigenic puzzle". Cambridge University Press, pp. 209-233.
Kolakowska et al., *British Journal of Psychiatry*, 146, 229-239 (1985).
Nimgaonkar et al., *Psychiatric Genetics*, 6, 23-27 (1996b).
Nimgaonkar et al., *American Journal of Medical Genetics (Neuropsychiatric Genetics)* 67:505-514 (1996a).
Owen et al., *Journal of Medical Genetics*, 33, 396-406 (1993).
Rao et al., *American Journal of Human Genetics*, 33, 396-406 (1981).
Terwilliger and Ott, *Human Heredity*, 42, 337-346 (1992).
Williams et al., *Lancet* 347:1294-6 (1996).

Clinical Trial Protocol Amendment I (final version, 04-May, 1998) Janssen Research Foundation

Risperidone vs. Olanzapine – Ris-USA-113

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JANSSEN RESEARCH FOUNDATION																						
International Clinical Research & Development																						
CLINICAL TRIAL PROTOCOL AMENDMENT																						
Number and final version date: II 22 May, 1998	Drug number: R064766																					
Trial number: RIS-USA-113	Clinical Phase: IV																					
Title: Risperidone vs. olanzapine in the treatment of schizophrenia																						
Summary: A multicenter, randomized, double blind, parallel group trial comparing the safety and efficacy of risperidone and olanzapine in the treatment of psychosis in patients with schizophrenia and schizoaffective disorder. The trial duration is 44 weeks.																						
Approvals: March 5, 1997 #030597005																						
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Clinical Trial Protocol Amendment II (final version, 22 May 1998) Janssen Research Foundation

Risperidone vs. Olanzapine – Ris-USA-113

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PROTOCOL AMENDMENT

The protocol dated 19-Jun-1998 for the above trial will be amended as follows:

The adverse event section, section 6 will be replaced by the following :

PART II: PROCEDURES

6.A ADVERSE EVENTS

6.A.1 DEFINITIONS

6.A.1.a Adverse event (AE)

Any untoward medical occurrence in a subject or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product (International Conference on Harmonisation ICH).

6.A.1.b Serious adverse event

Any untoward medical occurrence that at any dose:

- results in death
- is life-threatening
- requires inpatient hospitalisation or prolongation of existing hospitalisation,
- results in persistent or significant disability/incapacity,
- or
- is a congenital anomaly/birth defect (ICH).

Due to current reporting requirements in some countries, malignancies and adverse events that result from overdose will also be considered Serious Adverse Events.

Note: Medical and scientific judgement should be exercised in deciding whether expedited reporting is appropriate in other situations, such as important medical events that may not be immediately life-threatening or result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one of the outcomes listed in the definition above.

6.A.1.c Unlisted (Unexpected) adverse event

An adverse event, the nature or severity of which is not consistent with the applicable product information (e.g., Investigator's Brochure for an unapproved investigational product or package insert/summary of product characteristics for an approved product (ICH)).

Clinical Trial Protocol Amendment II (final version, 22 May 1998) Janssen Research Foundation

Risperidone vs. Olanzapine – Ris-USA-113

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6.A.1.d Life-Threatening

Any event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

6.A.1.e Associated with the use of the drug

An adverse event is considered associated with the use of the drug if the attribution is possible, probable or very likely.

Attribution definitions

Not related

An adverse event which is not related to the use of the drug.

Doubtful

An adverse event for which an alternative explanation is more likely - e.g. concomitant drug(s), concomitant disease(s), and/or the relationship in time suggests that a causal relationship is unlikely.

Possible

An adverse event which might be due to the use of the drug. An alternative explanation - e.g. concomitant drug(s), concomitant disease(s), - is inconclusive. The relationship in time is reasonable; therefore the causal relationship cannot be excluded.

Probable

An adverse event which might be due to the use of the drug. The relationship in time is suggestive (e.g. confirmed by dechallenge). An alternative explanation is less likely - e.g. concomitant drug(s), concomitant disease(s).

Very likely

An adverse event which is listed as a possible adverse reaction and cannot be reasonably explained by an alternative explanation - e.g. concomitant drug(s), concomitant disease(s). The relationship in time is very suggestive (e.g. it is confirmed by dechallenge and rechallenge).

6.A.2 REPORTING OF ADVERSE EVENTS

Adverse events will be reported between the first and the last dose administration of trial medication.

Medical events that occur between signing of the Informed Consent and the first intake of trial medication will be documented on the medical and surgical history page and concomitant diseases page of the CRF.

SAEs occurring within a period of 30 days following the last intake of trial medication will also be handled as such by JRF if spontaneously reported by the investigator.

The cause of death of a subject in a clinical trial, whether the event is expected or associated with the investigational agent, is an SAE.

Clinical Trial Protocol Amendment II (final version, 22 May 1998) Janssen Research Foundation

Risperidone vs. Olanzapine – Ris-USA-113

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All serious adverse events (SAE) and pregnancies occurring during clinical trials must be reported within one working day to:

Trial monitor:

Jodie Block

Project Manager

IRI

Rt. 22E

Annandale, NJ

908-730-1864

The first report of a serious adverse event may be made by telephone or facsimile (FAX). The investigator must provide the minimal information : i.e. trial number, subject's initials and date of birth, medication code number, period of intake, nature of the adverse event and investigator's attribution.

This report of a serious adverse event by telephone must always be confirmed by a written, more detailed report. For this purpose, the JRF contact person will provide the investigator with a Serious Adverse Event Form for Clinical Trials, to be completed and signed by the latter.

Pregnancies occurring during clinical trials are considered immediately reportable events. They must be reported as soon as possible using the same Serious Adverse Event Form for Clinical Trials. The outcome of the pregnancy must also be reported to the JRF.

The JRF will assume responsibility for appropriate reporting of adverse events to the authorities. The JRF will also report all serious adverse events that are unlisted and associated with the use of the drug to the investigators. It is the investigator's responsibility to report the adverse events which are classified by the JRF as serious, unlisted and associated with the use of the drug to the Independent Ethics Committee / Institutional Review Board (IEC/IRB) which has approved the protocol unless otherwise required and documented by the IEC/IRB.

Appendix 1.2

Sample Case Report Form



case report form

7/31

35113CCV

Risperidone vs. olanzapine in the treatment of schizophrenia.

RIS-USA-113

CRF ID

Risperidone vs olanzapine
RIS-USA-113

CRF ID

38113CCV
16901 7/31

Flow chart

	Entry ¹	Treatment period										
Visit ²	1	2	3	4	5	6	7	8	9	10	11	12 ⁵
Day	1	28	56	84	112	140	168	196	224	252	280	308
Week	0	4	8	12	16	20	24	28	32	36	40	44
Month	0	1	2	3	4	5	6	7	8	9	10	11
Informed consent	X											
Physical examination	X											X ⁵
Vital signs	X	X	X	X				X				X ⁵
Electrocardiogram	X											X ⁵
Lab	X ⁴	X ³	X ³	X ³				X ³				X ⁵
Prolactin	X							X				X ⁵
Body weight	X	X	X	X				X				X ⁵
Waist/Hip ratio				X				X				X ⁵
HAMD	X											X ⁵
ESRS	X	X	X	X				X				X ⁵
PANSS	X	X	X	X		X		X				X ⁵
CGI/CGI-C	X	X	X	X				X				X
Cognitive tests	X			X				X				X
Modified SIP	X			X				X				X
B-QoL	X			X				X				X
PRSQ	X			X				X				X
Quality of sleep	X	X	X	X				X				X
Daytime drowsiness		X	X	X				X				X
ACS	X	X	X	X				X				X
DAI	X			X				X				X
Concomitant therapy	X	X	X	X	X	X	X	X	X	X	X	X
Adverse events	X	X	X	X	X	X	X	X	X	X	X	X
Dispense medication	X	X	X	X	X	X	X	X	X	X	X	
Return medication		X	X	X	X	X	X	X	X	X	X	X

¹ The evaluations from Week 8 of RIS-USA-112 will be used for entry into RIS-USA-113.² Visits may be conducted within ± 3 days on either side of the scheduled assessment date.³ Liver transaminases only (AST, ALT, GGT)⁴ Includes cholesterol, lipid profile (HDL, LDL, triglycerides), thyroid panel (T₃, T₄ and TSH), HbA1c and CPK.⁵ Visit 12 and/or endpoint.⁶ Both CGI and the CGI-C will be evaluated at every visit. The CGI-C will be compared to the severity of illness at the randomization visit of the proceeding trial (RIS-USA-112).

Case Report Form (5 Nov 97)

Janssen Research Foundation

 Subject's initials 	 Site number 	 Randomization date m d y	 Medication number
Main investigator's name (first initial of first name + last name) 			
Location of centre (city - town) 			

7/31

38113CV1

Randomization Visit 1

The following assessments must be done on all subjects

- Obtain informed consent
- Check the inclusion and exclusion criteria
- Check concomitant therapy and complete the Concomitant therapy form
- Please call the Randomization Office. Follow the instructions. Insert the return-fax confirming the medication number in the source document

Please note:

- Any concomitant therapy continued at entry to the trial must be listed
- Anticholinergics and benzodiazepines must be recorded on a separate Concomitant therapy form
- Please insert one ply from each completed page of RIS-USA-112 Visit 9 into this visit

Risperidone vs olanzapine
RIS-USA-113

CRF ID

Date

m	d	y

RANDOMIZATION

VISIT 1

Inclusion / Exclusion criteria

Inclusion criteria

No

Yes

Does the subject meet each of the following inclusion criteria (check no or yes):

1. Subjects who continue to meet all of the inclusion criteria defined for RIS-USA-112 are eligible for this trial with the exception of age (subjects who were 64 years old upon entry into RIS-USA-112 may enter this study if they had turned 65 during the proceeding study). ☐ ☐
2. Subjects who have completed the proceeding study, RIS-USA-112, in its entirety. ☐ ☐
3. Diagnosis of schizophrenia or schizoaffective disorder (DSM-IV). ☐ ☐
4. Inpatients or outpatients. ☐ ☐
5. Subject and/or legal guardian or representative has signed the informed consent form. ☐ ☐

If the answer to any of the above is NO, do not enroll the subject.

Exclusion criteria

No

Yes

Does the subject meet any of the following exclusion criteria (check no or yes):

1. Subjects who have experienced a hypersensitivity reaction or suspected hypersensitivity reaction to the trial medication administered in RIS-USA-112. ☐ ☐
2. Subjects experiencing extrapyramidal symptoms (EPS) not adequately controlled with medication. ☐ ☐
3. The subject did not complete RIS-USA-112. ☐ ☐
4. A time lapse of more than 3 days since the completion of RIS-USA-112. ☐ ☐
5. A DSM-IV Axis I diagnosis other than schizophrenia or schizoaffective disorder (subjects with concurrent post-traumatic stress disorder which does not account for the subject's psychotic symptoms, in the opinion of the investigator, can be enrolled). ☐ ☐
6. A DSM-IV diagnosis of substance abuse or dependence within 3 months prior to selection (nicotine and caffeine dependence are not exclusionary). ☐ ☐

*If the answer to any of the above questions or the questions on the next page is YES, do not enroll the subject.*Case Report Form (5 Nov 97)
Janssen Research Foundation

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

RANDOMIZATION

VISIT 1

7/01

38113CV1

Inclusion / Exclusion criteria (continued)

Exclusion criteria (continued)

No

Yes

Does the subject meet any of the following exclusion criteria (check no or yes):

7. Documented disease of the central nervous system including, but not limited to stroke, tumor, Parkinson's disease, Alzheimer's disease, Huntington's disease, seizure disorder requiring anti-convulsants, history of brain trauma resulting in documented cognitive impairment, chronic infection or neurosyphilis. ☐ ☐
8. Hepatic, renal or gastrointestinal disease of sufficient degree to interfere with the excretion, absorption and/or metabolism of trial medication. Subjects with clinical signs of liver disease should be excluded from the study. ☐ ☐
9. Acute (e.g. infection), unstable (e.g. labile hypertension, unstable angina), significant or untreated medical illness; patients with diastolic blood pressure ≥ 95 mmHg at screening should be treated and stabilized before randomization. ☐ ☐
10. Patients with clinical signs of liver disease, should be excluded. ☐ ☐
11. Subjects with narrow angle glaucoma, chronic urinary retention and/or clinically significant prostatic hypertrophy, paralytic ileus or related conditions, which in the opinion of the investigator may be exacerbated by the anticholinergic effects of olanzapine. ☐ ☐
12. Pregnant or breast-feeding females. ☐ ☐
13. Female subjects of childbearing potential without adequate contraception. Adequate contraception includes: abstinence, oral contraceptives, intrauterine devices, barrier (diaphragm or condom) plus spermicide, Norplant™ or Depo Provera™. ☐ ☐
14. Use of disallowed concomitant therapy (see section 3.C.3. of protocol). ☐ ☐
15. Treatment with antidepressants within 28 days prior to screen. ☐ ☐
16. History of treatment with clozapine for more than 4 consecutive weeks. ☐ ☐
17. Treatment with clozapine within 28 days prior to screen. ☐ ☐
18. Participation in an investigational drug trial in the 28 days prior to the screening visit. ☐ ☐
19. History of severe drug allergy or hypersensitivity. ☐ ☐
20. Known sensitivity to risperidone or olanzapine. ☐ ☐
21. Subjects known to be unresponsive to either risperidone or olanzapine in the opinion of the investigator. ☐ ☐
22. History of neuroleptic malignant syndrome. ☐ ☐

*If the answer to any of the above is YES, do not enroll the subject.*Case Report Form (5 Nov 97)
Janssen Research Foundation

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

RANDOMIZATION

VISIT 1

Subject randomization

Please complete the items below.

Date of birth

m	d	y		

Medication number
from RIS-USA-112

Medication number
for RIS-USA-113

52

38113CV2

Week 4 Visit 2

- Record vital signs (including body weight)
- Take blood samples for liver transaminase levels
- Complete the ESRS
- Complete the PANSS
- Complete the CGI/CGI-C
- Have subject complete the visual analogue scales for quality of sleep and daytime drowsiness
- Complete ACS
- Check for (changes in) concomitant therapy and complete (if applicable) the Concomitant therapy form
- Check for (changes in) adverse events and complete (if applicable) the Adverse event form

Trial medication

Dispense the trial medication and give instruction on its use. Administration is done once daily, preferably in the morning, according to the described dosing schedule. Mark the date and the dose of the first intake on the Administration of trial medication form. If there is a change in dosing (or time of administration), please mark the new date and dose on the Administration of trial medication form.

Concomitant therapy

If the subject has had a change in concomitant therapy the new dose schedule or concomitant therapy should be recorded on the Concomitant therapy form.

Please note that anticholinergics and benzodiazepines must be recorded on a separate concomitant therapy form.

Adverse events

If the subject has had any undesirable experience during the trial (whether or not considered related to the trial medication) the events should be recorded on the Adverse event form.

Anticholinergics

If extrapyramidal symptoms emerge or worsen during the double-blind period, an additional ESRS should be performed. Following completion of this ESRS, the dose of trial medication should be reduced. If the symptoms do not resolve, anticholinergic medication may be initiated. At each subsequent scheduled visit the need for continuation of anticholinergic medication should be evaluated. Please make sure that the date of completion has been recorded on the top of the first page of the ESRS.

Risperidone vs olanzapine
RIS-USA-113

CRF ID

Date

m	d	y	

WEEK 4

VISIT 2

7/31

38113C/2

Vital signs

Position

Pulse
beats/minuteBlood pressure (mmHg)
systolic/diastolic

Supine, after 5 minutes rest

		/		

Standing, after 1 minute rest

		/		

Weight

lb

Laboratory data

Sampling

Sample date

m	d	y	

Sample reference of the laboratory

Risperidone vs olanzapine
RIS-USA-113

CRF ID

WEEK 4

VISIT 2

7/01

38113072

Extrapyramidal symptom rating scale (ESRS)**Questionnaire and Behavioural Scale**

Check the appropriate box for each item.

I Parkinsonism, Dystonia and Dyskinesia	Absent	Mild	Moderate	Severe
1. Impairment of slowness or weakness, difficulty in carrying out routine tasks	☐	☐	☐	☐
2. Difficulty walking or with balance	☐	☐	☐	☐
3. Difficulty swallowing or talking	☐	☐	☐	☐
4. Stiffness, stiff posture	☐	☐	☐	☐
5. Cramps or pains in limbs, back or neck	☐	☐	☐	☐
6. Restless, nervous, unable to keep still	☐	☐	☐	☐
7. Tremors, shaking	☐	☐	☐	☐
8. Oculogyric crisis, abnormal sustained posture	☐	☐	☐	☐
9. Increased salivation	☐	☐	☐	☐
10. Abnormal involuntary movements (dyskinesia) of extremities or trunk	☐	☐	☐	☐
11. Abnormal involuntary movements (dyskinesia) of tongue, jaw, lips or face	☐	☐	☐	☐
12. Dizziness when standing up (especially in the morning)	☐	☐	☐	☐

Case Report Form (5 Nov 97)
Janssen Research Foundation

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

WEEK 4

VISIT 2

7/31
3811302**Extrapyramidal symptom rating scale (ESRS) (continued)****Physician's examination**

Enter the appropriate score for each item.

II Parkinsonism	Score	Explanation
1. Expressive automatic movements (facial mask/speech)		0 normal 1 very mild decrease in facial expressiveness 2 mild decrease in facial expressiveness 3 rare spontaneous smile, decreased blinking, voice slightly monotonous 4 no spontaneous smile, staring gaze, low monotonous speech, mumbling 5 marked facial mask, unable to frown, slurred speech 6 extremely severe facial mask with unintelligible speech
2. Bradykinesia		0 normal 1 global impression of slowness in movements 2 definite slowness in movements 3 very mild difficulty in initiating movements 4 mild to moderate difficulty in initiating movements 5 difficulty in starting or stopping any movement, or freezing on initiating voluntary act 6 rare voluntary movement, almost completely immobile
3. Rigidity	right arm left arm right leg left leg	0 normal muscle tone 1 very mild, barely perceptible 2 mild (some resistance to passive movements) 3 moderate (definite resistance to passive movements) 4 moderately severe (moderate resistance but still easy to move the limb) 5 severe (marked resistance with definite difficulty to move the limb) 6 extremely severe (nearly frozen)
4. Gait and Posture		0 normal 1 mild decrease of pendular arm movement 2 moderate decrease of pendular arm movement, normal steps 3 no pendular arm movement, head flexed, steps more or less normal 4 stiff posture (neck, back), small step (shuffling gait) 5 more marked, festination or freezing on turning 6 triple flexion, barely able to walk

Case Report Form (5 Nov 97)
Janssen Research Foundation

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

WEEK 4

VISIT 2

7/31
38113CZ

Extrapyramidal symptom rating scale (ESRS) (continued)

Enter the appropriate score for each item.

II Parkinsonism - Physician's examination	Score	Explanation
5. Tremor		
right arm	☐	
left arm	☐	None 0
right leg	☐	Borderline 1
left leg	☐	Small amplitude 2 3 4
head	☐	Moderate amplitude 3 4 5
jaw/chin	☐	Large amplitude 4 5 6
tongue	☐	
lips	☐	
6. Akathisia	☐	0 none 1 looks restless, nervous, impatient, uncomfortable 2 needs to move at least one extremity 3 often needs to move one extremity or to change position 4 moves one extremity almost constantly if sitting, or stamps feet while standing 5 unable to sit down for more than a short period of time 6 moves or walks constantly
7. Sialorrhea	☐	0 absent 1 very mild 2 mild 3 moderate: impairs speech 4 moderately severe 5 severe 6 extremely severe: drooling
8. Postural stability	☐	0 normal 1 hesitation when pushed but no retropulsion 2 retropulsion but recovers unaided 3 exaggerated retropulsion without falling 4 absence of postural response, would fall if not caught by examiner 5 unstable while standing, even without pushing 6 unable to stand without assistance

Case Report Form (5 Nov 97)
Janssen Research Foundation

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

WEEK 4

VISIT 2

7/31
38113CV2**Extrapyramidal symptom rating scale (ESRS) (continued)***Enter the appropriate score for each item.***III Dystonia - Physician's examination**

1. Acute torsion dystonia	Score	Explanation		Score	Explanation
right arm	☐	0 absent	jaw	☐	0 absent
		1 very mild			1 very mild
left arm	☐	2 mild	tongue	☐	2 mild
		3 moderate			3 moderate
right leg	☐	4 moderately severe	lips	☐	4 moderately severe
		5 severe			5 severe
left leg	☐	6 extremely severe	eyes	☐	6 extremely severe
head	☐		trunk	☐	
2. Non-acute or chronic or tardive dystonia	Score	Explanation		Score	Explanation
right arm	☐	0 absent	jaw	☐	0 absent
		1 very mild			1 very mild
left arm	☐	2 mild	tongue	☐	2 mild
		3 moderate			3 moderate
right leg	☐	4 moderately severe	lips	☐	4 moderately severe
		5 severe			5 severe
left leg	☐	6 extremely severe	face	☐	6 extremely severe
head	☐		trunk	☐	

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Janssen Research Foundation

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

WEEK 4

VISIT 2

7/31

38113072

Extrapyramidal symptom rating scale (ESRS) (continued)*Enter the appropriate score for each item.*

IV Dyskinetic movements Physician's examination	Score	Explanation	Occasional	Frequent	Constant or almost so
1. Lingual movements Slow lateral or torsion movement of tongue		None Borderline Clearly present, within oral cavity With occasional partial protrusion With complete protrusion	0 1 2 3 4	3 4 5	4 5 6
2. Jaw movements Lateral movement, chewing, biting, clenching		None Borderline Clearly present, small amplitude Moderate amplitude, but without mouth opening Large amplitude, with mouth opening	0 1 2 3 4	3 4 5	4 5 6
3. Bucco-labial movements Puckering, pouting, smacking, etc...		None Borderline Clearly present, small amplitude Moderate amplitude, forward movement of lips Large amplitude, marked, noisy smacking of lips	0 1 2 3 4	3 4 5	4 5 6
4. Truncal movements Rocking, twisting, pelvic gyrations		None Borderline Clearly present, small amplitude Moderate amplitude Greater amplitude	0 1 2 3 4	3 4 5	4 5 6
5. Upper extremities Choreoathetoid movements only: arms, wrists, hands, fingers		None Borderline Clearly present, small amplitude, movement of one limb Moderate amplitude, movement of one limb or movement of small amplitude involving two limbs Greater amplitude, movement involving two limbs	0 1 2 3 4	3 4 5	4 5 6
6. Lower extremities Choreoathetoid movements only: legs, knees, ankles, toes		None Borderline Clearly present, small amplitude, movement of one limb Moderate amplitude, movement of one limb or movement of small amplitude involving two limbs Greater amplitude, movement involving two limbs	0 1 2 3 4	3 4 5	4 5 6
7. Other involuntary movements Swallowing, irregular respiration, frowning, blinking, grimacing, sighing, etc...		None Borderline Clearly present, small amplitude Moderate amplitude Greater amplitude	0 1 2 3 4	3 4 5	4 5 6

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

WEEK 4

VISIT 2

7/31	Extrapyramidal symptom rating scale (ESRS) (continued)
38113CV2	V Clinical global impression of severity of Parkinsonism
	<i>Considering your clinical experience, how severe is the parkinsonism at this time?</i>
	☐ absent
	☐ borderline
	☐ very mild
	☐ mild
	☐ moderate
	☐ moderately severe
	☐ marked
	☐ severe
	☐ extremely severe
	VI Clinical global impression of severity of Dystonia
	<i>Considering your clinical experience, how severe is the dystonia at this time?</i>
	☐ absent
	☐ borderline
	☐ very mild
	☐ mild
	☐ moderate
	☐ moderately severe
	☐ marked
	☐ severe
	☐ extremely severe

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

WEEK 4

VISIT 2

7/31	Extrapyramidal symptom rating scale (ESRS) (continued)
3811302	VII Clinical global impression of severity of Dyskinesia
	<i>Considering your clinical experience, how severe is the dyskinesia at this time?</i>
	☐ absent
	☐ borderline
	☐ very mild
	☐ mild
	☐ moderate
	☐ moderately severe
	☐ marked
	☐ severe
	☐ extremely severe
	VIII Stage of Parkinsonism (Hoehn & Yahr)
	☐ absent
	☐ unilateral involvement only, minimal or no functional impairment (stage I)
	☐ bilateral or midline involvement, without impairment of balance (stage II)
	☐ mild to moderate disabling: first signs of impaired righting or postural reflex (unsteadiness as the subject turns or when he is pushed from standing equilibrium with the feet together and eyes closed), subject is physically capable of leading independent life (stage III)
	☐ severely disabling: subject is still able to walk and stand unassisted but is markedly incapacitated (stage IV)
	☐ confinement to bed or wheelchair (stage V)

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

WEEK 4

VISIT 2

Positive and negative syndrome scale for schizophrenia (PANSS)*Enter the appropriate score for each item, refer to the Rating Manual for item definitions, description of anchoring points and scoring procedure.*

	Absent 1	Minimal 2	Mild 3	Moderate 4	Moderate severe 5	Severe 6	Extreme 7
1) Positive subscale							
P1 Delusions	☐	☐	☐	☐	☐	☐	☐
P2 Conceptual disorganization	☐	☐	☐	☐	☐	☐	☐
P3 Hallucinatory behavior	☐	☐	☐	☐	☐	☐	☐
P4 Excitement	☐	☐	☐	☐	☐	☐	☐
P5 Grandiosity	☐	☐	☐	☐	☐	☐	☐
P6 Suspiciousness/persecution	☐	☐	☐	☐	☐	☐	☐
P7 Hostility	☐	☐	☐	☐	☐	☐	☐
2) Negative subscale	1	2	3	4	5	6	7
N1 Blunted affect	☐	☐	☐	☐	☐	☐	☐
N2 Emotional withdrawal	☐	☐	☐	☐	☐	☐	☐
N3 Poor rapport	☐	☐	☐	☐	☐	☐	☐
N4 Passive/apathetic social withdrawal	☐	☐	☐	☐	☐	☐	☐
N5 Difficulty in abstract thinking	☐	☐	☐	☐	☐	☐	☐
N6 Lack of spontaneity and flow of conversation	☐	☐	☐	☐	☐	☐	☐
N7 Stereotyped thinking	☐	☐	☐	☐	☐	☐	☐

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Janssen Research Foundation

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

WEEK 4

VISIT 2

7/31
381130V2**Positive and negative syndrome scale for schizophrenia (PANSS)
(continued)***Enter the appropriate score for each item, refer to the Rating Manual for item definitions, description of anchoring points and scoring procedure.*

	Absent 1	Minimal 2	Mild 3	Moderate 4	Moderate severe 5	Severe 6	Extreme 7
3) General psychopathology subscale							
G1 Somatic concern	☐	☐	☐	☐	☐	☐	☐
G2 Anxiety	☐	☐	☐	☐	☐	☐	☐
G3 Guilt feelings	☐	☐	☐	☐	☐	☐	☐
G4 Tension	☐	☐	☐	☐	☐	☐	☐
G5 Mannerisms and posturing	☐	☐	☐	☐	☐	☐	☐
G6 Depression	☐	☐	☐	☐	☐	☐	☐
G7 Motor retardation	☐	☐	☐	☐	☐	☐	☐
G8 Uncooperativeness	☐	☐	☐	☐	☐	☐	☐
G9 Unusual thought content	☐	☐	☐	☐	☐	☐	☐
G10 Disorientation	☐	☐	☐	☐	☐	☐	☐
G11 Poor attention	☐	☐	☐	☐	☐	☐	☐
G12 Lack of judgement and insight	☐	☐	☐	☐	☐	☐	☐
G13 Disturbance of volition	☐	☐	☐	☐	☐	☐	☐
G14 Poor impulse control	☐	☐	☐	☐	☐	☐	☐
G15 Preoccupation	☐	☐	☐	☐	☐	☐	☐
G16 Active social avoidance	☐	☐	☐	☐	☐	☐	☐

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

WEEK 4

VISIT 2



7/31

38113C/2

Clinical global impression (CGI)

Considering your total clinical experience with this particular population, how **severe** is the subject's psychotic disorder at this time?

- ☐ not ill
- ☐ very mild
- ☐ mild
- ☐ moderate
- ☐ marked
- ☐ severe
- ☐ extremely severe

**Clinical global impression (CGI-C)**

Compared to the subject's condition at baseline, how much has he/she **changed**? (Rate the local change, whether or not, in your judgement, it is due entirely to the drug treatment.)

- ☐ very much improved
- ☐ much improved
- ☐ minimally improved
- ☐ unchanged
- ☐ minimally worse
- ☐ much worse
- ☐ very much worse

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

WEEK 4

VISIT 2

7/31

38113CV2

Visual analogue scale (VAS): quality of sleep

How well have you slept in the past 7 nights?

Please mark the line below with a slash (/) to indicate your quality of sleep.

Very badly

0

Very well

100

Score

mm

Visual analogue scale (VAS): daytime drowsiness

How often have you felt drowsy in the past 7 days?

Please mark the line below with a slash (/) to indicate your daytime drowsiness.

Not at all

0

All the time

100

Score

mm

Risperidone vs olanzapine
RIS-USA-113

CRF ID

WEEK 4

VISIT 2

Anticholinergic symptom survey (ACS)

INSTRUCTIONS: Please rate whether you have had each of the following symptoms or problems during the past week, and, if so, how bothered you have been by each symptom or problem. If you did not have the symptom or problem, please check the box under the "Did Not Have" heading.

	Did not have	Not at all bothered	Extremely bothered			
	0	1	2	3	4	5
1. Vision 						
a. blurry vision 	☐	☐	☐	☐	☐	☐
b. problems reading or writing due to vision	☐	☐	☐	☐	☐	☐
c. problems seeing signs or recognizing people at a distance due to vision 	☐	☐	☐	☐	☐	☐
2. Bowel function						
a. difficulty with bowel movements, including hard, dry, or painful stools	☐	☐	☐	☐	☐	☐
b. less frequent bowel movements	☐	☐	☐	☐	☐	☐
3. Urinary function						
a. difficulty starting urination	☐	☐	☐	☐	☐	☐
b. difficulty emptying bladder completely	☐	☐	☐	☐	☐	☐
c. difficulty controlling bladder	☐	☐	☐	☐	☐	☐
4. Dry mouth	☐	☐	☐	☐	☐	☐
5. Problems keeping your dentures or false teeth in place	☐	☐	☐	☐	☐	☐
<i>If you do not have dentures or false teeth, check box below and leave question blank.</i>						
☐ do not have dentures or false teeth						

Case Report Form (5 Nov 97)
Janssen Research Foundation

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5/2

38113CV3

Week 8 Visit 3

- Record vital signs (including body weight)
- Take blood samples for liver transaminase levels
- Complete the ESRS
- Complete the PANSS
- Complete the CGI/CGI-C
- Have subject complete the visual analogue scales for quality of sleep and daytime drowsiness
- Check for (changes in) concomitant therapy and complete (if applicable) the Concomitant therapy form
- Check for (changes in) adverse events and complete (if applicable) the Adverse event form

Trial medication

Dispense the trial medication and give instruction on its use. Administration is done once daily, preferably in the morning, according to the described dosing schedule. Mark the date and the dose of the first intake on the Administration of trial medication form. If there is a change in dosing (or time of administration), please mark the new date and dose on the Administration of trial medication form.

Concomitant therapy

If the subject has had a change in concomitant therapy the new dose schedule or concomitant therapy should be recorded on the Concomitant therapy form.

Please note that anticholinergics and benzodiazepines must be recorded on a separate concomitant therapy form.

Adverse events

If the subject has had any undesirable experience during the trial (whether or not considered related to the trial medication) the events should be recorded on the Adverse event form.

Anticholinergics

If extrapyramidal symptoms emerge or worsen during the double-blind period, an additional ESRS should be performed. Following completion of this ESRS, the dose of trial medication should be reduced. If the symptoms do not resolve, anticholinergic medication may be initiated. At each subsequent scheduled visit the need for continuation of anticholinergic medication should be evaluated. Please make sure that the date of completion has been recorded on the top of the first page of the ESRS.

Risperidone vs olanzapine
RIS-USA-113

CRF ID

Date

m	d	y	

WEEK 8

VISIT 3

7/31

38113C/3

Vital signs

Position	Pulse beats/minute	Blood pressure (mmHg) systolic/diastolic								
Supine, after 5 minutes rest	<table border="1"><tr><td></td><td></td><td></td></tr></table>				<table border="1"><tr><td></td><td></td><td>/</td><td></td><td></td></tr></table>			/		
		/								
Standing, after 1 minute rest	<table border="1"><tr><td></td><td></td><td></td></tr></table>				<table border="1"><tr><td></td><td></td><td>/</td><td></td><td></td></tr></table>			/		
		/								
Weight <table border="1"><tr><td></td><td></td><td></td></tr></table> lb										

Laboratory data

Sampling

Sample date

m	d	y

Sample reference of the laboratory

Clinically relevant changes in laboratory data

☐ No clinically relevant changes in laboratory data.

If yes, record all clinically relevant changes during the trial on the AE form.

Risperidone vs olanzapine
RIS-USA-113

CRF ID

WEEK 8

VISIT 3

7/31

38113C/3

Extrapyramidal symptom rating scale (ESRS)

Questionnaire and Behavioural Scale

Check the appropriate box for each item.

I Parkinsonism, Dystonia and Dyskinesia	Absent	Mild	Moderate	Severe
1. Impression of slowness or weakness, difficulty in carrying out routine tasks	☐	☐	☐	☐
2. Difficulty walking or with balance	☐	☐	☐	☐
3. Difficulty swallowing or talking	☐	☐	☐	☐
4. Stiffness, stiff posture	☐	☐	☐	☐
5. Cramps or pains in limbs, back or neck	☐	☐	☐	☐
6. Restless, nervous, unable to keep still	☐	☐	☐	☐
7. Tremors, shaking	☐	☐	☐	☐
8. Oculogyric crisis, abnormal sustained posture	☐	☐	☐	☐
9. Increased salivation	☐	☐	☐	☐
10. Abnormal involuntary movements (dyskinesia) of extremities or trunk	☐	☐	☐	☐
11. Abnormal involuntary movements (dyskinesia) of tongue, jaw, lips or face	☐	☐	☐	☐
12. Dizziness when standing up (especially in the morning)	☐	☐	☐	☐

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

WEEK 8

VISIT 3

7/31

38113CV3

Extrapyramidal symptom rating scale (ESRS) (continued)**Physician's examination**

Enter the appropriate score for each item.

II Parkinsonism	Score	Explanation
1. Expressive automatic movements (facial mask/speech)		0 normal 1 very mild decrease in facial expressiveness 2 mild decrease in facial expressiveness 3 rare spontaneous smile, decreased blinking, voice slightly monotonous 4 no spontaneous smile, staring gaze, low monotonous speech, mumbling 5 marked facial mask, unable to frown, slurred speech 6 extremely severe facial mask with unintelligible speech
2. Bradykinesia		0 normal 1 global impression of slowness in movements 2 definite slowness in movements 3 very mild difficulty in initiating movements 4 mild to moderate difficulty in initiating movements 5 difficulty in starting or stopping any movement, or freezing on initiating voluntary act 6 rare voluntary movement, almost completely immobile
3. Rigidity	right arm left arm right leg left leg	0 normal muscle tone 1 very mild, barely perceptible 2 mild (some resistance to passive movements) 3 moderate (definite resistance to passive movements) 4 moderately severe (moderate resistance but still easy to move the limb) 5 severe (marked resistance with definite difficulty to move the limb) 6 extremely severe (nearly frozen)
4. Gait and Posture		0 normal 1 mild decrease of pendular arm movement 2 moderate decrease of pendular arm movement, normal steps 3 no pendular arm movement, head flexed, steps more or less normal 4 stiff posture (neck, back), small step (shuffling gait) 5 more marked, festination or freezing on turning 6 triple flexion, barely able to walk

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

WEEK 8

VISIT 3

7/31

36113C03

Extrapyramidal symptom rating scale (ESRS) (continued)*Enter the appropriate score for each item.*

II Parkinsonism - Physician's examination	Score	Explanation
5. Tremor		
right arm	☐	
left arm	☐	None 0
right leg	☐	Borderline 1
left leg	☐	Small amplitude 2 3 4
head	☐	Moderate amplitude 3 4 5
jaw/chin	☐	Large amplitude 4 5 6
tongue	☐	
lips	☐	
6. Akathisia	☐	0 none 1 looks restless, nervous, impatient, uncomfortable 2 needs to move at least one extremity 3 often needs to move one extremity or to change position 4 moves one extremity almost constantly if sitting, or stamps feet while standing 5 unable to sit down for more than a short period of time 6 moves or walks constantly
7. Sialorrhea	☐	0 absent 1 very mild 2 mild 3 moderate: impairs speech 4 moderately severe 5 severe 6 extremely severe: drooling
8. Postural stability	☐	0 normal 1 hesitation when pushed but no retropulsion 2 retropulsion but recovers unaided 3 exaggerated retropulsion without falling 4 absence of postural response, would fall if not caught by examiner 5 unstable while standing, even without pushing 6 unable to stand without assistance

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Janssen Research Foundation

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

WEEK 8

VISIT 3

7/31
38113CV3

Extrapyramidal symptom rating scale (ESRS) (continued)

Enter the appropriate score for each item.

III Dystonia - Physician's examination

1. Acute torsion dystonia	Score	Explanation		Score	Explanation
right arm		0 absent	jaw		0 absent
		1 very mild			1 very mild
left arm		2 mild	tongue		2 mild
		3 moderate			3 moderate
right leg		4 moderately severe	lips		4 moderately severe
		5 severe			5 severe
left leg		6 extremely severe	eyes		6 extremely severe
head			trunk		
2. Non-acute or chronic or tardive dystonia	Score	Explanation		Score	Explanation
right arm		0 absent	jaw		0 absent
		1 very mild			1 very mild
left arm		2 mild	tongue		2 mild
		3 moderate			3 moderate
right leg		4 moderately severe	lips		4 moderately severe
		5 severe			5 severe
left leg		6 extremely severe	face		6 extremely severe
head			trunk		

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

WEEK 8

VISIT 3

7/31
38113CV3**Extrapyramidal symptom rating scale (ESRS) (continued)***Enter the appropriate score for each item.*

IV Dyskinetic movements Physician's examination	Score	Explanation	Occasional	Frequent	Constant or almost so
1. Lingual movements Slow lateral or torsion movement of tongue		None Borderline Clearly present, within oral cavity With occasional partial protrusion With complete protrusion	0 1 2 3 4	3 4 5	4 5 6
2. Jaw movements Lateral movement, chewing, biting, clenching		None Borderline Clearly present, small amplitude Moderate amplitude, but without mouth opening Large amplitude, with mouth opening	0 1 2 3 4	3 4 5	4 5 6
3. Bucco-labial movements Puckering, pouting, smacking, etc...		None Borderline Clearly present, small amplitude Moderate amplitude, forward movement of lips Large amplitude, marked, noisy smacking of lips	0 1 2 3 4	3 4 5	4 5 6
4. Truncal movements Rocking, twisting, pelvic gyrations		None Borderline Clearly present, small amplitude Moderate amplitude Greater amplitude	0 1 2 3 4	3 4 5	4 5 6
5. Upper extremities Choreoathetoid movements only: arms, wrists, hands, fingers		None Borderline Clearly present, small amplitude, movement of one limb Moderate amplitude, movement of one limb or movement of small amplitude involving two limbs Greater amplitude, movement involving two limbs	0 1 2 3 4	3 4 5	4 5 6
6. Lower extremities Choreoathetoid movements only: legs, knees, ankles, toes		None Borderline Clearly present, small amplitude, movement of one limb Moderate amplitude, movement of one limb or movement of small amplitude involving two limbs Greater amplitude, movement including two limbs	0 1 2 3 4	3 4 5	4 5 6
7. Other involuntary movements Swallowing, irregular respiration, frowning, blinking, grimacing, sighing, etc...		None Borderline Clearly present, small amplitude Moderate amplitude Greater amplitude	0 1 2 3 4	3 4 5	4 5 6

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Risperidone vs olanzapine
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VISIT 3

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Extrapyramidal symptom rating scale (ESRS) (continued)

38113CV3

V Clinical global impression of severity of Parkinsonism*Considering your clinical experience, how severe is the parkinsonism at this time?*

- ☐ absent
- ☐ borderline
- ☐ very mild
- ☐ mild
- ☐ moderate
- ☐ moderately severe
- ☐ marked
- ☐ severe
- ☐ extremely severe

VI Clinical global impression of severity of Dystonia*Considering your clinical experience, how severe is the dystonia at this time?*

- ☐ absent
- ☐ borderline
- ☐ very mild
- ☐ mild
- ☐ moderate
- ☐ moderately severe
- ☐ marked
- ☐ severe
- ☐ extremely severe

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3811300

Extrapyramidal symptom rating scale (ESRS) (continued)**VII Clinical global impression of severity of Dyskinesia***Considering your clinical experience, how **severe** is the dyskinesia at this time?*

- ☐ absent
- ☐ borderline
- ☐ very mild
- ☐ mild
- ☐ moderate
- ☐ moderately severe
- ☐ marked
- ☐ severe
- ☐ extremely severe

VIII Stage of Parkinsonism (Hoehn & Yahr)

- ☐ absent
- ☐ unilateral involvement only, minimal or no functional impairment (stage I)
- ☐ bilateral or midline involvement, without impairment of balance (stage II)
- ☐ mild to moderate disabling: first signs of impaired righting or postural reflex
(unsteadiness as the subject turns or when he is pushed from standing equilibrium with the feet together and eyes closed),
subject is physically capable of leading independent life (stage III)
- ☐ severely disabling: subject is still able to walk and stand unassisted but is markedly incapacitated (stage IV)
- ☐ confinement to bed or wheelchair (stage V)

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VISIT 3

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38113CV3

Positive and negative syndrome scale for schizophrenia (PANSS)*Enter the appropriate score for each item, refer to the Rating Manual for item definitions, description of anchoring points and scoring procedure.*

	Absent 1	Minimal 2	Mild 3	Moderate 4	Moderate severe 5	Severe 6	Extreme 7
1) Positive subscale							
P1 Delusions	☐	☐	☐	☐	☐	☐	☐
P2 Conceptual disorganization	☐	☐	☐	☐	☐	☐	☐
P3 Hallucinatory behavior	☐	☐	☐	☐	☐	☐	☐
P4 Excitement	☐	☐	☐	☐	☐	☐	☐
P5 Grandiosity	☐	☐	☐	☐	☐	☐	☐
P6 Suspiciousness/persecution	☐	☐	☐	☐	☐	☐	☐
P7 Hostility	☐	☐	☐	☐	☐	☐	☐
2) Negative subscale	1	2	3	4	5	6	7
N1 Blunted affect	☐	☐	☐	☐	☐	☐	☐
N2 Emotional withdrawal	☐	☐	☐	☐	☐	☐	☐
N3 Poor rapport	☐	☐	☐	☐	☐	☐	☐
N4 Passive/apathetic social withdrawal	☐	☐	☐	☐	☐	☐	☐
N5 Difficulty in abstract thinking	☐	☐	☐	☐	☐	☐	☐
N6 Lack of spontaneity and flow of conversation	☐	☐	☐	☐	☐	☐	☐
N7 Stereotyped thinking	☐	☐	☐	☐	☐	☐	☐

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Risperidone vs olanzapine
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VISIT 3

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38113Cv2**Positive and negative syndrome scale for schizophrenia (PANSS)
(continued)***Enter the appropriate score for each item, refer to the Rating Manual for item definitions, description of anchoring points and scoring procedure.*

	Absent 1	Minimal 2	Mild 3	Moderate 4	Moderate severe 5	Severe 6	Extreme 7
3) General psychopathology subscale							
G1 Somatic concern	☐	☐	☐	☐	☐	☐	☐
G2 Anxiety	☐	☐	☐	☐	☐	☐	☐
G3 Guilt feelings	☐	☐	☐	☐	☐	☐	☐
G4 Tension	☐	☐	☐	☐	☐	☐	☐
G5 Mannerisms and posturing	☐	☐	☐	☐	☐	☐	☐
G6 Depression	☐	☐	☐	☐	☐	☐	☐
G7 Motor retardation	☐	☐	☐	☐	☐	☐	☐
G8 Uncooperativeness	☐	☐	☐	☐	☐	☐	☐
G9 Unusual thought content	☐	☐	☐	☐	☐	☐	☐
G10 Disorientation	☐	☐	☐	☐	☐	☐	☐
G11 Poor attention	☐	☐	☐	☐	☐	☐	☐
G12 Lack of judgement and insight	☐	☐	☐	☐	☐	☐	☐
G13 Disturbance of volition	☐	☐	☐	☐	☐	☐	☐
G14 Poor impulse control	☐	☐	☐	☐	☐	☐	☐
G15 Preoccupation	☐	☐	☐	☐	☐	☐	☐
G16 Active social avoidance	☐	☐	☐	☐	☐	☐	☐

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CRF ID

WEEK 8

VISIT 3

7/81

38113C/3

Clinical global impression (CGI)

Considering your total clinical experience with this particular population, how **severe** is the subject's psychotic disorder at this time?

- ☐ not ill
- ☐ very mild
- ☐ mild
- ☐ moderate
- ☐ marked
- ☐ severe
- ☐ extremely severe

Clinical global impression (CGI-C)

Compared to the subject's condition at baseline, how much has he/she **changed**? (Rate the local change, whether or not, in your judgement, it is due entirely to the drug treatment.)

- ☐ very much improved
- ☐ much improved
- ☐ minimally improved
- ☐ unchanged
- ☐ minimally worse
- ☐ much worse
- ☐ very much worse

Risperidone vs olanzapine
RIS-USA-113

CRF ID

WEEK 8

VISIT 3

7/21
38113CV3

Visual analogue scale (VAS): quality of sleep

How well have you slept in the past 7 nights?

Please mark the line below with a slash (/) to indicate your quality of sleep.

Very badly |-----| Very well
0 |-----| 100

Score mm

Visual analogue scale (VAS): daytime drowsiness

How often have you felt drowsy in the past 7 days?

Please mark the line below with a slash (/) to indicate your daytime drowsiness.

Not at all |-----| All the time
0 |-----| 100

Score mm

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CRF ID

WEEK 8

VISIT 3

7/31

38113CV3

Anticholinergic symptom survey (ACS)

INSTRUCTIONS: Please rate whether you have had each of the following symptoms or problems during the past week, and, if so, how bothered you have been by each symptom or problem. If you did not have the symptom or problem, please check the box under the "Did Not Have" heading.

	Did not have	Not at all bothered	Extremely bothered			
	0	1	2	3	4	5
1. Vision						
a. blurry vision	☐	☐	☐	☐	☐	☐
b. problems reading or writing due to vision	☐	☐	☐	☐	☐	☐
c. problems seeing signs or recognizing people at a distance due to vision	☐	☐	☐	☐	☐	☐
2. Bowel function						
a. difficulty with bowel movements, including hard, dry, or painful stools	☐	☐	☐	☐	☐	☐
b. less frequent bowel movements	☐	☐	☐	☐	☐	☐
3. Urinary function						
a. difficulty starting urination	☐	☐	☐	☐	☐	☐
b. difficulty emptying bladder completely	☐	☐	☐	☐	☐	☐
c. difficulty controlling bladder	☐	☐	☐	☐	☐	☐
4. Dry mouth	☐	☐	☐	☐	☐	☐
5. Problems keeping your dentures or false teeth in place	☐	☐	☐	☐	☐	☐
If you do not have dentures or false teeth, check box below and leave question blank.						
☐ do not have dentures or false teeth						

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38113CV4

Week 12 Visit 4

- Record vital signs (including body weight)
- Take blood samples for liver transaminase levels
- Measure waist/hip circumference
- Complete the ESRS
- Complete the PANSS
- Complete the CGI/CGI-C
- Administer and record the results of the cognitive tests
- Administer the Modified SIP, B-QoLI, PRSQ, VAS, ACS and DAI

Trial medication

Dispense the trial medication and give instruction on its use. Administration is done once daily, preferably in the morning, according to the described dosing schedule. Mark the date and the dose of the first intake on the Administration of trial medication form. If there is a change in dosing (or time of administration), please mark the new date and dose on the Administration of trial medication form.

Concomitant therapy

If the subject has had a change in concomitant therapy the new dose schedule or concomitant therapy should be recorded on the Concomitant therapy form.

Please note that anticholinergics and benzodiazepines must be recorded on a separate concomitant therapy form.

Adverse events

If the subject has had any undesirable experience during the trial (whether or not considered related to the trial medication) the events should be recorded on the Adverse event form.

Anticholinergics

If extrapyramidal symptoms emerge or worsen during the double-blind period, an additional ESRS should be performed. Following completion of this ESRS, the dose of trial medication should be reduced. If the symptoms do not resolve, anticholinergic medication may be initiated. At each subsequent scheduled visit the need for continuation of anticholinergic medication should be evaluated. Please make sure that the date of completion has been recorded on the top of the first page of the ESRS.

Risperidone vs olanzapine
RIS-USA-113

CRF ID

Date

m	d	y		

WEEK 12

VISIT 4

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38113CV4

Vital signs

Position	Pulse beats/minute	Blood pressure (mmHg) systolic/diastolic									
Supine, after 5 minutes rest	<table border="1"><tr><td></td><td></td><td></td></tr></table>				<table border="1"><tr><td></td><td></td><td></td><td>/</td><td></td><td></td></tr></table>				/		
			/								
Standing, after 1 minute rest	<table border="1"><tr><td></td><td></td><td></td></tr></table>				<table border="1"><tr><td></td><td></td><td></td><td>/</td><td></td><td></td></tr></table>				/		
			/								
Weight <table border="1"><tr><td></td><td></td><td></td><td></td></tr></table> lb											

Laboratory data

Sampling

Sample date

m	d	y		

Sample reference of the laboratory

Clinically relevant changes in laboratory data

☐ No clinically relevant changes in laboratory data.

If yes, record all clinically relevant changes during the trial on the AE form.

Risperidone vs olanzapine

CRF ID

RIS-USA-113

WEEK 12

VISIT 4

701
3811304**Extrapyramidal symptom rating scale (ESRS)****Questionnaire and Behavioural Scale***Check the appropriate box for each item.*

I Parkinsonism, Dystonia and Dyskinesia	Absent	Mild	Moderate	Severe
1. Impression of slowness or weakness, difficulty in carrying out routine tasks	☐	☐	☐	☐
2. Difficulty walking or with balance	☐	☐	☐	☐
3. Difficulty swallowing or talking	☐	☐	☐	☐
4. Stiffness, stiff posture	☐	☐	☐	☐
5. Cramps or pains in limbs, back or neck	☐	☐	☐	☐
6. Restless, nervous, unable to keep still	☐	☐	☐	☐
7. Tremors, shaking	☐	☐	☐	☐
8. Oculogyric crisis, abnormal sustained posture	☐	☐	☐	☐
9. Increased salivation	☐	☐	☐	☐
10. Abnormal involuntary movements (dyskinesia) of extremities or trunk	☐	☐	☐	☐
11. Abnormal involuntary movements (dyskinesia) of tongue, jaw, lips or face	☐	☐	☐	☐
12. Dizziness when standing up (especially in the morning)	☐	☐	☐	☐

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Risperidone vs olanzapine
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WEEK 12

VISIT 4

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38113Cv4

Extrapyramidal symptom rating scale (ESRS) (continued)**Physician's examination***Enter the appropriate score for each item.*

II Parkinsonism	Score	Explanation
1. Expressive automatic movements (facial mask/speech)		0 normal 1 very mild decrease in facial expressiveness 2 mild decrease in facial expressiveness 3 rare spontaneous smile, decreased blinking, voice slightly monotonous 4 no spontaneous smile, staring gaze, low monotonous speech, mumbling 5 marked facial mask, unable to frown, slurred speech 6 extremely severe facial mask with unintelligible speech
2. Bradykinesia		0 normal 1 global impression of slowness in movements 2 definite slowness in movements 3 very mild difficulty in initiating movements 4 mild to moderate difficulty in initiating movements 5 difficulty in starting or stopping any movement, or freezing on initiating voluntary act 6 rare voluntary movement, almost completely immobile
3. Rigidity	right arm left arm right leg left leg	0 normal muscle tone 1 very mild, barely perceptible 2 mild (some resistance to passive movements) 3 moderate (definite resistance to passive movements) 4 moderately severe (moderate resistance but still easy to move the limb) 5 severe (marked resistance with definite difficulty to move the limb) 6 extremely severe (nearly frozen)
4. Gait and Posture		0 normal 1 mild decrease of pendular arm movement 2 moderate decrease of pendular arm movement, normal steps 3 no pendular arm movement, head flexed, steps more or less normal 4 stiff posture (neck, back), small step (shuffling gait) 5 more marked, festination or freezing on turning 6 triple flexion, barely able to walk

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Risperidone vs olanzapine
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WEEK 12

VISIT 4

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38113CV4**Extrapyramidal symptom rating scale (ESRS) (continued)***Enter the appropriate score for each item.*

II Parkinsonism - Physician's examination	Score	Explanation
5. Tremor		
right arm	☐	
left arm	☐	None 0
right leg	☐	Borderline 1
left leg	☐	Small amplitude 2 3 4
head	☐	Moderate amplitude 3 4 5
jaw/chin	☐	Large amplitude 4 5 6
tongue	☐	
lips	☐	
6. Akathisia	☐	0 none 1 looks restless, nervous, impatient, uncomfortable 2 needs to move at least one extremity 3 often needs to move one extremity or to change position 4 moves one extremity almost constantly if sitting, or stamps feet while standing 5 unable to sit down for more than a short period of time 6 moves or walks constantly
7. Sialorrhea	☐	0 absent 1 very mild 2 mild 3 moderate: impairs speech 4 moderately severe 5 severe 6 extremely severe: drooling
8. Postural stability	☐	0 normal 1 hesitation when pushed but no retropulsion 2 retropulsion but recovers unaided 3 exaggerated retropulsion without falling 4 absence of postural response, would fall if not caught by examiner 5 unstable while standing, even without pushing 6 unable to stand without assistance

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VISIT 4

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3813CV4

Extrapyramidal symptom rating scale (ESRS) (continued)

Enter the appropriate score for each item.

III Dystonia - Physician's examination

1. Acute torsion dystonia	Score	Explanation		Score	Explanation
right arm	☐	0 absent	jaw	☐	0 absent
		1 very mild			1 very mild
left arm	☐	2 mild	tongue	☐	2 mild
		3 moderate			3 moderate
right leg	☐	4 moderately severe	lips	☐	4 moderately severe
		5 severe			5 severe
left leg	☐	6 extremely severe	eyes	☐	6 extremely severe
head	☐		trunk	☐	
2. Non-acute or chronic or tardive dystonia	Score	Explanation		Score	Explanation
right arm	☐	0 absent	jaw	☐	0 absent
		1 very mild			1 very mild
left arm	☐	2 mild	tongue	☐	2 mild
		3 moderate			3 moderate
right leg	☐	4 moderately severe	lips	☐	4 moderately severe
		5 severe			5 severe
left leg	☐	6 extremely severe	face	☐	6 extremely severe
head	☐		trunk	☐	

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Risperidone vs olanzapine
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WEEK 12

VISIT 4

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38113CV4**Extrapyramidal symptom rating scale (ESRS) (continued)***Enter the appropriate score for each item.*

IV Dyskinetic movements Physician's examination	Score	Explanation	Occasional	Frequent	Constant or almost so
1. Lingual movements Slow lateral or torsion movement of tongue		None 0 Borderline 1 Clearly present, within oral cavity 2 With occasional partial protrusion 3 With complete protrusion 4		3 4 5 6	4 5 6
2. Jaw movements Lateral movement, chewing, biting, clenching		None 0 Borderline 1 Clearly present, small amplitude 2 Moderate amplitude, but without mouth opening 3 Large amplitude, with mouth opening 4		3 4 5 6	4 5 6
3. Bucco-labial movements Puckering, pouting, smacking, etc...		None 0 Borderline 1 Clearly present, small amplitude 2 Moderate amplitude, forward movement of lips 3 Large amplitude, marked, noisy smacking of lips 4		3 4 5 6	4 5 6
4. Truncal movements Rocking, twisting, pelvic gyrations		None 0 Borderline 1 Clearly present, small amplitude 2 Moderate amplitude 3 Greater amplitude 4		3 4 5 6	4 5 6
5. Upper extremities Choreoathetoid movements only: arms, wrists, hands, fingers		None 0 Borderline 1 Clearly present, small amplitude, movement of one limb 2 Moderate amplitude, movement of one limb or movement of small amplitude involving two limbs 3 Greater amplitude, movement involving two limbs 4		3 4 5 6	4 5 6
6. Lower extremities Choreoathetoid movements only: legs, knees, ankles, toes		None 0 Borderline 1 Clearly present, small amplitude, movement of one limb 2 Moderate amplitude, movement of one limb or movement of small amplitude involving two limbs 3 Greater amplitude, movement including two limbs 4		3 4 5 6	4 5 6
7. Other involuntary movements Swallowing, irregular respiration, frowning, blinking, grimacing, sighing, etc...		None 0 Borderline 1 Clearly present, small amplitude 2 Moderate amplitude 3 Greater amplitude 4		3 4 5 6	4 5 6

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VISIT 4

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38113CV4

Extrapyramidal symptom rating scale (ESRS) (continued)

V Clinical global impression of severity of Parkinsonism

Considering your clinical experience, how severe is the parkinsonism at this time?

- ☐ absent
- ☐ borderline
- ☐ very mild
- ☐ mild
- ☐ moderate
- ☐ moderately severe
- ☐ marked
- ☐ severe
- ☐ extremely severe

VI Clinical global impression of severity of Dystonia

Considering your clinical experience, how severe is the dystonia at this time?

- ☐ absent
- ☐ borderline
- ☐ very mild
- ☐ mild
- ☐ moderate
- ☐ moderately severe
- ☐ marked
- ☐ severe
- ☐ extremely severe

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Risperidone vs olanzapine
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WEEK 12

VISIT 4

7/11
38113CV4**Extrapyramidal symptom rating scale (ESRS) (continued)****VII Clinical global impression of severity of Dyskinesia***Considering your clinical experience, how severe is the dyskinesia at this time?*

- ☐ absent
- ☐ borderline
- ☐ very mild
- ☐ mild
- ☐ moderate
- ☐ moderately severe
- ☐ marked
- ☐ severe
- ☐ extremely severe

VIII Stage of Parkinsonism (Hoehn & Yahr)

- ☐ absent
- ☐ unilateral involvement only, minimal or no functional impairment (stage I)
- ☐ bilateral or midline involvement, without impairment of balance (stage II)
- ☐ mild to moderate disabling: first signs of impaired righting or postural reflex
(unsteadiness as the subject turns or when he is pushed from standing equilibrium with the feet together and eyes closed),
subject is physically capable of leading independent life (stage III)
- ☐ severely disabling: subject is still able to walk and stand unassisted but is markedly incapacitated (stage IV)
- ☐ confinement to bed or wheelchair (stage V)

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Risperidone vs olanzapine
RIS-USA-113

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WEEK 12

VISIT 4

7/31
38113CV4

Positive and negative syndrome scale for schizophrenia (PANSS)

Enter the appropriate score for each item, refer to the Rating Manual for item definitions, description of anchoring points and scoring procedure.

	Absent 1	Minimal 2	Mild 3	Moderate 4	Moderate severe 5	Severe 6	Extreme 7
1) Positive subscale							
P1 Delusions	☐	☐	☐	☐	☐	☐	☐
P2 Conceptual disorganization	☐	☐	☐	☐	☐	☐	☐
P3 Hallucinatory behavior	☐	☐	☐	☐	☐	☐	☐
P4 Excitement	☐	☐	☐	☐	☐	☐	☐
P5 Grandiosity	☐	☐	☐	☐	☐	☐	☐
P6 Suspiciousness/persecution	☐	☐	☐	☐	☐	☐	☐
P7 Hostility	☐	☐	☐	☐	☐	☐	☐
2) Negative subscale	1	2	3	4	5	6	7
N1 Blunted affect	☐	☐	☐	☐	☐	☐	☐
N2 Emotional withdrawal	☐	☐	☐	☐	☐	☐	☐
N3 Poor rapport	☐	☐	☐	☐	☐	☐	☐
N4 Passive/apathetic social withdrawal	☐	☐	☐	☐	☐	☐	☐
N5 Difficulty in abstract thinking	☐	☐	☐	☐	☐	☐	☐
N6 Lack of spontaneity and flow of conversation	☐	☐	☐	☐	☐	☐	☐
N7 Stereotyped thinking	☐	☐	☐	☐	☐	☐	☐

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Risperidone vs olanzapine
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VISIT 4

7/31
3811304**Positive and negative syndrome scale for schizophrenia (PANSS)
(continued)***Enter the appropriate score for each item, refer to the Rating Manual for item definitions, description of anchoring points and scoring procedure.*

	Absent 1	Minimal 2	Mild 3	Moderate 4	Moderate severe 5	Severe 6	Extreme 7
3) General psychopathology subscale							
G1 Somatic concern	☐	☐	☐	☐	☐	☐	☐
G2 Anxiety	☐	☐	☐	☐	☐	☐	☐
G3 Guilt feelings	☐	☐	☐	☐	☐	☐	☐
G4 Tension	☐	☐	☐	☐	☐	☐	☐
G5 Mannerisms and posturing	☐	☐	☐	☐	☐	☐	☐
G6 Depression	☐	☐	☐	☐	☐	☐	☐
G7 Motor retardation	☐	☐	☐	☐	☐	☐	☐
G8 Uncooperativeness	☐	☐	☐	☐	☐	☐	☐
G9 Unusual thought content	☐	☐	☐	☐	☐	☐	☐
G10 Disorientation	☐	☐	☐	☐	☐	☐	☐
G11 Poor attention	☐	☐	☐	☐	☐	☐	☐
G12 Lack of judgement and insight	☐	☐	☐	☐	☐	☐	☐
G13 Disturbance of volition	☐	☐	☐	☐	☐	☐	☐
G14 Poor impulse control	☐	☐	☐	☐	☐	☐	☐
G15 Preoccupation	☐	☐	☐	☐	☐	☐	☐
G16 Active social avoidance	☐	☐	☐	☐	☐	☐	☐

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

WEEK 12

VISIT 4

7/31

38113CV4

Clinical global impression (CGI)

Considering your total clinical experience with this particular population, how **severe** is the subject's psychotic disorder at this time?

- ☐ not ill
- ☐ very mild
- ☐ mild
- ☐ moderate
- ☐ marked
- ☐ severe
- ☐ extremely severe

Clinical global impression (CGI-C)

Compared to the subject's condition at baseline, how much has he/she **changed**? (Rate the local change, whether or not, in your judgement, it is due entirely to the drug treatment.)

- ☐ very much improved
- ☐ much improved
- ☐ minimally improved
- ☐ unchanged
- ☐ minimally worse
- ☐ much worse
- ☐ very much worse

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Waist/hip circumference ratio

Please measure in the horizontal plane with the subject standing, the minimum circumference between the costal margin and the iliac crest.

Waist circumference

		.		

 inch

Please measure in the horizontal plane the maximum circumference over the buttocks.

Hip circumference

		.		

 inch

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Date

m	d	y	

WEEK 12

VISIT 4

Cognitive assessment

Week 12 Assessment (perform these tests as soon as possible and not later than day 84 (visit 4))
Record the scores in the appropriate boxes. Please refer to the *Cognitive Assessment Manual*.

Test	Measure	Score					
		Left	Right				
SWMT (Spatial Working Memory Test)	total correct at 5 seconds	<table border="1"><tr><td></td><td></td></tr></table>			<table border="1"><tr><td></td><td></td></tr></table>		
total correct at 15 seconds	<table border="1"><tr><td></td><td></td></tr></table>			<table border="1"><tr><td></td><td></td></tr></table>			
non-adjacent errors at 5 seconds	<table border="1"><tr><td></td><td></td></tr></table>			<table border="1"><tr><td></td><td></td></tr></table>			
non-adjacent errors at 15 seconds	<table border="1"><tr><td></td><td></td></tr></table>			<table border="1"><tr><td></td><td></td></tr></table>			
CVLT (California Verbal Learning Test)	learning trial 1	<table border="1"><tr><td></td><td></td></tr></table>					
learning trials 1 to 5	<table border="1"><tr><td></td><td></td></tr></table>						
long-delay free recall	<table border="1"><tr><td></td><td></td></tr></table>						
recognition discriminability	<table border="1"><tr><td></td><td></td><td></td></tr></table>				%		
CPT (Continuous Performance Test)		Positive	Negative				
	d' block 1	☐	☐	<table border="1"><tr><td></td><td>.</td><td></td><td></td></tr></table>		.	
	.						
d' block 2	☐	☐	<table border="1"><tr><td></td><td>.</td><td></td><td></td></tr></table>		.		
	.						
d' block 3	☐	☐	<table border="1"><tr><td></td><td>.</td><td></td><td></td></tr></table>		.		
	.						
d' total	☐	☐	<table border="1"><tr><td></td><td>.</td><td></td><td></td></tr></table>		.		
	.						

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Cognitive assessment (continued)**Week 12 Assessment** (these tests should be performed as soon as possible and not later than day 84 (visit 4))
Record the scores in the appropriate boxes. Please refer to the Cognitive Assessment Manual.

Test	Measure	Score
VFE (Verbal Fluency Examinations)	category fluency - total score	
	category repetitions	
	category intrusions	
	letter fluency - total score	
	letter repetitions	
	letter intrusions	
Trail Making Test A and B	Part A	
	Part B	
WCST (Wisconsin Card Sorting Test)	categories	
	total errors	
	perseverative errors	
	perseverative responses	

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Modified version sickness impact profile (M-SIP)

Please refer to the instructions in protocol guidelines manual.

How would you describe your present health?

- ☐ very good
- ☐ good
- ☐ fair
- ☐ poor
- ☐ very poor

How would you describe your present quality of life?

- ☐ very good
- ☐ good
- ☐ fair
- ☐ poor
- ☐ very poor

A. These statements describe your sleep and rest today

1. I spend much of the day lying down in order to rest.
2. I sit for much of the day.
3. I am sleeping or dozing most of the time — day and night.
4. I lie down more often during the day in order to rest.
5. I sit around half asleep.
6. I sleep less at night, for example, I wake up easily, I do not fall asleep for a long time, I keep waking up.
7. I sleep or doze more during the day.

No

Yes

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38113CV4**Modified version sickness impact profile (M-SIP) (continued)****B. These statements describe your daily work around the house today**

No

Yes

1. I only do housework or work around the house for short periods of time or I rest often.
2. I am doing less of the daily household chores that I would usually do.
3. I am not doing any of the daily household chores that I would usually do.
4. I am not doing any of the maintenance or repair work that I would usually do in my house or garden.
5. I am not doing any of the shopping that I would usually do.
6. I am not doing any of the cleaning that I would usually do.
7. I have difficulties using my hands, for example turning taps, using kitchen gadgets, sewing or doing repairs.
8. I am not doing any of the clothes washing that I would usually do.
9. I am not doing heavy work around the house.
10. I have given up taking care of personal or household business affairs, for example, paying bills, banking or doing household accounts.

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Modified version sickness impact profile (M-SIP) (continued)**C. These statements describe your contact with your family and friends today**

No

Yes

1. I am going out less to visit people.	☐	☐
2. I am not going out to visit people at all.	☐	☐
3. I show less interest in other people's problems, for example, I do not listen when they tell me about their problems, I do not offer to help.	☐	☐
4. I am often irritable with those around me, for example, I snap at people or criticize easily.	☐	☐
5. I show less affection.	☐	☐
6. I take part in fewer social activities than I used to, for example, I go to fewer parties or social events.	☐	☐
7. I am cutting down the length of visits to friends.	☐	☐
8. I avoid having visitors.	☐	☐
9. My sexual activity is decreased.	☐	☐
10. I often express concern over what might be happening to my health.	☐	☐
11. I talk less with those around me.	☐	☐
12. I make many demands on other people, for example, I insist that they do things for me, or tell them how to do things.	☐	☐
13. I stay alone much of the time.	☐	☐
14. I am disagreeable with my family, for example, I act spitefully or stubbornly.	☐	☐
15. I frequently get angry with my family, for example, I hit them, scream or throw things at them.	☐	☐
16. I isolate myself as much as I can from the rest of my family.	☐	☐
17. I am paying less attention to the children.	☐	☐
18. I refuse contact with my family, for example, I turn away from them.	☐	☐
19. I am not doing the things I usually do to take care of my family.	☐	☐
20. I am not joking with my family members as I usually do.	☐	☐

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38113CV4**Modified version sickness impact profile (M-SIP) (continued)**

D. These statements describe your concentration, memory, attention and problem solving today	No	Yes
1. I am confused and start to do more than one thing at a time.	☐	☐
2. I have more minor accidents, for example, I drop things, I trip and fall, or bump into things.	☐	☐
3. I react slowly to things that are said or done.	☐	☐
4. I do not finish things I start.	☐	☐
5. I have difficulty reasoning and solving problems, for example, making plans, making decisions, learning new things.	☐	☐
6. I sometimes get confused, for example, I do not know where I am, who is around, or what day it is.	☐	☐
7. I forget a lot, for example things that happened recently, where I put things, or to keep appointments.	☐	☐
8. I do not keep my attention on any activity for long.	☐	☐
9. I make more mistakes than usual.	☐	☐
10. I have difficulty doing things which involve thought and concentration.	☐	☐
E. These statements describe your communication with others through writing and speaking today	No	Yes
1. I am having trouble writing or typing.	☐	☐
2. I communicate mostly by nodding my head, pointing or using sign language or other gestures.	☐	☐
3. My speech is understood only by a few people who know me well.	☐	☐
4. I often lose control of my voice when I talk, for example, my voice gets louder or softer, or changes unexpectedly.	☐	☐
5. I do not write except to sign my name.	☐	☐
6. I carry on a conversation only when very close to other people or looking directly at them.	☐	☐
7. I speak with difficulty, for example, I get stuck for words, I stutter, I stammer, I slur my words.	☐	☐
8. I am understood with difficulty.	☐	☐
9. I do not speak clearly when I am under stress.	☐	☐

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Modified version sickness impact profile (M-SIP) (continued)**F. The following statements describe the activities you usually do in your spare time for relaxation, entertainment or just to pass the time****No****Yes**

1. I spend shorter periods of time on my hobbies and recreation. ☐ ☐
2. I am going out to enjoy myself less often. ☐ ☐
3. I am cutting down on some of my usual inactive pastimes, for example, I watch less TV, play cards less, or read less. ☐ ☐
4. I am not doing any of my usual inactive pastimes, for example, I watch less TV, play cards less, or read less. ☐ ☐
5. I am doing more inactive pastimes in place of my other usual activities. ☐ ☐
6. I am taking part in fewer community activities. ☐ ☐
7. I am cutting down on some of my usual physical recreation or more active pastimes. ☐ ☐
8. I am not doing any of my usual physical recreation or more active pastimes. ☐ ☐

*Now please look through this questionnaire and make sure that you have read every question.**Thank you for your help.*

(Awad, 1990) (Revised 1992)

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38113C/4

B-QoLI**Section A: General Life Satisfaction**

Please look at this card. (Hand subject the Delighted-Terrible Scale.) This is called the Delighted-Terrible Scale (D-T Scale).

The scale goes from **terrible**, which is the lowest ranking of 1, to **delighted**, which is the highest ranking of 7. There are also points 2 through 6 with descriptions below them. (Read points on the scale.)

During the interview we'll be using this scale from time to time to help you tell me how you feel about different things in your life. All you have to do is tell me what on the scale best describes how you feel. For example, if I ask, "How do you feel about chocolate ice cream?", and you are someone who loves chocolate ice cream, you might point to "delighted." On the other hand, if you hate chocolate ice cream, you might point to "terrible." If you feel about equally satisfied and dissatisfied with chocolate ice cream, then you would point to the middle of the scale.

Do you have any questions about the scale? Please show me how you feel about chocolate ice cream. Let's begin.

The first question is a very general one.



1. How do you feel about your life in general? (Use D-T Scale)



Now, set the scale aside. I'll let you know when we need it again.

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B-QoLI (continued)

Section B: Living Situation

Living Situation Codes for the questions 1-3 that follow:

Code	Situation
01	Hospital
02	Skilled nursing facility: 24 hour nursing service
03	Intermediate care facility: less than 24 hour nursing facility
04	Supervised group living (generally long term)
05	Transitional group home (halfway or quarterway house)
06	Family foster care
07	Cooperative apartment, supervised (staff on premises)
08	Cooperative apartment, unsupervised (staff not on premises)
09	Board and care home (private proprietary home for adults, with program and supervision)
10	Boarding house (includes meals, no program or supervision)
11	Rooming or boarding house or hotel (includes single room occupancy, no meals are provided, cooking facilities may be available)
12	Private house or apartment
13	Shelter
14	Jail
15	No current residence (including the streets, bus stations, missions, etc.)
16	Other.

Now I am going to ask you some questions about your living situation.

1. What is your
- current**
- living situation? (use codes above)

(If respondent is currently in the hospital, and this hospitalization has lasted less than 3 months, "living situation" = living situation just prior to hospitalization. If the hospitalization has been for 3 months or more, code "hospital".)

2. List in order the places you have lived during the past month, including psychiatric hospitalizations, beginning with your
- current**
- living situation. (use codes above)

3. Which of these was your usual residence during the past month? (use codes above)

* If response is "Other" (code 16), describe:

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B-QoLI (continued)**Section B: Living Situation (continued)**

4. Now look at the D-T Scale again and answer the following:

(Hand respondent the D-T Scale. If respondent is currently in the hospital for less than 3 months, use more recent residence prior to hospitalization. If respondent is in the hospital 3 months or more, use hospital as the residence. Skip if homeless.)

How do you feel about:

- a. The living arrangements where you live?

☐

- b. The privacy you have there?

☐

- c. The prospect of staying on where you currently live for a long period of time?

☐**Section C: Daily Activities and Functioning**

1. Now let's talk about some of the things you did with your time in the
- past week**
- . I'm going to read you a list of things people may do with their free time. For each of these, please tell me if you did it during the past week. Did you... (read options A - H)

	 No	 Yes	 Missing
a. Go for a walk?	☐	☐	☐
b. Go shopping?	☐	☐	☐
c. Go to a restaurant or coffee shop?	☐	☐	☐
d. Read a book, magazine or newspaper?	☐	☐	☐
e. Go for a ride in a bus or car?	☐	☐	☐
f. Work on a hobby?	☐	☐	☐
g. Play a sport?	☐	☐	☐
h. Go to a park?	☐	☐	☐

2. Overall, how would you rate your functioning in home, social, school, and work settings at the present time? Would you say your functioning in these areas is excellent, good, fair or poor? (check one)

☐

excellent

☐

good

☐

fair

☐

poor

☐

missing

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B-QoLI (continued)

Section C: Daily Activities and Functioning (continued)

3. Now please look at the D-T Scale again. How do you feel about:

a. The way you spend your spare time?

☐

b. The chances you have to enjoy pleasant or beautiful things?

☐

c. The amount of fun you have?

☐

d. The amount of relaxation in your life?

☐

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B-QoLI (continued)**Section D: Family**

The next few questions are about your relationship with your family, including any relatives with whom you live.

1. In the past month, how often did you talk to a member of your family on the telephone? Would you say at least once a day, at least once a week, at least once a month, or not at all? *(check one)*

☐
☐
☐
☐
☐
☐

- at least once a day
at least once a week
at least once a month
not at all
no family *(go to Section E)*
missing

2. In the past month, how often did you get together with a member of your family — at least once a day, at least once a week, at least once a month, or not at all? *(check one)*

☐
☐
☐
☐
☐
☐

- at least once a day
at least once a week
at least once a month
not at all
no family *(go to Section E)*
missing

3. Please look at the D-T Scale again. How do you feel about:

- a. The way you and your family act toward each other?
- b. The way things are in general between you and your family?

☐
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B-QoLI (continued)**Section E: Social Relations***Now I'd like to know about other people in your life, that is, people who are not in your family.*

1. About how often do you do the following? Would you say, at least once a day, once a week, once a month, less than once a month, or not at all? (check one answer for each question)

	at least once a day	at least once a week	at least once a month	less than once a month	not at all	missing
a. Visit with someone who does not live with you?	☐	☐	☐	☐	☐	☐
b. Telephone someone who does not live with you?	☐	☐	☐	☐	☐	☐
c. Do something with another person that you planned ahead of time?	☐	☐	☐	☐	☐	☐
d. Spend time with someone you consider more than a friend, like a spouse, a boyfriend or a girlfriend?	☐	☐	☐	☐	☐	☐

2. Please look at the D-T Scale again. How do you feel about:

a. The things you do with other people?

☐

b. The amount of time you spend with other people?

☐

c. The people you see socially?

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38113CV4**B-QoLI (continued)****Section F: Finances***A few questions about money.*

1. In the past month, have you had any financial support from the following sources?

	 No	 Yes	 Missing
a. Earned income	☐	☐	☐
b. Social Security Benefits (SSA)	☐	☐	☐
c. Social Security Disability Income (SSDI)	☐	☐	☐
d. Supplemental Security Income (SSI)	☐	☐	☐
e. Armed Service connected disability payments	☐	☐	☐
f. Other Social Welfare benefits — state or county (general welfare, Aid to Families with Dependent Children (AFDC))	☐	☐	☐
g. Vocational program (Comprehensive Employment and Training Act (CETA)), vocational rehabilitation, sheltered workshop	☐	☐	☐
h. Unemployment compensation	☐	☐	☐
i. Retirement, investment or savings income	☐	☐	☐
j. Rent supplements (including HUD, Section 8 certificates, living programs receiving public assistance support)	☐	☐	☐
k. Alimony and child support	☐	☐	☐
l. Food stamps	☐	☐	☐
m. Family and/or spouse contribution	☐	☐	☐
n. Other source(s) (specify) 	☐	☐	☐

2. How much money did you receive during the **past month** from all of these sources?

specify

\$

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B-QoLI (continued)**Section F: Finances (continued)**

3. On the average, how much money did you have to spend on yourself in the **past month**, not counting money for room and meals?

specify

(Interviewer rating: How reliable do you think the subject's responses were to Q1?)

Do not read this to the subject.

☐
☐
☐
☐

- very reliable
generally reliable
generally unreliable
very unreliable

4. During the past month, did you generally have enough money each month to cover... (read options a — e)

	 No	 Yes	 Missing
a. Food?	☐	☐	☐
b. Clothing?	☐	☐	☐
c. Housing?	☐	☐	☐
d. Traveling around the city for things like shopping, medical appointments, or visiting friends and relatives?	☐	☐	☐
e. Social activities like movies or eating in restaurants?	☐	☐	☐

5. Now, I'd like you to use the D-T Scale again. In general, how do you feel about:

- a. The amount of money you get?
- b. How comfortable and well-off you are financially?
- c. The amount of money you have available to spend for fun?

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B-QoLI (continued)**Section G: Work and School**

1a. Are you working now?

☐
☐
☐
☐

- yes, currently working (go to question 2)
- no, not currently working (go to question 1b)
- yes, worked in the past year but not currently employed (go to section H)
- missing

1b. Have you worked in the past month?

☐
☐
☐

- yes
- no (go to Section H)
- missing

2. What kind of work do you do at the present time? (If more than one job, use job at which the respondent earns the higher weekly salary) (specify below)

3. How many hours a week do you usually work?

of hours

4. How much do you earn per hour/week at this job? (choose one)

\$ per hour

\$

\$ per week

\$

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B-QoLI (continued)

Section G: Work and School (continued)

5. (Job satisfaction: use D-T Scale). How do you feel about:

a. Your job?

☐

b. What it is like where you work (the physical surroundings)?

☐

c. The amount you get paid?

☐

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3811304**B-QoLI (continued)****Section H: Legal and Safety Issues**

1. In the past month, were you a victim of:

a. Any violent crimes such as assault, rape, mugging, or robbery?

☐ no
☐ yes
☐ missing

b. Any nonviolent crimes such as burglary, theft of your property or money, or being cheated?

☐ no
☐ yes
☐ missing

2. In the past month, have you been arrested or picked-up for any crimes?

arrests

3. Please look at the D-T Scale again. How do you feel about:

a. How safe you are on the streets in your neighborhood?

b. How safe you are where you live?

c. The protection you have against being robbed or attacked?

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38113OV4**B-QoLI (continued)****Section I: Health***Now I'd like to ask you about your health.*

1. In general, would you say your health was:

☐

excellent

☐

very good

☐

good

☐

fair

☐

poor

☐

missing

2. How do you feel about: *(use the D/T Scale)*

a. Your health in general?

☐

b. Your physical condition?

☐

c. Your emotional well-being?

☐**Section J: Global Rating**

1. And a very general question again. Using the D/T Scale again,

How do you feel about your life in general?

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Prolactin related symptom questionnaire (PRSQ)

INSTRUCTIONS: Please rate your experience, if any, with each of the following symptoms since your last study visit. If you did not have the symptom, please check the box under the "Did Not Have" heading.**MEN:** Skip question ONE, then complete question TWO and THREE.**WOMEN:** Complete questions ONE and TWO, then STOP.

	How MUCH of the symptom did you have?						How BOTHERED were you by the symptom?				
	Did not have	Hardly any	A little bit	Medium amount	Quite a bit	Very much	Not at all bothered				Extremely bothered
	0	1	2	3	4	5	1	2	3	4	5
1. Menstrual changes (<i>Women only</i>)											
a. longer than usual time between periods	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
b. fewer days than usual of flow (bleeding)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
c. Need a smaller number of pads or tampons than usual during my period	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
2. Chest (breast) symptoms (<i>Men and Women</i>)											
a. increased breast size	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
b. unusual breast tenderness	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
c. visible fluid at one or both nipples	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
d. staining of underclothes or bed sheets	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
e. crusting at nipples	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
3. Penile function (<i>Men only</i>)											
a. fewer night time erections	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
b. difficulty achieving erection	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
c. fewer "wet dreams"	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
d. difficulty achieving ejaculation	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

WEEK 12

VISIT 4

7/31
38113CVA

Visual analogue scale (VAS): quality of sleep

How well have you slept in the past 7 nights?

Please mark the line below with a slash (/) to indicate your quality of sleep.

Very badly |-----| Very well
0 100

Score mm

Visual analogue scale (VAS): daytime drowsiness

How often have you felt drowsy in the past 7 days?

Please mark the line below with a slash (/) to indicate your daytime drowsiness.

Not at all |-----| All the time
0 100

Score mm

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Risperidone vs olanzapine
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38113Cv4

Anticholinergic symptom survey (ACS)

INSTRUCTIONS: Please rate whether you have had each of the following symptoms or problems during the past week, and, if so, how bothered you have been by each symptom or problem. If you did not have the symptom or problem, please check the box under the "Did Not Have" heading.

	Did not have	Not at all bothered				Extremely bothered
	0	1	2	3	4	5
1: Vision						
a. blurry vision	☐	☐	☐	☐	☐	☐
b. problems reading or writing due to vision	☐	☐	☐	☐	☐	☐
c. problems seeing signs or recognizing people at a distance due to vision	☐	☐	☐	☐	☐	☐
2. Bowel function						
a. difficulty with bowel movements, including hard, dry, or painful stools	☐	☐	☐	☐	☐	☐
b. less frequent bowel movements	☐	☐	☐	☐	☐	☐
3. Urinary function						
a. difficulty starting urination	☐	☐	☐	☐	☐	☐
b. difficulty emptying bladder completely	☐	☐	☐	☐	☐	☐
c. difficulty controlling bladder	☐	☐	☐	☐	☐	☐
4. Dry mouth	☐	☐	☐	☐	☐	☐
5. Problems keeping your dentures or false teeth in place	☐	☐	☐	☐	☐	☐
If you do not have dentures or false teeth, check box below and leave question blank.						
☐ do not have dentures or false teeth						

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Risperidone vs olanzapine
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VISIT 4



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38113CV4

Drug attitude inventory

You are to answer some questions about how you view the use of the psychiatric medications you have taken in the **PAST MONTH** and the nature of your experiences on these drugs.

For each statement, you are to decide whether it is **true as applied to you** or **false as applied to you**. If a statement is **TRUE** or **MOSTLY TRUE**, answer **TRUE** to the statement. If a statement is **FALSE** or **NOT USUALLY TRUE**, answer **FALSE** to the statement. You are allowed to change your answer.

If a statement is worded not quite the way you would express it yourself, decide whether it is **mostly true** or **mostly false**. Remember to give **YOUR OWN OPINION** — there is no right or wrong answer.

The medications referred to in each statement are **psychiatric medications only**.

	True	False
1. For me, the good things about medication outweigh the bad	☐	☐
2. I feel weird, like a "zombie", on medication	☐	☐
3. I take medications of my own free choice	☐	☐
4. Medications make me feel more relaxed	☐	☐
5. Medication makes me feel tired and sluggish	☐	☐
6. I take medication only when I am sick	☐	☐
7. I feel more normal on medication	☐	☐
8. It is unnatural for my mind and body to be controlled on medication	☐	☐
9. My thoughts are clearer on medication	☐	☐
10. By staying on medications I can prevent getting sick	☐	☐

Write any comments you have about your psychiatric medication or this questionnaire below.

Was assistance provided to the subject in completing this assessment? (check one)

☐ yes

☐ no

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38113CV5

Week 16 Visit 5

Trial medication

Dispense the trial medication and give instruction on its use. Administration is done once daily, preferably in the morning, according to the described dosing schedule. If there is a change in dosing (or time of administration), please mark the new date and dose on the Administration of trial medication form. Please collect the unused trial medication.

Concomitant therapy

If the subject has had a change in concomitant therapy the new dose schedule or concomitant therapy should be recorded on the Concomitant therapy form.

Please note that anticholinergics and benzodiazepines must be recorded on a separate concomitant therapy form.

Adverse events

If the subject has had any undesirable experience during the trial (whether or not considered related to the trial medication) the events should be recorded on the Adverse event form.

Anticholinergics

If extrapyramidal symptoms emerge or worsen during the double-blind period, an additional ESRS should be performed. Following completion of this ESRS, the dose of trial medication should be reduced. If the symptoms do not resolve, anticholinergic medication may be initiated. At each subsequent scheduled visit the need for continuation of anticholinergic medication should be evaluated. Please make sure that the date of completion has been recorded on the top of the first page of the ESRS.

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36113CV8

Week 20 Visit 6

— Complete PANSS

Trial medication

Dispense the trial medication and give instruction on its use. Administration is done once daily, preferably in the morning, according to the described dosing schedule. If there is a change in dosing (or time of administration), please mark the new date and dose on the Administration of trial medication form. Please collect the unused trial medication.

Concomitant therapy

If the subject has had a change in concomitant therapy the new dose schedule or concomitant therapy should be recorded on the Concomitant therapy form.

Please note that anticholinergics and benzodiazepines must be recorded on a separate concomitant therapy form.

Adverse events

If the subject has had any undesirable experience during the trial (whether or not considered related to the trial medication) the events should be recorded on the Adverse event form.

Anticholinergics

If extrapyramidal symptoms emerge or worsen during the double-blind period, an additional ESRS should be performed. Following completion of this ESRS, the dose of trial medication should be reduced. If the symptoms do not resolve, anticholinergic medication may be initiated. At each subsequent scheduled visit the need for continuation of anticholinergic medication should be evaluated. Please make sure that the date of completion has been recorded on the top of the first page of the ESRS.

Risperidone vs olanzapine
RIS-USA-113

CRF ID

WEEK 20

VISIT 6

701
38113V8**Positive and negative syndrome scale for schizophrenia (PANSS)***Enter the appropriate score for each item, refer to the Rating Manual for item definitions, description of anchoring points and scoring procedure.*

	Absent 1	Minimal 2	Mild 3	Moderate 4	Moderate severe 5	Severe 6	Extreme 7
1) Positive subscale							
P1 Delusions	☐	☐	☐	☐	☐	☐	☐
P2 Conceptual disorganization	☐	☐	☐	☐	☐	☐	☐
P3 Hallucinatory behavior	☐	☐	☐	☐	☐	☐	☐
P4 Excitement	☐	☐	☐	☐	☐	☐	☐
P5 Grandiosity	☐	☐	☐	☐	☐	☐	☐
P6 Suspiciousness/persecution	☐	☐	☐	☐	☐	☐	☐
P7 Hostility	☐	☐	☐	☐	☐	☐	☐
2) Negative subscale	1	2	3	4	5	6	7
N1 Blunted affect	☐	☐	☐	☐	☐	☐	☐
N2 Emotional withdrawal	☐	☐	☐	☐	☐	☐	☐
N3 Poor rapport	☐	☐	☐	☐	☐	☐	☐
N4 Passive/apathetic social withdrawal	☐	☐	☐	☐	☐	☐	☐
N5 Difficulty in abstract thinking	☐	☐	☐	☐	☐	☐	☐
N6 Lack of spontaneity and flow of conversation	☐	☐	☐	☐	☐	☐	☐
N7 Stereotyped thinking	☐	☐	☐	☐	☐	☐	☐

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

WEEK 20

VISIT 6

7/01
38113CV8

Positive and negative syndrome scale for schizophrenia (PANSS)
(continued)

Enter the appropriate score for each item, refer to the Rating Manual for item definitions, description of anchoring points and scoring procedure.

	Absent 1	Minimal 2	Mild 3	Moderate 4	Moderate severe 5	Severe 6	Extreme 7
3) General psychopathology subscale							
G1 Somatic concern	☐	☐	☐	☐	☐	☐	☐
G2 Anxiety	☐	☐	☐	☐	☐	☐	☐
G3 Guilt feelings	☐	☐	☐	☐	☐	☐	☐
G4 Tension	☐	☐	☐	☐	☐	☐	☐
G5 Mannerisms and posturing	☐	☐	☐	☐	☐	☐	☐
G6 Depression	☐	☐	☐	☐	☐	☐	☐
G7 Motor retardation	☐	☐	☐	☐	☐	☐	☐
G8 Uncooperativeness	☐	☐	☐	☐	☐	☐	☐
G9 Unusual thought content	☐	☐	☐	☐	☐	☐	☐
G10 Disorientation	☐	☐	☐	☐	☐	☐	☐
G11 Poor attention	☐	☐	☐	☐	☐	☐	☐
G12 Lack of judgement and insight	☐	☐	☐	☐	☐	☐	☐
G13 Disturbance of volition	☐	☐	☐	☐	☐	☐	☐
G14 Poor impulse control	☐	☐	☐	☐	☐	☐	☐
G15 Preoccupation	☐	☐	☐	☐	☐	☐	☐
G16 Active social avoidance	☐	☐	☐	☐	☐	☐	☐

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38113CV7

Week 24 Visit 7

Trial medication

Dispense the trial medication and give instruction on its use. Administration is done once daily, preferably in the morning, according to the described dosing schedule. If there is a change in dosing (or time of administration), please mark the new date and dose on the Administration of trial medication form. Please collect the unused trial medication.

Concomitant therapy

If the subject has had a change in concomitant therapy the new dose schedule or concomitant therapy should be recorded on the Concomitant therapy form.

Please note that anticholinergics and benzodiazepines must be recorded on a separate concomitant therapy form.

Adverse events

If the subject has had any undesirable experience during the trial (whether or not considered related to the trial medication) the events should be recorded on the Adverse event form.

Anticholinergics

If extrapyramidal symptoms emerge or worsen during the double-blind period, an additional ESRS should be performed. Following completion of this ESRS, the dose of trial medication should be reduced. If the symptoms do not resolve, anticholinergic medication may be initiated. At each subsequent scheduled visit the need for continuation of anticholinergic medication should be evaluated. Please make sure that the date of completion has been recorded on the top of the first page of the ESRS.

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38113CVA

Week 28 Visit 8

- Record vital signs (including body weight)
- Take blood samples for liver transaminase levels
- Measure waist/hip circumference
- Complete the ESRS
- Complete the PANSS
- Complete the CGI/CGI-C
- Administer and record the results of the cognitive tests
- Administer the Modified SIP, B-QoLI, PRSQ, VAS, ACS and DAI

Trial medication

Dispense the trial medication and give instruction on its use. Administration is done once daily, preferably in the morning, according to the described dosing schedule. Mark the date and the dose of the first intake on the Administration of trial medication form. If there is a change in dosing (or time of administration), please mark the new date and dose on the Administration of trial medication form.

Concomitant therapy

If the subject has had a change in concomitant therapy the new dose schedule or concomitant therapy should be recorded on the Concomitant therapy form.

Please note that anticholinergics and benzodiazepines must be recorded on a separate concomitant therapy form.

Adverse events

If the subject has had any undesirable experience during the trial (whether or not considered related to the trial medication) the events should be recorded on the Adverse event form.

Anticholinergics

If extrapyramidal symptoms emerge or worsen during the double-blind period, an additional ESRS should be performed. Following completion of this ESRS, the dose of trial medication should be reduced. If the symptoms do not resolve, anticholinergic medication may be initiated. At each subsequent scheduled visit the need for continuation of anticholinergic medication should be evaluated. Please make sure that the date of completion has been recorded on the top of the first page of the ESRS.

Risperidone vs olanzapine
RIS-USA-113

CRF ID

Date

m	d	y		

WEEK 28

VISIT 8

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38113CV4

Vital signs

Position	Pulse beats/minute	Blood pressure (mmHg) systolic/diastolic								
Supine, after 5 minutes rest	<table border="1"><tr><td></td><td></td><td></td></tr></table>				<table border="1"><tr><td></td><td></td><td>/</td><td></td><td></td></tr></table>			/		
		/								
Standing, after 1 minute rest	<table border="1"><tr><td></td><td></td><td></td></tr></table>				<table border="1"><tr><td></td><td></td><td>/</td><td></td><td></td></tr></table>			/		
		/								
Weight <table border="1"><tr><td></td><td></td><td></td></tr></table> lb										

Laboratory data**Sampling**

Sample date

m	d	y		

Sample reference of the laboratory

Clinically relevant changes in laboratory data☐ No clinically relevant changes in laboratory data.

If yes, record all clinically relevant changes during the trial on the AE form.

Risperidone vs olanzapine
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WEEK 28

VISIT 8

7/31
38113CV4

Extrapyramidal symptom rating scale (ESRS)

Questionnaire and Behavioural Scale
Check the appropriate box for each item.

I Parkinsonism, Dystonia and Dyskinesia	Absent	Mild	Moderate	Severe
1. Impression of slowness or weakness, difficulty in carrying out routine tasks	☐	☐	☐	☐
2. Difficulty walking or with balance	☐	☐	☐	☐
3. Difficulty swallowing or talking	☐	☐	☐	☐
4. Stiffness, stiff posture	☐	☐	☐	☐
5. Cramps or pains in limbs, back or neck	☐	☐	☐	☐
6. Restless, nervous, unable to keep still	☐	☐	☐	☐
7. Tremors, shaking	☐	☐	☐	☐
8. Oculogyric crisis, abnormal sustained posture	☐	☐	☐	☐
9. Increased salivation	☐	☐	☐	☐
10. Abnormal involuntary movements (dyskinesia) of extremities or trunk	☐	☐	☐	☐
11. Abnormal involuntary movements (dyskinesia) of tongue, jaw, lips or face	☐	☐	☐	☐
12. Dizziness when standing up (especially in the morning)	☐	☐	☐	☐

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7/01

3811304

Extrapyramidal symptom rating scale (ESRS) (continued)**Physician's examination***Enter the appropriate score for each item.*

II Parkinsonism	Score	Explanation
1. Expressive automatic movements (facial mask/speech)		0 normal 1 very mild decrease in facial expressiveness 2 mild decrease in facial expressiveness 3 rare spontaneous smile, decreased blinking, voice slightly monotonous 4 no spontaneous smile, staring gaze, low monotonous speech, mumbling 5 marked facial mask, unable to frown, slurred speech 6 extremely severe facial mask with unintelligible speech
2. Bradykinesia		0 normal 1 global impression of slowness in movements 2 definite slowness in movements 3 very mild difficulty in initiating movements 4 mild to moderate difficulty in initiating movements 5 difficulty in starting or stopping any movement, or freezing on initiating voluntary act 6 rare voluntary movement, almost completely immobile
3. Rigidity	right arm left arm right leg left leg	0 normal muscle tone 1 very mild, barely perceptible 2 mild (some resistance to passive movements) 3 moderate (definite resistance to passive movements) 4 moderately severe (moderate resistance but still easy to move the limb) 5 severe (marked resistance with definite difficulty to move the limb) 6 extremely severe (nearly frozen)
4. Gait and Posture		0 normal 1 mild decrease of pendular arm movement 2 moderate decrease of pendular arm movement, normal steps 3 no pendular arm movement, head flexed, steps more or less normal 4 stiff posture (neck, back), small step (shuffling gait) 5 more marked, festination or freezing on turning 6 triple flexion, barely able to walk

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38113Cv4

Extrapyramidal symptom rating scale (ESRS) (continued)*Enter the appropriate score for each item.*

II Parkinsonism - Physician's examination	Score	Explanation
5. Tremor		
right arm		
left arm		None 0
right leg		Borderline 1
left leg		Small amplitude 2 3 4
head		Moderate amplitude 3 4 5
jaw/chin		Large amplitude 4 5 6
tongue		
lips		
6. Akathisia		0 none 1 looks restless, nervous, impatient, uncomfortable 2 needs to move at least one extremity 3 often needs to move one extremity or to change position 4 moves one extremity almost constantly if sitting, or stamps feet while standing 5 unable to sit down for more than a short period of time 6 moves or walks constantly
7. Sialorrhea		0 absent 1 very mild 2 mild 3 moderate: impairs speech 4 moderately severe 5 severe 6 extremely severe: drooling
8. Postural stability		0 normal 1 hesitation when pushed but no retropulsion 2 retropulsion but recovers unaided 3 exaggerated retropulsion without falling 4 absence of postural response, would fall if not caught by examiner 5 unstable while standing, even without pushing 6 unable to stand without assistance

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38113C04**Extrapyramidal symptom rating scale (ESRS) (continued)***Enter the appropriate score for each item.***III Dystonia - Physician's examination**

1. Acute torsion dystonia	Score	Explanation		Score	Explanation
right arm	☐	0 absent	jaw	☐	0 absent
		1 very mild			1 very mild
left arm	☐	2 mild	tongue	☐	2 mild
		3 moderate			3 moderate
right leg	☐	4 moderately severe	lips	☐	4 moderately severe
		5 severe			5 severe
left leg	☐	6 extremely severe	eyes	☐	6 extremely severe
head	☐		trunk	☐	
2. Non-acute or chronic or tardive dystonia	Score	Explanation		Score	Explanation
right arm	☐	0 absent	jaw	☐	0 absent
		1 very mild			1 very mild
left arm	☐	2 mild	tongue	☐	2 mild
		3 moderate			3 moderate
right leg	☐	4 moderately severe	lips	☐	4 moderately severe
		5 severe			5 severe
left leg	☐	6 extremely severe	face	☐	6 extremely severe
head	☐		trunk	☐	

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Extrapyramidal symptom rating scale (ESRS) (continued)

Enter the appropriate score for each item.

IV Dyskinetic movements Physician's examination	Score	Explanation	Occasional	Frequent	Constant or almost so
1. Lingual movements Slow lateral or torsion movement of tongue	☐	None Borderline Clearly present, within oral cavity With occasional partial protrusion With complete protrusion	0 1 2 3 4	3 4 5	4 5 6
2. Jaw movements Lateral movement, chewing, biting, clenching	☐	None Borderline Clearly present, small amplitude Moderate amplitude, but without mouth opening Large amplitude, with mouth opening	0 1 2 3 4	3 4 5	4 5 6
3. Bucco-labial movements Puckering, pouting, smacking, etc...	☐	None Borderline Clearly present, small amplitude Moderate amplitude, forward movement of lips Large amplitude, marked, noisy smacking of lips	0 1 2 3 4	3 4 5	4 5 6
4. Truncal movements Rocking, twisting, pelvic gyrations	☐	None Borderline Clearly present, small amplitude Moderate amplitude Greater amplitude	0 1 2 3 4	3 4 5	4 5 6
5. Upper extremities Choreoathetoid movements only: arms, wrists, hands, fingers	☐	None Borderline Clearly present, small amplitude, movement of one limb Moderate amplitude, movement of one limb or movement of small amplitude involving two limbs Greater amplitude, movement involving two limbs	0 1 2 3 4	3 4 5	4 5 6
6. Lower extremities Choreoathetoid movements only: legs, knees, ankles, toes	☐	None Borderline Clearly present, small amplitude, movement of one limb Moderate amplitude, movement of one limb or movement of small amplitude involving two limbs Greater amplitude, movement involving two limbs	0 1 2 3 4	3 4 5	4 5 6
7. Other involuntary movements Swallowing, irregular respiration, frowning, blinking, grimacing, sighing, etc...	☐	None Borderline Clearly present, small amplitude Moderate amplitude Greater amplitude	0 1 2 3 4	3 4 5	4 5 6

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7/31	Extrapyramidal symptom rating scale (ESRS) (continued)
38113CV4	V Clinical global impression of severity of Parkinsonism
	<i>Considering your clinical experience, how severe is the parkinsonism at this time?</i>
	☐ absent
	☐ borderline
	☐ very mild
	☐ mild
	☐ moderate
	☐ moderately severe
	☐ marked
	☐ severe
	☐ extremely severe
	VI Clinical global impression of severity of Dystonia
	<i>Considering your clinical experience, how severe is the dystonia at this time?</i>
	☐ absent
	☐ borderline
	☐ very mild
	☐ mild
	☐ moderate
	☐ moderately severe
	☐ marked
	☐ severe
	☐ extremely severe

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381130V4

Extrapyramidal symptom rating scale (ESRS) (continued)**VII Clinical global impression of severity of Dyskinesia***Considering your clinical experience, how severe is the dyskinesia at this time?*

- ☐ absent
- ☐ borderline
- ☐ very mild
- ☐ mild
- ☐ moderate
- ☐ moderately severe
- ☐ marked
- ☐ severe
- ☐ extremely severe

VIII Stage of Parkinsonism (Hoehn & Yahr)

- ☐ absent
- ☐ unilateral involvement only, minimal or no functional impairment (stage I)
- ☐ bilateral or midline involvement, without impairment of balance (stage II)
- ☐ mild to moderate disabling: first signs of impaired righting or postural reflex
(unsteadiness as the subject turns or when he is pushed from standing equilibrium with the feet together and eyes closed),
subject is physically capable of leading independent life (stage III)
- ☐ severely disabling: subject is still able to walk and stand unassisted but is markedly incapacitated (stage IV)
- ☐ confinement to bed or wheelchair (stage V)

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38113CV4

Positive and negative syndrome scale for schizophrenia (PANSS)

Enter the appropriate score for each item, refer to the Rating Manual for item definitions, description of anchoring points and scoring procedure.

	Absent 1	Minimal 2	Mild 3	Moderate 4	Moderate Severe 5	Severe 6	Extreme 7
1) Positive subscale							
P1 Delusions	☐	☐	☐	☐	☐	☐	☐
P2 Conceptual disorganization	☐	☐	☐	☐	☐	☐	☐
P3 Hallucinatory behavior	☐	☐	☐	☐	☐	☐	☐
P4 Excitement	☐	☐	☐	☐	☐	☐	☐
P5 Grandiosity	☐	☐	☐	☐	☐	☐	☐
P6 Suspiciousness/persecution	☐	☐	☐	☐	☐	☐	☐
P7 Hostility	☐	☐	☐	☐	☐	☐	☐
2) Negative subscale	1	2	3	4	5	6	7
N1 Blunted affect	☐	☐	☐	☐	☐	☐	☐
N2 Emotional withdrawal	☐	☐	☐	☐	☐	☐	☐
N3 Poor rapport	☐	☐	☐	☐	☐	☐	☐
N4 Passive/apathetic social withdrawal	☐	☐	☐	☐	☐	☐	☐
N5 Difficulty in abstract thinking	☐	☐	☐	☐	☐	☐	☐
N6 Lack of spontaneity and flow of conversation	☐	☐	☐	☐	☐	☐	☐
N7 Stereotyped thinking	☐	☐	☐	☐	☐	☐	☐

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VISIT 8

38113CV47/31

Positive and negative syndrome scale for schizophrenia (PANSS) (continued)							
Enter the appropriate score for each item, refer to the Rating Manual for item definitions, description of anchoring points and scoring procedure.							
	Absent	Minimal	Mild	Moderate	Moderate severe	Severe	Extreme
3) General psychopathology subscale	1	2	3	4	5	6	7
G1 Somatic concern	☐	☐	☐	☐	☐	☐	☐
G2 Anxiety	☐	☐	☐	☐	☐	☐	☐
G3 Guilt feelings	☐	☐	☐	☐	☐	☐	☐
G4 Tension	☐	☐	☐	☐	☐	☐	☐
G5 Mannerisms and posturing	☐	☐	☐	☐	☐	☐	☐
G6 Depression	☐	☐	☐	☐	☐	☐	☐
G7 Motor retardation	☐	☐	☐	☐	☐	☐	☐
G8 Uncooperativeness	☐	☐	☐	☐	☐	☐	☐
G9 Unusual thought content	☐	☐	☐	☐	☐	☐	☐
G10 Disorientation	☐	☐	☐	☐	☐	☐	☐
G11 Poor attention	☐	☐	☐	☐	☐	☐	☐
G12 Lack of judgement and insight	☐	☐	☐	☐	☐	☐	☐
G13 Disturbance of volition	☐	☐	☐	☐	☐	☐	☐
G14 Poor impulse control	☐	☐	☐	☐	☐	☐	☐
G15 Preoccupation	☐	☐	☐	☐	☐	☐	☐
G16 Active social avoidance	☐	☐	☐	☐	☐	☐	☐

Risperidone vs olanzapine
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Clinical global impression (CGI)

Considering your total clinical experience with this particular population, how **severe** is the subject's psychotic disorder at this time?

- ☐ not ill
- ☐ very mild
- ☐ mild
- ☐ moderate
- ☐ marked
- ☐ severe
- ☐ extremely severe

Clinical global impression (CGI-C)

Compared to the subject's condition at baseline, how much has he/she **changed**? (Rate the local change, whether or not, in your judgement, it is due entirely to the drug treatment.)

- ☐ very much improved
- ☐ much improved
- ☐ minimally improved
- ☐ unchanged
- ☐ minimally worse
- ☐ much worse
- ☐ very much worse

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Waist/hip circumference ratio

Please measure in the horizontal plane with the subject standing, the minimum circumference between the costal margin and the iliac crest.

Waist circumference . inch

Please measure in the horizontal plane the maximum circumference over the buttocks.

Hip circumference . inch

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m	d	y

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Cognitive assessment**Week 28 Assessment** (perform these tests as soon as possible and not later than day 196 (visit 8))
Record the scores in the appropriate boxes. Please refer to the Cognitive Assessment Manual.

Test	Measure	Score	
SWMT (Spatial Working Memory Test)		Left	Right
	total correct at 5 seconds	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>
	total correct at 15 seconds	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>
	non-adjacent errors at 5 seconds	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>
	non-adjacent errors at 15 seconds	<table border="1" style="width: 40px; height: 20px;"></table>	<table border="1" style="width: 40px; height: 20px;"></table>
CVLT (California Verbal Learning Test)	learning trial 1	<table border="1" style="width: 60px; height: 20px;"></table>	
	learning trials 1 to 5	<table border="1" style="width: 60px; height: 20px;"></table>	
	long-delay free recall	<table border="1" style="width: 60px; height: 20px;"></table>	
	recognition discriminability	<table border="1" style="width: 60px; height: 20px;"></table> %	
CPT (Continuous Performance Test)		Positive	Negative
	d' block 1	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>
	d' block 2	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>
	d' block 3	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>
	d' total	<table border="1" style="width: 20px; height: 20px;"></table>	<table border="1" style="width: 20px; height: 20px;"></table>

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Cognitive assessment (continued)		
Week 28 Assessment (these tests should be performed as soon as possible and not later than day 196 (visit 8)) Record the scores in the appropriate boxes. Please refer to the Cognitive Assessment Manual.		
Test	Measure	Score
VFE (Verbal Fluency Examinations)	category fluency - total score	
	category repetitions	
	category intrusions	
	letter fluency - total score	
	letter repetitions	
	letter intrusions	
Trail Making Test A and B	Part A	
	Part B	
WCST (Wisconsin Card Sorting Test)	categories	
	total errors	
	perseverative errors	
	perseverative responses	

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3811304**Modified version sickness impact profile (M-SIP)***Please refer to the instructions in protocol guidelines manual.*

How would you describe your present health?

- ☐ very good
☐ good
☐ fair
☐ poor
☐ very poor

How would you describe your present quality of life?

- ☐ very good
☐ good
☐ fair
☐ poor
☐ very poor¹²

A. These statements describe your sleep and rest today**No** **Yes**

1. I spend much of the day lying down in order to rest.	☐	☐
2. I sit for much of the day.	☐	☐
3. I am sleeping or dozing most of the time — day and night.	☐	☐
4. I lie down more often during the day in order to rest.	☐	☐
5. I sit around half asleep.	☐	☐
6. I sleep less at night, for example, I wake up easily, I do not fall asleep for a long time, I keep waking up.	☐	☐
7. I sleep or doze more during the day.	☐	☐

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7/01	Modified version sickness impact profile (M-SIP) (continued)		
38113 CV4	B. These statements describe your daily work around the house today	No	Yes
	1. I only do housework or work around the house for short periods of time or I rest often.	☐	☐
	2. I am doing less of the daily household chores that I would usually do.	☐	☐
	3. I am not doing any of the daily household chores that I would usually do.	☐	☐
	4. I am not doing any of the maintenance or repair work that I would usually do in my house or garden.	☐	☐
	5. I am not doing any of the shopping that I would usually do.	☐	☐
	6. I am not doing any of the cleaning that I would usually do.	☐	☐
	7. I have difficulties using my hands, for example turning taps, using kitchen gadgets, sewing or doing repairs.	☐	☐
	8. I am not doing any of the clothes washing that I would usually do.	☐	☐
	9. I am not doing heavy work around the house.	☐	☐
	10. I have given up taking care of personal or household business affairs, for example, paying bills, banking or doing household accounts.	☐	☐

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Modified version sickness impact profile (M-SIP) (continued)**C. These statements describe your contact with your family and friends today**

No

Yes

1. I am going out less to visit people.	☐	☐
2. I am not going out to visit people at all.	☐	☐
3. I show less interest in other people's problems, for example, I do not listen when they tell me about their problems, I do not offer to help.	☐	☐
4. I am often irritable with those around me, for example, I snap at people or criticize easily.	☐	☐
5. I show less affection.	☐	☐
6. I take part in fewer social activities than I used to, for example, I go to fewer parties or social events.	☐	☐
7. I am cutting down the length of visits to friends.	☐	☐
8. I avoid having visitors.	☐	☐
9. My sexual activity is decreased.	☐	☐
10. I often express concern over what might be happening to my health.	☐	☐
11. I talk less with those around me.	☐	☐
12. I make many demands on other people, for example, I insist that they do things for me, or tell them how to do things.	☐	☐
13. I stay alone much of the time.	☐	☐
14. I am disagreeable with my family, for example, I act spitefully or stubbornly.	☐	☐
15. I frequently get angry with my family, for example, I hit them, scream or throw things at them.	☐	☐
16. I isolate myself as much as I can from the rest of my family.	☐	☐
17. I am paying less attention to the children.	☐	☐
18. I refuse contact with my family, for example, I turn away from them.	☐	☐
19. I am not doing the things I usually do to take care of my family.	☐	☐
20. I am not joking with my family members as I usually do.	☐	☐

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7/31 38113 CV4	Modified version sickness impact profile (M-SIP) (continued)		
	D. These statements describe your concentration, memory, attention and problem solving today	No	Yes
	1. I am confused and start to do more than one thing at a time.	☐	☐
	2. I have more minor accidents, for example, I drop things, I trip and fall, or bump into things.	☐	☐
	3. I react slowly to things that are said or done.	☐	☐
	4. I do not finish things I start.	☐	☐
	5. I have difficulty reasoning and solving problems, for example, making plans, making decisions, learning new things.	☐	☐
	6. I sometimes get confused, for example, I do not know where I am, who is around, or what day it is.	☐	☐
	7. I forget a lot, for example things that happened recently, where I put things, or to keep appointments.	☐	☐
	8. I do not keep my attention on any activity for long.	☐	☐
	9. I make more mistakes than usual.	☐	☐
	10. I have difficulty doing things which involve thought and concentration.	☐	☐
	E. These statements describe your communication with others through writing and speaking today	No	Yes
	1. I am having trouble writing or typing.	☐	☐
	2. I communicate mostly by nodding my head, pointing or using sign language or other gestures.	☐	☐
	3. My speech is understood only by a few people who know me well.	☐	☐
	4. I often lose control of my voice when I talk, for example, my voice gets louder or softer, or changes unexpectedly.	☐	☐
	5. I do not write except to sign my name.	☐	☐
	6. I carry on a conversation only when very close to other people or looking directly at them.	☐	☐
	7. I speak with difficulty, for example, I get stuck for words, I stutter, I stammer, I slur my words.	☐	☐
	8. I am understood with difficulty.	☐	☐
	9. I do not speak clearly when I am under stress.	☐	☐

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3813CV4**Modified version sickness impact profile (M-SIP) (continued)****F. The following statements describe the activities you usually do in your spare time for relaxation, entertainment or just to pass the time**

No

Yes

1. I spend shorter periods of time on my hobbies and recreation. ☐ No ☐ Yes
2. I am going out to enjoy myself less often. ☐ No ☐ Yes
3. I am cutting down on some of my usual inactive pastimes, for example, I watch less TV, play cards less, or read less. ☐ No ☐ Yes
4. I am not doing any of my usual inactive pastimes, for example, I watch less TV, play cards less, or read less. ☐ No ☐ Yes
5. I am doing more inactive pastimes in place of my other usual activities. ☐ No ☐ Yes
6. I am taking part in fewer community activities. ☐ No ☐ Yes
7. I am cutting down on some of my usual physical recreation or more active pastimes. ☐ No ☐ Yes
8. I am not doing any of my usual physical recreation or more active pastimes. ☐ No ☐ Yes

*Now please look through this questionnaire and make sure that you have read every question.
Thank you for your help.*

(Awad, 1990) (Revised 1992)

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B-QoLI**Section A: General Life Satisfaction**

Please look at this card. (Hand subject the Delighted-Terrible Scale.) This is called the Delighted-Terrible Scale (D-T Scale).

The scale goes from **terrible**, which is the lowest ranking of 1, to **delighted**, which is the highest ranking of 7. There are also points 2 through 6 with descriptions below them. (Read points on the scale.)

During the interview we'll be using this scale from time to time to help you tell me how you feel about different things in your life. All you have to do is tell me what on the scale best describes how you feel. For example, if I ask, "How do you feel about chocolate ice cream?", and you are someone who loves chocolate ice cream, you might point to "delighted." On the other hand, if you hate chocolate ice cream, you might point to "terrible." If you feel about equally satisfied and dissatisfied with chocolate ice cream, then you would point to the middle of the scale.

Do you have any questions about the scale? Please show me how you feel about chocolate ice cream. Let's begin.

The first question is a very general one.

1. How do you feel about your life in general? (Use D-T Scale)



Now, set the scale aside. I'll let you know when we need it again.

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B-QoLI (continued)**Section B: Living Situation****Living Situation Codes for the questions 1-3 that follow:**

Code	Situation
01	Hospital
02	Skilled nursing facility: 24 hour nursing service
03	Intermediate care facility: less than 24 hour nursing facility
04	Supervised group living (generally long term)
05	Transitional group home (halfway or quarterway house)
06	Family foster care
07	Cooperative apartment, supervised (staff on premises)
08	Cooperative apartment, unsupervised (staff not on premises)
09	Board and care home (private proprietary home for adults, with program and supervision)
10	Boarding house (includes meals, no program or supervision)
11	Rooming or boarding house or hotel (includes single room occupancy, no meals are provided, cooking facilities may be available)
12	Private house or apartment
13	Shelter
14	Jail
15	No current residence (including the streets, bus stations, missions, etc.)
16	Other

Now I am going to ask you some questions about your living situation.

1. What is your **current** living situation? (use codes above)

(If respondent is currently in the hospital, and this hospitalization has lasted less than 3 months, "living situation" = living situation just prior to hospitalization. If the hospitalization has been for 3 months or more, code "hospital".)

2. List in order the places you have lived during the past month, including psychiatric hospitalizations, beginning with your **current** living situation. (use codes above)

3. Which of these was your usual residence during the past month? (use codes above)

* If response is "Other" (code 16), describe: _____

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B-QoLI (continued)**Section B: Living Situation (continued)**

4. Now look at the D-T Scale again and answer the following:

(Hand respondent the D-T Scale. If respondent is currently in the hospital for less than 3 months, use more recent residence prior to hospitalization. If respondent is in the hospital 3 months or more, use hospital as the residence. Skip if homeless.)

How do you feel about:

- a. The living arrangements where you live?

☐

- b. The privacy you have there?

☐

- c. The prospect of staying on where you currently live for a long period of time?

☐**Section C: Daily Activities and Functioning**

1. Now let's talk about some of the things you did with your time in the
- past week**
- . I'm going to read you a list of things people may do with their free time. For each of these, please tell me if you did it during the past week. Did you... (read options A - H)

	No	Yes	Missing
a. Go for a walk?	☐	☐	☐
b. Go shopping?	☐	☐	☐
c. Go to a restaurant or coffee shop?	☐	☐	☐
d. Read a book, magazine or newspaper?	☐	☐	☐
e. Go for a ride in a bus or car?	☐	☐	☐
f. Work on a hobby?	☐	☐	☐
g. Play a sport?	☐	☐	☐
h. Go to a park?	☐	☐	☐

2. Overall, how would you rate your functioning in home, social, school, and work settings at the present time? Would you say your functioning in these areas is excellent, good, fair or poor? (check one)

☐ excellent ☐ good ☐ fair ☐ poor ☐ missingCase Report Form (5 Nov 97)
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B-QoLI (continued)

Section C: Daily Activities and Functioning (continued)

3. Now please look at the D-T Scale again. How do you feel about:

a. The way you spend your spare time?

☐

b. The chances you have to enjoy pleasant or beautiful things?

☐

c. The amount of fun you have?

☐

d. The amount of relaxation in your life?

☐

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B-QoLI (continued)**Section D: Family***The next few questions are about your relationship with your family, including any relatives with whom you live.*

1. In the past month, how often did you talk to a member of your family on the telephone? Would you say at least once a day, at least once a week, at least once a month, or not at all? *(check one)*

- ☐ at least once a day
☐ at least once a week
☐ at least once a month
☐ not at all
☐ no family *(go to Section E)*
☐ missing

2. In the past month, how often did you get together with a member of your family — at least once a day, at least once a week, at least once a month, or not at all? *(check one)*

- ☐ at least once a day
☐ at least once a week
☐ at least once a month
☐ not at all
☐ no family *(go to Section E)*
☐ missing

3. Please look at the D-T Scale again. How do you feel about:

- a. The way you and your family act toward each other? ☐
b. The way things are in general between you and your family? ☐

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B-QoLI (continued)**Section E: Social Relations***Now I'd like to know about other people in your life, that is, people who are not in your family.*

1. About how often do you do the following? Would you say, at least once a day, once a week, once a month, less than once a month, or not at all? (*check one answer for each question*)

	at least once a day	at least once a week	at least once a month	less than once a month	not at all	missing
a. Visit with someone who does not live with you?	☐	☐	☐	☐	☐	☐
b. Telephone someone who does not live with you?	☐	☐	☐	☐	☐	☐
c. Do something with another person that you planned ahead of time?	☐	☐	☐	☐	☐	☐
d. Spend time with someone you consider more than a friend, like a spouse, a boyfriend or a girlfriend?	☐	☐	☐	☐	☐	☐

2. Please look at the D-T Scale again. How do you feel about:

a. The things you do with other people?

☐

b. The amount of time you spend with other people?

☐

c. The people you see socially?

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B-QoLI (continued)

Section F: Finances

A few questions about money.

1. In the past month, have you had any financial support from the following sources?

	No	Yes	Missing
a. Earned income	☐	☐	☐
b. Social Security Benefits (SSA)	☐	☐	☐
c. Social Security Disability Income (SSDI)	☐	☐	☐
d. Supplemental Security Income (SSI)	☐	☐	☐
e. Armed Service connected disability payments	☐	☐	☐
f. Other Social Welfare benefits — state or county (general welfare, Aid to Families with Dependent Children (AFDC))	☐	☐	☐
g. Vocational program (Comprehensive Employment and Training Act (CETA)), vocational rehabilitation, sheltered workshop	☐	☐	☐
h. Unemployment compensation	☐	☐	☐
i. Retirement, investment or savings income	☐	☐	☐
j. Rent supplements (including HUD, Section 8 certificates, living programs receiving public assistance support)	☐	☐	☐
k. Alimony and child support	☐	☐	☐
l. Food stamps	☐	☐	☐
m. Family and/or spouse contribution	☐	☐	☐
n. Other source(s) (specify)	☐	☐	☐

2. How much money did you receive during the **past month** from all of these sources?

specify \$

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B-QoLI (continued)

Section F: Finances (continued)

3. On the average, how much money did you have to spend on yourself in the past month, not counting money for room and meals?

specify \$

(Interviewer rating: How reliable do you think the subject's responses were to Q1?)
Do not read this to the subject.

☐ very reliable
☐ generally reliable
☐ generally unreliable
☐ very unreliable

4. During the past month, did you generally have enough money each month to cover... *(read options a — e)*

	No	Yes	Missing
a. Food?	☐	☐	☐
b. Clothing?	☐	☐	☐
c. Housing?	☐	☐	☐
d. Traveling around the city for things like shopping, medical appointments, or visiting friends and relatives?	☐	☐	☐
e. Social activities like movies or eating in restaurants?	☐	☐	☐

5. Now, I'd like you to use the D-T Scale again. In general, how do you feel about:

a. The amount of money you get?

b. How comfortable and well-off you are financially?

c. The amount of money you have available to spend for fun?

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B-QoLI (continued)**Section G: Work and School**

1a. Are you working now?

- ☐ yes, currently working (go to question 2)
- ☐ no, not currently working (go to question 1b)
- ☐ yes, worked in the past year but not currently employed (go to section H)
- ☐ missing

1b. Have you worked in the past month?

- ☐ yes
- ☐ no (go to Section H)
- ☐ missing

2. What kind of work do you do at the present time? (If more than one job, use job at which the respondent earns the higher weekly salary) (specify below)

3. How many hours a week do you usually work?

of hours

4. How much do you earn per hour/week at this job? (choose one)

\$ per hour

\$

\$ per week

\$

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B-QoLI (continued)

Section G: Work and School (continued)

5. (Job satisfaction: use D-T Scale). How do you feel about:

a. Your job?

b. What it is like where you work (the physical surroundings)?

c. The amount you get paid?

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B-QoLI (continued)**Section H: Legal and Safety Issues**

1. In the past month, were you a victim of:

a. Any violent crimes such as assault, rape, mugging, or robbery?

☐ no☐ yes☐ missing

b. Any nonviolent crimes such as burglary, theft of your property or money, or being cheated?

☐ no☐ yes☐ missing

2. In the past month, have you been arrested or picked-up for any crimes?

arrests

3. Please look at the D-T Scale again. How do you feel about:

a. How safe you are on the streets in your neighborhood?

b. How safe you are where you live?

c. The protection you have against being robbed or attacked?

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B-QoLI (continued)**Section I: Health***Now I'd like to ask you about your health.*

1. In general, would you say your health was:

- ☐ excellent
☐ very good
☐ good
☐ fair
☐ poor
☐ missing

2. How do you feel about: *(use the D/T Scale)*

a. Your health in general?

b. Your physical condition?

c. Your emotional well-being?

Section J: Global Rating

1. And a very general question again. Using the D/T Scale again,

How do you feel about your life in general?

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Prolactin related symptom questionnaire (PRSQ)

INSTRUCTIONS: Please rate your experience, if any, with each of the following symptoms since your last study visit. If you did not have the symptom, please check the box under the "Did Not Have" heading.**MEN:** Skip question ONE, then complete question TWO and THREE.**WOMEN:** Complete questions ONE and TWO, then STOP.

	How MUCH of the symptom did you have?						How BOTHERED were you by the symptom?				
	Did not have	Hardly any	A little bit	Medium amount	Quite a bit	Very much	Not at all bothered				Extremely bothered
	0	1	2	3	4	5	1	2	3	4	5
1. Menstrual changes (Women only)											
a. longer than usual time between periods	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
b. fewer days than usual of flow (bleeding)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
c. Need a smaller number of pads or tampons than usual during my period	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
2. Chest (breast) symptoms (Men and Women)											
a. increased breast size	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
b. unusual breast tenderness	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
c. visible fluid at one or both nipples	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
d. staining of underclothes or bed sheets	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
e. crusting at nipples	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
3. Penile function (Men only)											
a. fewer night time erections	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
b. difficulty achieving erection	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
c. fewer "wet dreams"	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
d. difficulty achieving ejaculation	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

WEEK 28

VISIT 8

731

3811304

Visual analogue scale (VAS): quality of sleep

How well have you slept in the past 7 nights?

Please mark the line below with a slash (/) to indicate your quality of sleep.

Very badly |-----| Very well
0 100

Score mm**Visual analogue scale (VAS): daytime drowsiness**

How often have you felt drowsy in the past 7 days?

Please mark the line below with a slash (/) to indicate your daytime drowsiness.

Not at all |-----| All the time
0 100

Score mmCase Report Form (5 Nov 97)
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100

Risperidone vs olanzapine
RIS-USA-113

CRF ID

WEEK 28

VISIT 8

701
38113CV4**Anticholinergic symptom survey (ACS)**

INSTRUCTIONS: Please rate whether you have had each of the following symptoms or problems during the past week, and, if so, how bothered you have been by each symptom or problem. If you did not have the symptom or problem, please check the box under the "Did Not Have" heading.

	Did not have	Not at all bothered				Extremely bothered
	0	1	2	3	4	5
1. Vision						
a. blurry vision	☐	☐	☐	☐	☐	☐
b. problems reading or writing due to vision	☐	☐	☐	☐	☐	☐
c. problems seeing signs or recognizing people at a distance due to vision	☐	☐	☐	☐	☐	☐
2. Bowel function						
a. difficulty with bowel movements, including hard, dry, or painful stools	☐	☐	☐	☐	☐	☐
b. less frequent bowel movements	☐	☐	☐	☐	☐	☐
3. Urinary function						
a. difficulty starting urination	☐	☐	☐	☐	☐	☐
b. difficulty emptying bladder completely	☐	☐	☐	☐	☐	☐
c. difficulty controlling bladder	☐	☐	☐	☐	☐	☐
4. Dry mouth	☐	☐	☐	☐	☐	☐
5. Problems keeping your dentures or false teeth in place	☐	☐	☐	☐	☐	☐
If you do not have dentures or false teeth, check box below and leave question blank.						
☐ do not have dentures or false teeth						

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Risperidone vs olanzapine
RIS-USA-113

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WEEK 28

VISIT 8

7/31
38113CV4**Drug attitude inventory**

You are to answer some questions about how you view the use of the psychiatric medications you have taken in the **PAST MONTH** and the nature of your experiences on these drugs.

For each statement, you are to decide whether it is **true as applied to you** or **false as applied to you**. If a statement is **TRUE** or **MOSTLY TRUE**, answer **TRUE** to the statement. If a statement is **FALSE** or **NOT USUALLY TRUE**, answer **FALSE** to the statement. You are allowed to change your answer.

If a statement is worded not quite the way you would express it yourself, decide whether it is **mostly true** or **mostly false**. Remember to give **YOUR OWN OPINION** — there is no right or wrong answer.

The medications referred to in each statement are **psychiatric** medications only.

	True	False
1. For me, the good things about medication outweigh the bad	☐	☐
2. I feel weird, like a "zombie", on medication	☐	☐
3. I take medications of my own free choice	☐	☐
4. Medications make me feel more relaxed	☐	☐
5. Medication makes me feel tired and sluggish	☐	☐
6. I take medication only when I am sick	☐	☐
7. I feel more normal on medication	☐	☐
8. It is unnatural for my mind and body to be controlled on medication	☐	☐
9. My thoughts are clearer on medication	☐	☐
10. By staying on medications I can prevent getting sick	☐	☐

Write any comments you have about your psychiatric medication or this questionnaire below:

Was assistance provided to the subject in completing this assessment? (check one)

☐ yes

☐ no

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38113CV9

Week 32 Visit 9

Trial medication

Dispense the trial medication and give instruction on its use. Administration is done once daily, preferably in the morning, according to the described dosing schedule. Mark the date and the dose of the first intake on the Administration of trial medication form. If there is a change in dosing (or time of administration), please mark the new date and dose on the Administration of trial medication form.

Concomitant therapy

If the subject has had a change in concomitant therapy the new dose schedule or concomitant therapy should be recorded on the Concomitant therapy form.

Please note that anticholinergics and benzodiazepines must be recorded on a separate concomitant therapy form.

Adverse events

If the subject has had any undesirable experience during the trial (whether or not considered related to the trial medication) the events should be recorded on the Adverse event form.

Anticholinergics

If extrapyramidal symptoms emerge or worsen during the double-blind period, an additional ESRS should be performed. Following completion of this ESRS, the dose of trial medication should be reduced. If the symptoms do not resolve, anticholinergic medication may be initiated. At each subsequent scheduled visit the need for continuation of anticholinergic medication should be evaluated. Please make sure that the date of completion has been recorded on the top of the first page of the ESRS.

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38113CV9

Week 36 Visit 10

Trial medication

Dispense the trial medication and give instruction on its use. Administration is done once daily, preferably in the morning, according to the described dosing schedule. Mark the date and the dose of the first intake on the Administration of trial medication form. If there is a change in dosing (or time of administration), please mark the new date and dose on the Administration of trial medication form.

Concomitant therapy

If the subject has had a change in concomitant therapy the new dose schedule or concomitant therapy should be recorded on the Concomitant therapy form.

Please note that anticholinergics and benzodiazepines must be recorded on a separate concomitant therapy form.

Adverse events

If the subject has had any undesirable experience during the trial (whether or not considered related to the trial medication) the events should be recorded on the Adverse event form.

Anticholinergics

If extrapyramidal symptoms emerge or worsen during the double-blind period, an additional ESRS should be performed. Following completion of this ESRS, the dose of trial medication should be reduced. If the symptoms do not resolve, anticholinergic medication may be initiated. At each subsequent scheduled visit the need for continuation of anticholinergic medication should be evaluated. Please make sure that the date of completion has been recorded on the top of the first page of the ESRS.

7/31

38113CV9

Week 40 Visit 11

Trial medication

Dispense the trial medication and give instruction on its use. Administration is done once daily, preferably in the morning, according to the described dosing schedule. Mark the date and the dose of the first intake on the Administration of trial medication form. If there is a change in dosing (or time of administration), please mark the new date and dose on the Administration of trial medication form.

Concomitant therapy

If the subject has had a change in concomitant therapy the new dose schedule or concomitant therapy should be recorded on the Concomitant therapy form.

Please note that anticholinergics and benzodiazepines must be recorded on a separate concomitant therapy form.

Adverse events

If the subject has had any undesirable experience during the trial (whether or not considered related to the trial medication) the events should be recorded on the Adverse event form.

Anticholinergics

If extrapyramidal symptoms emerge or worsen during the double-blind period, an additional ESRS should be performed. Following completion of this ESRS, the dose of trial medication should be reduced. If the symptoms do not resolve, anticholinergic medication may be initiated. At each subsequent scheduled visit the need for continuation of anticholinergic medication should be evaluated. Please make sure that the date of completion has been recorded on the top of the first page of the ESRS.

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38113CV12

Final Visit __

- Record vital signs (including body weight)
- Take blood and urine samples for haematology, biochemistry, urinalysis and prolactin
- Measure waist/hip circumference
- Perform a physical examination
- Perform electrocardiogram
- Complete the ESRS
- Complete the PANSS
- Complete the CGI/CGI-C
- Complete the HAM-D
- Administer and record the results of the cognitive tests
- Administer the Modified SIP, B-QoLI, PRSQ, VAS, ACS and DAI

Trial medication

Please collect all the used and unused trial medication.

Concomitant therapy

If the subject has had a change in concomitant therapy the new dose schedule or concomitant therapy should be recorded on the Concomitant therapy form.

Please note that anticholinergics and benzodiazepines must be recorded on a separate concomitant therapy form.

Adverse events

If the subject has had any undesirable experience during the trial (whether or not considered related to the trial medication) the events should be recorded on the Adverse event form.

Risperidone vs olanzapine
RIS-USA-113

CRF ID

Date

m	d	y	

FINAL

VISIT

7/31

38113CV12

Vital signs

Position	Pulse beats/minute	Blood pressure (mmHg) systolic/diastolic								
Supine, after 5 minutes rest	<table border="1"><tr><td></td><td></td><td></td></tr></table>				<table border="1"><tr><td></td><td></td><td>/</td><td></td><td></td></tr></table>			/		
		/								
Standing, after 1 minute rest	<table border="1"><tr><td></td><td></td><td></td></tr></table>				<table border="1"><tr><td></td><td></td><td>/</td><td></td><td></td></tr></table>			/		
		/								
Weight <table border="1"><tr><td></td><td></td><td></td></tr></table> lb										

Laboratory data

Sampling

Sample date

m	d	y.

Sample reference of the laboratory

Clinically relevant changes in laboratory data

☐ No clinically relevant changes in laboratory data.

If yes, record all clinically relevant changes during the trial on the AE form.

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Risperidone vs olanzapine
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CRF ID

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VISIT **Physical examination***Please review all body parts/organs and body systems and check the appropriate box for each.*

Body part or system	Normal	Abnormal	Specify all changes (positive and negative) since last examination
General appearance	☒	☐	
Skin	☐	☐	
Eyes	☐	☐	
Ears, nose, throat	☐	☐	
Head and neck	☐	☐	
Heart	☐	☐	
Chest and lungs	☐	☐	
Breasts	☐	☐	
Abdomen	☐	☐	
Extremities	☐	☐	
Back	☐	☐	
Lymph nodes	☐	☐	
Peripheral pulses	☐	☐	
Musculoskeletal	☐	☐	
Neurological	☐	☐	
Other, specify:	☐	☐	

*Please complete the Adverse Event Form if the physical examination discloses a clinically relevant change in findings.*Case Report Form (5 Nov 97)
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Risperidone vs olanzapine
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VISIT **Electrocardiogram**

Date performed

m	d	y

Heart rate

beats/min

QRS width

ms

PR interval

ms

QT interval

ms

QTc interval

ms

Rhythm

- ☐ sinus bradycardia (≤ 60 beats/min)
- ☐ sinus tachycardia (≥ 100 beats/min)
- ☐ supraventricular premature beat(s)
- ☐ ventricular premature beat(s)
- ☐ atrial fibrillation

Hypertrophy

- ☐ left ventricular hypertrophy

Infarction

- ☐ acute
- ☐ subacute (recent)
- ☐ old

Conduction

- AV block ☐ first degree
- ☐ second degree
- ☐ third degree
- LBB block ☐ incomplete
- ☐ complete
- RBB block ☐ incomplete
- ☐ complete

Morphology

- ☐ myocardial ischaemia
- ☐ atypical repolarisation disturbance(s)

Other abnormalities, specify: _____

ECG within normal limits

- ☐ yes ☐ no

Clinically relevant changes in electrocardiographic evaluation

- ☐ clinically relevant changes in electrocardiographic evaluation

If yes, record all clinically relevant changes during the trial on the Adverse Event Form.

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Risperidone vs olanzapine
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VISIT __

7/31
38113CV12**Extrapyramidal symptom rating scale (ESRS)****Questionnaire and Behavioural Scale***Check the appropriate box for each item.*

I Parkinsonism, Dystonia and Dyskinesia	Absent	Mild	Moderate	Severe
1. Impression of slowness or weakness, difficulty in carrying out routine tasks	☐	☐	☐	☐
2. Difficulty walking or with balance	☐	☐	☐	☐
3. Difficulty swallowing or talking	☐	☐	☐	☐
4. Stiffness, stiff posture	☐	☐	☐	☐
5. Cramps or pains in limbs, back or neck	☐	☐	☐	☐
6. Restless, nervous, unable to keep still	☐	☐	☐	☐
7. Tremors, shaking	☐	☐	☐	☐
8. Oculogyric crisis, abnormal sustained posture	☐	☐	☐	☐
9. Increased salivation	☐	☐	☐	☐
10. Abnormal involuntary movements (dyskinesia) of extremities or trunk	☐	☐	☐	☐
11. Abnormal involuntary movements (dyskinesia) of tongue, jaw, lips or face	☐	☐	☐	☐
12. Dizziness when standing up (especially in the morning)	☐	☐	☐	☐

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7/91
38113CV12

Extrapyramidal symptom rating scale (ESRS) (continued)

Physician's examination
Enter the appropriate score for each item.

II Parkinsonism	Score	Explanation
1. Expressive automatic movements (facial mask/speech)		0 normal 1 very mild decrease in facial expressiveness 2 mild decrease in facial expressiveness 3 rare spontaneous smile, decreased blinking, voice slightly monotonous 4 no spontaneous smile, staring gaze, low monotonous speech, mumbling 5 marked facial mask, unable to frown, slurred speech 6 extremely severe facial mask with unintelligible speech
2. Bradykinesia		0 normal 1 global impression of slowness in movements 2 definite slowness in movements 3 very mild difficulty in initiating movements 4 mild to moderate difficulty in initiating movements 5 difficulty in starting or stopping any movement, or freezing on initiating voluntary act 6 rare voluntary movement, almost completely immobile
3. Rigidity	right arm left arm right leg left leg	0 normal muscle tone 1 very mild, barely perceptible 2 mild (some resistance to passive movements) 3 moderate (definite resistance to passive movements) 4 moderately severe (moderate resistance but still easy to move the limb) 5 severe (marked resistance with definite difficulty to move the limb) 6 extremely severe (nearly frozen)
4. Gait and Posture		0 normal 1 mild decrease of pendular arm movement 2 moderate decrease of pendular arm movement, normal steps 3 no pendular arm movement, head flexed, steps more or less normal 4 stiff posture (neck, back), small step (shuffling gait) 5 more marked, festination or freezing on turning 6 triple flexion, barely able to walk

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Risperidone vs olanzapine
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VISIT 701
38113CV12**Extrapyramidal symptom rating scale (ESRS) (continued)***Enter the appropriate score for each item.*

II Parkinsonism - Physician's examination	Score	Explanation
5. Tremor		
right arm		
left arm		None 0
right leg		Borderline 1
left leg		Small amplitude 2 3 4
head		Moderate amplitude 3 4 5
jaw/chin		Large amplitude 4 5 6
tongue		
lips		
6. Akathisia		0 none 1 looks restless, nervous, impatient, uncomfortable 2 needs to move at least one extremity 3 often needs to move one extremity or to change position 4 moves one extremity almost constantly if sitting, or stamps feet while standing 5 unable to sit down for more than a short period of time 6 moves or walks constantly
7. Sialorrhea		0 absent 1 very mild 2 mild 3 moderate: impairs speech 4 moderately severe 5 severe 6 extremely severe: drooling
8. Postural stability		0 normal 1 hesitation when pushed but no retropulsion 2 retropulsion but recovers unaided 3 exaggerated retropulsion without falling 4 absence of postural response, would fall if not caught by examiner 5 unstable while standing, even without pushing 6 unable to stand without assistance

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Risperidone vs olanzapine
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VISIT 7/31
38113CV12**Extrapyramidal symptom rating scale (ESRS) (continued)***Enter the appropriate score for each item.***III Dystonia - Physician's examination**

1. Acute torsion dystonia	Score	Explanation		Score	Explanation
right arm	☐	0 absent	jaw	☐	0 absent
		1 very mild			1 very mild
left arm	☐	2 mild	tongue	☐	2 mild
		3 moderate			3 moderate
right leg	☐	4 moderately severe	lips	☐	4 moderately severe
		5 severe			5 severe
left leg	☐	6 extremely severe	eyes	☐	6 extremely severe
head	☐		trunk	☐	
2. Non-acute or chronic or tardive dystonia	Score	Explanation		Score	Explanation
right arm	☐	0 absent	jaw	☐	0 absent
		1 very mild			1 very mild
left arm	☐	2 mild	tongue	☐	2 mild
		3 moderate			3 moderate
right leg	☐	4 moderately severe	lips	☐	4 moderately severe
		5 severe			5 severe
left leg	☐	6 extremely severe	face	☐	6 extremely severe
head	☐		trunk	☐	

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Extrapyramidal symptom rating scale (ESRS) (continued)*Enter the appropriate score for each item.*

IV Dyskinetic movements Physician's examination	Score	Explanation	Occasional	Frequent	Constant or almost so
1. Lingual movements Slow lateral or torsion movement of tongue		None Borderline Clearly present, within oral cavity With occasional partial protrusion With complete protrusion	0 1 2 3 4		
2. Jaw movements Lateral movement, chewing, biting, clenching		None Borderline Clearly present, small amplitude Moderate amplitude, but without mouth opening Large amplitude, with mouth opening	0 1 2 3 4		
3. Bucco-labial movements Puckering, pouting, smacking, etc...		None Borderline Clearly present, small amplitude Moderate amplitude, forward movement of lips Large amplitude, marked, noisy smacking of lips	0 1 2 3 4		
4. Truncal movements Rocking, twisting, pelvic gyrations		None Borderline Clearly present, small amplitude Moderate amplitude Greater amplitude	0 1 2 3 4		
5. Upper extremities Choreoathetoid movements only: arms, wrists, hands, fingers		None Borderline Clearly present, small amplitude, movement of one limb Moderate amplitude, movement of one limb or movement of small amplitude involving two limbs Greater amplitude, movement involving two limbs	0 1 2 3 4		
6. Lower extremities Choreoathetoid movements only: legs, knees, ankles, toes		None Borderline Clearly present, small amplitude, movement of one limb Moderate amplitude, movement of one limb or movement of small amplitude involving two limbs Greater amplitude, movement including two limbs	0 1 2 3 4		
7. Other involuntary movements Swallowing, irregular respiration, frowning, blinking, grimacing, sighing, etc...		None Borderline Clearly present, small amplitude Moderate amplitude Greater amplitude	0 1 2 3 4		

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Extrapyramidal symptom rating scale (ESRS) (continued)**V Clinical global Impression of severity of Parkinsonism***Considering your clinical experience, how severe is the parkinsonism at this time?*

- ☐ absent
- ☐ borderline
- ☐ very mild
- ☐ mild
- ☐ moderate
- ☐ moderately severe
- ☐ marked
- ☐ severe
- ☐ extremely severe

VI Clinical global impression of severity of Dystonia*Considering your clinical experience, how severe is the dystonia at this time?*

- ☐ absent
- ☐ borderline
- ☐ very mild
- ☐ mild
- ☐ moderate
- ☐ moderately severe
- ☐ marked
- ☐ severe
- ☐ extremely severe

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38113QY12

Extrapyramidal symptom rating scale (ESRS) (continued)**VII Clinical global impression of severity of Dyskinesia***Considering your clinical experience, how severe is the dyskinesia at this time?*

- ☐ absent
- ☐ borderline
- ☐ very mild
- ☐ mild
- ☐ moderate
- ☐ moderately severe
- ☐ marked
- ☐ severe
- ☐ extremely severe

VIII Stage of Parkinsonism (Hoehn & Yahr)

- ☐ absent
- ☐ unilateral involvement only, minimal or no functional impairment (stage I)
- ☐ bilateral or midline involvement, without impairment of balance (stage II)
- ☐ mild to moderate disabling: first signs of impaired righting or postural reflex
(unsteadiness as the subject turns or when he is pushed from standing equilibrium with the feet together and eyes closed),
subject is physically capable of leading independent life (stage III)
- ☐ severely disabling: subject is still able to walk and stand unassisted but is markedly incapacitated (stage IV)
- ☐ confinement to bed or wheelchair (stage V)

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Positive and negative syndrome scale for schizophrenia (PANSS)*Enter the appropriate score for each item, refer to the Rating Manual for item definitions, description of anchoring points and scoring procedure.*

	Absent 1	Minimal 2	Mild 3	Moderate 4	Moderate severe 5	Severe 6	Extreme 7
1) Positive subscale							
P1 Delusions	☐	☐	☐	☐	☐	☐	☐
P2 Conceptual disorganization	☐	☐	☐	☐	☐	☐	☐
P3 Hallucinatory behavior	☐	☐	☐	☐	☐	☐	☐
P4 Excitement	☐	☐	☐	☐	☐	☐	☐
P5 Grandiosity	☐	☐	☐	☐	☐	☐	☐
P6 Suspiciousness/persecution	☐	☐	☐	☐	☐	☐	☐
P7 Hostility	☐	☐	☐	☐	☐	☐	☐
2) Negative subscale	1	2	3	4	5	6	7
N1 Blunted affect	☐	☐	☐	☐	☐	☐	☐
N2 Emotional withdrawal	☐	☐	☐	☐	☐	☐	☐
N3 Poor rapport	☐	☐	☐	☐	☐	☐	☐
N4 Passive/apathetic social withdrawal	☐	☐	☐	☐	☐	☐	☐
N5 Difficulty in abstract thinking	☐	☐	☐	☐	☐	☐	☐
N6 Lack of spontaneity and flow of conversation	☐	☐	☐	☐	☐	☐	☐
N7 Stereotyped thinking	☐	☐	☐	☐	☐	☐	☐

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VISIT _

7/31
38113CV12**Positive and negative syndrome scale for schizophrenia (PANSS)
(continued)***Enter the appropriate score for each item, refer to the Rating Manual for item definitions, description of anchoring points and scoring procedure.*

	Absent 1	Minimal 2	Mild 3	Moderate 4	Moderate severe 5	Severe 6	Extreme 7
3) General psychopathology subscale							
G1 Somatic concern	☐	☐	☐	☐	☐	☐	☐
G2 Anxiety	☐	☐	☐	☐	☐	☐	☐
G3 Guilt feelings	☐	☐	☐	☐	☐	☐	☐
G4 Tension	☐	☐	☐	☐	☐	☐	☐
G5 Mannerisms and posturing	☐	☐	☐	☐	☐	☐	☐
G6 Depression	☐	☐	☐	☐	☐	☐	☐
G7 Motor retardation	☐	☐	☐	☐	☐	☐	☐
G8 Uncooperativeness	☐	☐	☐	☐	☐	☐	☐
G9 Unusual thought content	☐	☐	☐	☐	☐	☐	☐
G10 Disorientation	☐	☐	☐	☐	☐	☐	☐
G11 Poor attention	☐	☐	☐	☐	☐	☐	☐
G12 Lack of judgement and insight	☐	☐	☐	☐	☐	☐	☐
G13 Disturbance of volition	☐	☐	☐	☐	☐	☐	☐
G14 Poor impulse control	☐	☐	☐	☐	☐	☐	☐
G15 Preoccupation	☐	☐	☐	☐	☐	☐	☐
G16 Active social avoidance	☐	☐	☐	☐	☐	☐	☐

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38113CV12

HAM-D*Please enter the appropriate score for each item.*

Item	Score	Legend
1. Depressed mood (Sadness, hopeless, helpless, worthless)		0 absent 1 these feeling states indicated only on questioning 2 these feeling states spontaneously reported verbally 3 communicates feeling states only non-verbally, i.e. facial expression, posture, voice, and tendency to weep 4 subject reports virtually only these feeling states in his/her spontaneous and non-verbal communication
2. Feelings of guilt		0 absent 1 self reproach, feels he/she has let people down 2 ideas of guilt or rumination over past errors or sinful deeds 3 present illness is a punishment. Delusion of guilt. 4 hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations
3. Suicide		0 absent 1 feels life is not worth living 2 wishes he/she were dead or any thoughts of possible death to self 3 suicide ideas or gestures 4 attempts at suicide (any serious attempt rate 4)
4. Insomnia early		0 no difficulty falling asleep 1 complains of occasional difficulty falling asleep - i.e., more than half an hour 2 complains of nightly difficulty falling asleep
5. Insomnia middle		0 no difficulty 1 subject complains of being restless and disturbed during the night 2 waking during the night - any getting out of bed rates 2 (except for purposes of voiding)
6. Insomnia late		0 no difficulty 1 Waking in early hours of the morning but goes back to sleep 2 Unable to fall asleep again if he/she gets out of bed
7. Work and activities		0 no difficulty 1 thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies 2 loss of interest in activity; hobbies or work - either directly reported by the subject, or indirect in listlessness, indecision and vacillation (he/she feels he/she has to push self to work or activities). 3 decrease in actual time spent in activities or decrease in productivity. In hospital rate 3 if subject does not spend at least three hours a day in job or activities (hospital hobbies) exclusive of ward chores. 4 stopped working because of present illness. In hospital rate 4 if subject engages in no activities except ward chores, or if subject fails to perform ward chores unassisted.
8. Retardation (Slowness of thought and speech; impaired ability to concentrate; decreased motor activity)		0 normal speech and thought 1 slight retardation at interview 2 obvious retardation at interview 3 interview difficult 4 complete stupor

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HAM-D (continued)		
Please enter the appropriate score for each item.		
Physician's examination	Score	Legend
9. Agitation	☐	0 none 1 fidgetiness 2 playing with hands, hair, etc. 3 moving about, can't sit still 4 hand wringing, nail biting, hair-pulling, biting of lips
10. Anxiety psychic	☐	0 no difficulty 1 subjective tension and irritability 2 worrying about minor matters 3 apprehensive attitude, apparent in face or speech 4 fears expressed without questioning
11. Anxiety somatic (Physiological concomitants of anxiety, such as: Gastro-intestinal: dry mouth, wind, indigestion, diarrhea, cramps, belching; Cardio-vascular: palpitations, headaches; Respiratory: hyperventilation, sighing; Urinary frequency; Sweating)	☐	0 absent 1 mild 2 moderate 3 severe 4 incapacitating
12. Somatic symptoms gastrointestinal	☐	0 none 1 loss of appetite but eating without staff encouragement. Heavy feelings in abdomen. 2 difficulty eating without staff urging. Requests or requires laxatives or bowel medications for or medication for G.I. symptoms.
13. Somatic symptoms general	☐	0 none 1 heaviness in limbs, back or head. Backaches, headache, muscle aches. Loss of energy and fatigability. 2 any clear-cut symptom rates 2.
14. Genital symptoms (Symptoms such as: loss of libido, menstrual disturbances)	☐	0 absent 1 mild 2 severe
15. Hypochondriasis	☐	0 not present 1 self-absorption (bodily) 2 preoccupation with health 3 frequent complaints, requests for help, etc. 4 hypochondriacal delusions
16. Loss of weight A. When rating by history Rate either A or B B. On weekly ratings by ward psychiatrist, when actual weight changes are measured	☐	0 no weight loss 1 probable weight loss associated with present illness 2 definite (according to subject) weight loss 3 not assessed 0 less than 1 kg, weight loss in week 1 greater than 1 kg, weight loss in week 2 greater than 2 kg, weight loss in week 3 not assessed

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HAM-D (continued)		
Please enter the appropriate score for each item.		
Physician's examination	Score	Legend
17. Insight		0 acknowledges being depressed and ill 1 acknowledges illness but attributes cause to bad food, climate, overwork, virus, need for rest, etc. 2 denies being ill at all
18. Diurnal variation A. Note whether symptoms are worse in morning or evening. If no diurnal variation, mark 0. B. When present, mark the severity of the variation. Mark 0 if no variation.	 	0 no variation 1 worse in a.m. 2 worse in p.m. 0 none 1 mild 2 severe
19. Depersonalization and derealization (such as: Feelings of unreality, nihilistic ideas)		0 absent 1 mild 2 moderate 3 severe 4 incapacitating
20. Paranoid symptoms		0 none 1 suspicious 2 ideas of reference 3 delusions of reference and persecution
21. Obsessional and compulsive symptoms		0 absent 1 mild 2 severe

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38113CV12**Clinical global impression (CGI)**

Considering your total clinical experience with this particular population, how **severe** is the subject's psychotic disorder at this time?

- ☐ not ill
- ☐ very mild
- ☐ mild
- ☐ moderate
- ☐ marked
- ☐ severe
- ☐ extremely severe

Clinical global impression (CGI-C)

Compared to the subject's condition at baseline, how much has he/she **changed**? (Rate the local change, whether or not, in your judgement, it is due entirely to the drug treatment.)

- ☐ very much improved
- ☐ much improved
- ☐ minimally improved
- ☐ unchanged
- ☐ minimally worse
- ☐ much worse
- ☐ very much worse

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38113 CV12**Waist/hip circumference ratio**

Please measure in the horizontal plane with the subject standing, the minimum circumference between the costal margin and the iliac crest.

Waist circumference . inch

Please measure in the horizontal plane the maximum circumference over the buttocks.

Hip circumference . inchCase Report Form (5 Nov 97)
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Date

m	d	y		

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Cognitive assessment

Final Assessment (perform these tests as soon as possible and not later than day 308 (visit 12))
 Record the scores in the appropriate boxes. Please refer to the Cognitive Assessment Manual.

Test	Measure	Score	
		Left	Right
SWMT (Spatial Working Memory Test)	total correct at 5 seconds		
	total correct at 15 seconds		
	non-adjacent errors at 5 seconds		
	non-adjacent errors at 15 seconds		
CVLT (California Verbal Learning Test)	learning trial 1		
	learning trials 1 to 5		
	long-delay free recall		
	recognition discriminability		%
CPT (Continuous Performance Test)		Positive	Negative
	d' block 1	☐	☐
	d' block 2	☐	☐
	d' block 3	☐	☐
	d' total	☐	☐

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Cognitive assessment (continued)		
Final Assessment (these tests should be performed as soon as possible and not later than day 308 (visit 12)) Record the scores in the appropriate boxes. Please refer to the Cognitive Assessment Manual.		
Test	Measure	Score
VFE (Verbal Fluency Examinations)	category fluency - total score	
	category repetitions	
	category intrusions	
	letter fluency - total score	
	letter repetitions	
	letter intrusions	
Trail Making Test A and B	Part A	
	Part B	
WCST (Wisconsin Card Sorting Test)	categories	
	total errors	
	perseverative errors	
	perseverative responses	

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VISIT 731
38113CV12**Modified version sickness impact profile (M-SIP)***Please refer to the instructions in protocol guidelines manual.*

How would you describe your present health?

- ☐ very good
- ☐ good
- ☐ fair
- ☐ poor
- ☐ very poor

How would you describe your present quality of life?

- ☐ very good
- ☐ good
- ☐ fair
- ☐ poor
- ☐ very poor

A. These statements describe your sleep and rest today**No** **Yes**

1. I spend much of the day lying down in order to rest.	☐	☐
2. I sit for much of the day.	☐	☐
3. I am sleeping or dozing most of the time — day and night.	☐	☐
4. I lie down more often during the day in order to rest.	☐	☐
5. I sit around half asleep.	☐	☐
6. I sleep less at night, for example, I wake up easily, I do not fall asleep for a long time, I keep waking up.	☐	☐
7. I sleep or doze more during the day.	☐	☐

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VISIT 7/01
38113CV12**Modified version sickness impact profile (M-SIP) (continued)****B. These statements describe your daily work around the house today**

No

Yes

1. I only do housework or work around the house for short periods of time or I rest often.
2. I am doing less of the daily household chores that I would usually do.
3. I am not doing any of the daily household chores that I would usually do.
4. I am not doing any of the maintenance or repair work that I would usually do in my house or garden.
5. I am not doing any of the shopping that I would usually do.
6. I am not doing any of the cleaning that I would usually do.
7. I have difficulties using my hands, for example turning taps, using kitchen gadgets, sewing or doing repairs.
8. I am not doing any of the clothes washing that I would usually do.
9. I am not doing heavy work around the house.
10. I have given up taking care of personal or household business affairs, for example, paying bills, banking or doing household accounts.

☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐Case Report Form (5 Nov 97)
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Modified version sickness impact profile (M-SIP) (continued)**C. These statements describe your contact with your family and friends today**

No

Yes

1. I am going out less to visit people.	☐	☐
2. I am not going out to visit people at all.	☐	☐
3. I show less interest in other people's problems, for example, I do not listen when they tell me about their problems, I do not offer to help.	☐	☐
4. I am often irritable with those around me, for example, I snap at people or criticize easily.	☐	☐
5. I show less affection.	☐	☐
6. I take part in fewer social activities than I used to, for example, I go to fewer parties or social events.	☐	☐
7. I am cutting down the length of visits to friends.	☐	☐
8. I avoid having visitors.	☐	☐
9. My sexual activity is decreased.	☐	☐
10. I often express concern over what might be happening to my health.	☐	☐
11. I talk less with those around me.	☐	☐
12. I make many demands on other people, for example, I insist that they do things for me, or tell them how to do things.	☐	☐
13. I stay alone much of the time.	☐	☐
14. I am disagreeable with my family, for example, I act spitefully or stubbornly.	☐	☐
15. I frequently get angry with my family, for example, I hit them, scream or throw things at them.	☐	☐
16. I isolate myself as much as I can from the rest of my family.	☐	☐
17. I am paying less attention to the children.	☐	☐
18. I refuse contact with my family, for example, I turn away from them.	☐	☐
19. I am not doing the things I usually do to take care of my family.	☐	☐
20. I am not joking with my family members as I usually do.	☐	☐

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Modified version sickness impact profile (M-SIP) (continued)

D. These statements describe your concentration, memory, attention and problem solving today

No Yes

1. I am confused and start to do more than one thing at a time.	☐	☐
2. I have more minor accidents, for example, I drop things, I trip and fall, or bump into things.	☐	☐
3. I react slowly to things that are said or done.	☐	☐
4. I do not finish things I start.	☐	☐
5. I have difficulty reasoning and solving problems, for example, making plans, making decisions, learning new things.	☐	☐
6. I sometimes get confused, for example, I do not know where I am, who is around, or what day it is.	☐	☐
7. I forget a lot, for example things that happened recently, where I put things, or to keep appointments.	☐	☐
8. I do not keep my attention on any activity for long.	☐	☐
9. I make more mistakes than usual.	☐	☐
10. I have difficulty doing things which involve thought and concentration.	☐	☐

E. These statements describe your communication with others through writing and speaking today

No Yes

1. I am having trouble writing or typing.	☐	☐
2. I communicate mostly by nodding my head, pointing or using sign language or other gestures.	☐	☐
3. My speech is understood only by a few people who know me well.	☐	☐
4. I often lose control of my voice when I talk, for example, my voice gets louder or softer, or changes unexpectedly.	☐	☐
5. I do not write except to sign my name.	☐	☐
6. I carry on a conversation only when very close to other people or looking directly at them.	☐	☐
7. I speak with difficulty, for example, I get stuck for words, I stutter, I stammer, I slur my words.	☐	☐
8. I am understood with difficulty.	☐	☐
9. I do not speak clearly when I am under stress.	☐	☐

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38113CV12**Modified version sickness impact profile (M-SIP) (continued)****F. The following statements describe the activities you usually do in your spare time for relaxation, entertainment or just to pass the time**

No

Yes

1. I spend shorter periods of time on my hobbies and recreation. ☐ No ☐ Yes
2. I am going out to enjoy myself less often. ☐ No ☐ Yes
3. I am cutting down on some of my usual inactive pastimes, for example, I watch less TV, play cards less, or read less. ☐ No ☐ Yes
4. I am not doing any of my usual inactive pastimes, for example, I watch less TV, play cards less, or read less. ☐ No ☐ Yes
5. I am doing more inactive pastimes in place of my other usual activities. ☐ No ☐ Yes
6. I am taking part in fewer community activities. ☐ No ☐ Yes
7. I am cutting down on some of my usual physical recreation or more active pastimes. ☐ No ☐ Yes
8. I am not doing any of my usual physical recreation or more active pastimes. ☐ No ☐ Yes

*Now please look through this questionnaire and make sure that you have read every question.
Thank you for your help.*

(Awad, 1990) (Revised 1992)

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VISIT 7/31
38113CV12**B-QoLI****Section A: General Life Satisfaction**

Please look at this card. (Hand subject the Delighted-Terrible Scale.) This is called the Delighted-Terrible Scale (D-T Scale).

*The scale goes from **terrible**, which is the lowest ranking of 1, to **delighted**, which is the highest ranking of 7. There are also points 2 through 6 with descriptions below them. (Read points on the scale.)*

During the interview we'll be using this scale from time to time to help you tell me how you feel about different things in your life. All you have to do is tell me what on the scale best describes how you feel. For example, if I ask, "How do you feel about chocolate ice cream?", and you are someone who loves chocolate ice cream, you might point to "delighted." On the other hand, if you hate chocolate ice cream, you might point to "terrible." If you feel about equally satisfied and dissatisfied with chocolate ice cream, then you would point to the middle of the scale.

Do you have any questions about the scale? Please show me how you feel about chocolate ice cream. Let's begin.

The first question is a very general one.

1. How do you feel about your life in general? (Use D-T)



Now, set the scale aside. I'll let you know when we need it again.

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B-QoLI (continued)**Section B: Living Situation****Living Situation Codes for the questions 1-3 that follow:**

Code	Situation
01	Hospital
02	Skilled nursing facility: 24 hour nursing service
03	Intermediate care facility: less than 24 hour nursing facility
04	Supervised group living (generally long term)
05	Transitional group home (halfway or quarterway house)
06	Family foster care
07	Cooperative apartment, supervised (staff on premises)
08	Cooperative apartment, unsupervised (staff not on premises)
09	Board and care home (private proprietary home for adults, with program and supervision)
10	Boarding house (includes meals, no program or supervision)
11	Rooming or boarding house or hotel (includes single room occupancy, no meals are provided, cooking facilities may be available)
12	Private house or apartment
13	Shelter
14	Jail
15	No current residence (including the streets, bus stations, missions, etc.)
16	Other

Now I am going to ask you some questions about your living situation.

1. What is your **current** living situation? (use codes above)

(If respondent is currently in the hospital, and this hospitalization has lasted less than 3 months, "living situation" = living situation just prior to hospitalization. If the hospitalization has been for 3 months or more, code "hospital".)

2. List in order the places you have lived during the past month, including psychiatric hospitalizations, beginning with your **current** living situation. (use codes above)

3. Which of these was your usual residence during the past month? (use codes above)

* If response is "Other" (code 16), describe: _____

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VISIT 7/31
38113CV12**B-QoLI (continued)****Section B: Living Situation (continued)**

4. Now look at the D-T Scale again and answer the following:

(Hand respondent the D-T Scale. If respondent is currently in the hospital for less than 3 months, use more recent residence prior to hospitalization. If respondent is in the hospital 3 months or more, use hospital as the residence. Skip if homeless.)

How do you feel about:

a. The living arrangements where you live?

☐

b. The privacy you have there?

☐

c. The prospect of staying on where you currently live for a long period of time?

☐**Section C: Daily Activities and Functioning**1. Now let's talk about some of the things you did with your time in the **past week**. I'm going to read you a list of things people may do with their free time. For each of these, please tell me if you did it during the past week. Did you... *(read options A - H)*

	No	Yes	Missing
a. Go for a walk?	☐	☐	☐
b. Go shopping?	☐	☐	☐
c. Go to a restaurant or coffee shop?	☐	☐	☐
d. Read a book, magazine or newspaper?	☐	☐	☐
e. Go for a ride in a bus or car?	☐	☐	☐
f. Work on a hobby?	☐	☐	☐
g. Play a sport?	☐	☐	☐
h. Go to a park?	☐	☐	☐

2. Overall, how would you rate your functioning in home, social, school, and work settings at the present time? Would you say your functioning in these areas is excellent, good, fair or poor? *(check one)*☐ excellent ☐ good ☐ fair ☐ poor ☐ missingCase Report Form (5 Nov 97)
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B-QoLI (continued)

Section C: Daily Activities and Functioning (continued)

3. Now please look at the D-T Scale again. How do you feel about:

- a. The way you spend your spare time?
- b. The chances you have to enjoy pleasant or beautiful things?
- c. The amount of fun you have?
- d. The amount of relaxation in your life?

☐
☐
☐
☐

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VISIT 7/31
38113CV12**B-QoLI (continued)****Section D: Family**

The next few questions are about your relationship with your family, including any relatives with whom you live.

1. In the past month, how often did you talk to a member of your family on the telephone? Would you say at least once a day, at least once a week, at least once a month, or not at all? *(check one)*

- ☐ at least once a day
☐ at least once a week
☐ at least once a month
☐ not at all
☐ no family *(go to Section E)*
☐ missing

2. In the past month, how often did you get together with a member of your family — at least once a day, at least once a week, at least once a month, or not at all? *(check one)*

- ☐ at least once a day
☐ at least once a week
☐ at least once a month
☐ not at all
☐ no family *(go to Section E)*
☐ missing

3. Please look at the D-T Scale again. How do you feel about:

- a. The way you and your family act toward each other? ☐
b. The way things are in general between you and your family? ☐

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38113CV12**B-QoLI (continued)****Section E: Social Relations***Now I'd like to know about other people in your life, that is, people who are not in your family.*

1. About how often do you do the following? Would you say, at least once a day, once a week, once a month, less than once a month, or not at all? *(check one answer for each question)*

	at least once a day	at least once a week	at least once a month	less than once a month	not at all	missing
a. Visit with someone who does not live with you?	☐	☐	☐	☐	☐	☐
b. Telephone someone who does not live with you?	☐	☐	☐	☐	☐	☐
c. Do something with another person that you planned ahead of time?	☐	☐	☐	☐	☐	☐
d. Spend time with someone you consider more than a friend, like a spouse, a boyfriend or a girlfriend?	☐	☐	☐	☐	☐	☐

2. Please look at the D-T Scale again. How do you feel about:

a. The things you do with other people?

☐

b. The amount of time you spend with other people?

☐

c. The people you see socially?

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1. In the past month, have you had any financial support from the following sources?

	No	Yes	Missing
a. Earned income	☐	☐	☐
b. Social Security Benefits (SSA)	☐	☐	☐
c. Social Security Disability Income (SSDI)	☐	☐	☐
d. Supplemental Security Income (SSI)	☐	☐	☐
e. Armed Service connected disability payments	☐	☐	☐
f. Other Social Welfare benefits — state or county (general welfare, Aid to Families with Dependent Children (AFDC))	☐	☐	☐
g. Vocational program (Comprehensive Employment and Training Act (CETA)), vocational rehabilitation, sheltered workshop	☐	☐	☐
h. Unemployment compensation	☐	☐	☐
i. Retirement, investment or savings income	☐	☐	☐
j. Rent supplements (including HUD, Section 8 certificates, living programs receiving public assistance support)	☐	☐	☐
k. Alimony and child support	☐	☐	☐
l. Food stamps	☐	☐	☐
m. Family and/or spouse contribution	☐	☐	☐
n. Other source(s) (specify)	☐	☐	☐

2. How much money did you receive during the **past month** from all of these sources?

specify

\$

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VISIT 7/31
38113CV12**B-QoLI (continued)****Section F: Finances (continued)**

3. On the average, how much money did you have to spend on yourself in the past month, not counting money for room and meals?

specify

\$

*(Interviewer rating: How reliable do you think the subject's responses were to Q1?)***Do not read this to the subject.**

- ☐ very reliable
- ☐ generally reliable
- ☐ generally unreliable
- ☐ very unreliable

4. During the past month, did you generally have enough money each month to cover... *(read options a — e)*

	No	Yes	Missing
a. Food?	☐	☐	☐
b. Clothing?	☐	☐	☐
c. Housing?	☐	☐	☐
d. Traveling around the city for things like shopping, medical appointments, or visiting friends and relatives?	☐	☐	☐
e. Social activities like movies or eating in restaurants?	☐	☐	☐

5. Now, I'd like you to use the D-T Scale again. In general, how do you feel about:

- a. The amount of money you get?
- b. How comfortable and well-off you are financially?
- c. The amount of money you have available to spend for fun?

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VISIT 7/31
38113CV12**B-QoLI (continued)****Section G: Work and School**

1a. Are you working now?

- ☐ yes, currently working (go to question 2)
- ☐ no, not currently working (go to question 1b)
- ☐ yes, worked in the past year but not currently employed (go to section H)
- ☐ missing

1b. Have you worked in the past month?

- ☐ yes
- ☐ no (go to Section H)
- ☐ missing

2. What kind of work do you do at the present time? (If more than one job, use job at which the respondent earns the higher weekly salary) (specify below)

3. How many hours a week do you usually work?

of hours

4. How much do you earn per hour/week at this job? (choose one)

\$ per hour

\$

\$ per week

\$

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B-QoLI (continued)

Section G: Work and School (continued)

5. (Job satisfaction: *use D-T Scale*). How do you feel about:

a. Your job?

b. What it is like where you work (the physical surroundings)?

c. The amount you get paid?

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B-QoLI (continued)

Section H: Legal and Safety Issues

1. In the past month, were you a victim of:

a. Any violent crimes such as assault, rape, mugging, or robbery?

- ☐ no
☐ yes
☐ missing

b. Any nonviolent crimes such as burglary, theft of your property or money, or being cheated?

- ☐ no
☐ yes
☐ missing

2. In the past month, have you been arrested or picked-up for any crimes?

arrests

3. Please look at the D-T Scale again. How do you feel about:

a. How safe you are on the streets in your neighborhood?

b. How safe you are where you live?

c. The protection you have against being robbed or attacked?

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38113CV12**B-QoLI (continued)****Section I: Health***Now I'd like to ask you about your health.*

1. In general, would you say your health was:

- ☐ excellent
- ☐ very good
- ☐ good
- ☐ fair
- ☐ poor
- ☐ missing

2. How do you feel about: *(use the D/T Scale)*

a. Your health in general?

b. Your physical condition?

c. Your emotional well-being?

Section J: Global Rating

1. And a very general question again. Using the D/T Scale again,

How do you feel about your life in general?

Risperidone vs olanzapine
RIS-USA-113

CRF ID

FINAL

VISIT 7/01
38113CV12

Prolactin related symptom questionnaire (PRSQ)

INSTRUCTIONS: Please rate your experience, if any, with each of the following symptoms since your last study visit. If you did not have the symptom, please check the box under the "Did Not Have" heading.

MEN: Skip question ONE, then complete question TWO and THREE.

WOMEN: Complete questions ONE and TWO, then STOP.

	How MUCH of the symptom did you have?						How BOTHERED were you by the symptom?				
	Did not have	Hardly any	A little bit	Medium amount	Quite a bit	Very much	Not at all bothered			Extremely bothered	
	0	1	2	3	4	5	1	2	3	4	5
1. Menstrual changes (Women only)											
a. longer than usual time between periods	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
b. fewer days than usual of flow (bleeding)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
c. Need a smaller number of pads or tampons than usual during my period	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
2. Chest (breast) symptoms (Men and Women)											
a. increased breast size	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
b. unusual breast tenderness	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
c. visible fluid at one or both nipples	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
d. staining of underclothes or bed sheets	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
e. crusting at nipples	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
3. Penile function (Men only)											
a. fewer night time erections	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
b. difficulty achieving erection	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
c. fewer "wet dreams"	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
d. difficulty achieving ejaculation	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

FINAL

VISIT 701
38113CV12**Visual analogue scale (VAS): quality of sleep**

How well have you slept in the past 7 nights?

Please mark the line below with a slash (/) to indicate your quality of sleep.

Very badly |-----| Very well
0 100

Score mm**Visual analogue scale (VAS): daytime drowsiness**

How often have you felt drowsy in the past 7 days?

Please mark the line below with a slash (/) to indicate your daytime drowsiness.

Not at all |-----| All the time
0 100

Score mmCase Report Form (5 Nov 97)
Janssen Research Foundation

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

FINAL

VISIT

7/31

38113CV12

Anticholinergic symptom survey (ACS)

INSTRUCTIONS: Please rate whether you have had each of the following symptoms or problems during the past week, and, if so, how bothered you have been by each symptom or problem. If you did not have the symptom or problem, please check the box under the "Did Not Have" heading.

	Did not have	Not at all bothered	1	2	3	4	Extremely bothered
	0						5
1. Vision							
a. blurry vision	☐	☐	☐	☐	☐	☐	☐
b. problems reading or writing due to vision	☐	☐	☐	☐	☐	☐	☐
c. problems seeing signs or recognizing people at a distance due to vision	☐	☐	☐	☐	☐	☐	☐
2. Bowel function							
a. difficulty with bowel movements, including hard, dry, or painful stools	☐	☐	☐	☐	☐	☐	☐
b. less frequent bowel movements	☐	☐	☐	☐	☐	☐	☐
3. Urinary function							
a. difficulty starting urination	☐	☐	☐	☐	☐	☐	☐
b. difficulty emptying bladder completely	☐	☐	☐	☐	☐	☐	☐
c. difficulty controlling bladder	☐	☐	☐	☐	☐	☐	☐
4. Dry mouth	☐	☐	☐	☐	☐	☐	☐
5. Problems keeping your dentures or false teeth in place	☐	☐	☐	☐	☐	☐	☐
If you do not have dentures or false teeth, check box below and leave question blank.							
☐ do not have dentures or false teeth							

Case Report Form (5 Nov 97)
Janssen Research Foundation

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

FINAL

VISIT

7/01

38113CV12

Drug attitude inventory

You are to answer some questions about how you view the use of the psychiatric medications you have taken in the **PAST MONTH** and the nature of your experiences on these drugs.

For each statement, you are to decide whether it is **true as applied to you** or **false as applied to you**. If a statement is **TRUE** or **MOSTLY TRUE**, answer **TRUE** to the statement. If a statement is **FALSE** or **NOT USUALLY TRUE**, answer **FALSE** to the statement. You are allowed to change your answer.

If a statement is worded not quite the way you would express it yourself, decide whether it is **mostly true** or **mostly false**. Remember to give **YOUR OWN OPINION** — there is no right or wrong answer.

The medications referred to in each statement are **psychiatric** medications only.

	True	False
1. For me, the good things about medication outweigh the bad	☐	☐
2. I feel weird, like a "zombie", on medication	☐	☐
3. I take medications of my own free choice	☐	☐
4. Medications make me feel more relaxed	☐	☐
5. Medication makes me feel tired and sluggish	☐	☐
6. I take medication only when I am sick	☐	☐
7. I feel more normal on medication	☐	☐
8. It is unnatural for my mind and body to be controlled on medication	☐	☐
9. My thoughts are clearer on medication	☐	☐
10. By staying on medications I can prevent getting sick	☐	☐

Write any comments you have about your psychiatric medication or this questionnaire below:

Was assistance provided to the subject in completing this assessment? (check one)

☐ yes

☐ no

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

38113CTM
tm901 7/31**Administration of trial medication**

Record the complete dose schedule of trial medication used by the subject.

Any change in dose must be recorded on a separate line. Interruptions should be recorded as '0'.

 From date	 To date	 No. of capsules/day (QD)	Reason for change		
			PP*	AE**	Other
m d y	m d y				

*PP = As per protocol **AE = Adverse event

Case Report Form (5 Nov 97)
Janssen Research Foundation

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

38113CTM
Im901 7/31**Administration of trial medication (continued)***Record the complete dose schedule of trial medication used by the subject.**Any change in dose must be recorded on a separate line. Interruptions should be recorded as '0'.*

From date	To date	No. of capsules/day (QD)	Reason for change		
			PP*	AE**	Other
m d y	m d y				

*PP = As per protocol **AE = Adverse event

Case Report Form (5 Nov 97)
Janssen Research Foundation

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

38113CTM fm901 7/31

Administration of trial medication (continued)*Record the complete dose schedule of trial medication used by the subject.**Any change in dose must be recorded on a separate line. Interruptions should be recorded as '0'.*

From date	To date	No. of capsules/day (QD)	Reason for change		
			PP*	AE**	Other
m d y	m d y				
m d y	m d y				
m d y	m d y				
m d y	m d y				
m d y	m d y				
m d y	m d y				
m d y	m d y				
m d y	m d y				
m d y	m d y				
m d y	m d y				
m d y	m d y				
m d y	m d y				
m d y	m d y				
m d y	m d y				

* PP = As per protocol **AE = Adverse event

Case Report Form (5 Nov 97)
Janssen Research Foundation

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

Concomitant therapy (except benzodiazepines and anticholinergics)

Was the subject taking any therapy at entry, or did the subject take any concomitant therapy (except benzodiazepines and anticholinergics) during the trial (prescription and non-prescription medication, including oral contraceptives)?

☐ None (to be checked at the end of the trial only)

If yes, specify below

Therapy (describe literally as prescribed) e.g. Perdoan Mono C 200 mg BID PO	Indication	Start of therapy	End of therapy
1. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y
2. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y
3. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y
4. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y
5. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y
6. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y
7. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y

If medication is used for a pre-existing concomitant disease, list the disease on the Concomitant Disease Form.

If medication is used for a new indication, list the event on the Adverse Event Form.

Case Report Form (5 Nov 97)

Janssen Research Foundation

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

38113CCT c801 7/31

Concomitant therapy (except benzodiazepines and anticholinergics)			
Was the subject taking any therapy at entry, or did the subject take any concomitant therapy (except benzodiazepines and anticholinergics) during the trial (prescription and non-prescription medication, including oral contraceptives)?			
☐ No additional concomitant therapies			
If yes, specify below			
Therapy (describe literally as prescribed) e.g. Valium 5 mg BID PO	Indication	Start of therapy	End of therapy
8. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y
9. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y
10. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y
11. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y
12. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y
13. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y
14. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y

If medication is used for a pre-existing concomitant disease, list the disease on the Concomitant Disease Form.
If medication is used for a new indication, list the event on the Adverse Event Form.

Case Report Form (5 Nov 97)
Janssen Research Foundation

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

38113CCT
c901 7/31**Concomitant therapy (except benzodiazepines and anticholinergics)**

Was the subject taking any therapy at entry, or did the subject take any concomitant therapy (except benzodiazepines and anticholinergics) during the trial (prescription and non-prescription medication, including oral contraceptives)?

☐ No additional concomitant therapies

If yes, specify below

Therapy (describe literally as prescribed) e.g. Valium 5 mg BID PO	Indication	Start of therapy	End of therapy																
15. _____ Daily dose _____	_____	☐ pre trial. If not, <table border="1"><tr><td> </td><td> </td><td> </td><td> </td></tr><tr><td>m</td><td>d</td><td>y</td><td> </td></tr></table>					m	d	y		☐ ongoing post trial. If not, <table border="1"><tr><td> </td><td> </td><td> </td><td> </td></tr><tr><td>m</td><td>d</td><td>y</td><td> </td></tr></table>					m	d	y	
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m	d	y																	
m	d	y																	

If medication is used for a pre-existing concomitant disease, list the disease on the Concomitant Disease Form.

If medication is used for a new indication, list the event on the Adverse Event Form.

Case Report Form (5 Nov 97)

Janssen Research Foundation

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

38113CCT
d5901 7/31**Concomitant therapy (except benzodiazepines and anticholinergics)**

Was the subject taking any therapy at entry, or did the subject take any concomitant therapy (except benzodiazepines and anticholinergics) during the trial (prescription and non-prescription medication, including oral contraceptives)?

☐ No additional concomitant therapies

If yes, specify below

Therapy (describe literally as prescribed) e.g. Valium 5 mg BID PO	Indication	Start of therapy	End of therapy																
22. _____ Daily dose _____	_____ _____ _____	☐ pre trial. If not, <table><tr><td></td><td></td><td></td><td></td></tr><tr><td>m</td><td>d</td><td>y</td><td></td></tr></table>					m	d	y		☐ ongoing post trial. If not, <table><tr><td></td><td></td><td></td><td></td></tr><tr><td>m</td><td>d</td><td>y</td><td></td></tr></table>					m	d	y	
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If medication is used for a pre-existing concomitant disease, list the disease on the Concomitant Disease Form.

If medication is used for a new indication, list the event on the Adverse Event Form.

Case Report Form (5 Nov 97)
Janssen Research Foundation

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

38113CCT
e801 731**Concomitant therapy (except benzodiazepines and anticholinergics)**

Was the subject taking any therapy at entry, or did the subject take any concomitant therapy (except benzodiazepines and anticholinergics) during the trial (prescription and non-prescription medication, including oral contraceptives)?

☐ No additional concomitant therapies

If yes, specify below

Therapy (describe literally as prescribed) e.g. Valium 5 mg BID PO	Indication	Start of therapy	End of therapy
29. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y
30. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y
31. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y
32. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y
33. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y
34. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y
35. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y

If medication is used for a pre-existing concomitant disease, list the disease on the Concomitant Disease Form.

If medication is used for a new indication, list the event on the Adverse Event Form.

Case Report Form (5 Nov 97)

Janssen Research Foundation

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

38113CCT c801 7/31

Concomitant therapy (benzodiazepines and anticholinergics)

Was the subject taking any benzodiazepines or anticholinergics at entry, or did the subject take any benzodiazepines or anticholinergics during the trial?

☐ None (to be checked at the end of the trial only)

If yes, specify below

Therapy (describe literally as prescribed) e.g. Perdolan Mono C 200 mg BID PO	Indication	Start of therapy	End of therapy
1. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y
2. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y
3. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y
4. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y
5. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y
6. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y
7. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y

If medication is used for a pre-existing concomitant disease, list the disease on the Concomitant Disease Form.

If medication is used for a new indication, list the event on the Adverse Event Form.

Case Report Form (5 Nov 97)

Janssen Research Foundation

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

38113CCT
c901 7/31**Concomitant therapy (benzodiazepines and anticholinergics)**

Was the subject taking any benzodiazepines or anticholinergics at entry, or did the subject take any benzodiazepines or anticholinergics during the trial?

☐ No additional benzodiazepines or anticholinergics

If yes, specify below

Therapy (describe literally as prescribed) e.g. Valium 5 mg BID PO	Indication	Start of therapy	End of therapy
8. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y
9. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y
10. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y
11. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y
12. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y
13. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y
14. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y

If medication is used for a pre-existing concomitant disease, list the disease on the Concomitant Disease Form.

If medication is used for a new indication, list the event on the Adverse Event Form.

Case Report Form (5 Nov 97)

Janssen Research Foundation

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

38113CCT c801 7/31

Concomitant therapy (benzodiazepines and anticholinergics)

Was the subject taking any benzodiazepines or anticholinergics at entry, or did the subject take any benzodiazepines or anticholinergics during the trial?

☐ No additional benzodiazepines or anticholinergics

If yes, specify below

Therapy (describe literally as prescribed) e.g. Valium 5 mg BID PO	Indication	Start of therapy	End of therapy																
15. _____ Daily dose _____	_____	☐ pre trial. If not, <table border="1"><tr><td> </td><td> </td><td> </td><td> </td></tr><tr><td>m</td><td>d</td><td>y</td><td> </td></tr></table>					m	d	y		☐ ongoing post trial. If not, <table border="1"><tr><td> </td><td> </td><td> </td><td> </td></tr><tr><td>m</td><td>d</td><td>y</td><td> </td></tr></table>					m	d	y	
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If medication is used for a pre-existing concomitant disease, list the disease on the Concomitant Disease Form.

If medication is used for a new indication, list the event on the Adverse Event Form.

Case Report Form (5 Nov 97)

Janssen Research Foundation

153

Risperidone vs olanzapine
RIS-USA-113

CRF ID

38113CCT
c901 7/31**Concomitant therapy (benzodiazepines and anticholinergics)**

Was the subject taking any benzodiazepines or anticholinergics at entry, or did the subject take any benzodiazepines or anticholinergics during the trial?

☐ No additional benzodiazepines or anticholinergics

If yes, specify below

Therapy (describe literally as prescribed) e.g. Valium 5 mg BID PO	Indication	Start of therapy	End of therapy
22. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y
23. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y
24. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y
25. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y
26. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y
27. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y
28. _____ Daily dose _____	_____	☐ pre trial. If not, m d y	☐ ongoing post trial. If not, m d y

If medication is used for a pre-existing concomitant disease, list the disease on the Concomitant Disease Form.

If medication is used for a new indication, list the event on the Adverse Event Form.

Case Report Form (5 Nov 97)

Janssen Research Foundation

154

Risperidone vs olanzapine
RIS-USA-113

CRF ID

381130CT
c901 7/31**Concomitant therapy (benzodiazepines and anticholinergics)**

Was the subject taking any benzodiazepines or anticholinergics at entry, or did the subject take any benzodiazepines or anticholinergics during the trial?

☐ No additional benzodiazepines or anticholinergics

If yes, specify below

Therapy (describe literally as prescribed) e.g. Valium 5 mg BID PO	Indication	Start of therapy	End of therapy																
29. _____ Daily dose _____	_____	☐ pre trial. If not, <table border="1"><tr><td> </td><td> </td><td> </td><td> </td></tr><tr><td>m</td><td>d</td><td>y</td><td> </td></tr></table>					m	d	y		☐ ongoing post trial. If not, <table border="1"><tr><td> </td><td> </td><td> </td><td> </td></tr><tr><td>m</td><td>d</td><td>y</td><td> </td></tr></table>					m	d	y	
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If medication is used for a pre-existing concomitant disease, list the disease on the Concomitant Disease Form.

If medication is used for a new indication, list the event on the Adverse Event Form.

Case Report Form (5 Nov 97)

Janssen Research Foundation

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7/31

38113CAE

Instructions for Adverse events form

- All adverse events (serious and non-serious) must be recorded on the Adverse events form.
- In addition all pregnancies and serious adverse events must be reported within 1 working day to the Trial Centre Manager by means of the 'Serious adverse event form' or by phone (to be followed by the form).
- Definition of adverse event:

Any untoward medical occurrence in a subject or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product (ICH).

- Definition of Serious Adverse Event:

Any untoward medical occurrence that at any dose:

- results in death
- is life-threatening
- requires in-patient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- or
- is a congenital anomaly/birth defect (ICH).

Due to current reporting requirements in some countries, malignancies and adverse events that result from overdose will also be considered Serious Adverse Events.

Note: Medical and scientific judgement should be exercised in deciding whether expedited reporting is appropriate in other situations, such as important medical events that may not be immediately life-threatening or result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one of the outcomes listed in the definition above.

7/31

38113CAE



Adverse Event		Severity	Action taken regarding trial med.	Conc. therapy started because of AE	Relation to trial med.	Subject outcome	Reported as serious
From date	To date	mild 1 moderate 2 severe 3	none 1 dose adjusted 2 temporary stop 3 permanent stop 4	no 1 yes 2	none 1 doubtful 2 possible 3 probable 4 very likely 5	recovered from this AE 1 not yet recovered 2 died due to this AE 3	no 1 yes 2
1. 							
2. 							
3. 							
4. 							
5. 							
6. 							

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Has the subject had any undesirable experience during the trial, whether or not considered related to the trial medication?

☐ No additional adverse events

If yes, specify below

[illegible]

Serious adverse events and pregnancies must be reported to the Trial Centre Manager within 1 working day by faxing the 'Serious adverse event form', or by telephone (to be followed by the signed form).

Case Report Form (5 Nov 97)
Janssen Research Foundation

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

731
38113CAE

Adverse events (continued)

Has the subject had any undesirable experience during the trial, whether or not considered related to the trial medication?

☐ No additional adverse events

If yes, specify below

Adverse Event	Severity	Action taken regarding trial med.	Conc. therapy started because of AE	Relation to trial med.	Subject outcome	Reported as serious	
From date	To date						
		mild 1 moderate 2 severe 3	none 1 dose adjusted 2 temporary stop 3 permanent stop 4	no 1 yes 2	none 1 doubtful 2 possible 3 probable 4 very likely 5	recovered from this AE 1 not yet recovered 2 died due to this AE 3	no 1 yes 2
13. _____ m d y m d y							
14. _____ m d y m d y							
15. _____ m d y m d y							
16. _____ m d y m d y							
17. _____ m d y m d y							
18. _____ m d y m d y							

Serious adverse events and pregnancies must be reported to the Trial Centre Manager within 1 working day by faxing the 'Serious adverse event form', or by telephone (to be followed by the signed form).

Case Report Form (5 Nov 97)
Janssen Research Foundation

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38113CAE 7/31

Adverse events (continued)

Has the subject had any undesirable experience during the trial, whether or not considered related to the trial medication?

☐ No additional adverse events

If yes, specify below

[illegible]

Serious adverse events and pregnancies must be reported to the Trial Centre Manager within 1 working day by faxing the 'Serious adverse event form', or by telephone (to be followed by the signed form).

Case Report Form (5 Nov 97)
Janssen Research Foundation

159

Has the subject had any undesirable experience during the trial, whether or not considered related to the trial medication?

☐ No additional adverse events

If yes, specify below

[illegible]

Serious adverse events and pregnancies must be reported to the Trial Centre Manager within 1 working day by faxing the 'Serious adverse event form', or by telephone (to be followed by the signed form).

Case Report Form (5 Nov 97)
Janssen Research Foundation

160

Risperidone vs olanzapine

CRF ID

RIS-USA-113

7/31
38113CAE**Adverse events (continued)**

Has the subject had any undesirable experience during the trial, whether or not considered related to the trial medication?

☐ No additional adverse events

If yes, specify below

Adverse Event	Severity	Action taken regarding trial med.	Conc. therapy started because of AE	Relation to trial med.	Subject outcome	Reported as serious	
From date	To date						
		mild 1 moderate 2 severe 3	none 1 dose adjusted 2 temporary stop 3 permanent stop 4	no 1 yes 2	none 1 doubtful 2 possible 3 probable 4 very likely 5	recovered from this AE 1 not yet recovered 2 dead due to this AE 3	no 1 yes 2
31. _____ m d y m d y							
32. _____ m d y m d y							
33. _____ m d y m d y							
34. _____ m d y m d y							
35. _____ m d y m d y							
36. _____ m d y m d y							

Serious adverse events and pregnancies must be reported to the Trial Centre Manager within 1 working day by faxing the 'Serious adverse event form', or by telephone (to be followed by the signed form).

Case Report Form (5 Nov 97)

Janssen Research Foundation

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

7/31
38113CAE

Adverse events (continued)

Has the subject had any undesirable experience during the trial, whether or not considered related to the trial medication?

☐ No additional adverse events

If yes, specify below

Adverse Event	Severity	Action taken regarding trial med.	Conc. therapy started because of AE	Relation to trial med.	Subject outcome	Reported as serious	
From date	To date						
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37. _____ m d y m d y	☐	☐	☐	☐	☐	☐	
38. _____ m d y m d y	☐	☐	☐	☐	☐	☐	
39. _____ m d y m d y	☐	☐	☐	☐	☐	☐	
40. _____ m d y m d y	☐	☐	☐	☐	☐	☐	
41. _____ m d y m d y	☐	☐	☐	☐	☐	☐	
42. _____ m d y m d y	☐	☐	☐	☐	☐	☐	

Serious adverse events and pregnancies must be reported to the Trial Centre Manager within 1 working day by faxing the 'Serious adverse event form', or by telephone (to be followed by the signed form).

Case Report Form (5 Nov 97)
Janssen Research Foundation

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

Trial termination

Date of last contact with subject (visit, call, ...) in this trial

m	d	y

☐ Subject completed the entire course of the trial as specified in the protocol

If not, specify the reason why not (check one box only):

☐ adverse event (including death, abnormal lab values, intercurrent illnesses)

specify the line number(s) of the AE on the AE form

 ,

 ,

- ☐ insufficient response
- ☐ subject asymptomatic/cured
- ☐ subject ineligible to continue the trial
- ☐ subject lost to follow-up
- ☐ subject withdrew consent
- ☐ subject non-compliant
- ☐ other, specify: _____

Risperidone vs olanzapine
RIS-USA-113

CRF ID



7/31

38113CTT

Code breaking

The code can be broken only in **certain cases of emergency**.

In these emergencies the further treatment of the subject will depend on the trial medication being taken.

Has the double-blind code been broken?

☐

No



If yes, date of code breaking

m	d	y



Specify the reason:



If the code has been broken for an adverse event, list the event on the Adverse Event Form.

Case Report Form (5 Nov 97)
Janssen Research Foundation

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

7131

Remarks

38113CTT

Date (m/d/y)	Remark

Case Report Form (5 Nov 97)
Janssen Research Foundation

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

7/31

38113CTT

Main investigator's statement concerning data verification

I have verified the data entries for all visits in this Case Report Form and have determined that they are complete, accurate and compatible with source documents. All entries were made either by me or a person under my supervision who had signed the Site Signature Log.

If, for whatever reason, the main investigator cannot make the above statement, a medical doctor who has signed the Site Signature Log, may do so and sign instead.

Only to be filled in in case of premature discontinuation.

The subject discontinued prematurely at visit no

inclusive.



No data is recorded on subsequent visit pages

to

Investigator's name (printed)

Investigator's signature

Date



m	d	y	

Case Report Form (5 Nov 97)
Janssen Research Foundation

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7/31

38113CU1

Unscheduled visit 1

If extrapyramidal symptoms emerge or worsen during the double-blind period, an additional ESRS should be performed. Following completion of this ESRS, the dose of trial medication should be reduced. If the symptoms do not resolve, anticholinergic medication may be initiated. At each subsequent scheduled visit the need for continuation of anticholinergic medication should be evaluated.

- Complete the ESRS. Please make sure that the date of completion has been recorded on the top of the first page of the ESRS
- Reduce the dose of the trial medication and mark the new date and dose on the Administration of trial medication form

Risperidone vs olanzapine
RIS-USA-113

CRF ID

Date

m	d	y

UNSCHEDULED VISIT 1

Extrapyramidal symptom rating scale (ESRS)

Questionnaire and Behavioural Scale

Check the appropriate box for each item.

I Parkinsonism, Dystonia and Dyskinesia	Absent	Mild	Moderate	Severe
1. Impression of slowness or weakness, difficulty in carrying out routine tasks	☐	☐	☐	☐
2. Difficulty walking or with balance	☐	☐	☐	☐
3. Difficulty swallowing or talking	☐	☐	☐	☐
4. Stiffness, stiff posture	☐	☐	☐	☐
5. Cramps or pains in limbs, back or neck	☐	☐	☐	☐
6. Restless, nervous, unable to keep still	☐	☐	☐	☐
7. Tremors, shaking	☐	☐	☐	☐
8. Oculogyric crisis, abnormal sustained posture	☐	☐	☐	☐
9. Increased salivation	☐	☐	☐	☐
10. Abnormal involuntary movements (dyskinesia) of extremities or trunk	☐	☐	☐	☐
11. Abnormal involuntary movements (dyskinesia) of tongue, jaw, lips or face	☐	☐	☐	☐
12. Dizziness when standing up (especially in the morning)	☐	☐	☐	☐

Case Report Form (5 Nov 97)
Janssen Research Foundation

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

UNSCHEDULED VISIT 1

701

3811301

Extrapyramidal symptom rating scale (ESRS) (continued)**Physician's examination***Enter the appropriate score for each item.*

II Parkinsonism	Score	Explanation
1. Expressive automatic movements (facial mask/speech)		0 normal 1 very mild decrease in facial expressiveness 2 mild decrease in facial expressiveness 3 rare spontaneous smile, decreased blinking, voice slightly monotonous 4 no spontaneous smile, staring gaze, low monotonous speech, mumbling 5 marked facial mask, unable to frown, slurred speech 6 extremely severe facial mask with unintelligible speech
2. Bradykinesia		0 normal 1 global impression of slowness in movements 2 definite slowness in movements 3 very mild difficulty in initiating movements 4 mild to moderate difficulty in initiating movements 5 difficulty in starting or stopping any movement, or freezing on initiating voluntary act 6 rare voluntary movement, almost completely immobile
3. Rigidity	right arm left arm right leg left leg	0 normal muscle tone 1 very mild, barely perceptible 2 mild (some resistance to passive movements) 3 moderate (definite resistance to passive movements) 4 moderately severe (moderate resistance but still easy to move the limb) 5 severe (marked resistance with definite difficulty to move the limb) 6 extremely severe (nearly frozen)
4. Gait and Posture		0 normal 1 mild decrease of pendular arm movement 2 moderate decrease of pendular arm movement, normal steps 3 no pendular arm movement, head flexed, steps more or less normal 4 stiff posture (neck, back), small step (shuffling gait) 5 more marked, festination or freezing on turning 6 triple flexion, barely able to walk

Case Report Form (5 Nov 97)
Janssen Research Foundation

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

UNSCHEDULED VISIT 1

7/31
38113CU1

II Parkinsonism - Physician's examination		Score	Explanation
5. Tremor			
right arm	☐		Occasional
left arm	☐		Frequent
right leg	☐		Constant or almost so
left leg	☐		
head	☐		
jaw/chin	☐		
tongue	☐		
lips	☐		
6. Akathisia	☐		0 none 1 looks restless, nervous, impatient, uncomfortable 2 needs to move at least one extremity 3 often needs to move one extremity or to change position 4 moves one extremity almost constantly if sitting, or stamps feet while standing 5 unable to sit down for more than a short period of time 6 moves or walks constantly
7. Sialorrhea	☐		0 absent 1 very mild 2 mild 3 moderate: impairs speech 4 moderately severe 5 severe 6 extremely severe: drooling
8. Postural stability	☐		0 normal 1 hesitation when pushed but no retropulsion 2 retropulsion but recovers unaided 3 exaggerated retropulsion without falling 4 absence of postural response, would fall if not caught by examiner 5 unstable while standing, even without pushing 6 unable to stand without assistance

Case Report Form (5 Nov 97)
Janssen Research Foundation

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

UNSCHEDULED VISIT 17/31
38113CU1**Extrapyramidal symptom rating scale (ESRS) (continued)***Enter the appropriate score for each item.***III Dystonia - Physician's examination**

1. Acute torsion dystonia	Score	Explanation		Score	Explanation
right arm		0 absent	jaw		0 absent
		1 very mild			1 very mild
left arm		2 mild	tongue		2 mild
		3 moderate			3 moderate
right leg		4 moderately severe	lips		4 moderately severe
		5 severe			5 severe
left leg		6 extremely severe	eyes		6 extremely severe
head			trunk		
2. Non-acute or chronic or tardive dystonia	Score	Explanation		Score	Explanation
right arm		0 absent	jaw		0 absent
		1 very mild			1 very mild
left arm		2 mild	tongue		2 mild
		3 moderate			3 moderate
right leg		4 moderately severe	lips		4 moderately severe
		5 severe			5 severe
left leg		6 extremely severe	face		6 extremely severe
head			trunk		

Case Report Form (5 Nov 97)
Janssen Research Foundation

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

UNSCHEDULED VISIT 1

Extrapyramidal symptom rating scale (ESRS) (continued)

Enter the appropriate score for each item.

IV Dyskinetic movements Physician's examination	Score	Explanation	Occasional	Frequent	Constant or almost so
1. Lingual movements Slow lateral or torsion movement of tongue		None Borderline Clearly present, within oral cavity With occasional partial protrusion With complete protrusion	0 1 2 3 4	3 4 5 6	4 5 6
2. Jaw movements Lateral movement, chewing, biting, clenching		None Borderline Clearly present, small amplitude Moderate amplitude, but without mouth opening Large amplitude, with mouth opening	0 1 2 3 4	3 4 5 6	4 5 6
3. Bucco-labial movements Puckering, pouting, smacking, etc...		None Borderline Clearly present, small amplitude Moderate amplitude, forward movement of lips Large amplitude, marked, noisy smacking of lips	0 1 2 3 4	3 4 5 6	4 5 6
4. Truncal movements Rocking, twisting, pelvic gyrations		None Borderline Clearly present, small amplitude Moderate amplitude Greater amplitude	0 1 2 3 4	3 4 5 6	4 5 6
5. Upper extremities Choreoathetoid movements only: arms, wrists, hands, fingers		None Borderline Clearly present, small amplitude, movement of one limb Moderate amplitude, movement of one limb or movement of small amplitude involving two limbs Greater amplitude, movement involving two limbs	0 1 2 3 4	3 4 5 6	4 5 6
6. Lower extremities Choreoathetoid movements only: legs, knees, ankles, toes		None Borderline Clearly present, small amplitude, movement of one limb Moderate amplitude, movement of one limb or movement of small amplitude involving two limbs Greater amplitude, movement involving two limbs	0 1 2 3 4	3 4 5 6	4 5 6
7. Other involuntary movements Swallowing, irregular respiration, frowning, blinking, grimacing, sighing, etc...		None Borderline Clearly present, small amplitude Moderate amplitude Greater amplitude	0 1 2 3 4	3 4 5 6	4 5 6

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

UNSCHEDULED VISIT 1

7/01	Extrapyramidal symptom rating scale (ESRS) (continued)
38113CU	V Clinical global impression of severity of Parkinsonism
	<i>Considering your clinical experience, how severe is the parkinsonism at this time?</i>
	☐ absent
	☐ borderline
	☐ very mild
	☐ mild
	☐ moderate
	☐ moderately severe
	☐ marked
	☐ severe
	☐ extremely severe
	VI Clinical global impression of severity of Dystonia
	<i>Considering your clinical experience, how severe is the dystonia at this time?</i>
	☐ absent
	☐ borderline
	☐ very mild
	☐ mild
	☐ moderate
	☐ moderately severe
	☐ marked
	☐ severe
	☐ extremely severe

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

UNSCHEDULED VISIT 1

7/01	Extrapyramidal symptom rating scale (ESRS) (continued)
38113CU1	VII Clinical global Impression of severity of Dyskinesia
	<i>Considering your clinical experience, how severe is the dyskinesia at this time?</i>
	☐ absent
	☐ borderline
	☐ very mild
	☐ mild
	☐ moderate
	☐ moderately severe
	☐ marked
	☐ severe
	☐ extremely severe
	VIII Stage of Parkinsonism (Hoehn & Yahr)
	☐ absent
	☐ unilateral involvement only, minimal or no functional impairment (stage I)
	☐ bilateral or midline involvement, without impairment of balance (stage II)
	☐ mild to moderate disabling: first signs of impaired righting or postural reflex (unsteadiness as the subject turns or when he is pushed from standing equilibrium with the feet together and eyes closed). subject is physically capable of leading independent life (stage III)
	☐ severely disabling: subject is still able to walk and stand unassisted but is markedly incapacitated (stage IV)
	☐ confinement to bed or wheelchair (stage V)

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Unscheduled visit 2

3811302

If extrapyramidal symptoms emerge or worsen during the double-blind period, an additional ESRS should be performed. Following completion of this ESRS, the dose of trial medication should be reduced. If the symptoms do not resolve, anticholinergic medication may be initiated. At each subsequent scheduled visit the need for continuation of anticholinergic medication should be evaluated.

- Complete the ESRS. Please make sure that the date of completion has been recorded on the top of the first page of the ESRS
- Reduce the dose of the trial medication and mark the new date and dose on the Administration of trial medication form

Risperidone vs olanzapine
RIS-USA-113

CRF ID

Date

m	d	y

UNSCHEDULED VISIT 2

Extrapyramidal symptom rating scale (ESRS)

Questionnaire and Behavioural Scale

Check the appropriate box for each item.

I Parkinsonism, Dystonia and Dyskinesia	Absent	Mild	Moderate	Severe
1. Impression of slowness or weakness, difficulty in carrying out routine tasks	☐	☐	☐	☐
2. Difficulty walking or with balance	☐	☐	☐	☐
3. Difficulty swallowing or talking	☐	☐	☐	☐
4. Stiffness, stiff posture	☐	☐	☐	☐
5. Cramps or pains in limbs, back or neck	☐	☐	☐	☐
6. Restless, nervous, unable to keep still	☐	☐	☐	☐
7. Tremors, shaking	☐	☐	☐	☐
8. Oculogyric crisis, abnormal sustained posture	☐	☐	☐	☐
9. Increased salivation	☐	☐	☐	☐
10. Abnormal involuntary movements (dyskinesia) of extremities or trunk	☐	☐	☐	☐
11. Abnormal involuntary movements (dyskinesia) of tongue, jaw, lips or face	☐	☐	☐	☐
12. Dizziness when standing up (especially in the morning)	☐	☐	☐	☐

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

UNSCHEDULED VISIT 2

7/31
38113CU2

Extrapyramidal symptom rating scale (ESRS) (continued)

Physician's examination
Enter the appropriate score for each item.

II Parkinsonism	Score	Explanation
1. Expressive automatic movements (facial mask/speech)	☐	0 normal 1 very mild decrease in facial expressiveness 2 mild decrease in facial expressiveness 3 rare spontaneous smile, decreased blinking, voice slightly monotonous 4 no spontaneous smile, staring gaze, low monotonous speech, mumbling 5 marked facial mask, unable to frown, slurred speech 6 extremely severe facial mask with unintelligible speech
2. Bradykinesia	☐	0 normal 1 global impression of slowness in movements 2 definite slowness in movements 3 very mild difficulty in initiating movements 4 mild to moderate difficulty in initiating movements 5 difficulty in starting or stopping any movement, or freezing on initiating voluntary act 6 rare voluntary movement, almost completely immobile
3. Rigidity	right arm ☐ left arm ☐ right leg ☐ left leg ☐	0 normal muscle tone 1 very mild, barely perceptible 2 mild (some resistance to passive movements) 3 moderate (definite resistance to passive movements) 4 moderately severe (moderate resistance but still easy to move the limb) 5 severe (marked resistance with definite difficulty to move the limb) 6 extremely severe (nearly frozen)
4. Gait and Posture	☐	0 normal 1 mild decrease of pendular arm movement 2 moderate decrease of pendular arm movement, normal steps 3 no pendular arm movement, head flexed, steps more or less normal 4 stiff posture (neck, back), small step (shuffling gait) 5 more marked, festination or freezing on turning 6 triple flexion, barely able to walk

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Risperidone vs olanzapine
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UNSCHEDULED VISIT 2

II Parkinsonism - Physician's examination		Score	Explanation
5. Tremor			
right arm	☐		Occasional
left arm	☐		Frequent
right leg	☐		Constant or almost so
left leg	☐		
head	☐		
jaw/chin	☐		
tongue	☐		
lips	☐		
6. Akathisia	☐		0 none 1 looks restless, nervous, impatient, uncomfortable 2 needs to move at least one extremity 3 often needs to move one extremity or to change position 4 moves one extremity almost constantly if sitting, or stamps feet while standing 5 unable to sit down for more than a short period of time 6 moves or walks constantly
7. Sialorrhea	☐		0 absent 1 very mild 2 mild 3 moderate: impairs speech 4 moderately severe 5 severe 6 extremely severe: drooling
8. Postural stability	☐		0 normal 1 hesitation when pushed but no retropulsion 2 retropulsion but recovers unaided 3 exaggerated retropulsion without falling 4 absence of postural response, would fall if not caught by examiner 5 unstable while standing, even without pushing 6 unable to stand without assistance

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

UNSCHEDULED VISIT 27/31
381130J2**Extrapyramidal symptom rating scale (ESRS) (continued)***Enter the appropriate score for each item.***III Dystonia - Physician's examination**

1. Acute torsion dystonia	Score	Explanation		Score	Explanation
right arm	☐	0 absent	jaw	☐	0 absent
		1 very mild			1 very mild
left arm	☐	2 mild	tongue	☐	2 mild
		3 moderate			3 moderate
right leg	☐	4 moderately severe	lips	☐	4 moderately severe
		5 severe			5 severe
left leg	☐	6 extremely severe	eyes	☐	6 extremely severe
head	☐		trunk	☐	
2. Non-acute or chronic or tardive dystonia	Score	Explanation		Score	Explanation
right arm	☐	0 absent	jaw	☐	0 absent
		1 very mild			1 very mild
left arm	☐	2 mild	tongue	☐	2 mild
		3 moderate			3 moderate
right leg	☐	4 moderately severe	lips	☐	4 moderately severe
		5 severe			5 severe
left leg	☐	6 extremely severe	face	☐	6 extremely severe
head	☐		trunk	☐	

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Risperidone vs olanzapine
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CRF ID

UNSCHEDULED VISIT 2

7/31
38113CU2

Extrapyramidal symptom rating scale (ESRS) (continued)					
Enter the appropriate score for each item.					
IV Dyskinetic movements Physician's examination	Score	Explanation	Occasional	Frequent	Constant or almost so
1. Lingual movements Slow lateral or torsion movement of tongue	☐	None Borderline Clearly present, within oral cavity With occasional partial protrusion With complete protrusion	0 1 2 3 4	3 4 5 6	4 5 6
2. Jaw movements Lateral movement, chewing, biting, clenching	☐	None Borderline Clearly present, small amplitude Moderate amplitude, but without mouth opening Large amplitude, with mouth opening	0 1 2 3 4	3 4 5 6	4 5 6
3. Bucco-labial movements Puckering, pouting, smacking, etc...	☐	None Borderline Clearly present, small amplitude Moderate amplitude, forward movement of lips Large amplitude, marked, noisy smacking of lips	0 1 2 3 4	3 4 5 6	4 5 6
4. Truncal movements Rocking, twisting, pelvic gyrations	☐	None Borderline Clearly present, small amplitude Moderate amplitude Greater amplitude	0 1 2 3 4	3 4 5 6	4 5 6
5. Upper extremities Choreoathetoid movements only: arms, wrists, hands, fingers	☐	None Borderline Clearly present, small amplitude, movement of one limb Moderate amplitude, movement of one limb or movement of small amplitude involving two limbs Greater amplitude, movement involving two limbs	0 1 2 3 4	3 4 5 6	4 5 6
6. Lower extremities Choreoathetoid movements only: legs, knees, ankles, toes	☐	None Borderline Clearly present, small amplitude, movement of one limb Moderate amplitude, movement of one limb or movement of small amplitude involving two limbs Greater amplitude, movement involving two limbs	0 1 2 3 4	3 4 5 6	4 5 6
7. Other involuntary movements Swallowing, irregular respiration, frowning, blinking, grimacing, sighing, etc...	☐	None Borderline Clearly present, small amplitude Moderate amplitude Greater amplitude	0 1 2 3 4	3 4 5 6	4 5 6

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

UNSCHEDULED VISIT 2

7/31

38113CJ2

Extrapyramidal symptom rating scale (ESRS) (continued)

V Clinical global impression of severity of Parkinsonism

Considering your clinical experience, how severe is the parkinsonism at this time?

- ☐ absent
- ☐ borderline
- ☐ very mild
- ☐ mild
- ☐ moderate
- ☐ moderately severe
- ☐ marked
- ☐ severe
- ☐ extremely severe

VI Clinical global impression of severity of Dystonia

Considering your clinical experience, how severe is the dystonia at this time?

- ☐ absent
- ☐ borderline
- ☐ very mild
- ☐ mild
- ☐ moderate
- ☐ moderately severe
- ☐ marked
- ☐ severe
- ☐ extremely severe

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UNSCHEDULED VISIT 2

7/31 38113CU2	Extrapyramidal symptom rating scale (ESRS) (continued)
VII Clinical global impression of severity of Dyskinesia	
<i>Considering your clinical experience, how severe is the dyskinesia at this time?</i>	
☐ absent	
☐ borderline	
☐ very mild	
☐ mild	
☐ moderate	
☐ moderately severe	
☐ marked	
☐ severe	
☐ extremely severe	
VIII Stage of Parkinsonism (Hoehn & Yahr)	
☐ absent	
☐ unilateral involvement only, minimal or no functional impairment (stage I)	
☐ bilateral or midline involvement, without impairment of balance (stage II)	
☐ mild to moderate disabling: first signs of impaired righting or postural reflex (unsteadiness as the subject turns or when he is pushed from standing equilibrium with the feet together and eyes closed), subject is physically capable of leading independent life (stage III)	
☐ severely disabling: subject is still able to walk and stand unassisted but is markedly incapacitated (stage IV)	
☐ confinement to bed or wheelchair (stage V)	

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38113C02

Unscheduled visit 3

If extrapyramidal symptoms emerge or worsen during the double-blind period, an additional ESRS should be performed. Following completion of this ESRS, the dose of trial medication should be reduced. If the symptoms do not resolve, anticholinergic medication may be initiated. At each subsequent scheduled visit the need for continuation of anticholinergic medication should be evaluated.

- Complete the ESRS. Please make sure that the date of completion has been recorded on the top of the first page of the ESRS
- Reduce the dose of the trial medication and mark the new date and dose on the Administration of trial medication form

Risperidone vs olanzapine
RIS-USA-113

CRF ID

Date

m	d	y	

UNSCCHEDULED VISIT 3



7/01

38113CU3

Extrapyramidal symptom rating scale (ESRS)**Questionnaire and Behavioural Scale**

Check the appropriate box for each item.

I Parkinsonism, Dystonia and Dyskinesia	Absent	Mild	Moderate	Severe
1. Impression of slowness or weakness, difficulty in carrying out routine tasks	☐	☐	☐	☐
2. Difficulty walking or with balance	☐	☐	☐	☐
3. Difficulty swallowing or talking	☐	☐	☐	☐
4. Stiffness, stiff posture	☐	☐	☐	☐
5. Cramps or pains in limbs, back or neck	☐	☐	☐	☐
6. Restless, nervous, unable to keep still	☐	☐	☐	☐
7. Tremors, shaking	☐	☐	☐	☐
8. Oculogyric crisis, abnormal sustained posture	☐	☐	☐	☐
9. Increased salivation	☐	☐	☐	☐
10. Abnormal involuntary movements (dyskinesia) of extremities or trunk	☐	☐	☐	☐
11. Abnormal involuntary movements (dyskinesia) of tongue, jaw, lips or face	☐	☐	☐	☐
12. Dizziness when standing up (especially in the morning)	☐	☐	☐	☐

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

UNSCHEDULED VISIT 3

701

3811303

Extrapyramidal symptom rating scale (ESRS) (continued)**Physician's examination***Enter the appropriate score for each item.*

II Parkinsonism	Score	Explanation
1. Expressive automatic movements (facial mask/speech)		0 normal 1 very mild decrease in facial expressiveness 2 mild decrease in facial expressiveness 3 rare spontaneous smile, decreased blinking, voice slightly monotonous 4 no spontaneous smile, staring gaze, low monotonous speech, mumbling 5 marked facial mask, unable to frown, slurred speech 6 extremely severe facial mask with unintelligible speech
2. Bradykinesia		0 normal 1 global impression of slowness in movements 2 definite slowness in movements 3 very mild difficulty in initiating movements 4 mild to moderate difficulty in initiating movements 5 difficulty in starting or stopping any movement, or freezing on initiating voluntary act 6 rare voluntary movement, almost completely immobile
3. Rigidity	right arm left arm right leg left leg	0 normal muscle tone 1 very mild, barely perceptible 2 mild (some resistance to passive movements) 3 moderate (definite resistance to passive movements) 4 moderately severe (moderate resistance but still easy to move the limb) 5 severe (marked resistance with definite difficulty to move the limb) 6 extremely severe (nearly frozen)
4. Gait and Posture		0 normal 1 mild decrease of pendular arm movement 2 moderate decrease of pendular arm movement, normal steps 3 no pendular arm movement, head flexed, steps more or less normal 4 stiff posture (neck, back), small step (shuffling gait) 5 more marked, festination or freezing on turning 6 triple flexion, barely able to walk

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CRF ID

UNSCCHEDULED VISIT 3

7/31
381130J3

Extrapyramidal symptom rating scale (ESRS) (continued)				
Enter the appropriate score for each item.				
II Parkinsonism - Physician's examination	Score	Explanation		
5. Tremor				
right arm	☐		Occasional	
left arm	☐	None		Frequent
right leg	☐	Borderline		Constant or almost so
left leg	☐	Small amplitude	2	3
head	☐	Moderate amplitude	3	4
jaw/chin	☐	Large amplitude	4	5
tongue	☐			6
lips	☐			
6. Akathisia	☐	0 none 1 looks restless, nervous, impatient, uncomfortable 2 needs to move at least one extremity 3 often needs to move one extremity or to change position 4 moves one extremity almost constantly if sitting, or stamps feet while standing 5 unable to sit down for more than a short period of time 6 moves or walks constantly		
7. Sialorrhea	☐	0 absent 1 very mild 2 mild 3 moderate: impairs speech 4 moderately severe 5 severe 6 extremely severe: drooling		
8. Postural stability	☐	0 normal 1 hesitation when pushed but no retropulsion 2 retropulsion but recovers unaided 3 exaggerated retropulsion without falling 4 absence of postural response, would fall if not caught by examiner 5 unstable while standing, even without pushing 6 unable to stand without assistance		

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UNSCHEDULED VISIT 3

Extrapyramidal symptom rating scale (ESRS) (continued)

Enter the appropriate score for each item.

III Dystonia - Physician's examination

1. Acute torsion dystonia	Score	Explanation		Score	Explanation
right arm	☐	0 absent	jaw	☐	0 absent
		1 very mild			1 very mild
left arm	☐	2 mild	tongue	☐	2 mild
		3 moderate			3 moderate
right leg	☐	4 moderately severe	lips	☐	4 moderately severe
		5 severe			5 severe
left leg	☐	6 extremely severe	eyes	☐	6 extremely severe
head	☐		trunk	☐	
2. Non-acute or chronic or tardive dystonia	Score	Explanation		Score	Explanation
right arm	☐	0 absent	jaw	☐	0 absent
		1 very mild			1 very mild
left arm	☐	2 mild	tongue	☐	2 mild
		3 moderate			3 moderate
right leg	☐	4 moderately severe	lips	☐	4 moderately severe
		5 severe			5 severe
left leg	☐	6 extremely severe	face	☐	6 extremely severe
head	☐		trunk	☐	

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UNSCHEDULED VISIT 3

7/01
38113CU3

Extrapyramidal symptom rating scale (ESRS) (continued)

Enter the appropriate score for each item.

IV Dyskinetic movements Physician's examination	Score	Explanation	Occasional	Frequent	Constant or almost so
1. Lingual movements Slow lateral or torsion movement of tongue	☐	None Borderline Clearly present, within oral cavity With occasional partial protrusion With complete protrusion	0 1 2 3 4	3 4 5	4 5 6
2. Jaw movements Lateral movement, chewing, biting, clenching	☐	None Borderline Clearly present, small amplitude Moderate amplitude, but without mouth opening Large amplitude, with mouth opening	0 1 2 3 4	3 4 5	4 5 6
3. Bucco-labial movements Puckering, pouting, smacking, etc...	☐	None Borderline Clearly present, small amplitude Moderate amplitude, forward movement of lips Large amplitude, marked, noisy smacking of lips	0 1 2 3 4	3 4 5	4 5 6
4. Truncal movements Rocking, twisting, pelvic gyrations	☐	None Borderline Clearly present, small amplitude Moderate amplitude Greater amplitude	0 1 2 3 4	3 4 5	4 5 6
5. Upper extremities Choreoathetoid movements only: arms, wrists, hands, fingers	☐	None Borderline Clearly present, small amplitude, movement of one limb Moderate amplitude, movement of one limb or movement of small amplitude involving two limbs Greater amplitude, movement involving two limbs	0 1 2 3 4	3 4 5	4 5 6
6. Lower extremities Choreoathetoid movements only: legs, knees, ankles, toes	☐	None Borderline Clearly present, small amplitude, movement of one limb Moderate amplitude, movement of one limb or movement of small amplitude involving two limbs Greater amplitude, movement including two limbs	0 1 2 3 4	3 4 5	4 5 6
7. Other involuntary movements Swallowing, irregular respiration, frowning, blinking, grimacing, sighing, etc...	☐	None Borderline Clearly present, small amplitude Moderate amplitude Greater amplitude	0 1 2 3 4	3 4 5	4 5 6

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Risperidone vs olanzapine
RIS-USA-113

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UNSCHEDULED VISIT 3

7/01	Extrapyramidal symptom rating scale (ESRS) (continued)
3/11/03	V Clinical global impression of severity of Parkinsonism
	<i>Considering your clinical experience, how severe is the parkinsonism at this time?</i>
	☐ absent
	☐ borderline
	☐ very mild
	☐ mild
	☐ moderate
	☐ moderately severe
	☐ marked
	☐ severe
	☐ extremely severe
	VI Clinical global impression of severity of Dystonia
	<i>Considering your clinical experience, how severe is the dystonia at this time?</i>
	☐ absent
	☐ borderline
	☐ very mild
	☐ mild
	☐ moderate
	☐ moderately severe
	☐ marked
	☐ severe
	☐ extremely severe

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UNSCHEDULED VISIT 3

7/91 38113CU3	Extrapyramidal symptom rating scale (ESRS) (continued)
	VII Clinical global impression of severity of Dyskinesia <i>Considering your clinical experience, how severe is the dyskinesia at this time?</i> ☐ absent ☐ borderline ☐ very mild ☐ mild ☐ moderate ☐ moderately severe ☐ marked ☐ severe ☐ extremely severe
	VIII Stage of Parkinsonism (Hoehn & Yahr) ☐ absent ☐ unilateral involvement only, minimal or no functional impairment (stage I) ☐ bilateral or midline involvement, without impairment of balance (stage II) ☐ mild to moderate disabling: first signs of impaired righting or postural reflex (unsteadiness as the subject turns or when he is pushed from standing equilibrium with the feet together and eyes closed), subject is physically capable of leading independent life (stage III) ☐ severely disabling: subject is still able to walk and stand unassisted but is markedly incapacitated (stage IV) ☐ confinement to bed or wheelchair (stage V)

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7/31

38113CUZ

Unscheduled visit 4

If extrapyramidal symptoms emerge or worsen during the double-blind period, an additional ESRS should be performed. Following completion of this ESRS, the dose of trial medication should be reduced. If the symptoms do not resolve, anticholinergic medication may be initiated. At each subsequent scheduled visit the need for continuation of anticholinergic medication should be evaluated.

- Complete the ESRS. Please make sure that the date of completion has been recorded on the top of the first page of the ESRS
- Reduce the dose of the trial medication and mark the new date and dose on the Administration of trial medication form

Risperidone vs olanzapine
RIS-USA-113

CRF ID

Date

m	d	y

UNSCHEDULED VISIT 4

7/31

381130J4

Extrapyramidal symptom rating scale (ESRS)**Questionnaire and Behavioural Scale**

Check the appropriate box for each item.

I Parkinsonism, Dystonia and Dyskinesia	Absent	Mild	Moderate	Severe
1. Impression of slowness or weakness, difficulty in carrying out routine tasks	☐	☐	☐	☐
2. Difficulty walking or with balance	☐	☐	☐	☐
3. Difficulty swallowing or talking	☐	☐	☐	☐
4. Stiffness, stiff posture	☐	☐	☐	☐
5. Cramps or pains in limbs, back or neck	☐	☐	☐	☐
6. Restless, nervous, unable to keep still	☐	☐	☐	☐
7. Tremors, shaking	☐	☐	☐	☐
8. Oculogyric crisis, abnormal sustained posture	☐	☐	☐	☐
9. Increased salivation	☐	☐	☐	☐
10. Abnormal involuntary movements (dyskinesia) of extremities or trunk	☐	☐	☐	☐
11. Abnormal involuntary movements (dyskinesia) of tongue, jaw, lips or face	☐	☐	☐	☐
12. Dizziness when standing up (especially in the morning)	☐	☐	☐	☐

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

UNSCHEDULED VISIT 4

701
3811304

Extrapyramidal symptom rating scale (ESRS) (continued)

Physician's examination
Enter the appropriate score for each item.

II Parkinsonism	Score	Explanation
1. Expressive automatic movements (facial mask/speech)	☐	0 normal 1 very mild decrease in facial expressiveness 2 mild decrease in facial expressiveness 3 rare spontaneous smile, decreased blinking, voice slightly monotonous 4 no spontaneous smile, staring gaze, low monotonous speech, mumbling 5 marked facial mask, unable to frown, slurred speech 6 extremely severe facial mask with unintelligible speech
2. Bradykinesia	☐	0 normal 1 global impression of slowness in movements 2 definite slowness in movements 3 very mild difficulty in initiating movements 4 mild to moderate difficulty in initiating movements 5 difficulty in starting or stopping any movement, or freezing on initiating voluntary act 6 rare voluntary movement, almost completely immobile
3. Rigidity	right arm ☐ left arm ☐ right leg ☐ left leg ☐	0 normal muscle tone 1 very mild, barely perceptible 2 mild (some resistance to passive movements) 3 moderate (definite resistance to passive movements) 4 moderately severe (moderate resistance but still easy to move the limb) 5 severe (marked resistance with definite difficulty to move the limb) 6 extremely severe (nearly frozen)
4. Gait and Posture	☐	0 normal 1 mild decrease of pendular arm movement 2 moderate decrease of pendular arm movement, normal steps 3 no pendular arm movement, head flexed, steps more or less normal 4 stiff posture (neck, back), small step (shuffling gait) 5 more marked, festination or freezing on turning 6 triple flexion, barely able to walk

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

UNSCHEDULED VISIT 4

7/31

38113CU4

Extrapyramidal symptom rating scale (ESRS) (continued)*Enter the appropriate score for each item.*

II Parkinsonism - Physician's examination	Score	Explanation
5. Tremor		
right arm		
left arm		None 0
right leg		Borderline 1
left leg		Small amplitude 2 3 4
head		Moderate amplitude 3 4 5
jaw/chin		Large amplitude 4 5 6
tongue		
lips		
6. Akathisia		0 none 1 looks restless, nervous, impatient, uncomfortable 2 needs to move at least one extremity 3 often needs to move one extremity or to change position 4 moves one extremity almost constantly if sitting, or stamps feet while standing 5 unable to sit down for more than a short period of time 6 moves or walks constantly
7. Sialorrhea		0 absent 1 very mild 2 mild 3 moderate: impairs speech 4 moderately severe 5 severe 6 extremely severe: drooling
8. Postural stability		0 normal 1 hesitation when pushed but no retropulsion 2 retropulsion but recovers unaided 3 exaggerated retropulsion without falling 4 absence of postural response, would fall if not caught by examiner 5 unstable while standing, even without pushing 6 unable to stand without assistance

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Risperidone vs olanzapine
RIS-USA-113

CRF ID

UNSCHEDULED VISIT 47/31
3811304**Extrapyramidal symptom rating scale (ESRS) (continued)***Enter the appropriate score for each item.***III Dystonia - Physician's examination**

1. Acute torsion dystonia	Score	Explanation		Score	Explanation
right arm	☐	0 absent	jaw	☐	0 absent
		1 very mild			1 very mild
left arm	☐	2 mild	tongue	☐	2 mild
		3 moderate			3 moderate
right leg	☐	4 moderately severe	lips	☐	4 moderately severe
		5 severe			5 severe
left leg	☐	6 extremely severe	eyes	☐	6 extremely severe
head	☐		trunk	☐	
2. Non-acute or chronic or tardive dystonia	Score	Explanation		Score	Explanation
right arm	☐	0 absent	jaw	☐	0 absent
		1 very mild			1 very mild
left arm	☐	2 mild	tongue	☐	2 mild
		3 moderate			3 moderate
right leg	☐	4 moderately severe	lips	☐	4 moderately severe
		5 severe			5 severe
left leg	☐	6 extremely severe	face	☐	6 extremely severe
head	☐		trunk	☐	

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Risperidone vs olanzapine
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CRF ID

UNSCHEDULED VISIT 4

7/01
38113CU4

Extrapyramidal symptom rating scale (ESRS) (continued)

Enter the appropriate score for each item.

IV Dyskinetic movements Physician's examination	Score	Explanation	Occasional	Frequent	Constant or almost so
1. Lingual movements Slow lateral or torsion movement of tongue	☐	None Borderline Clearly present, within oral cavity With occasional partial protrusion With complete protrusion	0 1 2 3 4	3 4 5	4 5 6
2. Jaw movements Lateral movement, chewing, biting, clenching	☐	None Borderline Clearly present, small amplitude Moderate amplitude, but without mouth opening Large amplitude, with mouth opening	0 1 2 3 4	3 4 5	4 5 6
3. Bucco-labial movements Puckering, pouting, smacking, etc...	☐	None Borderline Clearly present, small amplitude Moderate amplitude, forward movement of lips Large amplitude, marked, noisy smacking of lips	0 1 2 3 4	3 4 5	4 5 6
4. Truncal movements Rocking, twisting, pelvic gyrations	☐	None Borderline Clearly present, small amplitude Moderate amplitude Greater amplitude	0 1 2 3 4	3 4 5	4 5 6
5. Upper extremities Choreoathetoid movements only: arms, wrists, hands, fingers	☐	None Borderline Clearly present, small amplitude, movement of one limb Moderate amplitude, movement of one limb or movement of small amplitude involving two limbs Greater amplitude, movement involving two limbs	0 1 2 3 4	3 4 5	4 5 6
6. Lower extremities Choreoathetoid movements only: legs, knees, ankles, toes	☐	None Borderline Clearly present, small amplitude, movement of one limb Moderate amplitude, movement of one limb or movement of small amplitude involving two limbs Greater amplitude, movement including two limbs	0 1 2 3 4	3 4 5	4 5 6
7. Other involuntary movements Swallowing, irregular respiration, frowning, blinking, grimacing, sighing, etc...	☐	None Borderline Clearly present, small amplitude Moderate amplitude Greater amplitude	0 1 2 3 4	3 4 5	4 5 6

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UNSCHEDULED VISIT 4

701	Extrapyramidal symptom rating scale (ESRS) (continued)
3811304	V Clinical global Impression of severity of Parkinsonism
	<i>Considering your clinical experience, how severe is the parkinsonism at this time?</i>
	☐ absent
	☐ borderline
	☐ very mild
	☐ mild
	☐ moderate
	☐ moderately severe
	☐ marked
	☐ severe
	☐ extremely severe
	VI Clinical global impression of severity of Dystonia
	<i>Considering your clinical experience, how severe is the dystonia at this time?</i>
	☐ absent
	☐ borderline
	☐ very mild
	☐ mild
	☐ moderate
	☐ moderately severe
	☐ marked
	☐ severe
	☐ extremely severe

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UNSCHEDULED VISIT 4

7/31	Extrapyramidal symptom rating scale (ESRS) (continued)
38113C/4	VII Clinical global impression of severity of Dyskinesia
	<i>Considering your clinical experience, how severe is the dyskinesia at this time?</i>
	☐ absent
	☐ borderline
	☐ very mild
	☐ mild
	☐ moderate
	☐ moderately severe
	☐ marked
	☐ severe
	☐ extremely severe
	VIII Stage of Parkinsonism (Hoehn & Yahr)
	☐ absent
	☐ unilateral involvement only, minimal or no functional impairment (stage I)
	☐ bilateral or midline involvement, without impairment of balance (stage II)
	☐ mild to moderate disabling: first signs of impaired righting or postural reflex (unsteadiness as the subject turns or when he is pushed from standing equilibrium with the feet together and eyes closed), subject is physically capable of leading independent life (stage III)
	☐ severely disabling: subject is still able to walk and stand unassisted but is markedly incapacitated (stage IV)
	☐ confinement to bed or wheelchair (stage V)

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A3

Date

m	d	y	

ADDITIONAL

7/31

38113CAP

HAM-D*Please enter the appropriate score for each item.*

Item	Score	Legend
1. Depressed mood (Sadness, hopeless, helpless, worthless)		0 absent 1 these feeling states indicated only on questioning 2 these feeling states spontaneously reported verbally 3 communicates feeling states only non-verbally, i.e. facial expression, posture, voice, and tendency to weep 4 subject reports virtually only these feeling states in his/her spontaneous and non-verbal communication
2. Feelings of guilt		0 absent 1 self reproach, feels he/she has let people down 2 ideas of guilt or rumination over past errors or sinful deeds 3 present illness is a punishment. Delusion of guilt. 4 hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations
3. Suicide		0 absent 1 feels life is not worth living 2 wishes he/she were dead or any thoughts of possible death to self 3 suicide ideas or gestures 4 attempts at suicide (any serious attempt rate 4)
4. Insomnia early		0 no difficulty falling asleep 1 complains of occasional difficulty falling asleep - i.e., more than half an hour 2 complains of nightly difficulty falling asleep
5. Insomnia middle		0 no difficulty 1 subject complains of being restless and disturbed during the night 2 waking during the night - any getting out of bed rates 2 (except for purposes of voiding)
6. Insomnia late		0 no difficulty 1 Waking in early hours of the morning but goes back to sleep 2 Unable to fall asleep again if he/she gets out of bed
7. Work and activities		0 no difficulty 1 thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies 2 loss of interest in activity; hobbies or work - either directly reported by the subject, or indirect in listlessness, indecision and vacillation (he/she feels he/she has to push self to work or activities) 3 decrease in actual time spent in activities or decrease in productivity. In hospital rate 3 if subject does not spend at least three hours a day in job or activities (hospital hobbies) exclusive of ward chores. 4 stopped working because of present illness. In hospital rate 4 if subject engages in no activities except ward chores, or if subject fails to perform ward chores unassisted.
8. Retardation (Slowness of thought and speech; impaired ability to concentrate; decreased motor activity)		0 normal speech and thought 1 slight retardation at interview 2 obvious retardation at interview 3 interview difficult 4 complete stupor

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Risperidone vs olanzapine
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A3

ADDITIONAL

7/31

38113CAP

HAM-D (continued)*Please enter the appropriate score for each item.*

Physician's examination	Score	Legend
9. Agitation		0 none 1 fidgetiness 2 playing with hands, hair, etc. 3 moving about, can't sit still 4 hand wringing, nail biting, hair-pulling, biting of lips
10. Anxiety psychic		0 no difficulty 1 subjective tension and irritability 2 worrying about minor matters 3 apprehensive attitude, apparent in face or speech 4 fears expressed without questioning
11. Anxiety somatic (Physiological concomitants of anxiety, such as: Gastro-intestinal: dry mouth, wind, indigestion, diarrhea, cramps, belching; Cardio-vascular: palpitations, headaches; Respiratory: hyperventilation, sighing; Urinary frequency; Sweating)		0 absent 1 mild 2 moderate 3 severe 4 incapacitating
12. Somatic symptoms gastrointestinal		0 none 1 loss of appetite but eating without staff encouragement. Heavy feelings in abdomen. 2 difficulty eating without staff urging. Requests or requires laxatives or bowel medications for or medication for G.I. symptoms.
13. Somatic symptoms general		0 none 1 heaviness in limbs, back or head. Backaches, headache, muscle aches. Loss of energy and fatigability. 2 any clear-cut symptom rates 2.
14. Genital symptoms (Symptoms such as: loss of libido, menstrual disturbances)		0 absent 1 mild 2 severe
15. Hypochondriasis		0 not present 1 self-absorption (bodily) 2 preoccupation with health 3 frequent complaints, requests for help, etc. 4 hypochondriacal delusions
16. Loss of weight A. When rating by history Rate either A or B B. On weekly ratings by ward psychiatrist, when actual weight changes are measured		0 no weight loss 1 probable weight loss associated with present illness 2 definite (according to subject) weight loss 3 not assessed 0 less than 1 kg, weight loss in week 1 greater than 1 kg, weight loss in week 2 greater than 2 kg, weight loss in week 3 not assessed

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Risperidone vs olanzapine
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A3

ADDITIONAL

7/81

38113CAP

HAM-D (continued)		
Please enter the appropriate score for each item.		
Physician's examination	Score	Legend
17. Insight	☐	0 acknowledges being depressed and ill 1 acknowledges illness but attributes cause to bad food, climate, overwork, virus, need for rest, etc. 2 denies being ill at all
18. Diurnal variation A. Note whether symptoms are worse in morning or evening. If no diurnal variation, mark 0. B. When present, mark the severity of the variation. Mark 0 if no variation.	☐ ☐	0 no variation 1 worse in a.m. 2 worse in p.m. 0 none 1 mild 2 severe
19. Depersonalization and derealization (such as: Feelings of unreality, nihilistic ideas)	☐	0 absent 1 mild 2 moderate 3 severe 4 incapacitating
20. Paranoid symptoms	☐	0 none 1 suspicious 2 ideas of reference 3 delusions of reference and persecution
21. Obsessional and compulsive symptoms	☐	0 absent 1 mild 2 severe

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Appendix 1.3

Sample Consent Form and Representative Written Information for Subject

SUBJECT CONSENT FORM FOR GENETIC TYPING OF DISEASE

It has been found that the severity of the disease that you suffer from and the response to therapy may depend on whether or not your disease is associated with certain genetic (hereditary) factors. You are therefore being asked if a blood sample may be taken and used for DNA-testing (typing of these genetic characteristics). These results might allow the doctors and sponsors to determine if the medication is used in a group of patients who have similar disease. The blood sample will be stored for maximum 10 years from the date it is drawn and will thereafter be properly destroyed. Neither your name nor your individual results will be reported or publicized under any circumstances.

The sample will be taken at the same time as your other required samples for the RIS-USA-113 research study. The nurse will take an extra 8ml (1 tablespoon) of blood at this time. There will not be an extra needle prick. This extra blood will be taken only one time during the course of the study.

There will be no direct benefit to you from the results of the research/tests which may be done on your sample. There may be future benefit for those who suffer from the same disease that you do.

The risks observed for drawing blood are minor. Some local pain, bruising, swelling, soreness and discoloration have been observed.

Your refusal to give permission to the storage and possible use of this blood sample will have no influence on you future medical care. You can still participate in this research trial without giving your permission for the storage and possible use of this blood sample.

Confidentiality

All records and documents pertaining to your participation in this trial will be held strictly confidential and your name will not be reported in any publications resulting from this trial. All records and documents will be reviewed by the sponsor (the Janssen Research Foundation, Inc.) or representatives of the sponsor and may be reviewed by the Food and Drug Administration (FDA), and/or registration authorities in the European Community countries.

Before signing this consent form, you are free to ask your doctor about any aspects of this trial that are not clear to you. You will be given a copy of this consent form.

Compensation

There are no costs to you to participate in this trial. All costs for the required doctor laboratory procedures are covered by the Janssen Research Foundation, the sponsor of this trial.

In the event an illness or injury is directly attributable to this procedure, the cost of emergency care will be provided by Janssen Research Foundation, Inc.. Financial compensation for such things as disability or discomfort due to injury, transportation

costs, etc., is not available. Any medical expenses due to self-inflicted injury are your responsibility.

Additional Information/Research Related Injury

If you have any questions regarding this study, side effects or a research related injury or if you have additional concerns while you are participating in this study, you may contact _____, your study doctor, at _____.

This research has been reviewed by an institutional review board (IRB) for the purpose of protecting your rights. If you have any questions about your rights as a study participant, you may contact _____ (chairperson) of the IRB at _____.

I (print name) have read the above text and fully understand the nature and purpose of the storage and possible use of my blood sample. I have had the opportunity to ask questions and discuss the procedure and have received satisfactory answers.

I hereby consent to the storage and possible use of this blood sample for genetic tests to determine the type of schizophrenia or schizoaffective disorder I suffer from.

...../...../.....
Subject's / Legal Guardian's Signature Date

...../...../.....
Investigator's Signature Date

...../...../.....
Investigator's Name - Printed Date

Appendix 1.4.1

List of Investigators and Institutional Review Boards/Ethics Committees

List of Investigators and IRBs/IECs

Principal Investigator/ Site	IRB/IEC	Other Participants and their Role in the Study		Training/Experience	No. Subjects
BAKER, Robert W, M.D. University Of Mississippi Medical Center - Dept Of Psychiatry and Human Behavior 2500 N. State Street Jackson, MO 39216 Inpatient Unit Sony Montgomery Veterans Administration hospital MS 39216 USA	Institutional Review Board University of Mississippi Medical Center 2500 North State Street Jackson, MS39216 USA	Halaris, Angelos, M.D., Ph.D. Kleinman, Paul, M.D. Daniels, Renee, R.N. Burton, Bradley, Ph.D. Redd Robin, Jones, Richard	Co-Investigator Co-Investigator Study coordinator Co-Investigator Research Technician H.N.		

List of Investigators and IRBs/IECs

Principal Investigator/ Site	IRB/IEC	Other Participants and their Role in the Study		Training/Experience	No. Subjects
BERMAN, Ileana, M.D. Taunton State Hospital Southeasrte Area of Massachusetts 60 Hodges Ave Taunton, MA 02780 USA Community Counseling of Bristol County Southeastern Area of Massachusetts 19 Cedar Street Taunton, MA 02780	Central Office Review Committee Commonwealth of Massachusetts Executive Office of Health and Human Services Department of Mental Health 25 Staniford Street Boston, MA 02114	Angeles, Gary, M.D. Austria, Julieta, M.D. Bayog, Rogelio, M.D. Bedard, Judith, R.N. Catipon, Jacinta, M.D. Chang, Howard, M.D. Chatfield-Taylor, Robert jr., M.D. Chesebrough Connie, Lic.S.W. Figman, Robert, M.D. Galen, Kenneth, M.D. Kelly, Kathryn, M.S., R.N., C.S. Langfield, Joanne, R.N. Langlois, Joseph, C.A.G.S. Osser, David, N., M.D. Pappas, Demetra, B.S. Patel, Charu, M.D. Rahman, Reza, M.D., M.R.C.P., P.C. Sigadel, Robert, M.D. Wu, Christina, B.A. Fiedosewicz, M.S. Savu, Raluca I, M.D. Angeles, Gary, M.D. Fiedosewicz, Hannah	Co-investigator Co-investigator Co-investigator Co-investigator Co-investigator Co-investigator Co-investigator Co-investigator Co-investigator Research Assistant Co-investigator Co-investigator Research coordinator		

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List of Investigators and IRBs/IECs

Principal Investigator/ Site	IRB/IEC	Other Participants and their Role in the Study	Training/Experience	No. Subjects
BRENNER, Ronald, M.D. St John's Episcopal Hospital, South Shore 327 Beach 19Th St Far Rockaway, NY 11691 USA	St. John's Episcopal Hospital Institutional Review Board 327 Beach 19 th Street Far Rockaway, New York 11691	Madhusoodanan, Subramoniam Sindagi, Jagadeesh B., M.D. Korn, Zamir Pawlowska, Monika Pirog, Elizabeth Samuels, Jack, R.N. Gaite, Alfonso C. Brodsky, Ella, M.D. McVey Merry Manger, Jennifer	Co- PI Co-investigator Co-investigator Coordinator Coordinator Coordinator Co-investigator	
BROWN, David, M.D. Community Clinical Research Inc 4411 Medical Parkway Austin, Texas 78756 USA Charter Hospital 8402 Cross Park Dr. Austin, Texas 78756 USA Williamson County MH Center at Round Rock 212 Commerce Blvd. Round Rock, Texas 78664 Lee County Mental Health Center 898 E. Richmond Suite 101 Giddings, Texas 78942	Western IRB P.O Box 12029 3535 7 th Avenue, SW Olympia, WA 98508	Privitera William, M.D. Jarrell, Jack, R.N. Hse, Lisa C, LMSW-ACP Din, Rosa, R.N. Morrison, David Anson, Byron Race, Carol Despi, Tushas	Co-investigator Study Coordinator Study Co-ordinator Back-up coordinator Rater Research assistant Study Coordinator Back-up PI	

List of Investigators and IRBs/IECs

Principal Investigator/ Site	IRB/IEC	Other Participants and their Role in the Study		Training/Experience	No. Subjects
CARMAN, John S. Carman Research 4015 South Cobb Drive Suite 245 Smyrna, GA, 30080 USA Curry John S, Ph.D. The Psychology Center of Atlanta 4015 South Cobb Drive, #220 Smyrna, GA 30080 USA Ridgeview Institute 3995 South Cobb Drive Smyrna, GA 30080	Western Institutional Review Board P.O Box 12029 3535 7th Avenue, SW Olympia, WA 98502	Enloe, Deborah, R.N. Mitchell, Mittie, R.N. Robinson-Hart, Lynette, R.M.N. Currie, John S, Ph.D. Heyrman, Kathleen A, R.N. Golightly, Daniel, M.D. Kupkowski Marlene A, R.N. Roberts Marcia, R.N. Carman, Candace Padery Edwinia L, Miller, Amanda G Fleming, Maria Y. Fears Dawn Ballou	Back-up rater Study Coordinator, PANSS rater Back-up rater Co-investigator Co-investigator Research coordinator, back-up rater Medical records Medical records Medical Records Research coordinator Co-investigator		
CHENGAPPA, Roy K.N., M.D. Special Studies Center Mayview State Hospital 1601 Mayview Road Bridgeville, PA 15017 University of Pittsburgh Medical Center Beaver Valley Mental Health Services 178 Virginia Avenue Rochester, PA 157074	University of Pittsburgh Institutional Review Board for Biomedical Research Room 219 Nese/Barkan Building c/o Western Psychiatric Institute & Clinic 3811 O'Hara Street Pittsburgh, PA152134	Parepally, Haranath, M.D. Baird, James, Ph.D. Delaney, Joyce, R.N. Kang, Jasbir S., M.D. Atzert Rebecca, R.N. Bezner Joan, B.S.N. Zoretich, Rebecca, M.Sc.	Co-investigator Co-investigator Study coordinator Co-investigator Clinical spec. Trial Nurse Senior Research Assoc.		

List of Investigators and IRBs/IECs

Principal Investigator/ Site	IRB/IEC	Other Participants and their Role in the Study		Training/Experience	No. Subjects
COHN, Cal, M.D. The Cohn Center Psychiatry 7777 Southwest Fwy Ste 1036 Suite 1036 Houston, TX 77074 USA	Western Institutional Review board P.O. Box 12029 Olympia, WA 98508-2029	Francis, Beatriz, J Obmaces, Karen Elkins, Cecil.W., L.V.N. Reagan, Lucy, R.N.C. Hernandez, Jesusa Samuels, Douglas, M.D. Jennings, Floyd, Ph.D. Hernandez, Carlos, M.D. Croft, Steven, M.D.	Study Coordinator CCRC Study Coordinator RNC MA Co-investigator Co-investigator Co-investigator Co-investigator		
		Lubetkin, Sanford, M.D. Grinstead, William C, M.D. Murphy, Hallie, M.A. Ramirez, Nancy Rando, Kevin, Q.A. Obmaces, Karen, Townsend, Shelly M. Francis, Judith Galvan, Erica Rain, Mary	Co-investigator Co-investigator Psychometrician (p15) CRC QA CCRC Psychol Practicum Student study Coordinator medical assistant CRC		
CONLY, Robert Maryland Psychiatric Center Mprc Po Box 21247 Baltimore, MD 21228 USA	University of Maryland at Baltimore 655 West Baltimore Street Bressler Research Building Room 14-016 Baltimore, Maryland 21201-1559	Love, Raymond Reynolds, Rhonda Zaremba, Sandra Aleszk, Michael	co Principal investigator Trial Nurse Trial Nurse Co-investigator		

List of Investigators and IRBs/IECs

Principal Investigator/ Site	IRB/IEC	Other Participants and their Role in the Study	Training/Experience	No. Subjects
CSERNANSKY, John, M.D. Metropolitan St. Louis Psychiatric Ctr 5351 Delmar St. Louis, MO 63112 Washington University School of Medicine Dept of Psychiatry 4940 Childrens Place Saint Louis, MO 63110 USA	Washington University School of medicine Human Studies Committee, Box 8089 660 S. Euclid St. Louis, MO 63110-1093	Rastogi-Cruz, Devnandini, M.D. Quadri, Omar, M.D. Posener, Joel, M.D. Bishop, Juanita Haines, Kevin, M.S.W. Menckowski, Stephanie, B.A. Jones, Don	Co-investigator Co-investigator Co-investigator prof. rater Research coordinator Research assistant Research coordinator	
DAMLUJI, Namir, M.D. NAMIR DAMLUJI - PRIVATE PRACTICE 591 Camino De La Reina, Suite 410 San Diego, CA 92108 USA Hussam Mihtar, M.D. 899 University Center Lane, Suite 380 San Diego, CA 92122 USA	Western Institutional Review Board P.O Box 12029 3535 7th Avenue, SW Olympia, WA 98502	Mihtar, Hussam, M.D. Fowler, Richard C, M.D. Denish, George W, M.D. Tilker, Theresa D, L.C.S.W. Evans, William J., B.A. Collard, Daniel, B.A. Clark, Jennifer, B.A. Mason, Ellen	Co PI Co-investigator Co-investigator Study coordinator Study Coordinator	

List of Investigators and IRBs/IECs

Principal Investigator/ Site	IRB/IEC	Other Participants and their Role in the Study		Training/Experience	No. Subjects
DANIEL, David, M.D. Clinical Studies Ltd, - Washington 6404 Seven Corners Pl Falls Church, VA 22044 USA	Western IRB P.O Box 12029 3535 7 th Avenue, SW Olympia, WA 98508	Baily, Becky A., Ph.D. Gebhardt, Diana, R.N. Moseley, Charles D., M.D. Gopalan, Ram, M.D. Issa, Fuad, M.D. Lee, Mary R., M.D. Meenehan, Beth, M.S.N., R.N., C.S.	Co-investigator Research coordinator Co-investigator Co-investigator Co-investigator Co-investigator Coordinator		
Columbia/Dominion Hospital 2960 Sleep Hollow Road Falls Church, VA 22044	Columbia Arlington Hospital Institutional review Board 1701 N. George Mason Drive Arlington, VA 22205	Prochnik, Elisabeth, L.C.S.W. Vasquez, Emily, R.N., B.S.N Whitcomb, Stacy R	Recruitment Research coordinator Research coordinator		
Columbia Arlington Hospital 1701 N. George Mason Drive Arlington, VA 22205	Vencor Hospital-Arlington Institutional Review Board 601 S. Carlin Springs Road Arlington, VA 22204	Hill, Danielle Pyle, Claudia, R.N., M.S., C.C.R.C.	Research assistant Research Assistant		
Vencor Hospital-Arlington 301 S-Carlin Springs Road Arlington, VA 22204		Tran, Frances H Shaikh, Farook, M.D. Linn, Barbara, R.N. Pyle, Laura Ketcham Danielle Soler, Rosa McClanahan, Virginia, R.N. Bernstein Suzanne Shaikh, Farook, M.D. Hyneman, Victoria Makvandi, Eric Hyneman, Victoria Maiorrra, Megan,	Research coordinator Research coordinator Coordinator Research assistant Research coordinator Research Coordinator Co-investigator Lab Technician Lab Technician		

List of Investigators and IRBs/IECs

Principal Investigator/ Site	IRB/IEC	Other Participants and their Role in the Study		Training/Experience	No. Subjects
DEPRIEST, Michael, M.D. Pharmacology Research Corporation 6039 Edlora Avenue, Suite H Las Vegas, NV 89102 Pharmacology Research Corporation 343 Elm Street, Suite 404 Reno, NV 89503	Western IRB P.O Box 12029 3535 7 th Avenue, SW Olympia, WA 98502	Bralliar, Richard, M.D. Ferguson, James M., M.D. Danks, Patricia, Ph.D. Mack, Kathryn Powell, Latonya D Early, Sula Bradley, Leslie J Centric, Ronald W, D.O. Cole, Barry E, M.D. Atkinson, Kimberly K, B.S. Billinson, Stephen, B.S. Costa, Joseph S, C.N.A. Billinson Cindy C., B.S.	Co PI Psychometrician Coordinator Co-investigator Coordinator Research Coordinator Coordinator		
FABRE, Lou, M.D. Faber Research Clinic 5503 Crawford St Houston, TX 77004 USA	Human Investigation Committee of Houston, Texas 5503 Crawford Houston, Texas 77004	Powers Vettraino, Julia, R.N., M.S.N., C.N.S. Rodriguez John, F.M.G. Buckner, Shirley, R.N. Prater, Rodney, R.N.	Trial Nurse Study coordinator Trial Nurse Trial Nurse		
FEIFEL, David West Wing - Psychiatry - UCSD Medical Center 200 West Arbor Drive. San Diego, CA 92103-8620 USA	UCSD Human subjects Committee University of California, San Diego, 0052 9500 Gilman Drive La Jolla, CA 92093-0052	Perry, William, Ph.D. Kuck, Julie, Ph.D. Farber, Robert, M.A. Lawrence, Cynthia L., M.F.S. Minassian, Arpi, M.A. Moutier, Christine, M.D.	Co-investigator Co-investigator Coordinator Co-investigator	Psychiatry Psychiatry Psychology Psychiatry Psychology Psychiatry	

List of Investigators and IRBs/IECs

Principal Investigator/ Site	IRB/IEC	Other Participants and their Role in the Study		Training/Experience	No. Subjects
FLAUM, Michael University Of Iowa Hospitals And Clinics - Dept Of Psychiatry 200 Hawkins Dr. C33-Pulmonary/Internal Medicine Iowa City, IA 52242 USA	University Of Iowa IRB 300 CMAB Iowa City, Iowa 52242-1320	Ho, B.C., M.D. Oliver, Susan, M.S. Fleming, Frank, B.S.N. Esgate, Susan, B.S.N. Peterson-Creze, Colleen, B.S.N. Sievers, Melanie, B.S.N. O'Leary, Dan, Ph.D. Warren-Boyd, Lois, B.S.W. Holman, Tim, M.A. Tranel Alane	Co-investigator Study coordinator Co-investigator Co-investigator Co-investigator Co-investigator Co-investigator Co-investigator		
HOWANITZ, Evelyn, M.D. Lyons Va Medical Center - 116A 151 Knollcroft Rd Lyons, NJ 07939 USA	Research and Development Committee and Human Studies subcommittee East Orange Campus, Department of Veterans Affairs New Jersey Health Care System East Orange, New Jersey 07019	Engelhart, Charles, Ph.D. Broad, Doreen, R.N. Choe, Yeon, M.D. Eisenstein, Norman, Ph.D. Pan, Jane	Co-investigator Co-investigator Research assistant		
KANOF, Philip Psychiatry Services 116A - Tucson Medical Center Building #66, rooms #122 - #124 3601 S. 6TH Ave Tucson, AZ 85723 USA	Human Subjects Committee 1622 E. Mabel Street Tucson, AZ 85724	Bell, Iris, M.D. Hoover, Kim, M.D. Fain, Robin, M.A. Roun, David Scherer, Katalin	Co-investigator Co-investigator Study Coordinator Research Assistant Research Assistant		

List of Investigators and IRBs/IECs

Principal Investigator/ Site	IRB/IEC	Other Participants and their Role in the Study		Training/Experience	No. Subjects
KNESEVICH, Mary Ann, M.D. St. Paul Medical Center at Southwestern Medical Center 5959 Harry Hines Blvd Suite 924 Dallas, TX 75235 USA	Western Institutional Review Board 3535 7 th Ave, S.W. P.O. Box 12029 Olympia, WA 98508-2029	Prosser, John, Ph.D. Collingwood Lisa, M.S.	Co-investigator		
KOPELOWICZ, Alex, M.D. San Fernando Mental Health Center 15535 San Fernando Mission Hill Blvd Mission Hills, CA 91345 USA	Friends Medical Science Research Center, Inc 18401 Burbank Blvd., Suite 208 Tarzana CA 91356	Green, Michael, Ph.D. Zarate, Roberto, M.A. Tripodis, Dino, M.D. Mangano, Robert, B.S. Gonzalez, Veronica, B.A. Mangano, Robert	Co-investigator Rater Co-investigator Project coordinator Project coordinator		

List of Investigators and IRBs/IECs

Principal Investigator/ Site	IRB/IEC	Other Participants and their Role in the Study		Training/Experience	No. Subjects
LAURIELLO, John, M.D. University Of New Mexico/mental Health Center - Department Of Psychiatry Med-6 Building 943 Stanford Drive NE Albuquerque, NM 87131-5326 USA	University of New Mexico School of Medicine Human Research Review Committee Office of the Dean, Basic Medical Science Building, room 177 915 Stanford Drive NE Albuquerque, NM 87131-5116	Bustillo, Juan, M.D. Hammond, Roger, M.D. Jaramillo, Ulla, R.N. Landgraf, Elma, R.N. Landy, Janice, M.D. Bonner, Lauren, M.D. resident physician Schnierow, Brad, M.D. resident physician Temes, Melissa, B.A. Mental Health Associate II Touchet, Mia, B.A., Mental Health Associate II Mattox, Paul, M.D. , resident physician Shaw, Patricia K, M.S. Reeve, Alison, M.D. Del Fabbro, Anilla, M.D., Resident Physician Hinrichs, Bruce, M.D., Resident Physician Shaw, Patricia, K., M.S., Cessna, Andy	Co-investigator Co-investigator Study coordinator Study coordinator Co-investigator Co-investigator Co-investigator Study Coordinator Co-investigator Research assistant – Cognitive tester Co-investigator Co-investigator Co-investigator Research assistant Mental Health Associate		
LAWSON, William, M.D., Ph.D. Richard L. Roudebush VA Medical Center - 1481 W 10TH St Indianapolis, IN 46202 USA	Research & Sponsored Programs IUPUI Union Building #618 620 Union Drive Indianapolis, IN 46202	Baker, F.M., M.D. Mayeda, Aimee, M.D. Magnes, Carolyn	Co-investigator Co-investigator		

List of Investigators and IRBs/IECs

Principal Investigator/ Site	IRB/IEC	Other Participants and their Role in the Study		Training/Experience	No. Subjects
LESEM, Michael, M.D. Claghorn-Lesem Research Clinic Inc 6750 West Loop S. Ste 1050 Bellaire, TX 77401 USA	Western Institutional Review Board P.O Box 12029 3535 7 th Avenue, SW Olympia, WA 98502	Claghorn, James, M.D. Carney, Richard, M.D. Brown, Patricia, R.N. Waligura, Angela, R.N. Reed, Jesse Allan, III, Ph.D. Tagliabue, Elizabeth, R.N. Simpson, Karen Olurin, Jacqueline, R.N. Smith, Rick, R.N.	Co-Investigator Co-Investigator CRC CRC Ph.D. CRC lab technician R.N. R.N.		
LEVINSON, Douglas, M.D. Medical College Of Pennsylvania - Department Of Psychiatry - Eastern Pennsylvania Psychiatry Instit 3200 Henry Ave Philadelphia, PA 19129 USA NSH Clinical Research center Norristown State Hospital, Building 52	Committee for protection of human subjects Allgeheny University of the Health Sciences 1-140 New College Bldg., Mail Stop 444 Philadelphia, PA 19102 Bnorrison State Hospital IRB Building 19 1001 Sterigere Street Norristown, PA 19401	Shaughnessy Rita, M.D., Ph.D. Stanilla, Joseph, M.D. Nair, Chand, M.D. Lekhwani, M.D. Korslund, Kathryn Saurahb, M.D. Gratz, Silvia, D.O. Roth, Linda, R.N. Yoder, Karen, R.N. Schwartz, Michael, D.O. Sureshkumar, Thambipillai, M.D. Koffler, Sandra, Ph.D. Luthra, Veena, M.D. Bartolie, Eduard, Ph.D.	Co-investigator Co-investigator Coordinator Coordinator Psychometrician Co-investigator D.O. Trial Nurse Coordinator Co-investigator Co-investigator Co-investigator Neuropsychologist		

List of Investigators and IRBs/IECs

Principal Investigator/ Site	IRB/IEC	Other Participants and their Role in the Study		Training/Experience	No. Subjects
LINDENMAYER, Jean- Pierre, M.D. Manhattan Psychiatric Center Ward's Island Complex New York NYC 10035 125 th St Clinic, 12 th flor Adam Clayto9n Powel Bldg. New York, N.Y. 10027 Nathan Kline Institute Rockland Psychiatric Center Orangeburg, N.Y. 10962 USA Nyanack Consultation Center 18 churst st; Nyack, N.Y. 10968	Manhattan Psychiatric Center, Institutional Review Board Manhattan Psychiatric Center Ward's Island Complex New York NY 10035 Nathan Kline Institute Rockland Psychiatric Center Institutional Review Board 140 Old Organgeburge Rd, Bldg 37 Orangeburg, N.Y. 10962	Citrome, Leslie, M.D. Iskander, Adel, M.D. Limchua, Rebecca, R.N. King-Davis, Shirletta R.N. Volavka, Jan, M.D. Parker, Benedicto, M.D. Parak, Mohan, M.D. Mohr, Pavel, M.D. Kotsaftis, Antonis, Ph.D. Podell Paul, M.D. Carneal, Floyd, M.D. Green, Maurice, M.D. Nelson, Fritz, M.D. Walters, Denny, M.D. Walton, Robert, M.D. Serrano, Jesus, M.D. Nagel, Jacione, R.N. Vaidian, Santhamma, R.N. Lucero, Carolina, R.N. Cutler, Cynthia Levinson, Brett Platt Meredith, Ph.D. Nolan, Karen, Ph.D. Kamberakis, Kay Townsend, Michael Welch, Toni Patalinjug, Marilou, M.D.	No patients enrolled		

List of Investigators and IRBs/IECs

Principal Investigator/ Site	IRB/IEC	Other Participants and their Role in the Study		Training/Experience	No. Subjects
LOGUE, H.E., M.D. Birmingham Psychiatry Pharmaceutical Studies Inc 3490 Independence Drive Birmingham, AL 35209 USA	Brookwood Medical Center IRB 2010 Medical Center Drive Birmingham, Alabama 35209	McLean Kay H., M.S.N., R.N., C.N.S. Hagemeyer James Ashley, M.D. Tieszen Stuart C, M.D. Xavier, Narithookil S., M.D. Lavender, Lucy Chambers, Mary Nelson, Christi	Coordinator Co-investigator Co-investigator Co-investigator Research Assistant Research Assistant Research Assistant		
MANSCHRECK, Theo, M.D. Corrigan Mental Health Center 49 Hillside St Fall River, MA 02720 USA	Central Office Research Review Committee (C.O.R.R.C.) Department of Mental Health 25 Stanford St. Boston, MA 02114-2575	Sousa Sharon A., R.N., E.J.D Redmond Deborah A., M.A. Belkin, Gary, M.D. Harrop, Daniel, M.D. Furtado, Ruth Popoil, Mary-Anne, M.S.W. Boshes, Roger, M.D. Sousa, Jose J.C., M.D. Conforti, Lara, B.A. Massad, Peter, R. Ph. Makowski, Michael, M.D. Winzig, Laura, B.A. Rosato, Melissa, B.A. Candella, Steven, B.A. Keller, Kelli, B.A. Seavey, Lara Rock, Jason	Co-investigator Co-investigator Co-investigator Co-investigator Pharmacist Physician Research assistant Research assistant Research assistant Research assistant Research assistant	Licensed Psychologist Psychiatry Psychiatry Psychiatry	

List of Investigators and IRBs/IECs

Principal Investigator/ Site	IRB/IEC	Other Participants and their Role in the Study	Training/Experience	No. Subjects
MCEVOY, Joseph Adult Admissions Unit John Umstead Hospital 1003 12 th st. Butner, NC 27509 USA	Research Committee John Umstead Hospital 1003 12 th street Butner, NC 27509 DUMC IRB Committee Seeley g. Mudd Building DUMC Box 3001 Durham, NC 27710	Wilson, William H, Ph.D. Shawn, Patricia Baily, George	Co – PI Coordinator HC assistant	
MELTZER, Herbert, M.D. Psychiatric Hospital at Vanderbilt 1601 23 rd Avenue, S., Suite 306 Nashville, TN 37212	The Committee for the protection of Human subjects, Institutional Review Board CCC-3322 Medical Center North Nashville, TN 37232-2103 Education and training committee Mental Health Cooperative 275 Cumberland bend Dr Nashville, TN37228 Alvin C. York VAMC 3400 Lebanon Road Murfreesboro, TN 37130	McGurk, Susan Prakash, Rudra, M.D. Lee, Myung, M.D. Briggs, Karen, M.D. Hudek, Sabitha, M.D. Milam, Carol, M.D. Khan, Shaukat, M.D. Montautti-Alana, Silviana, M.D. Fritzus, Vicki, D.Ph. Morrison, Jan, M.Ed. Fortney, Margo, M.A. Harris, Rose, M.S.N. Salzer, Mark, Ph.D. Chronic, Kate, M.A. Hutchinson, Connie, M.A. Roy Ajanta, M.S. Smith Becky, R.N. Cope Rosemary, M.A. Yank, Glenn, M.D. Hinkle, Pam, M.S. Seiler, Kim, B.A. Bianchi, Vicki	Co- PI Co-investigator Co-investigator Co-investigator Co-investigator Co-investigator Co-investigator Study coordinator R.A. III Rater / research nurse Research assistant Research assistant Rater Study coordinator Co-investigator Clinical Pharmacist	

List of Investigators and IRBs/IECs

Principal Investigator/ Site	IRB/IEC	Other Participants and their Role in the Study		Training/Experience	No. Subjects
MENDELOWITZ, Alan Hillside Hospital 75-59 263rd St Glen Oaks, NY 11004 USA	Human Subjects Review Committee (HSRC) 420 Lakeville Road, Room 133 New Hyde Park, NY 11042 USA	Botts, Sheila, Pharm. D. Loebel, Antony, M.D. Gunduz, Handan, M.D. Sah, Mukesh, M.D. Petrides, Georgios, M.D. Howard, Alfreda, M.S. Meyer, Sabina, B.A. Wolf, Dennis, M.D. Bates, John, M.A. Reiter, Gail, M.A. Conley, Jennifer, B.A. Dunlop, Judith Porto, Linda,	Co-investigator Co-investigator Co-investigator Co-investigator Co-investigator Coordinator Coordinator Co-investigator Research Nurse Research Nurse		
MILLER, Alexander, M.D. University Health Center Downtown West Annex 1115 West Martin San Antonio, TX 78207 USA	Institutional Review Board The university of Texas Health Science Center at San Antonio 7703 Floyd Curl Drive San Antonio, TX 78284-7830	Chiles, John, M.D. Dassori, Albana, M.D. Gonzales, Cheryl, M.D. Olsen, Gerry G, M.D. Alvarez, Inna, M.D. Krasnoff, Amy Tabor, Regina, R.Ph. Hilbig, Donna Naylor, Roxana V. Herrera, Miguel A., L.V.N. Dickson, James	Co-Investigator Co-Investigator Co-Investigator Co-Investigator SSRA Study coordinator Research Pharmacist Research assistant Co-Investigator		

List of Investigators and IRBs/IECs

Principal Investigator/ Site	IRB/IEC	Other Participants and their Role in the Study		Training/Experience	No. Subjects
NAKRA, Raj, M.D. Midwest Psychiatry 100 No. Euclid, Ste. 1104 St. Louis, MO 63108	Human Studies Committee 660 South Euclid St. Louis, MO 63108	Mc Cullough, Allison Stasen, Anne Hohmann, Annette, R.N. Nakra, Rashmi, M.D. Griffin, Walter, M.D. Hicks, Robert, M.D. Daniels, John S., M.D.	Study Coordinator Back-up coordinator Back-up coordinator Co-Investigator Medical Physician Back-up Psychiatrist Medical physician		
PAHL, Jorg, M.D. Pahl Brain Associates P.C. 3909 N. Classen Oklahoma City, OK 73118	Western Institutional Review Board P.O Box 12029 3535 7 th Avenue, SW Olympia, WA 98502	Hennessee, John, M.D. Jenkins, Forrest, L.P.N., C.C.R.C. Wright, Keiko, B.S., C.C.R.C. Ward, Louis, M.Ed., L.P.C., L.M.F.T. Ware, Michelle, M.D. Vernon, Michelle, B.A. Raines, Amy, R.A Semtner, Carol, R.N. Watson-Carpenter, Gail, L.P.N. Bradley, Douglas C., R.A.. Davis, Julie D Wilson, Gail	Co-Investigator Clinical research coordinator Clinical research coordinator Psycho Metric Co-investigator Psych. research asst. Research assistant Clinical research assistant Clinical research assit. Clinical research coordinator Clinical research coordinator		

List of Investigators and IRBs/IECs

Principal Investigator/ Site	IRB/IEC	Other Participants and their Role in the Study		Training/Experience	No. Subjects
PANDURANGI, Ananda, M.D., P.I. McDaniel Kent, G, M.D., Co P.I. Medical College of Virginia/Virginia Commonwealth University Department of Psychiatry MCV Hospitals- North Hospital, RM 3-075 1300 E. Marshall St Richmond, VA 23219	Committee on the conduct of Human Research VCU-MCV, Box 980568 MCV Richmond, VA 23298-0568	McDaniel, Lisa, B.S. Seegers, Debra, R.N., F.N.P. Compton, Am,elia Ph.D. Keys-Aldridge, Linda D., M.S.W. Marrow, Bonnie, M.S. Lynch, Valerie, M.S.W. McDaniel, Kent, M.D.	Rater Coordinator Coordinator Co-P.I.		

List of Investigators and IRBs/IECs

Principal Investigator/ Site	IRB/IEC	Other Participants and their Role in the Study		Training/Experience	No. Subjects
PLOPPER, Michael, M.D. Mesa Vista Hospital 7850 Vista Hill Ave San Diego, CA 92123 Southbay 1261 third Avenue Suite H Chula Vista, CA 91911 El Cajon I 333 W. Lexington El Cajon, CA 92020 USA	Western Institutional Review Board P.O Box 12029 3535 7th Avenue, SW Olympia, WA 98502-2029	Owens, David, M.D. Minick, Joseph, M.D. Golden, Joshua, M.D. Amantea, Marianne, R.N. Ingraham, Mary, R.N. Saben, Laurence R, M.D. Bari, Mohammed A., M.D. Kuzman, William, M.D. Lesinski, John, Rh.P., B.S. Morrill, Julia, R.N. Lee-Higgins, Margaret Morano, Rocco Berger, Fred, M.D. Reiner, Marc H., M.D. Ishaque, Saleem, M.D. Zechar, Margaret, R.N. Dougherty, Donald, M.D. Tanner, Cheryl Franz, Mary, R.N. DeAnn, Romero, Ph.D. Howard, Tiffany	Co-Investigator Co-Investigator Co-Investigator Clinical Research Coordinator Co-Investigator Co-Investigator Co-Investigator Clinical Research Coordinator Co-Investigator Co-Investigator Co-Investigator Co-Investigator Research Manager Clinical Research Coordinator		
REDDY, Narayana, M.D. Human Service Center 228 NE Jefferson Avenue Peoria, IL 61615 Health Advance Institue 222 NE Monroe, Suite 904 Peoria, IL 61602	Western Institutional Review Board 3535 7th Avenue S.W. P.O. box 12029 Olympia, WA 98508-2029	Lickiss, Vickie, Fillmore,, Jane. Coyner, Jenny, Pace, Amy	C.C.R.C. C.C.R.C. C.R.C. Research Assistant		

List of Investigators and IRBs/IECs

Principal Investigator/ Site	IRB/IEC	Other Participants and their Role in the Study		Training/Experience	No. Subjects
ROY- BYRNE, Peter Harborview Medical Center – Department of Psychiatry Box 359896 - 5 S. Psychiatry 325 ninth Ave nue Seattle, WA 98104 USA	Human Subjects Division Grants and Contracts Services Box 355752 3935 University Way NE Seattle, WA 98195	Wingerson, Dane K, M.D. Ries, Richard K, M.D. Zacharias, Pamela, ARNP	Co-investigator Co-investigator Coordinator		
SCHULZ, Charles, M.D. Case Western Reserve - University Hospital Of Cleveland - Department Of Psychiatry Hanna Pavilion Cleveland, OH 44106 USA	Although the study was performed in compliance with GCP, the IRB approval letter with the address details could not be located at the time of writing the report.	Aclegg, Kathleen Gilliland, Joyce Camlin, Kelly Cola, Diane Wise, Alexandra Berry, Sally, M.D. Getz, Glen Heimburg, C, M.D.	Co-PI Coordinator Research assistant Research assistant Research assistant Co-investigator Research Assistant Co-investigator		

List of Investigators and IRBs/IECs

Principal Investigator/ Site	IRB/IEC	Other Participants and their Role in the Study		Training/Experience	No. Subjects
STERN, Robert G, M.D. Mount Sinai School of Medicine Dept. of Psychiatry One Gustave L. Levy Place New York, NY 10029	Institutional review Board Mount Sinai School of medicine Annenberg 5 th floor, box 1075 One gustave L. Levy Place New York, NY 10029	Schnur, Elke Ballou, Sarah Kim, Julie Harwitz, David, M.D. Crisanto, Irish, M.D. Benoit-Rock, Lionel, M.D. Millet, Shirley, M.D. Friedman, Joseph, M.D. Dron, Felix, M.D. Saeed, Waheed, M.D. Jabour, Banna, M.D. Anderson, Kristen Levin, Michelle	R. Supervisor Research assistant Research Assistant Co-investigator Co-investigator Co-investigator Co-investigator Co-investigator Co-investigator M.D. Fellow M.D. Fellow		
Bronx VA Medical Center dept. of Psychiatry 130 W. Kingsbridge Road Bronx, NY 10468 USA	General Medical Research Research Building Bronx VA Medical Center 130 W. Kingsbridge Road Bronx, NY 10468	Zimmerman, Leslie Skin, Robert G	Research Assistant Research Assistant/ study coordinator Research Assistant Assistent		

List of Investigators and IRBs/IECs

Principal Investigator/ Site	IRB/IEC	Other Participants and their Role in the Study		Training/Experience	No. Subjects
Strakowski, Stephen, M.D. Psychotic Disorders Research Program University of Cincinnati College of Medicine 231 Bethesda Avenue Suite 7103, ML559 Cincinnati, OH 45267 USA	Institutional Review Board 140 Health Professions Way University of Cincinnati Medical Center Eden and Bethesda Avenue Cincinnati, OH 45267-0587 USA	Bourne, Michelle, B.A. Friedman, Loren M., M.S. Hawkins John, M.D. Isbell, Tami Jo, B.A. Keck Paul, M.D. Runck Elise, B.S. Sax Kenji, Ph.D. Tugrul, Karen, R.N. Delbello, Melissa, M.D. Gannon, Melanie, B.A. Zimmerman, Molly, B.A. Dunayevich, Eduardo, M.D. Haskins, John M	Co-investigator Co-investigator Coordinator Co-investigator Back up coordinator Co-investigator Study Nurse Co-investigator Recruiter PANSS rater Co-investigator Co-investigator		
SWANN, Alan C., M.D. University Of Texas Mental Sciences Center - Department Of Psychiatry 1300 Moursund St Houston, TX 77030 Harris County Psychiatric Center 2800 South McGregor Houston, TX 77021 USA	Committee for the Protection of Human Subjects University of Texas Medical School – Houston 6431 Fannin, Suite G.700 Houston, Tx 77030	Moeller Gerard F., M.D. Green, Lisa, M.D. (left site) Wassef, Adel, M.D. Barber, Marilyn, Ph.D. Tudor, Monica Grimes, Pam, M.S.N.	Co-investigator Co-investigator Co-investigator Co-investigator Outpatient coordinator PMH - NP		

List of Investigators and IRBs/IECs

Principal Investigator/ Site	IRB/IEC	Other Participants and their Role in the Study		Training/Experience	No. Subjects
TARGUM, Steven, M.D. Clinical Studies, Philadelphia, 400 Market Street Suite 425, Philadelphia PA 19106 Charter-Fairmount Behavioral Health System, 561 Fairthorne Avenue Philadelphia, PA 19128 Crozer-Chester medical Center Chec House Garden Drive, Upland PA 19013 USA	Western Institutional Review Board P.O Box 12029 3535 7th Avenue, SW Olympia, WA 98502	Kennish, Margaret, C.C.R.C. VanDyke, Jean, M.S.N., R.N. Caputo, Kevin P, M.D. Leyden Patti, R.N. Worrells, Lisa A., P.A.-C. Eisen, Steven, M.D., F.R.C.P. Harman Scott, M.D. Baldassono, Claudia, M.D. Stuccio-White, Nina, D.O. Finkel, Patti	Back-up coordinator Back-up coordinator Co-investigator Trial Nurse Co-investigator Co-investigator Co-investigator Study Coordinatord		
VAN KAMMEN, Daniel P., M.D. VA Pittsburgh Healthcare System Highland Drive Division 7180 Highland Dr Pittsburgh, PA 15206 USA	Research and Development Committee VA Pittsburgh Healthcare system Highland Drive Division 7180 Highland Dr. Pittsburgh, PA 15206	Gurklis, John, M.D. Peters, Jeffrey, M.D. Barry, Ethan Asman, Stephanie, M.S. Otterman, Kelly Allen, Daniel, Ph.D. Dewalt, Marti, M.S.W.	Psychiatrist Co-investigator Coordinator Coordinator Research coordinator Psychologist Social Worker		

List of Investigators and IRBs/IECs

Principal Investigator/ Site	IRB/IEC	Other Participants and their Role in the Study		Training/Experience	No. Subjects
WIRSHING, Donna, M.D. West L A Veterans Affairs, Medical Center 11301 Wilshire Blvd Bldg 210, Basement, rm 15 Los Angeles, CA 90073 USA	Research and Development Committee/Internal Review Board West Los Angeles Affairs Medical Center Bldg 258 (B151A) 11301 Wilshire Blvd Los Angeles, CA 90073	Wirshing, William C, M.D. Marder, Stephen R, M.D. Saunders Charles Scott, M.D. McKenzie Joanne, R.N. German, Craig Benveniste, Robert Dupree, James Strough, Alix Dupree, Jim	Co-investigator Co-investigator Co-investigator Trial Nurse Study Coordinator Study Coordinator Study Coordinator Study Coordinator		

Appendix 1.4.2

Principal Investigators Curriculum Vitae

A list of publications and presentations may not be provided as part of the investigator's curriculum vitae. Information on publications and presentations for each investigator is on file with the sponsor and is available upon request.

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January 6, 1997

CURRICULUM VITAE

BIOGRAPHICAL

NAME: Robert Winfield Baker, M.D. **BIRTHDATE:** September 4, 1958
BIRTHPLACE: Pittsburgh, PA **CITIZENSHIP:** U.S.A.
BUSINESS ADDRESS: University of Mississippi Medical Center
Department of Psychiatry and Human Behavior
2500 North State Street
Jackson, MS 39216
PHONE: (601) 984-5800
FAX: (601) 984-5885

EDUCATION AND TRAINING

UNDERGRADUATE:

1976-78	Northwestern University Evanston, IL Honors Program in Medical Education	B.S. Medical Sciences 1980

GRADUATE:

1978-82	Northwestern University Medical School Chicago, IL	M.D. 1982

POSTGRADUATE:

1982-83	Montefiore Hospital University of Pittsburgh School of Medicine Pittsburgh, PA	Intern Internal Medicine (flexible)
1983-86	Western Psychiatric Institute and Clinic University of Pittsburgh School of Medicine Pittsburgh, PA	Resident General Psychiatry

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APPOINTMENTS AND POSITIONS

ACADEMIC:

1986-88	University of Pittsburgh School of Medicine Pittsburgh, PA	Clinical Instructor Psychiatry
1988- 1996	University of Pittsburgh School of Medicine Pittsburgh, PA	Assistant Professor Psychiatry
1997- present	University of Mississippi School of Medicine Jackson, MS	Associate Professor Psychiatry

NON-ACADEMIC:

1985-86	Mental Health Unit Allegheny County Jail Pittsburgh, PA	Consultant Psychiatrist
1986- present	Western Psychiatric Institute and Clinic Pittsburgh, PA	Medical Staff
1986- present	Mayview State Hospital Bridgeville, PA	Medical Staff
1986-87	Mayview State Hospital Bridgeville, PA	Inpatient Unit Director
1987-89	Mayview State Hospital Bridgeville, PA	Psychiatric Supervisor and Director of Admissions
1989	Mayview State Hospital Bridgeville, PA	Psychiatric Supervisor and Director of Research
1989	Highland Drive V.A. Hospital Pittsburgh, PA	Staff Psychiatrist(part time) Schizophrenia Research
1989- 1996	Western Psychiatric Institute and Clinic Pittsburgh, PA	Director of Special Studies Center at Mayview State Hospital
1989- 1996	Schizophrenia Module Western Psychiatric Institute and Clinic Pittsburgh, PA	Attending Psychiatrist

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1989- 1996	Benedum Geriatric Center University of Pittsburgh Pittsburgh, PA	Attending Psychiatrist
1990- 1996	Diagnostic & Evaluation Center Western Psychiatric Institute and Clinic Pittsburgh, PA	Attending Psychiatrist
1991- 1996	Presbyterian University Hospital Pittsburgh, PA	Medical Staff
1996	EPICS Research Program (Environmental and Personal Indicators of Course in Schizophrenia) Western Psychiatric Institute and Clinic Pittsburgh, PA (Program Director: Gerard Hogarty)	Medical Director
1997- present	University of Mississippi Medical Center Jackson, MS	Medical Staff
1997- present	University of Mississippi Medical Center	Director of Inpatient Psychiatric Services

CERTIFICATION AND LICENSURE

MEDICAL LICENSURE:

1984	Commonwealth of Pennsylvania	REDACTED
1996	State of Mississippi	

CERTIFICATION:

1983	National Board of Medical Examiners
1987	American Board of Psychiatry and Neurology
1991	Added Qualifications in Geriatric Psychiatry Certificate, American Board of Psychiatry and Neurology

MEMBERSHIPS IN PROFESSIONAL SOCIETIES

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1979-82	American Medical Student Association
1986-present	American Psychiatric Association
1986-1996	Pennsylvania Psychiatric Association

HONORS:

1981	Elected to Alpha Omega Alpha Honor Society
1992	Exemplary Psychiatrist Award National Alliance For the Mentally Ill
1995	Rev. C. Leroy Hacker Ambassador Award for outstanding service to Mayview State Hospital
1996	Mayview State Hospital Board of Trustees Award Recognizing Research and Clinical Contributions

PUBLICATIONS:

1. *Refereed Articles*

Zipursky RB, Baker RW, Zimmer B: Alprazolam withdrawal delirium unresponsive to diazepam: Case report. J Clin Psychiatry 46:344-5, 1985.

Trzepacz PT, Baker RW, Greenhouse J: A symptom rating scale for delirium. Psychiatry Res 23:89-97, 1988.

Conley RR, Baker RW: Family response to improvement by a relative with schizophrenia. Hosp and Community Psych 41:989-901, 1990.

Baker RW, Conley RR: Seizures during clozapine therapy . (letter) Am J Psychiatry 148:1265-1266, 1991.

Birmaher B, Baker R, Kapur S, Quintana H, Ganguli R: Clozapine for the treatment of adolescents with schizophrenia. J American Academy of Child and Adolescent Psychiatry 31:160-164, 1992.

Baker RW: Fluoxetine and schizophrenia in a patient with obsessional thinking. (letter). Journal of Neuropsychiatry 4:232-3, 1992.

Baker RW, Chengappa KNR, Baird JW, Steingard S, Schooler N, Christ MA: Emergence of obsessive-compulsive symptoms during treatment with clozapine. J Clin Psychiatry 53:439-442, 1992.

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Steingard S, Chengappa KNR, Baker RW, Schooler NR: Clozapine, obsessive symptoms, and serotonergic mechanisms (letter). *Am J Psychiatry* 150:1435, 1993.

Chengappa KNR, Baker RW, Baird J: Iron for chronic and persistent akathisia? (letter). *J Clin Psychiatry* 54:320-321, 1993

Chengappa KNR, Shelton MD, Baker RW, Schooler NR, Baird J, Delaney J: The prevalence of akathisia in patients receiving stable doses of clozapine. *J Clin Psychiatry* 55:142-145, 1994.

Chengappa KNR, Baker RW, Harty I: Seizures and clozapine dosing schedule (letter). *J Clin Psychiatry* 55: 456, 1994.

Chengappa KNR, Baker RW, Kreinbrook SB, Adair D: Clozapine use in female geriatric patients with psychoses. *J Geriatric Psychiatry* 8: 12-15, 1995.

Chengappa KNR, Baker RW, Sirri C: The successful use of clozapine in ameliorating self mutilation in a patient with borderline personality disorder. *J Personality Disorders*, 9:76-82, 1995.

Baker RW, Chengappa KNR: Further Study of Neuroleptic Malignant Syndrome (letter), *Am J Psychiatry* 152: 1831, 1995.

Chengappa KNR, Baker R, Pelucio M, Cole D: Recurrent pancreatitis on clozapine rechallenge. *J Psychopharmacology*, 9: 367-368, 1995.

John JP, Chengappa KNR, Baker RW, Gupta B, Mortimer MT: Assessment of Changes in Both Weight and Frequency of Use of Medications for the Treatment of Gastrointestinal Symptoms Among Clozapine-Treated Patients. *Ann Clin Psychiatry*, 7: 119-125, 1995.

Baker RW, Ames D, Umbricht DSG, Chengappa KNR, Schooler NR: Obsessive-Compulsive Symptoms in Schizophrenia: A Comparison of Olanzapine and Placebo. *Psychopharmacol Bull*, 32: 89-93, 1996.

Chengappa KNR, Gopalani A, Haught MK, McChesney K, Baker RW, Schooler NR: The Treatment of Clozapine-Associated Agranulocytosis with Granulocyte Colony-Stimulating Factor (G-CSF). *Psychopharmacol Bull*, 32: 111-121, 1996.

2. Books

Trzepacz PT, Baker RW, The Psychiatric Mental Status Examination, Oxford University Press, 202 pages, New York, 1993.

3. Other

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Conley RR, Schulz SC, Baker RW, Collins JF, Bell JA: Clozapine Efficacy in Schizophrenic Nonresponders. Psychopharmacol Bull 24: 269-74, 1988.

Schulz SC, Kahn EM, Baker RW, Conley RR: Lithium and Carbamazepine Augmentation in Treatment Refractory Schizophrenia. Chapter in The Neuroleptic Nonresponsive Patients: Characterization and Treatment: Angrist, B and Schulz SC. (Eds). American Psychiatric Press, Washington, 1990.

Baker RW, Chengappa KNR, Steingard S, Schooler NR, Baird JW: More on obsessive-compulsive symptoms and clozapine (reply to letter to the editor). J Clin Psychiatry 55:312, 1994.

PROFESSIONAL ACTIVITIES:

CURRENT TEACHING AND EXAMINATION:

1989-1996	Supervisor to University of Pittsburgh Psychiatry Residents, Schizophrenia Module; Lecturer to University of Pittsburgh Residents, Introduction to Psychiatry and Psychopharmacology Courses.
1989-1996	Clinical supervision and/or teaching to various trainees posted at the Special Studies Center, including University of Pittsburgh psychiatry residents, psychology interns, social work interns, and medical students, and Allegheny County Community College Nursing Students
1988-present	Associate Examiner, Part II Psychiatry Certification Exam, American Board of Psychiatry and Neurology
1992-present	Member, Psychiatry Minor Committee Part I Certification Exam, American Board of Psychiatry and Neurology (prepare and select neurology questions for psychiatry board exam).

SELECTED PRESENTATIONS AND INVITED LECTURES:

"Neurological Abnormalities in Schizophrenics." Conley RR, McDermott A, Baker RW, Collins JF, Bell JA, Schulz SC. Oral Presentation, International Congress on Schizophrenia, Clearwater FL, March 1987.

BAKER, RW

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"Clozapine Efficacy in Schizophrenic Nonresponders." Conley RR, Schulz SC, Baker RW, Collins JF, Bell JA. Paper Presentation, American Psychiatric Association Annual Meeting, Chicago IL, May, 1987.

"Clozapine Efficacy in Schizophrenic Nonresponders." Conley RR, Schulz SC, Baker RW, Collins JF, Bell JA. Oral Presentation, New Clinical Drug Evaluation Unit, Key Biscayne FL, May 1987.

"Neuroleptic Malignant Syndrome: Current Review." Fifth Annual Schizophrenia Conference, sponsored by Western Psychiatric Institute and Clinic and Mayview State Hospital, Pittsburgh PA, November 1988.

"EEG and Medication Response in Schizophrenia." Kahn EM, Schulz SC, Baker RW, and Brenner RP. Poster Presentation, International Congress on Schizophrenia Research, San Diego CA, April 1989.

"Psychiatric Manpower in State Hospitals." Wilson J, Baker RW, Conley RR. Workshop presentation, American Psychiatric Association Annual Meeting, San Francisco CA, May 1989.

"Clinical Efficacy of Clozapine Administered Openly to 37 Treatment-Resistant Patients With Schizophrenia." Fifth Annual Pennsylvania Schizophrenia Conference, Philadelphia PA, March 1990.

"Functional Brain Scanning in Schizophrenia." Grand rounds, Western Psychiatric Institute and Clinic, July 1990.

"When Hospital is Home." Sixth Annual Pennsylvania Schizophrenia Conference, Pittsburgh PA, March 1991.

"SPECT in Chronic Schizophrenia: Preliminary Findings." Baker RW, Schooler NR, Shah AN, Delaney JB, Baird JW, Li LL; Poster presentation, annual meeting of the American Psychiatric Association, May, 1992.

"Association of Clinical Variables With SPECT Findings in Schizophrenia." Baker RW, Schooler NR, Shah AN, Baird JW. Poster presentation, International Congress on Schizophrenia Research, Colorado Springs, Colorado, April 19, 1993. Abstract published in Schizophrenia Research 9:192, 1993.

"Psychopathology, SPECT and Institutionalization." Baker RW, Schooler, Baird JW. Symposium oral presentation, annual meeting of The American Psychiatric Association, San Francisco, California, May 24, 1993.

"Clozapine and Akathisia." Chengappa KNR, Shelton MD, Baker RW, Baird, JW; Schooler NR. Poster presentation, annual meeting of The

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American Psychiatric Association, San Francisco, California, May 26, 1993. Abstract published Biological Psychiatry, 33:126A.

"Clozapine Utilization: The First Year's Experience In a State Hospital System." Baker RW, Kreinbrook SB, Schooler, NR, Dumpman SJ. Paper presentation, annual meeting of The American Psychiatric Association, San Francisco, California, May 27, 1993.

"Emerging Treatments for Psychosis" Grand Rounds, Cooper Hospital/University Medical Center, Camden NJ, December 10, 1993.

"Serotonin and Dopamine Blocking Antipsychotic Drugs." Grand Rounds, VAMC Pittsburgh PA, March 16, 1994; Patrick Harris Hospital, Anderson SC June 15, 1994; and VAMC, Coatesville PA, June 30, 1994.

"Risperidone and Related Newer Antipsychotic Drugs" Grand Rounds, Eastern Tennessee Medical School Department of Psychiatry, Johnson City Tennessee, September 16, 1994.

"Antipsychotic Medications in the 90's" Moderator of Symposium and Teleconference, WPIC Office of Education and Regional Programming, November 10, 1994.

"Efficacy of Clozapine vs. Haloperidol in a Long Term Clinical Trial: Preliminary Findings" Schooler N, Kane J, Marder S, Baker R, Safferman A, Wirshing W, Ames D, Ganguli R, Umbricht D, Borenstein M. Poster Presentation, ACNP, San Juan, Puerto Rico, December 1994

"DSM IV Schizophrenia and Other Psychotic Disorders" Teleconference, WPIC Office of Education and Regional Programming, January 17, 1994.

"The Atypical Side Effects of Atypical Antipsychotics" The Vermont State Hospital, February 23, 1995.

"Efficacy of Clozapine vs. Haloperidol in a Long-Term Clinical Trial: Preliminary Results" Kane JM, Marder SR, Schooler NR, Umbricht D, Ames D, Wirshing WC, Baker R, Ganguli R, Safferman A, Borenstein M. Oral Presentation, APA Annual Meeting, Miami FL, May 1995.

"Clozapine Associated Agranulocytosis: Treatment with GCSF" Chengappa KNR, Baker RW, Schooler NR, Haught M, Gopalani A. Poster presentation NCDEU, Orlando FL, June 1, 1995

"Olanzapine's Impact on Depressive and Obsessive-Compulsive Symptoms in Schizophrenia" Baker RW, Ames D, Umbricht D, Chengappa KNR, Schooler NR. Poster presentation, NCDEU, Orlando FL, June 1, 1995

"Advances in the Pharmacotherapy of Schizophrenia". Annual Schizophrenia Conference, Pittsburgh, PA, December 1, 1995.

BAKER, RW
Page 9

"New Uses for Atypical Antipsychotic Drugs". Psychiatry Grand Rounds, St. Francis General Hospital, Pittsburgh, PA, March 28, 1996.

"Dealing with Treatment Refractory Psychoses". Psychiatry Grand Rounds, Allegheny General Hospital, Pittsburgh, PA, June 20, 1996.

"Sertindole and Olanzapine". Grand Rounds, University of Mississippi Medical Center, Department of Psychiatry, November 14, 1996

FUNDED RESEARCH:

- 1986 Senior Resident, "Characterization and Treatment of Schizophrenic Patients Poorly Responsive to Treatment With Neuroleptics." Conducted at WPIC. Principal Investigator: S. C. Schulz. Funded by Scottish Rite Foundation.
- 1986-1987 Assistant, "Double-Blind Comparative Evaluation of Oral Clozaril Versus Chlorpromazine Plus Benztropine In Treatment-Resistant Schizophrenic Patients Who Have Failed on Haloperidol Plus Benztropine," (multicenter). Conducted at Mayview State Hospital. Principal Investigator: S. C. Schulz (1986); M. Shostak (1986-1987). Funded by Sandoz Research Institute of Sandoz Pharmaceuticals.
- 1987-90 Coinvestigator, "Clozaril in Treatment Resistant Schizophrenics," (multicenter). Conducted at Mayview State Hospital and Western Psychiatric Institute and Clinic. Principal Investigator: R. Conley (1987-1989), R. Ganguli (1989-1990). Funded: Sandoz Research Institute, Sandoz Pharmaceuticals.
- 1987-1988 Coinvestigator, "Equivalency of Watson and McNeil Haloperidol Tablets in Schizophrenia." Conducted at Mayview State Hospital. Principal Investigator: R. Conley. Funded by Watson Laboratories.
- 1988-1991 Coinvestigator, "A Multicenter Double Blind Study Comparing Four Doses of Haloperidol Decanoate Injection in the Maintenance Treatment of Patients with Schizophrenia," (multicenter). Conducted at Mayview State Hospital. Principal Investigator: R. Conley (1988-1989); N. Schooler (1989-1991). Funded by McNeil Pharmaceutical.

BAKER, RW
Page 10

1989-1991	Co-Principal Investigator, "Risperidone In the Treatment of Chronic Schizophrenic Patients: An International Multicenter Placebo-Controlled Double-Blind Parallel Group Study versus Haloperidol. Protocol number 0204/R 64 766; Co-principal investigator N. Schooler. Funded by Janssen Research Foundation.
1989-1994	Co-Principal Investigator, "Long term safety of risperidone in the treatment of schizophrenia. An open label group extension study. Protocol numbers 0205/R4 766 and 0206; Co-principal investigator N. Schooler. Funded by Janssen Research Foundation.
1990-1992	Principal Investigator, "Biological Correlates of Poor Outcome in Schizophrenia." Co-investigators: N. Schooler, A. Shah. Funded by National Alliance For Research in Schizophrenia and Depression Young Investigator Award.
1992-1995	Co-Principal Investigator, "Clozapine: Treatment Response and Disability." Principal Investigator N. Schooler. NIMH 1 R01 MH46672-01A2.
1992-1993	Principal Investigator, "A double-blind, placebo-controlled study of the safety and efficacy of sertindole in schizophrenic patients". Protocol M92-762. Co-principal investigator N. Schooler. Funded by Abbott Laboratories.
1993-1994	Co-principal Investigator, "Olanzapine versus placebo in the treatment of schizophrenia." Protocol F1D-MC-HGAP. Co-principal investigator N. Schooler. Funded by Lilly Research Laboratories.
1994-1995	Principal Investigator, "A double-blind, placebo-controlled, dose-response comparison of the safety and efficacy of three doses of sertindole and three doses of haldol in schizophrenic patients" Co-principal investigator N. Schooler. Funded by Abbott Laboratories.
1995-1996	Principal Investigator, "A multicenter, double-blind, randomized comparison of seroquel and chlorpromazine in the treatment of hospitalized subjects with treatment-resistant schizophrenia and an open-label extension study." Co-principal investigator N. Schooler. Funded by Zeneca Pharmaceuticals Group.

BAKER, RW
Page 11

1995-1996 Co-Principal Investigator, "New Antipsychotics:
Clinical Trials and Followup." Principal
Investigator N. Schooler. NIMH 2 R01 MH46672-04

1995-1996 Co-Principal Investigator, "New Antipsychotics: Use
in New Populations." Principal Investigator
N.Schooler NIMH 3 R01 MH46672-04S1

SERVICE:

1984-85 Patient Care Audit Committee, Western Psychiatric
Institute and Clinic

1986-87 and Pharmacy and Therapeutics Committee, Mayview State
1989-91 Hospital

1986-87 Chair, Tardive Dyskinesia Task Force, Mayview State
Hospital

1986-89 Patients' Rights Committee, Mayview State Hospital

1988 Psychiatric Consultant, Commonwealth of Pennsylvania
Medical Assistance Inspection of Care Survey, Warren
State Hospital and Woodville State Hospital

1989-1996 Chair, Education Committee of the Mayview State
Hospital-University of Pittsburgh Dean's Committee

1989-1996 Hospital Review Board, Mayview State Hospital

1989-90 Medication Error Task Force, Mayview State Hospital

1993-1996 Planning and Budget Committee, Western Psychiatric
Institute and Clinic

1993-1994 Planning and Budget Committee, Office of the Senior
Vice Chancellor for Health Sciences, University of
Pittsburgh

1993-1994 Vice-President, Mayview State Hospital Medical Staff

1994-present Recent peer-reviewing for these journals: Journal
of Neuropsychiatry and Clinical Neurosciences,
International Journal of Psychiatry in Medicine,
Journal of Clinical Psychiatry

1996 Consultant, Pharmacy and Therapeutics Committee,
Mayview State Hospital

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July 1, 1998
DATE OF REG. *Thomas S. Stevens MD*
SIGNATURE OFFICIAL

Curriculum Vitae

Name: Ileana Berman

Address: Home: REDACTED

Office: Taunton State Hospital
Taunton, Massachusetts

Date of Birth: March 3, 1959

Place of Birth: Bucharest, Romania

Education:

1984 M.D. Medical School: Institute of Medicine and Pharmacy, Bucharest,
Romania
Graduated top 3% of the class

Postdoctoral Training:

Internship and Residencies:

1986-1990 Psychiatry Residency Training Program, Maimonides
Medical Center, Brooklyn, New York

Research Fellowship:

1990-1992 Clinical Research Fellow in Psychiatry, Massachusetts Mental
Health Center, Harvard Medical School, Boston, MA

Other Professional Training:

1988-1989 Attended the courses: Psychoanalysis for Psychiatry Residents and
Psychology Interns at The New York Psychoanalytic Institute:
"The Mind in Conflict," Dr. C. Brenner;
"The Principles of Psychotherapies," Dr. M. Horowitz.

Licensure and Certification:

1989 New York State medical license REDACTED
1990 Massachusetts Board of Registration in Medicine, full license
REDACTED
1991 American Board of Psychiatry and Neurology (Psychiatry)

Academic appointments:

1989-1990	Chief resident in Psychiatry, Maimonides Medical Center, Brooklyn, New York
1990-1992	Clinical Fellow in Psychiatry, Harvard Medical School
1992-1995	Assistant Clinical Professor in Psychiatry, Mount Sinai School of Medicine, New York
1995- present	Instructor in Psychiatry, Harvard Medical School

Hospital Appointments:

1995-present	Director of Research, Taunton State Hospital, Commonwealth Research Center
1993-1995	Chief of Clinical Research in Psychiatry, FDR VA Hospital, Montrose, New York

Major Committee Assignments:

1993-1995	Member of the Medical Executive Committee, FDR VA Hospital
1993-1995	Member of the Research Committee, FDR VA Hospital
1994-1995	Chief of the Research Committee, FDR VA Hospital
1996-present	Member of the Research Steering Committee, Commonwealth of Massachusetts, Department of Mental Health, Southeastern Area

Major Research Interests:

1. Neuropharmacology of schizophrenia
2. Cognitive Function in Schizophrenia
3. Brain imaging in schizophrenia

Research experience:

1988-1990	Clinical significance of obsessive-compulsive symptoms in schizophrenic patients National survey designed to examine psychiatrists' views about aspects of psychiatric practice
1990-1994	Clomipramine treatment of chronic schizophrenic patients with obsessive-compulsive symptoms Clinical trials of atypical neuroleptics (risperidone, clozapine, olanzapine, sertindole) in chronic schizophrenic patients Biochemical changes in chronic psychotic patients treated with atypical neuroleptics

- 1992-1994 Safety and tolerance of risperidone in elderly patients with behavioral disturbances
Changes in regional cerebral blood flow in schizophrenic patients treated with risperidone
Cognitive changes in schizophrenic patients treated with atypical neuroleptics.
Emotional activation SPECT changes in schizophrenic patients with negative symptoms compared with those without significant negative symptoms
- 1994- Cognitive deficits in schizophrenic patients: relationships between specific cognitive deficits and schizophrenic symptoms.
Effect of atypical neuroleptics on cognitive function in schizophrenia.
New pharmacologic treatments in schizophrenia

Research Funding:

1989-1990	Maimonides Medical Center	PI	Obsessive-Compulsive Symptoms in Schizophrenia
1992-1994	Janssen Research Foundation	Co-PI	Risperidone in elderly
1992-1995	Eli Lilly & Co	Co-PI	Olanzapine vs haloperidol in outpatient schizophrenic patients
1994-1995	Abbott Laboratories	Co-PI	Sertindole in schizophrenic patients
1996-1997	Janssen Research Foundation	Co-PI	Efficacy of risperidone versus haloperidol versus clozapine in treatment resistant schizophrenia
1997	Pfizer	PI	128-121; Toleration and safety of intramuscular ziprasidone compared to haloperidol
1997	Pfizer	PI	128-125/127E; Toleration and safety of two doses of intramuscular ziprasidone
1997	Janssen Research Foundation	PI	RIS-USA-112/113; The efficacy of risperidone versus olanzapine in schizophrenia

Principal Clinical and Hospital Service Responsibilities:

- 1995-present Psychiatrist Taunton State Hospital, Taunton, Massachusetts
- 1993-1995 Psychiatrist FDR VA Hospital, Montrose, New York

Major Administrative Responsibilities:

1989-1990	Chief Resident in Psychiatry, Maimonides Medical Center, Brooklyn, New York
1992-1995	Coordinator of a 25 patient psychiatric unit, FDR VA Hospital Montrose, New York
1993-1995	Chief of Clinical Research in Psychiatry, FDR VA Hospital, Montrose, New York
1993-1995	Member of Medical Executive Committee, FDR VA Hospital, Montrose, New York
1994-1995	Chief of Research Committee, FDR VA Hospital, Montrose, New York
1995-present	Director of Research, Taunton State Hospital

Self Report of Teaching:

a). Advisory and Supervisory Responsibilities:

1989-1990	Instructor for medical students and psychiatry residents
1992-1995	Supervisor and mentor for three clinical research fellows
1995-	Supervisor and mentor of a premedical student
1997	Participated in the Psychopharmacology Course for Psychiatric Residents, Brockton VA, Brockton, MA

b). Regional, National or International Contributions:

1989	Obsessive-compulsive Symptoms in Schizophrenia. Grand Rounds, Maimonides Medical Center, Brooklyn New York
1989	Treating obsessions in Schizophrenic Spectrum Illness. Original Paper Session, Brooklyn Psychiatric Society
1990	Obsessions and Compulsions in Schizophrenia. Grand Rounds, Manhattan State Hospital, New York
1991	Psychiatry Today: Biology versus Psychology. Original Paper Session, Brooklyn Psychiatric Society
1995	Treatment of obsessive-compulsive symptoms in schizophrenic patients with clomipramine. Grand Rounds Providence VA, Providence, RI
1997	Cognitive Function in Schizophrenia. Grand Rounds Maimonides Medical Center, Brooklyn, NY

Bibliography:

Original reports:

1. Zaharovits (Berman) I, Lipkowitz MH: Imipramine in the treatment of obsessive-compulsive symptoms in schizophrenic spectrum illness: three case reports. *Jefferson Journal of Psychiatry* 22-27, 1990.
2. Berman I, Zalma A, DuRand CJ, Green AI: Clozapine-induced myoclonic jerks and drop attacks. *J of Clin Psychiatry* 53:329-330, 1992.
3. DuRand CJ, Jaretz NJ, Laddis A, Berman I, Green AI: Clozapine refusal. *Hospital and Community Psychiatry* 1992; 43:85.
4. Green AI, Zalma A, Berman I, DuRand CJ, Salzman C: Clozapine following ECT: a two-step treatment. *J Clin Psychiatry* 1994; 53:329-330.
5. Berman I, Kalinowski A, Berman SM, Lengua JA, Green AI: Obsessive and compulsive symptoms in chronic schizophrenia. *Comprehensive Psychiatry*, 1995; 36:6-10.
6. Berman I, Fried W, Berman SM, Lengua JA: Psychiatry today: biology versus psychology. *Academic Psychiatry* 1995.
7. Berman I, Sapers BL, Chang HHJ, Losonczy MF, Schmilder J, Green AI: Treatment of obsessive-compulsive symptoms in schizophrenic patients with clomipramine. *J of Clin Psychopharm* 1995; 15:206-210.
8. Berman I, Merson A, Berman SM, Fried W, Losonczy MF, Alpert M: Psychiatrists' attitudes towards psychiatry. *Academic Medicine* 1996; 71:110-11.
9. Berman I, Merson A, Rachov-Pavlov J, Allan E, Davidson M, Losonczy MF: Risperidone in elderly schizophrenic patients: an open-label trial. Pilot study. *Am J Geriatric Psychiatry*, 1996; 4:173-179
10. Berman I, Merson A, Sison C, Allan E, Schaefer C, Loberboym M, Losonczy MF: Regional Cerebral Blood Flow changes associated with risperidone treatment in elderly schizophrenic patients. *Psychopharm Bull* 1996; 32:95-100
11. Allan E, Alpert M, Citrome L, Laury G, Sison C, Berman I: Adjunctive nadolol in the treatment of acutely aggressive schizophrenic patients. *J Clin Psychiatry* 1996.
12. Berman I, Viegner B, Merson A, Alan E, Pappas D, Green AI: Differential relationships between positive and negative symptoms and neuropsychological deficits in schizophrenia. *Schizophrenia Research* 1997; 25:1-10

13. Berman I, Merson A, Viegner B, Losonczy MF, Pappas D, Green AI : Obsessions and compulsions as a distinct cluster of symptoms in schizophrenia: a neuropsychological study. J Nervous and Mental Disease (revisions resubmitted)

Reviews and Educationally Relevant Publications:

14. Zaharovits (Berman) I: Treating obsessive-compulsive symptoms in schizophrenia. The Brooklyn Psychiatrist 21: 9, 1989.
15. Berman I, Sapers BL, Salzman C: Sertraline, a new serotonergic antidepressant. Hospital and Community Psychiatry 43:85, 1992
16. Berman I, Pappas, D, Berman SM: Obsessive-Compulsive Symptoms in Schizophrenia: Are They Manifestations of a Distinct Subclass of Schizophrenia? CNS Spectrums 2(3): 45-48, 1997

Abstracts:

17. Zaharovits (Berman) I, Fried W, Lengua JA: Psychiatry today: biology vs psychology. American Psychiatric Association Annual Meeting, 1990, New Research.
18. Zaharovits (Berman) I, Lengua JA: Obsessions and compulsions in schizophrenia. American Psychiatric Association Annual Meeting, 1990, New Research.
19. Berman I, Sapers BL, Chang HHJ, Alpert M, Losonczy MF, Green AI: Adjunctive clomipramine in obsessive schizophrenia. American Psychiatric Association Annual Meeting, 1993, New Research.
20. Green AI, DuRand CJ, Chang HJ, Berman I, Pappalardo KM, Schildkraut JJ. Catecholamine metabolites and clozapine response. American Psychiatric Association Annual Meeting Proceedings, 1992
21. Berman I, Berman SM, Fried W, Allan ER, Losonczy MF: Changes in psychiatrists' self-perception over time. American Psychiatric Association Annual Meeting, 1993, New Research.
22. Berman I, Rachov-Pavlov J, Losonczy MF, Allan ER, Davidson M: Risperidone in elderly schizophrenic patients. NCDEU 1994.
23. Berman I, Rachov-Pavlov J, Loberboym M, Shaeffer C, Losonczy MF: SPECT changes in the elderly with risperidone. American Psychiatric Association Annual Meeting 1994, New Research.
24. Berman I, Rachov-Pavlov J, Kammalama D, Merson A, Pontecorvo M, Losonczy MF: Risperidone in elderly psychotic patients. American Psychiatric Association Annual Meeting 1994, New Research.

25. Losonczy MF, Berman I, Sison C, Schaefer C, Alpert M: Positive and Negative symptoms in schizophrenia: SPECT activation studies. Society of Biological Psychiatry Annual Meeting 1994
26. Berman I, Merson A, Allan E, Sison C, Losonczy FM: Cerebral Blood Flow Changes with risperidone treatment in elderly patients. NCDEU, Orlando, Florida, 1995.
27. Berman I, Merson A, Allan E, Alexis C, Sison C, Losonczy FM: Cognitive effect of risperidone and haloperidol in elderly schizophrenic patients. NCDEU, Orlando, Florida, 1995..
28. Berman I, Allan E, Pappas D, Sison C, Merson A: Risperidone vs Haloperidol in Elderly Schizophrenics. American Psychiatric Association Annual Meeting 1997, New Research.
29. Berman I, Pappas D, Leventhal N, Osser D, Sigadel R, Patel C: Ginkgo Biloba Extract in Schizophrenic Patients. NCDEU, Boca Raton, Florida, 1997.
30. Berman I, Pappas D, Leventhal N, et. al: The Relationship Between Changes in Schizophrenic Symptoms and Cognitive Deficits During Treatment with an Atypical Neuroleptic. American Psychiatric Association Annual Meeting 1997, New Research.
31. Pappas D, Leventhal N, Langlois J, Osser D, Chang H, Berman I: Effect of Risperidone on Cognitive Function in Schizophrenic Patients: An Open Label Study. American Psychiatric Association Annual Meeting 1997, New Research.
32. Pappas D, Bayog R, Osser D, Chang H, Berman I: Patients' Characteristics in a Long Term Hospital. American Psychiatric Association Annual Meeting 1997, New Research.
33. Berman I, Merson A, Viegner B, Losonczy ML, Pappas D, Green AI: Obsessions and Compulsions as a Distinct Cluster of Symptoms in Schizophrenia: a Neuropsychological Study. American Psychiatric Association Annual Meeting 1997

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If this license is lost or destroyed, notify the Board of Registration in Medicine at 10 West St., Boston, MA 02111 (617) 727-3086.

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ILEANA BERMAN M.D.
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03/03/2000

RICHARD BRALLIAR, D. O.
Psychiatrist
Pharmacology Research Clinic
6039 Eldora Ave - Suite H
Las Vegas, Nevada 89102
702-257-2600

and

General Psychiatrist
Mountainview Medical Center
3150 N. Tenaya Way - Suite 415
Las Vegas, Nevada 89128
702-240-0500

EDUCATION:

1975 to 1979	Loma Linda University Loma Linda, California Degree: BSN
1973 to 1974	Pacific Union College Angwin, California Coursework in Humanities and Sciences
1970 to 1972	Pacific Union College Angwin, California Coursework in Humanities and Sciences

MEDICAL SCHOOL:

1980 to 1985	University of Health Sciences College of Osteopathic Medicine Kansas City, Missouri Degree: Doctor of Osteopathic Medicine

POST-RESIDENCY:

1986 to 1997	Psychiatric Consultant Eastern Mental Health Center Struthers, Ohio
1986 to 1996	Psychiatric Consultant Churchill Counseling Center Liberty, Ohio
1995 to 1996	Staff Psychiatrist Wooside State Hospital Youngstown, Ohio

Richard Bralliar, DO - Curriculum Vitae
Page 2 of 3

1992 to 1996

Medical Director
Center for Family Studies
Warren, Ohio

1992 to 1995

Medical Director
1st Medical Psychiatric Counseling Associates
Boardman, Ohio

RESIDENCY:

1991 to 1992

University of Kansas School of Medicine-Wichita
Department of Psychiatry
Wichita, Kansas
(Rotations: St. Francis Medical Center/Charter Hospital)

1986 to 1990

Akron General Medical Center
Northeast Ohio Universities College of Medicine (NEUQCOM)
Akron, Ohio

RESIDENCY:
(Work Experiences)

1997

Psychiatric Consultant
Mahoning County Chemical Dependency Program
Youngstown, Ohio

1995 to 1997

Psychiatric Consultant
2 North Park (Chemical Dependency)
Warren, Ohio

1990 to 1991

Outpatient Private Practice
Specialty Care Psychiatric Emergency Room
Boardman, Ohio

1990

Attending Physician
St. Vincent's Charity Hospital-Psychiatric Emergency Room
Cleveland, Ohio

1988 to 1989

House Officer
Falkviews Psychiatric Hospital
Akron, Ohio

1987 to 1988

Admitting Officer
St. Thomas Medical Center
Akron, Ohio

INTERNSHIP:

1985 to 1986

Family Practice Residency
Barberton Citizens Hospital
Barberton, Ohio

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Richard Bralhar, DO – Curriculum Vitae
Page 3 of 3

LICENSURE:

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DEA Registration Certificate
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Expiration Date: July 31, 2001

CURRENT POSITIONS:

1999 to Present Principal Investigator/Psychiatrist
Pharmacology Research Center
Las Vegas, Nevada

General Psychiatrist
Mountainview Medical Center
Las Vegas, Nevada

PROFESSIONAL MEMBERSHIPS:

1996 Member of Clinical Pathway Committee
Woodside State Hospital

1994 Member of Trumbull County Board of Mental Health
Drug and Alcohol Rehabilitation

HOSPITAL AFFILIATIONS:

1998 to Present Staff Psychiatrist
Valley Hospital

1998 to Present Staff Psychiatrist
Mountain View Hospital

1998 to Present Staff Psychiatrist
Montevista Hospital

1996 to 1997 Belmont Pines Psychiatric Hospital
Outpatient Clinic

1992 to 1996 Associate Staff
Trumbull Memorial Hospital
Warren, Ohio

Psychiatric Consultant
Nathan Adelson Hospital
Las Vegas, Nevada

Psychiatric Consultant
Torrey Pines Care Center

CV version date 1-22-99 nrr



**Nevada State Board of
Chiropractic Medicine**

RICHARD BRALLIAR

D.O.

CERTIFICATE NO. **REDACTED**

EXPIRES

DEC. 31, 1999

LARRY J. TARNO, D.O.
Executive Director

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I. PERSONAL DATA

Name: Ronald Brenner, M.D.
S.S.#: REDACTED
Mailing Address: 327 Beach 19th Street
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Telephone No.: Office (718) 869-7248
Home: REDACTED
Date and Place
of Birth: 10/16/49
Tel Aviv, Israel

II. EDUCATION

A. Degrees

Doctor of Medicine
Facultad de Medicina, Valencia, Spain, June, 1974

B. Training

Participated in an accelerated studies
program - completed a 3 year program in
1 1/2 years.

Rotary Internship, University of Valencia,
Spain - July, 1974 - June, 1975

College of University Studies -
Facultad de Medicina, Cochabamba, Bolivia
1968 - 1972

Honors: Dean's List - Upper 5% of Class

Residencies & Fellowships

Residency Training in Psychiatry
St. Luke's Hospital Center, Columbia University
July, 1975 to June, 1978

Chief Resident at St. Luke's Hospital Medical Center,
Columbia University
July, 1977 to July, 1978

-2-

New York University Research Fellowship in
Psychopharmacology
Bronx Psychiatric Center
July, 1978 to July, 1979

C. Licensures

- New York License No. REDACTED issued 7/24/78
- Washington, D.C. License No. REDACTED issued 8/22/77
- Valencia, Spain License No. REDACTED issued 7/20/74
- New Jersey License No. REDACTED - issued 2/23/84

D. Board Certifications

- Board of Psychiatry and Neurology,
October, 1979, No. 19721
- Board Certified in Administrative Psychiatry
1994

III. APPOINTMENTS

A. Academic

Clinical Professor of Psychiatry
State University of New York
Health Science Center at Brooklyn
January, 1986 to Present

Assistant Instructor of Psychiatry
Mount Sinai Medical Center
July, 1980 - September, 1981

Assistant Attending Psychiatrist
Columbia University
Attending Psychiatrist
St. Luke's/Roosevelt Medical Center.
January, 1979 to 1988

Assistant Clinical Professor
New York University Medical Center
July, 1978 - July, 1979

Visiting Fellow in Clinical Psychiatry at
Columbia University
1975 - 1978

-3-

Assistant Professor of Physiology &
Research in Physiology, University of
Valencia Spain, July, 1974 - July, 1975

New York University Medical Center
Research Fellowship in Psychopharmacology
Director, Affective Disorder Clinic
Bronx Psychiatric Center
July, 1978 to July, 1979

New York University Medical Center
Research Fellowship in Psychopharmacology
Affective Disorders Unit/Lithium Clinic

Physiology Research
University of Valencia, Spain
July, 1974 - July, 1974

B. Hospital & Other

Chairman
Department of Psychiatry
St. John's Episcopal Hospital, South Shore
May, 1985 to Present

Director of Psychiatry
Nepositt Health Care Center
April, 1988 to Present

Attending Psychiatrist
Hillside Hospital
Long Island Jewish Medical Center
January, 1984 to Present

Consulting Psychiatrist
Promenade Nursing Home - 1986 to present
St. John's Episcopal Hospital Nursing Home - 1987 to present
Lawrence Nursing Home - 1986 to present
Central Manor Adult Home - 1990 to present

Service Chief
Hillside Hospital
Long Island Jewish Medical Center
January, 1984 - May, 1985

Service Chief for Schizophrenia,
Hillside Hospital,
Long Island Jewish Medical Center
Responsible for two inpatient units
January, 1984 - May, 1985

-4-

Unit Chief, Inpatient Teaching Service,
Hillside Hospital
Long Island Jewish Medical Center
March, 1983 - January, 1984

Research Attending, Walk-in-Clinic and
Inpatient Service, Under the direction of
John Kane, M.D.
Hillside Hospital,
Long Island Jewish Medical Center
September, 1981 - February, 1982

Director of Emergency Services and Research Attending
Mount Sinai Medical Center
July, 1980 - Sept., 1981.

Director of Medical Education and Director
of Treatment Services at Rockland Psychiatric Center.
July, 1979 - July, 1980

IV. AWARDS AND HONORS

Awarded "Teacher of the Year" for the
Department of Psychiatry
State University of New York
Health Science Center at Brooklyn

V. PROFESSIONAL MEMBERSHIPS

A. Society Memberships

- American Psychiatric Association
- American Psychiatric Association,
Nassau County Branch
- Greater New York Hospital Association
- American Medical Association
- Queens and Brooklyn Consortiums of Providers
- Area I Sub-Regional
- GNYHA (Greater New York Hospital Association)
Mental Health/Substance Abuse Services Committee
- American Association of General Hospital Psychiatrists

B. Committee Memberships

- Co-Chairman, Ethics Committee
- Member Hospital Quality Improvement Committee
- Member Pharmacy & Therapeutics Committee
- Member Institutional Review Board

-5-

VI. PAST AND PRESENT RESEARCH ACTIVITIES

Present:

- Flushing in Panic Disorder: Clinical Report and Pathophysiology
- Study Comparing Patients' Perceptions, Understanding, and Interpretation of Medical Procedures (G.I. & Pulmonary) to Physician's Explanation of Such Procedures
- RIS-USA-64 An Open, Multicenter Study to Evaluate the Tolerability and Safety of Risperdal Tablets In Elderly Subjects With Psychotic Disorders. Sponsored by Janssen Research Foundation - Principal Investigator - 1995 to 1996.
- MAZ-INT-01 Mazapertine Dose Finding Trial comparing three fixed dosages of Mazapertine to Risperidone and Placebo: Multicenter, double blind, parallel-group study. Sponsored by Janssen Research Foundation. March to July, 1996
- RIS-USA-63B - A randomized, double blind, placebo controlled study of Risperidone for treatment of behavioral disturbances in subjects with dementia. Principal Investigator. August, 1996 through March, 1997.
- RIS-USA-79 - A comparison of Risperidone and Haloperidol for prevention of relapse in subjects with schizophrenia and schizoaffective disorder. Principal Investigator. To start 8/96 - Two years in progress.
- RIS-USA-78 - A study of the efficacy of Risperidone, Haloperidol and Clozapine in treatment resistant schizophrenic subjects. Principal Investigator. To start 8/96. Six months in progress.
- DONEPEZIL - An open-label, multicenter clinical trial evaluating the safety and efficacy of Donepezil Hydrochloride in patients with Alzheimer's Disease. Started January, 1997.
- GAL.USA-1 - Efficacy, Tolerability and Safety of Galantamine in treatment of Alzheimer's Disease. Principal Investigator. In progress.
- A Phase III Randomized Study Comparing two Doses of Intra-muscular Ziprasidone (2mg and 10mg) in subjects with Psychosis and Acute Agitation. Starting in April, 1997.

-6-

- An Open Extension Study Evaluating the Safety and Outcome of 40 mg - 200 mg Daily of Oral Ziprasidone in the Treatment of Subjects who have participated in Previous Ziprasidone Clinical Trials. Starting in April, 1997.
- An Open Trial of Olanzapine in Elderly Subjects with Psychosis and Behavioral Disturbances Associated with Schizophrenia, Schizoaffective Disorder, Dementias and Bipolar Disorders. In progress.
- RIS-USA-70 - An open label Long Term-Study of Treatment of Behavioral in Subjects with Dementia. Principal Investigator - In progress.

Past:

- Serotonin levels in discreet areas of rat brains after light stimulation. Valencia, Spain - 1973
- Phase IV Trials for Depression with the following medications:
 - . Fluoxetine - 1991
 - . Sertraline - 1992
 - . Paroxetine - 1993

VII. PUBLICATIONS AND PRESENTATIONS

The Use of Monamine Oxidase Inhibitors
in Schizophrenia.

Ronald Brenner, M.D., Baron Shopsin, M.D.
Biol. Psychiatry, 1980 - August 15 (4) 633-47

Plasma, Imipramine Concentrations in
Patients Receiving Concomitant
Fluphenazine Decanoate.

Samuel G. Siris, M.D., Thomas B. Cooper,
M.A., Arthur Rifkin, M.D., Ronald Brenner,
M.D., and Jeffrey Lieberman, M.D.
American Journal of Psychiatry, Vol. 139, 1982, Page 104-106

The Measurement of Lithium Level in Human Tears.

Ronald Brenner, M.D., Thomas Cooper, M.A.,
M. Yablonski, M.D., J. Lieberman, M.D.,
Michael Lesser, M.D., Samuel Siris, M.D., A. Rifkin, M.D.
American Journal of Psychiatry,
Vol. 139: 678-679, 1982

-7-

Dexamethasone Suppression Tests in
Patients with Panic Disorder.
Jeffrey A. Lieberman, M.D., Ronald
Brenner, M.D., Michael Lesser, M.D.,
Emil Coccaro, M.D., Michael Borenstein,
M.D., John M. Kane, M.D.,
American Journal of Psychiatry 140:917-919, 1983

Tricyclic Antidepressants and Metabolic
Levels in Chronic Renal Failure.
Jeffrey A. Lieberman, M.D., Thomas B.
Cooper, M.A., Roman Sukow, Ph.D.,
Herbert Steinberger, M.D., Michael
Borenstein, M.D., Ronald Brenner, M.D.,
John M. Kane, M.D.
Clinical Pharmacology, Vol. 37 Page 301-307, March, 1985

Alprazolam-Induced Manic Reaction:
Case Report
Michael Lesser, M.D., Ronald Brenner, M.D.
David Mayerhoff, M.D.
New York State Journal of Medicine
June, 1986 - Vol. 86, No. 6, Page 320

Prophylactic Treatment of Neuroleptic
Malignant Syndrome with Dantrolene Sodium.
Michael Lesser, M.D., Michael Kahan, M.D.
Ronald Brenner, M.D.
Hillside Journal of Clinical Psychiatry,
1986, Volume 8, Number 1, page 34

Dysrhythmia Associated with Fluoxetine
Treatment in an Elderly Patient With
Cardiac Disease.
Daniel D. Buff, M.D., Ronald Brenner, M.D.,
Sanjay S. Kirtane, M.D., & Ramaan Gilboa,
M.D., Journal of Clinical Psychiatry,
Vol. 52, No. 4, April, 1991.

The Effect of Anxiety and Depression on Completion/Withdrawal
Status in Patients Admitted to Substance Abuse Detoxification
Program. Journal of Substance Abuse Treatment - Vol.13 No.1,
pp61-66, 1996.

Efficacy of Risperidone Treatment for Psychoses Associated
with Schizophrenia, Schizoaffective Disorder, Bipolar Disorder
or Senile Dementia in 11 Geriatric Patients: A Case Series."
Journal of Clinical Psychiatry, 56:11, Nov. 1995, 514-518.

Abstract: "Opiate Withdrawal Using Dextromethorphan" -
Presented at 149th Annual Meeting, 1996 at the American
psychiatric Association.

-8-

Reversible Choreiform Dyskinesia and extrapyramidal symptoms associated with Sertraline Therapy - Journal of Clinical Psychopharmacology -Vo.17 No.2 April, 1997.

Risperidone Induced Ejaculatory and Urinary Dysfunction
Journal of Clinical Psychiatry - 57-11, November, 1996.

Letters:

Is Bromocriptine a Dopamine Antagonist Treatment?
Jeffrey A. Lieberman, M.D., Michael Lesser, M.D.,
Ronald Brenner, M.D.
Archives of General Psychiatry, 40:467-470, 1983

Lithium in Tears.
Ronald Brenner, M.D., Michael Lesser, M.D.
Journal of Clinical Psychiatry, 46:150, 1985

Another Case of Alprazolam Withdrawal Syndrome.
Jacques Vital-Herne, M.D., Ronald Brenner, M.D.,
Michael Lesser, M.D. The American Journal of Psychiatry,
142:1515, 1985

Presentations:

Methylphenidate Challenge and Course of Schizophrenia.
Jeffrey A. Lieberman, M.D., J. Kane, M.D.,
Domenick Gadaleta, M.D., Ronald Brenner, M.D.,
Michael Lesser, M.D., Bruce Kinon, M.D.
1983 American Psychiatric Association Annual Meeting.

Monthly Radio presentations on Clinical
Psychiatric Disorders on Radio Station Radio WADO.
May, 1983 - Present

- Effect of Gender on the Performance of Procedures
by Medical Housestaff.
Abstract presented at the annual (18th) Spring meeting of
the Association of Program Directors in Internal Medicine
(APDIM), Atlanta, Georgia - 1994
- Abstract on "The Effect of Anxiety and Depression on
Completion/Withdrawal Status in Patients Admitted to
Substance Abuse Detoxification Program" presented in
St. Petersburg, Russia in September, 1996 at the 18th
World Conference of Therapeutic Communities.

- 9 -

- 1990 to present - Lectured at numerous functions and community hospitals to psychiatrists as well as other specialty physicians on the subjects of depression, anxiety, and sleep disorders almost on a weekly basis.
- MOST RECENT LECTURES:
 - 9/24/96 - Nassau Psychiatric Society
Topic: "New Treatment in Geriatric Depression"
 - 11/13/96 - Lecture to Queens psychiatric Physicians on "Update on Antidepressants"
 - 11/21/96 - Saratoga/Warren County Physicians Group
Topic: "Pharmacotherapy for Depression: A New paradigm Shift"
 - 12/8/96 - Association of American Philippino Physicians of New York - Topic: "Geriatric Depression"
 - 12/10/96 - South Oaks Hospital
Topic: "New Treatment in Geriatric Depression"
 - 12/12/96 - Medical College of Georgia
Topic: "Anxiety & Depression: Focus on Clinical Pitfalls in the Substance Abuse Geriatric Populations".
 - 12/12/96 - Medical College of Georgia
Topic: "New Treatments in Geriatric Depression"
 - 12/15/96 - Wyckoff Medical Center
Topic: "New Treatment in Geriatric Depression"
 - 1/8/97 Neponsit Health Care Center
Topic: New Modalities in Geriatric Depression
 - 1/9/97 Syosset Hospital
Topic: Panic Attacks
 - 2/21/97 St. Vincent's - North Richmond Community Mental Health Center - Topic: "Geriatric Depression"

REFERENCES FURNISHED UPON REQUEST.

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PHYSICIAN

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David W. Brown, M.D.

Office:

4411 Medical Parkway
Austin, Texas 78756
(512) 323-2622

Residence:

REDACTED

Texas License Number: REDACTED

Texas DPS Registration: REDACTED

DEA Registration: REDACTED

Education St. Mary's University, San Antonio, Texas; B.A. in Biology, graduated magna cum laude, 1982.

University of Texas Medical School at Houston, Houston, Texas; M.D., 1986.

Residency Department of Psychiatry, University of Texas Medical School at Houston, Houston, Texas; 1986-1990.

Psychiatry Resident in Training Examination (PRITE), overall national percentile scores:

1989: psychiatry -- 97, neurology -- 96

1988: psychiatry -- 97, neurology -- 98.

PGY4 activities included one year of clinical EEG interpretation, supervised by Edward L. Reilly, M.D. and Nashaat Boutros, M.D..

Fellowship Biological Psychiatry Branch, National Institute of Mental Health, Bethesda, Maryland; 6/90 - 7/91.

Fellowship provided training in conducting clinical drug trials and in the correlation of quantitative EEG with neuro-imaging and in the neuroscience of anxiety and affective disorders. Fellowship supervised by Robert Post, M.D..

Board Eligibility/ Certification American Board of Psychiatry and Neurology, Board Certified, February, 1993. Board Certificate Number: 36730.

American Medical Electroencephalographic Association, Board Eligible, 7/90.

Publications Brown, DW, Ketter TA, Crumlish J, Post RM: Carbamazepine induced increases in total serum cholesterol - clinical and theoretical implications; Journal of Clinical Psychopharmacology, December, 1992.

Wolfe HG, Bartke A, Amador A, Van Sickle M, Dalterio S, Brown DW: Effects of inhibitory and stimulatory photoperiods and sexual maturation on the ability of hamster testes to respond to hCG in vitro; International Journal of Andrology, 8(1985) 232-242.

Bartke A, Matt KS, Amador AG, Klemcke HG, Brown DW, Gonzales D, Hogan MD: Testicular function of strains of mice selected for differences in gonadotrophin induced ovulation rate; Journal of Endocrinology, 90 (1981) 367-373.

Presentations "Pharmacotherapy for Depression" for Austin Association of Physician Assistants, Austin, Texas, 9/95.

"New Treatments for Schizophrenia" for Medco Behavioral Health, Houston, Texas, 8/95; Dallas, Texas, 9/95.

"Successful Strategies for Patient Enrollment and Retainment" for a Pharmaceutical Company, West Palm Beach, Florida, 12/95.

"Psychiatric Presentations of Epilepsy" for Seton Hospital Grand Rounds, Austin, Texas, 11/95.

"Advances in the Treatment of Bipolar Disorder" for the Depressive-Manic Depressive Association of Austin, Austin, Texas, 10/95.

"Pharmacology of Geriatric Depression" for the Waco Veterans Administration Medical Center/ telecast to the Temple Veterans Administration Medical Center, Waco, Texas, 7/95.

"Pharmacotherapy Update for Therapists" for Personal Performance Consultants, Austin, Texas, 4/95.

"Interview on Bipolar Disorder" for Good Morning, Austin, K-BVO Television Station, Austin, Texas, 3/95.

"Kindling and Bipolar Disorder" for St. David's Hospital Family Practice Department, Austin, Texas, 10/94.

"Biological Explanations for Mood Disorders" for the Texas Alliance for the Mentally Ill 1993 Convention, Austin, Texas, 9/93.

"Biology and Bipolar Disorder" for C.P.C. Capital Hospital Spring Lecture Series, Austin, Texas, 3/93.

"Kindling Hypothesis" for the University of Arkansas School for Medical Sciences (UAMS) Symposium, "Current Perspectives on Bipolar Disorder," Little Rock, Arkansas, 3/92.

"Pharmacologic Treatment of Post-Traumatic Stress Disorder" for the UAMS Symposium, "Panic Disorder in Minorities and the Underserved," Little Rock, Arkansas, 6/92.

**Participation
in Clinical
Research**

An agent for the treatment of Alzheimer's Disease; Supported by a Pharmaceutical Company, Principal Investigator, ongoing Phase III study.

An anti-migraine compound for the treatment of Acute Migraine; Supported by a Pharmaceutical Company, Principal Investigator, ongoing Phase III study.

An agent for the treatment of agitation and psychosis in Alzheimer's Disease; Supported by a Pharmaceutical Company, Principal Investigator, ongoing Phase III study.

A pharmacokinetic study of an injectable formulation of an antipsychotic; Supported by a Pharmaceutical Company, Principal Investigator, ongoing Phase III study.

An SSRI compound for the treatment of Panic Disorder; Supported by a Pharmaceutical Company, Principal Investigator, ongoing Phase III study.

A pharmacokinetic study of a new formulation of an antipsychotic compound; Principal Investigator, ongoing Phase III study.

An antipsychotic in the treatment of stable outpatients with schizophrenia and schizoaffective disorder; Supported by a Pharmaceutical Company; Principal Investigator, ongoing Phase III study.

An antipsychotic in the treatment of stable outpatients with schizophrenia and schizoaffective disorder; Supported by a Pharmaceutical Company, Principal Investigator, ongoing Phase III study.

An antipsychotic in the treatment of stable geriatric outpatients with schizophrenia; Supported by a Pharmaceutical Company, Principal Investigator, Phase III study, 1996.

An antipsychotic in the treatment of acutely relapsing inpatients with schizophrenia; Supported by a Pharmaceutical Company, Principal Investigator, Phase II study, 1995 - 1996.

An antipsychotic in the treatment of acutely relapsing inpatients with schizophrenia; Supported by a Pharmaceutical Company; Principal Investigator, Phase III study, 1995-1996.

An antidepressant in the treatment of depression; Supported by a Pharmaceutical Company; Principal Investigator, Phase II study, 1995.

An hypnotic in the treatment of insomnia; Supported by a Pharmaceutical Company; Principal Investigator, Phase II study, 1994.

An antidepressant in the treatment of post-traumatic stress disorder; Supported by a Pharmaceutical Company.; University of Arkansas for Medical Sciences, Little Rock, Arkansas, 1991-1992.

An anxiolytic in panic disorder; Supported by a Pharmaceutical Company; Institute for Behavior and Health; Rockville, Maryland, 1990-1991.

An antidepressant in geriatric depression; Supported by a Pharmaceutical Company; Institute for Behavior and Health; Rockville, Maryland, 1990-1991.

An anxiolytic in panic disorder; Supported by a Pharmaceutical Company; Institute for Behavior and Health; Rockville, Maryland, 1990-1991.

Evaluation of nimodipine in bipolar disorder; National Institutes of Mental Health, Biological Psychiatry Branch; Bethesda, Maryland, 1990-1991.

Lithium augmentation of nortriptylene in major depression with psychosis (principal investigator); University of Texas Medical School at Houston, 1989-1990.

Multicenter evaluation of an anticonvulsant in bipolar disorder; Supported by a Pharmaceutical Company; University of Texas Medical School at Houston, Houston, Texas, 1989-1990.

Evaluation of an antipsychotic in schizophrenia; Supported by a Pharmaceutical Company; University of Texas Medical School at Houston, Houston, Texas, 1989-1990.

**Other
Relevant
Experience**

Chair, Credentialing Committee, Shoal Creek Hospital, Austin, Texas, 12/94 to the present.

Member, Peer Review Committee, St. David's Pavilion, Austin, Texas,

1/95 to the present.

Visiting Lecturer, Psychiatry Residency Program, Austin State Hospital, Austin, Texas. 8/93 to the present.

Member, Quality Management/ Credentialing Committee, Metra Health Network, Austin Texas, 6/93 to 10/95.

Member, Pharmacy and Therapeutics Committee, CPC Capital Hospital, Austin, Texas, 9/93 to 8/94.

Chair of Psychiatry, Seton Northwest Hospital, Austin, Texas, 3/93 to 8/94.

Staff Psychiatrist, Austin Travis County Mental Health and Mental Retardation, 1430 Collier Street, Austin, Texas, 8/92 to 7/93.

Assistant Professor of Psychiatry, UAMS, 4301 West Markham, Little Rock, Arkansas, 7/91 - 8/92.

Consultant, Institute of Behavior and Health, Rockville, Maryland, 9/90 - 6/91.

Bilingual in English and Spanish.

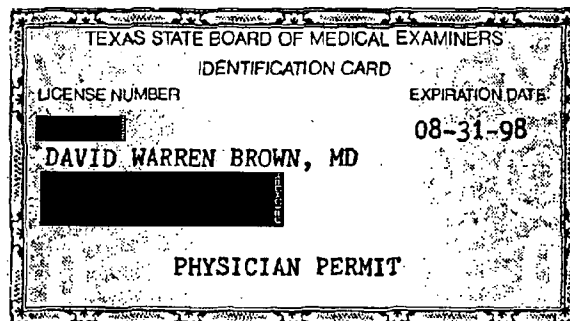
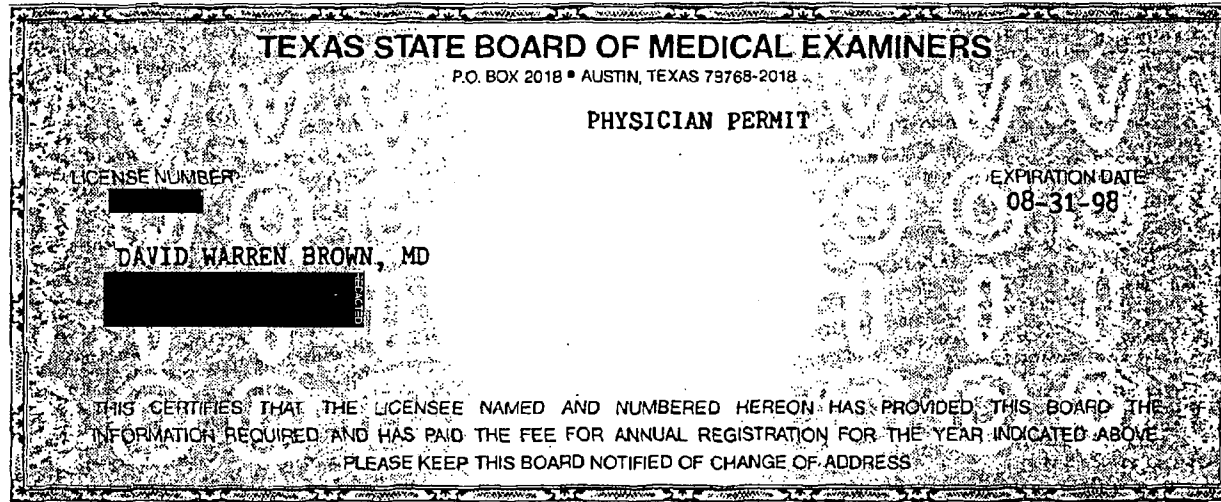
References University of Arkansas for Medical Sciences:
Craig Karson, M.D.

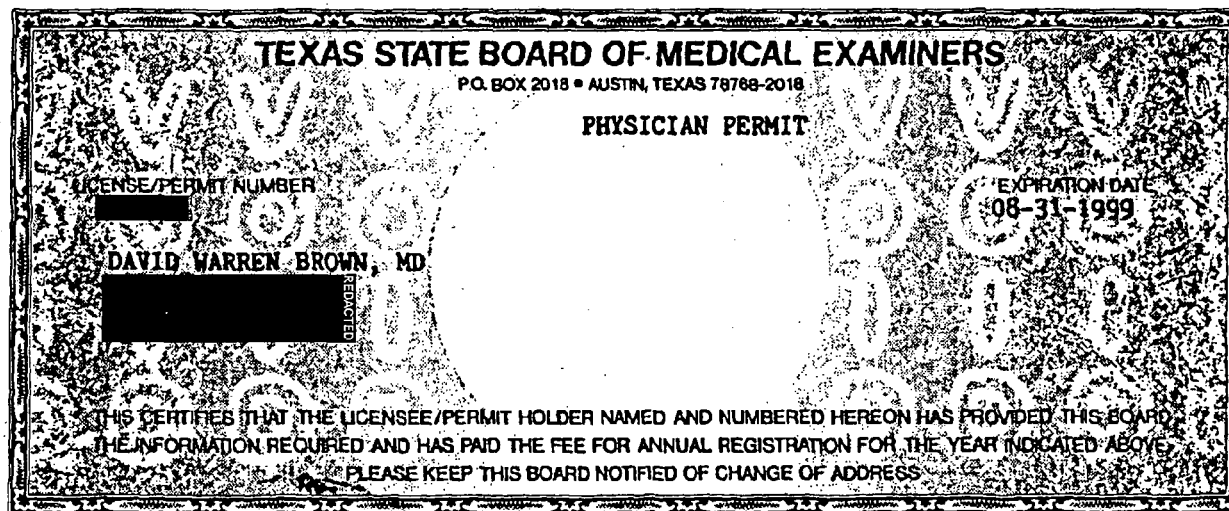
National Institutes of Mental Health:
Robert M. Post, M.D., Chief, Biological Psychiatry Branch

Institute of Behavior and Health:
Robert Dupont, M.D.

University of Texas Medical School at Houston:
Robert Guynn, M.D., Chair, Department of Psychiatry
Alan Swann, M.D., Assistant Chair for Research, Department
of Psychiatry
Edward L. Reilly, M.D., Residency Training Director, Department
of Psychiatry

Michael Lesem, M.D., Houston, Texas





C U R R I C U L U M V I T A E

NAME: JOHN S. CARMAN, M.D.

SOCIAL SECURITY NUMBER: REDACTED

DATE AND PLACE OF BIRTH: March 3, 1945; Teaneck, New Jersey

HOME ADDRESS: REDACTED

WORK ADDRESS: Carman Research, 4015 South Cobb Drive,
Suite 245, Smyrna, Georgia 30080

MARITAL STATUS: Divorced; seven children

EDUCATIONAL AND TRAINING:

- 1963 - 1967 - B.S., Magna cum Laude in Chemistry, University of Notre Dame; South Bend, Indiana
- 1967 - 1971 - M.D., State University of New York, Upstate Medical Center (UMC); Syracuse, New York
- 1971 - 1974 - Resident in Psychiatry, University of North Carolina Memorial Hospital; Chapel Hill, North Carolina

FULL TIME PROFESSIONAL POSITIONS:

- 1973 - 1974 - Clinical Associate and Admissions Coordinator, Biological Psychiatry Branch, National Institute of Mental Health (NIMH); Bethesda, Maryland
- 1974 - 1978 - Clinical Associate and Ward Administrator, Laboratory of Clinical Psychopharmacology, Division of Special Mental Health Research, Intramural Research Program, NIMH; Washington, D.C.
- 1978 - 1981 - Associate Professor in Psychiatry, University of Alabama in Birmingham (UAB); Birmingham, Alabama
- 1979 - 1981 - Clinical Service Coordinator, Adult Inpatient Psychiatric Unit, University Hospital, UAB
- 1979 - 1981 - Preceptor in Clinical Psychopharmacology, UAB
- 1981 - Director, Psychopharmacology Clinic, UAB
- 1981 - 1983 - Director, Adult Treatment Service, Brawner Psychiatric Institute (BPI); Smyrna, Georgia
- 1981-Present- Active Staff, Brawner Psychiatric Institute (BPI); Smyrna, Georgia
- 1982 - 1983 - Director of Geropsychiatry, BPI
- 1982 - 1988 - Clinical Assistant Professor of Psychiatry, Emory University, School of Medicine
- 1984 - 1988 - Director of Research, Center for Psychiatry Studies; Smyrna, Georgia
- 1988-Present- Director, Carman Research; Smyrna, Georgia
- 1996-Present- Active Staff, Ridgeview Institute; Smyrna, Georgia

CURRICULUM VITAE

John S. Carman, M.D.

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OTHER PROFESSIONAL EXPERIENCE AND ACTIVITIES:

1967 - Research Fellow in Pediatric Endocrinology, UMC
1968 - Research Fellow in Psychologic Testing, UMC
1969 - Research Fellow in Anesthesiology, UMC
1969 - 1971 - Medical Extern, Onandaga County Penitentiary; Jamesville, New York
1975 - 1976 - Staff Psychiatrist, Alexandria Mental Health Center, Virginia
1977 - 1978 - Staff Psychiatrist, Mount Vernon Mental Health Center, Virginia
1980 - 1981 - Leader, Psychiatric Residents' Sensitivity Training Group, UAB
1980 - 1981 - PSRO Committee, UAB
1978 - 1981 - Research Committee, Neuroscience Program, UAB
1981 - General Clinical Research Center - Scientific Advisory Committee, UAB
1981 - 1982 - Clinical Management Committee, BPI
1981-Present- Institutional Review Board for Research Involving Human Subjects, BPI

HONORS AND AWARDS:

1966 - 1967 - Student President, College of Science, University of Notre Dame
1963 - 1967 - Academic Tuition Scholarship at Notre Dame
1967 - 1971 - New York State Regents Scholarship in Medicine
1967 - 1971 - Health Professions Scholarship
1978 - Clinical Science A.E. Bennett Award from the Society of Biological Psychiatry
1979 - Curt P. Richter Award from the International Society of Psychoneuroendocrinology

BOARD CERTIFICATIONS:

1972 - National Board of Medical Examiners
1977 - American Board of Psychiatry and Neurology

REDACTED

MEDICAL LICENSURES:

1971 - 1974 - North Carolina
1975 - 1980 - Virginia
1978 - Present - Alabama
1981 - Present - Georgia

REDACTED

CURRICULAM VITAE

John S. Carman, M.D.

Page 3

MEMBERSHIPS:

American Psychiatric Association
Society of Biological Psychiatry
International Society of Psychoneuroendocrinology
American Medical Association

MILITARY SERVICE:

1973 - 1978 - Assistant Surgeon (04), U.S. Public Health Service, Honorable Discharge

RESEARCH GRANTS OR CONTRACTS AWARDED:

Term of Study	Source of Funding	Purpose	F.D.A. Phase
10/79 - 9/80	Burroughs-Wellcome	Wellbutrin in Depression	III
10/79 - 9/80	Burroughs-Wellcome	Neuroleptic (radioreceptor) Assay Kit Studies	N/A
10/80 - 9/81	McNeil	Pimozide vs Mellaril in Acute Schizophrenia	III
10/80 - 7/83	Sandoz	Mellaril vs. Haldol oral liquid preparations in Psychogeriatric Inpatients	IV
10/80 - 10/83	Burroughs-Wellcome	BW 234 in Mania	II
3/82 - 5/83	Merrell-Dow	Gamma Vinyl Gaba in Tardive Dyskinesia	II
3/82 - 6/84	Burroughs-Wellcome	BW 647 vs. placebo in Depression	II

CURRICULAM VITAE

John S. Carman, M.D.

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RESEARCH GRANTS OR CONTRACTS AWARDED - Cont'd:

Term of Study	Source of Funding	Purpose	F.D.A. Phase
2 - 12/83	Ciba-Geigy	Oxaprotaline vs. Amitriptyline in Depression	III
6/83 - 8/84	Mead Johnson	Trazadone vs. Doxepin in Depression	IV
7/83 - 4/85	Upjohn	Adinazolam vs. Ami triptyline in Depression	III
1/84 - 7/84	Lilly	Fluoxetine vs. placebo in Depression	IV
4/84 - 7/84	Rorer	Indalpine vs. Amitriptyline vs. placebo in Depression	III
5/84 - 6/85	Pfizer	Citalopram vs. Imipramine vs. placebo in Depression	II
11/85 - 11/87	Organon	Mianserin vs. Amitriptyline vs. placebo in Depression	III
9/86 - 9/89	McNeil	Etoferidone (EB) vs. Amitriptyline in Major Depressive Disorder (MDD)	III
9/86 - 9/89	McNeil	Etoferidone (AMI) vs. Amitriptyline vs. placebo in MDD	III
9/87 - 4/89	Burroughs-Wellcome	Wellbutrin 300 mg. vs. placebo in MDD	III

CURRICULAM VITAE

John S. Carman, M.D.

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RESEARCH GRANTS OR CONTRACTS AWARDED - Cont'd:

Term of Study	Source of Funding	Purpose	F.D.A. Phase
1/88 - 4/89	Boots	Dothiepin open in Depression	III
2/88 - 12/89	Organon	Long-term open trial of Org 3770 (Mepirzepine) in MDD	III
4/88 - 3/89	Lorex	Alpidem vs. Diazepam vs. placebo in Generalized Anxiety Disorder (GAD)	III
4/88 - 4/90	Bristol-Myers	Gepirone open in MDD	II
		Gepirone vs. placebo in MDD	III
4/88 - 4/90	Bristol-Myers	Gepirone vs. placebo in GAD	III
5/88 - 6/89	Pfizer	Sertraline vs. placebo in Obesity	III
6/88 - 8/90	Wyeth	Venlafaxine vs. Trazodone vs. placebo in MDD and long-term extension	III
3/89 - 6/90	Miles	Ipsapirone vs. placebo in GAD	III
9/89 - 9/91	Upjohn	Deracyn vs. placebo in GAD	III
1/90 - 11/90	Reid-Rowell	Fluvoxamine vs. placebo in MDD	III

CURRICULUM VITAE

John S. Carman, M.D.

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RESEARCH GRANTS OR OTHER CONTRACTS AWARDED - Con'd:

Term of Study	Source of Funding	Purpose	F.D.A. Phase
4/90 - 7/92	Merck	Remoxipride vs. placebo in Schizophrenia	III
5/90 - 10/90	Merrell-Dow	MDL 72,394 in MDD	II
9/90 - 3/94	Janssen	Risperidone vs. placebo vs. Haloperidol in Chronic Schizophrenia	II
11/90 - 2/92	Wyeth-Ayerst	Zalospirone vs. placebo in GAD	II
11/90 - 12/91	Wyeth-Ayerst	Zalospirone vs. placebo in MDD	II
11/90 - 3/92	ICI Pharmaceuticals	Seroquel vs. placebo in hospitalized Schizophrenics	II
12/90 - 5/92	Miles	Ipsapirone vs. placebo in MDD	II
1/91 - 11/91	SmithKline- Beecham	Paroxetine vs. Fluoxetine vs. placebo in MDD	II
3/91 - 7/92	Sandoz	Abecarnil low dose vs. high dose, vs. placebo vs. . Buspirone in GAD	III
3/91 - 11/91	SmithKline- Beecham	Switching Fluoxetine treated patients to Paroxetine without washout	IV

CURRICULUM VITAE

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RESEARCH GRANTS OR CONTRACTS AWARDED - Cont'd:

Term of Study	Source of Funding	Purpose	F.D.A. Phase
5/91 - 10/91	Upjohn	Xanax SR vs. placebo in Panic Disorder	IV
9/91 - 3/92	Pfizer	Sertraline vs. Amitriptyline vs. placebo in MDD	IV
12/91 - 12/93	Wyeth-Ayerst	Venlafaxine bid vs. tid vs. placebo in MDD	III
1/92 - 9/93	Sandoz	Open Label Abecarnil in GAD	III
1/92 - 9/92	Eli Lilly	LY237733 vs. placebo vs. Lorazepam in GAD	II
4/92 - 11/92	Bristol-Myers Squibb	Buspar bid vs. tid in GAD	IV
6/92 - 9/94	Eli Lilly	Olanzapine vs. placebo vs. Haloperidol in Schizophrenia	II
7/92 - 7/93	Lundbeck	Citalopram vs. placebo in Moderate to Severe Depression	III
8/92 - 10/93	Organon	Org 4428 vs. placebo in MDD	II
12/92 - 2/93	Wyeth-Ayerst	Venlafaxine open with one year double-blind extension (relapse prevention in MDD	III
1/93 - 3/94	TAP	DN-2327 vs. placebo in GAD double-blind and long-term extension	II

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RESEARCH GRANTS OR CONTRACTS AWARDED - Cont'd:

Term of Study	Source of Funding	Purpose	F.D.A. Phase
6/93 - 2/94	Abbott	A75200 vs. placebo in MDD	II
6/93 - 8/94	Burroughs-Wellcome	Open Wellbutrin SR in Depression	IV
7/93 - 1/94	SmithKline-Beecham	Paxil vs. placebo in Panic Disorder double-blind and long-term extension	III
7/93 - 5/94	Zeneca	Seroquel in prevention of Schizophrenic Relapse	III
8/93 - 7/94	Miles	Ipsapirone-CR vs. placebo in MDD with open extension	III
10/93 - 1/95	Abbott	Sertindole open label in Schizophrenic and related disorders	III
2/94 - 3/96	Miles	Metrifonate vs. placebo in Alzheimer's Disease	II
2/94 - 6/96	Pfizer	Sertraline vs. Imipramine in Chronic Depression and MDD with Dysthymia with continuation and crossover and relapse prevention	IV
2/94 - 11/94	Pfizer	Sertaline vs. placebo in Panic Disorder with long-term extension	III

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RESEARCH GRANTS OR CONTRACTS AWARDED - Cont'd:

Term of Study	Source of Funding	Purpose	F.D.A. Phase
4/94 - 3/95	Abbott	Sertindole vs. Haldol vs. placebo in inpatient Schizophrenics or Schizoaffectives with long-term open extension	III
8/94 - 2/96	Pfizer	Ziprasidone in Schizophrenic outpatients and inpatients	II
8/94 - 7/95	Wyeth-Ayerst	Adatsanserin in GAD	II
9/94 - 10/95	Solvay	Flesinoxan vs. placebo in MDD	II
3/95 - 12/95	Organon	4428 vs. Prozac vs. placebo in Depression	III
3/95 - 12/95	Organon	4428 vs. Prozac vs. placebo in Depression: One year extension	III
6/95 - 2/96	Bayer	Ipsapirone vs. Prozac vs. placebo in Depression	III
9/95 - 12/95	Janssen	Risperidone in Schizophrenic and Schizoaffective Disorder	IV
10/95 - 4/96	Wyeth-Ayerst	Venlafaxine ER vs. Prozac vs. placebo in Depression	II
12/95 - present	Wyeth-Ayerst	Venlafaxine ER vs. Buspar vs. placebo in GAD	II

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Term of Study	Source of Funding	Purpose	F.D.A. Phase
6/96 - 1/97	Parke-Davis	Tacrine GITS in Alzheimer's Disease	III
6/96 - 8/96	Zeneca	Seroquel vs. Fluoxetine vs. Imipramine Pharmacokinetic	III
9/96 - present	Wyeth-Ayerst	Venlafaxine vs. Fluoxetine vs. placebo double-blind in inpatient MDD with Melancholia	IV
7/96 - present	Wyeth-Ayerst	Venlafaxine-ER vs. placebo in Prevention of Relapse in Depression	III
9/96 - present	Forest Laboratories	Citalopram vs. Sertraline vs. placebo double-blind in Depression	III
6/96 - present	Pfizer	CP-93,393 10 mg CR vs. CP-93,393 30 mg CR vs. placebo double-blind in Depression	II
2/97 - present	Merck	L-754,030 vs. Paroxetine vs. placebo double-blind in Depression	II
6/96 - present	Pfizer	CP-93,393 10 mg CR vs. CP-93,393 30 mg CR vs. placebo double-blind in GAD	II

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RESEARCH GRANTS OR CONTRACTS AWARDED - Cont'd:

Term of Study	Source of Funding	Purpose	F.D.A. Phase
9/96 - 1/97	Solvay	Flesinoxan vs. Buspirone vs. placebo double-blind in GAD	III
2/96 - present	Wyeth-Ayerst	Venlafaxine-ER vs. Buspar vs. placebo double-blind in GAD	III
12/96 - present	SmithKline Beecham	Paroxetine-CR vs. placebo double-blind in Panic Disorder	III
3/97 - present	Protodigm, Ltd.	Lazabemide vs. placebo double-blind in Alzheimer's Disease	III
3/97 - present	Pfizer	Ziprasidone 2mg vs. Ziprasidone 20mg in in Psychosis with Agitation	III
3/97 - present	Pfizer	Ziprasidone open extension in Psychosis	III
5/97 - present	Novartis	Exelon open-label in Alzheimer's Disease	III
5/97 - present	Organon	Remeron vs. placebo double-blind in MDD	IV

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95. Freed, W.J., Perlow, M.J., Carman, J.S., Wyatt, R.J.: Calcitonin reduces feeding in man, monkey and rat. Pharmacol. Biochem. Behav. 12: 609-612, 1980.
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97. Carman, J.S., Jimerson, D.C., Post, R.M.: Electrolyte changes associated with shifts in affective states, In: Electrolytes and Neuropsychiatric Disorders, (Alexander, P., ed.), Plenum Press, New York, 1981, pp. 277-293.
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John S. Carman, M.D.

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100. Carman, J.S.: Calcium Psychiatric Illness, In: The Role of Calcium in Biological Systems. Vol. III (Anghileri, L.J., Tuffet-Anghileri, A.M., eds.) CRC Press, Boca Raton, Florida, 1982, pp. 157-173.
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105. Carman, J.S., Wyatt, E.S., Smith, W., Post, R.M., Ballenger, J.C.: Calcium and Calcitonin in Bipolar Affective Disorder, In: The Neurobiology of Mood Disorders (Post, R.M., and Ballenger, J.C., eds.), Williams and Wilkins Company, Baltimore 1984, pp. 340-355.

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John S. Carman, M.D.

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107. Gold, M.S., Carman, J.S.: Thyroid Failure and Clinical Misdiagnosis. pp. 67-82. *ibid.*
108. Lydiard, R.B., Carman, J.S., Gold, M.S.: Antipsychotics: Predicting Response/Maximizing Efficacy. pp. 179-224.
109. The Role of the Laboratory in Psychiatry. Gold, M.S., Pottash, A.C., Carman, J.S., and Lydiard, R.B., pp. 307-318. *ibid.*
110. Carman, J.S., Wyatt, E.S., Fleck, R., Martin, D., Gold, M.: Neuroleptic Compliance in Schizophrenic Outpatients. Psychiatric Hosp. 15: 173-178, 1984.
111. Carman, J.S., Wyatt-Knowles, E.S.: Calcium and Affective Disorder, In: Biological Psychiatry 1985. (eds.: Shagas, C., Josiasson, R.C., Bridges, W.H., Weiss, K.J., Stoff, D., Simpson, G.M.) Elsevier Press, New York, 1986, pp. 323-325.
112. Crews, E.L., Wyatt, E.S., Carman, J.S.: Salmon Calcitonin: Effects on tardive Dyskinesia. (Submitted)
113. Hall, K.R., Carman, J.S., Wyatt, E.S.: Bupropion: Antimanic prophylaxis and spectrum of antidepressant efficacy and its relationship to dexamethasone suppression of a dopaminergic thymoleptic. (Submitted)
114. Carman, J.S.: Marked but asymptomatic thyroid hormone elevations in a paranoid schizophrenic on low phenylamine diet. (Submitted)
115. Wyatt, E.S., Carman, J.S., Crews, E.L., Spencer, S., Bush, J.: Computerized Cerebral Tomography in Schizophrenia: Failure to Predict Neuroleptic Response or Side Effects. (In Press)

CURRICULUM VITAE

John S. Carman, M.D.

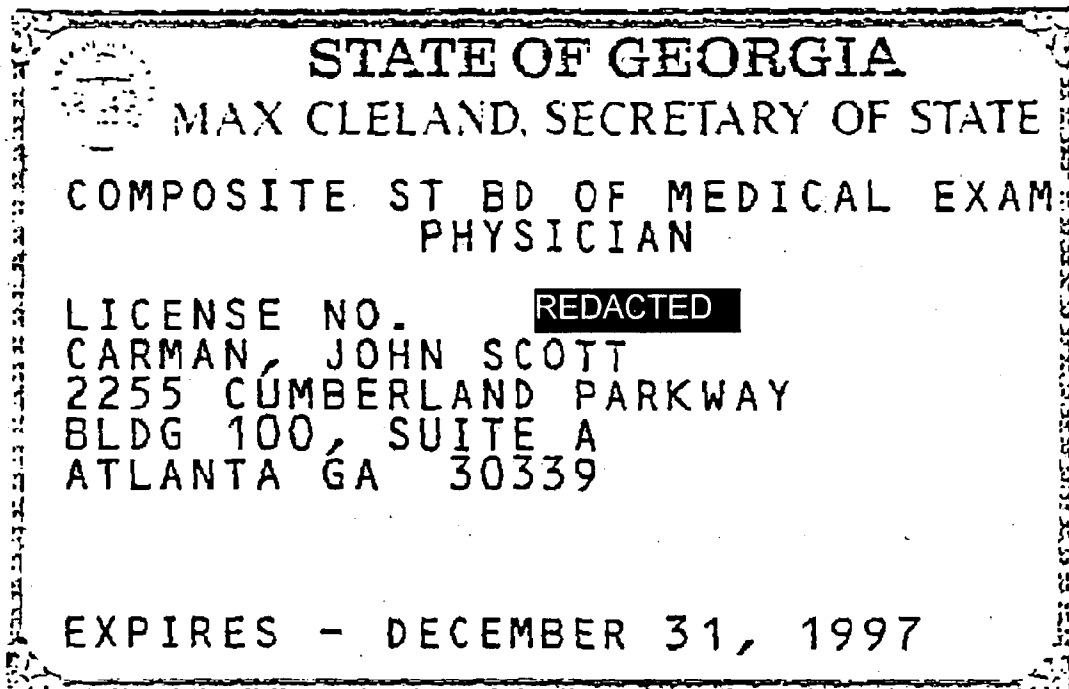
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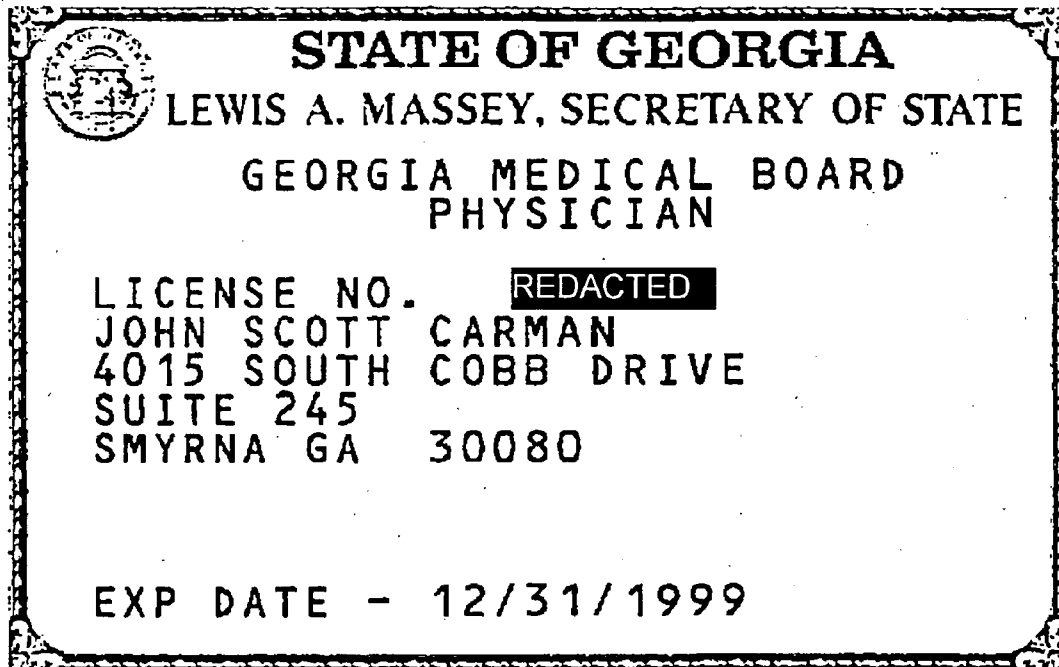
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117. Carman, J.S., Adieh, H., Wyatt-Knowles, E.S., Warga, E., Panagides, J.: A controlled study of Mianserin in moderately to severely depressed outpatients. Psychopharmacology Bulletin 27 No. 2: 135-139.
118. Cunningham, L.A., Borison, R.A., Carman, J.S., et al: A comparison of Venlafaxine, Trazodone and placebo in Major Depression. J. Clin. Psychopharm. 1993.
119. Marder, S.R., Meibach, R.C., Carman, J.S., et al: Risperidone in the Treatment of Schizophrenia. A. J. Psychiatry 151: 802-835, 1994.
120. Walczak, D.D., Halikas, J.A., Carman, J.S., et al: The Oral Dose-Effect Relationship for Fluvoxamine: A Fixed-Dose Comparison against Placebo in Depressed Outpatients. Annals of Clinical Psychiatry: (Submitted).
121. Carman, J. S., Peuskens, J., Vangeneugden, T.: Risperidone in the treatment of negative symptoms of schizophrenia: a meta-analysis. International Clinical Psychopharmacology: 1995 (In press).
122. Beasley, C., Tollefson, G., Tran, P., Satterlee, W., Sanger, T., Hamilton, S., and the HGAD Study Group: Carman, J. S.: Olanzapine vs. placebo and haloperidol: acute phase results of the North American double-blind Olanzapine trial. Neuropsychopharmacology: 1995 (In press).





CURRICULUM VITAE
University of Pittsburgh
School of Medicine

BIOGRAPHICAL

Name: Kadiamada Nanaiah Roy Chengappa **Birth Date:** September 26, 1955
Home Address: REDACTED **Birth Place:** Bangalore, India
Home Phone: REDACTED **Citizenship:** USA
Business Address: Associate Professor of Psychiatry (effective October 1, 1997)
Western Psychiatric Institute & Clinic
3811 O'Hara Street
Pittsburgh, PA 15213-2593 **Social Security #:** REDACTED
Business Phone: 412-624-4443 or 412-257-6650

EDUCATION and TRAINING

UNDERGRADUATE:

<i>Dates Attended</i>	<i>Name and Location of Institution</i>	<i>Degree Received and Year</i>	<i>Major Subject</i>
1963-1972	Lawrence School, Lovedale, India	All India Higher Secondary Examination	Science Stream
1973-1974	Christ College, Bangalore, India	I.B.Sc. Pre-Med	Pre-Med

GRADUATE:

<i>Dates Attended</i>	<i>Name and Location of Institution</i>	<i>Degree Received and Year</i>	<i>Major Advisor and Discipline</i>
1975-1980	Kasturba Medical College University of Mysore Manipal, India	Bachelor of Medicine Bachelor of Surgery MD, 1981	A.K. Rao, MD; Dean Medicine

POST-GRADUATE:

<i>Dates Attended</i>	<i>Name and Location of Institution</i>	<i>Name of Program Director and Discipline</i>
1989-1991	University of Pittsburgh, WPIC Pittsburgh, PA, USA	NIMH Clinical Research Fellow in Schizophrenia Rohan Ganguli, M.D. Medical and Research Director, Schizophrenia Module, WPIC
1986-1988	Dalhousie University Halifax, Canada	Resident in Psychiatry Dr. McCormick Director of Post-Graduate Education
1983-1986	Edinburgh University Edinburgh, Scotland	Resident in Psychiatry R.E. Kendell, M.D. Department Head
1982-1983	National Institute of Mental Health and Neurosciences Bangalore, India	Resident in Psychiatry Dr. Kapur Department Head
1981-1982	Kasturba Medical College Hospital Manipal, India	Resident in Medicine/Psychiatry Dr. Kundaje Department Head
1980-1981	Kasturba Medical College Hospital Manipal, India	Internship (Rotating) Dr. Thimmapaiah Medical Director

APPOINTMENTS and POSITIONS

ACADEMIC:

<i>Years Inclusive</i>	<i>Name & Location of Institution of Organization</i>	<i>Rank/Title</i>
Effective October 1, 1997	Department of Psychiatry University of Pittsburgh School of Medicine	Associate Professor of Psychiatry
1991-1997	Department of Psychiatry University of Pittsburgh School of Medicine	Assistant Professor of Psychiatry

NON-ACADEMIC:

<i>Years Inclusive</i>	<i>Name & Location of Institution of Organization</i>	<i>Rank/Title</i>
1986-1987	Valley Health Services Association Kentville, Nova Scotia, Canada	Consulting Psychiatrist
1989-1993	Allegheny East MH/MR, Inc. Partial Hospital Program Wilkinsburg, PA, USA	Consulting Psychiatrist
1991-Current	Schizophrenia Treatment & Research Center Western Psychiatric Institute & Clinic Pittsburgh, PA, USA	Attending Psychiatrist
1991-Current	Mayview State Hospital and University of Pittsburgh Special Studies Center Bridgeville, PA, USA	Director and Attending Psychiatrist
1995-Current	Stanley Center of the Innovative Treatment of Bipolar Disorder Western Psychiatric Institute & Clinic University of Pittsburgh Pittsburgh, PA, USA	Center Psychiatrist

CERTIFICATION and LICENSURE

SPECIALTY CERTIFICATION:

<i>Certifying Board</i>	<i>Year</i>
American Board of Psychiatry and Neurology (Added Qualifications in Geriatric Psychiatry)	1992
American Board of Psychiatry and Neurology	1990
F.R.C.P.C. Fellow of the Royal College of Physicians and Surgeons of Canada (Psychiatry)	1988
M.R.C.Psych., Member, Royal College of Psychiatrists, London, UK	1986

MEDICAL LICENSURE:

<i>Licensing Board/State</i>	<i>Year</i>
State Medical Board, Pennsylvania, USA	1989
Provincial Medical Board of Nova Scotia, Canada	1985
General Medical Council, London, UK	1983
Karnataka Medical Council, India	1981

MEMBERSHIPS in PROFESSIONAL and SCIENTIFIC SOCIETIES

Organization	Year
American Society for Clinical Psychopharmacology	1995
Society for Biological Psychiatry	1993
Royal College of Physicians and Surgeons of Canada	1988
Canadian Psychiatric Association	1988
Canadian Medical Association	1985
British Medical Association	1984
Indian Medical Association	1981

HONORS

Title of Award	Year
Best Outgoing Student, Kasturba Medical College	1980
First Prize, Ophthalmology	1979
Gold Medal, Pathology	1978

PUBLICATIONS

REFEREED ARTICLES:

1. Kundaje GN, Shatpathy P, Prabhu SG, Subramanya R, Chengappa KNR (1983): Marfan's syndrome. *Journal of The Association of Physicians of India*, 31: 809-811.
2. Chengappa KNR, Carpenter AB, Keshavan MS, Yang ZW, Kelly RH, Rabin BS, Ganguli R. Elevated IgG and IgM anticardiolipin antibodies in a subgroup of medicated and unmedicated schizophrenic patients. *Biol Psychiatry*, 30:731-735, 1991.
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4. Chengappa KNR, Ganguli R, Ulrich R, Rabin BS, Cochran J, Brar JS, Yang ZW, DeLeo M. The prevalence of auto-antibodies among right- and left-handed schizophrenic patients and control subjects. *Biol Psychiatry*, 32:803-811, 1992
5. Chengappa KNR, Carpenter AB, Yang ZW, Brar JS, Rabin BS, Ganguli R. Elevated levels of IgG antihistone antibodies in a subgroup of medicated schizophrenic patients. *Schiz Res*, 7:49-54, 1992
6. Ganguli R, Brar JS, Solomon W, Chengappa KNR, Rabin BS. Altered IL-2 production in schizophrenia: Association between clinical state and autoantibody production. *Psych Res*, 44:113-123, 1992

7. Chengappa KNR, Ganguli R, Yang ZW, Brar JS, Li L, Rabin BS. Left-handed first-episode, neuroleptic-naive schizophrenic patients have higher prevalence of autoantibodies. *Schiz Res*, 8:75-80, 1992.
8. Chengappa KNR, Ganguli R, Yang ZW, Shurin G, Cochran J, Brar JS, Rabin BS. Non-right sidedness: An association with lower IL-2 production. *Life Sciences*, 51(24):1843-1849, 1992.
9. Baker RW, Chengappa KNR, Baird JW, Steingard S, Christ MG, Schooler NR. Emergence of obsessive-compulsive symptoms during treatment with Clozapine. *J Clin Psychiatry*, 53(12):439-442, 1992.
10. Ganguli R, Brar JS, Chengappa KNR, Nimgaonkar VL, Yang ZW, Rabin BS. Autoimmunity in schizophrenia: A review of recent findings. *Annals of Medicine*, 25:489-496, 1993.
11. Chengappa KNR, Shelton MD, Baker RW, Schooler NR, Baird J, Delaney J. The prevalence of akathisia in patients receiving stable doses of Clozapine. *Journal of Clinical Psychiatry*, 55:142-145, 1994.
12. Yang ZW, Chengappa KNR, Shurin G, Brar JS, Rabin BS, Gubbi AV, Ganguli R. An association between antihippocampal antibody level and lymphocyte production of IL-2 in patients with schizophrenia. *Psychological Medicine*, 24: 449-455, 1994.
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14. Chengappa KNR, Ganguli R, Yang ZW, Schurin G, Brar JS, Rosenbleet JA, Rabin BS. Differences in serum interleukin-6 (IL-6) between healthy dextral and non-dextral subjects. *Neuroscience Research*, 20:185-188, 1994.
15. Chengappa KNR, Baker RW, Kreinbrook SB, Adair D. The use of Clozapine in female geriatric patients with psychoses. *Journal of Geriatric Psychiatry and Neurology*, 8:12-15, 1995.
16. Chengappa KNR, Baker RW, Sirri C. The successful use of Clozapine in ameliorating severe self mutilation in a patient with borderline personality disorder. *Journal of Personality Disorders*, 9:76-82, 1995.
17. Chengappa KNR, Ganguli R, Yang ZW, Shurin G, Brar JS, Rabin BS. Impaired mitogen (PHA) responsiveness in caucasian schizophrenic patients with the HLA B8/DR3 phenotype. *Biological Psychiatry*, 37:546-549, 1995.
18. Chengappa KNR, Nimgaonkar VL, Bachert C, Yang ZW, Rabin BS, Ganguli R. Obstetric complications and autoantibodies in schizophrenia. *Acta Psychiatrica Scandinavica*, 92:270-273, 1995.
19. Ganguli R, Brar JS, Chengappa KNR, DeLeo M, Yang ZW, Shurin G, Rabin BS. Mitogen-stimulated IL-2 production in never-medicated, first episode schizophrenic patients: The influence of age of onset and negative symptoms. *Archives of General Psychiatry*, 52:668-672, 1995.
20. Chengappa KNR, Pelucio M, Baker RW, Cole D. Recurrent pancreatitis on Clozapine re-challenge. *Journal of Psychopharmacology*, 9:381-382, 1995.
21. John JP, Chengappa KNR, Baker RW, Gupta B, Mortimer-Thompson M. Assessment of changes in both weight and frequency of use of medications for the treatment of gastrointestinal symptoms among Clozapine treated patients. *Annals of Clinical Psychiatry*, 7:119-125, 1995.

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23. Baker RW, Ames D, Umbricht DSG, Chengappa KNR & Schooler, NR. Obsessive-compulsive symptoms in schizophrenia: A comparison of Olanzapine and placebo. *Psychopharmacology Bulletin*, 32(1):89-93, 1996.
24. Baker RW, Bermanzohn PC, Wirshing DA, Chengappa KNR. (1997) Obsessions, Compulsions, Clozapine, and Risperidone. *CNS Spectrums*, 2(3):26-36.

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1. Chengappa KNR, Steingard S, Brar JS, Keshavan MS (1989): Delusions of pregnancy in men. *British J Psychiatry*, 155:422-423.
2. Chengappa KNR, Cochran J, Rabin BS, Ganguli R (1991): Handedness and autoantibodies. *Lancet*, 338:694.
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4. Steingard S, Chengappa KNR, Baker RW, Schooler NR (1993). Clozapine, Obsessive Symptoms, and Serotonergic Mechanisms. *American Journal of Psychiatry*, 150:9 1435.
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6. Baker RW, Chengappa KNR. (1995) Further Study of Neuroleptic Malignant Syndrome. *Am J Psychiatry* 152:1831.

BOOK CHAPTERS:

1. Chengappa KNR, Flynn P. Drug-induced akathisia. In: Keshavan MS, Kennedy J (eds): Drug-Induced Dysfunction in Psychiatry: Diagnosis and Treatment. Hemisphere Publications, Washington, D.C., 1991, pp. 153-168.
2. Keshavan MS, Chengappa KNR. Adverse hepatic effects. In: Keshavan MS, Kennedy J (eds): Drug-Induced Dysfunction in Psychiatry-Diagnosis and Treatment. Hemisphere Publications, Washington, D.C., 1991, pp. 259-264.
3. Chengappa KNR, Nimgaonkar VL, Ganguli R. Immunological alterations. In: Keshavan MS, Kennedy J (eds): Drug-Induced Dysfunction in Psychiatry-Diagnosis and Treatment. Hemisphere Publications, Washington, D.C., 1991, pp 311-324.
4. Chengappa KNR. Autoimmune mechanisms may play a role in the pathogenesis of schizophrenia. In: Khanna S, Chamabasavanna SM, Keshavan MS (eds): Methods in Biological Psychiatric Research. Tata-McGraw Hill, New Delhi, 1995, pp 175-189.
5. Masand PS, Chengappa KNR, Edwards W. Somatic treatments in psychiatry. In: Wise T and Goldman LS (eds): Handbook of Psychiatry in Primary Care. AMA Press, Chicago, IL, (in press).
6. Keshavan MS, Chengappa KNR. Management of side effects of antipsychotic drugs. In: Balon R (ed): Practical Management of Psychotropic Drug Side Effects. Marcel Dekker, Inc., New York, NY (in press).

7. Keshavan MS, Mamo D, Chengappa KNR. Neuroleptic drugs. In: Ananth J (ed): Textbook of Psychopharmacology. Jaypee Publishers, N. Delhi, India (in press).

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1. Chengappa KNR, Carpenter AB, Keshavan MS, Yang ZW, Kelly RW, Rabin BS, Ganguli R (1991). Cardiolipin Antibodies in a Subgroup of Medicated and Never-Medicated Schizophrenic Patients. *Biological Psychiatry*, 29:109A.
2. Ganguli R, Chengappa KNR, Yang ZW, Kelly RH, Rabin BS (1991): Clinical and immunological correlates of anti-brain antibodies in schizophrenic patients. *Biol Psychiatry*, 29:71 (abstract).
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4. Chengappa KNR, Ganguli R, Carpenter AB, Yang ZW, Brar JS, Ganguli R (1992). Anti-Histone Antibodies in Schizophrenia. *Biological Psychiatry*, 31:208A.
5. Chengappa KNR, Ganguli R, Carpenter AB, Yang ZW, Brar JS, Rabin BS (1992). Handedness and autoantibodies in Schizophrenic and Control Subjects. *Biological Psychiatry*, 31:208A.
6. Nimgaonkar VL, Chengappa KNR, Ganguli R, Rabin BS (1992). An Association Between Obstetric Complications and Autoantibodies in Schizophrenia. *Biological Psychiatry*, 31:209A.
7. Ganguli R, Rabin BS, Chengappa KNR, Nimgaonkar VL, McAllister CT, Yang ZW, Brar JS (1992): Autoimmune phenomena in schizophrenic patients. *Schizophrenia Research*, 6:140-141.
8. Chengappa KNR, Yang ZW, Schurin G, Farooqui SM, Rabin BS, Ganguli R. (1993) Antibodies to D2-Receptor in Neuroleptic-Naive Schizophrenic Patients. *Biological Psychiatry*, 33, 97A.
9. Chengappa KNR, Shelton MD, Baker RW, Schooler NR, Baird J, Delaney J. (1993). The Prevalence of Akathisia and Tardive Dyskinesia in Patients Receiving Clozapine. *Biological Psychiatry*, 33:126A.
10. Chengappa KNR, Baker RW, Schooler NR, Haught M, Gopalani A. (1995). Clozapine Associated Agranulocytosis: Treatment with G-CSF. New Clinical Drug Evaluation Unit Program (NCDEU) Abstracts, 35th Annual Meeting. Orlando, Florida. May 31-June 3, 1995.
11. Baker R, Ames D, Umbricht D, Chengappa KNR, Schooler N. (1995). Olanzapine's Impact on Depressive and Obsessive-Compulsive Symptoms in Schizophrenia. New Clinical Drug Evaluation Unit Program (NCDEU) Abstracts, 35th Annual Meeting. Orlando, Florida. May 31-June 3, 1995.
12. Brar JS, Chengappa KNR, Sandman AR, Kreinbrook SB, Sheth SA, Ganguli R. (1997). Effect of Clozapine on Negative Symptoms in Schizophrenic Patients with Minimal Positive Symptoms. *Biological Psychiatry*, 41:72S.

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1. Chengappa KNR, Flynn P (1988): An unusual psychiatric presentation of bronchogenic carcinoma. *The Nova Scotia Medical Journal*, 203-204.

2. Chengappa KNR, Jain U, Flynn P (1989): Patient's who "fake" illness: A medical quagmire. *The Nova Scotia Medical Journal*, 92-94.
-

PROFESSIONAL ACTIVITIES

TEACHING:

- 1989 Western Psychiatric Institute and Clinic, University of Pittsburgh, School of Medicine. Medical and research students, psychiatry residents, psychology interns, and social work interns.
- 1986-88 Dalhousie University, Halifax, Nova Scotia, Canada. Clinical and bedside teaching of medical and nursing students, and psychology and social work interns.
- 1983-86 Edinburgh University, Edinburgh, Scotland, U.K. Clinical and bedside teaching of medical and nursing students, and psychology and social work interns.
- 1980-81 Kasturba Medical College, Manipal, India. Clinical bedside teaching of medical and nursing students.

Didactic Courses Taught at the University of Pittsburgh

- 1997-Current Clinical Pharmacology Course (Stevan P. Tofovic, MD, PhD, Course Director). Selective Course, PBL- Psychiatric Disorders, University of Pittsburgh School of Medicine. 1.5 hours, 8 medical students.
- 1996-Current Pharmacology of Mood Disorders. Distinction between Mania and Schizophrenia. (PGY II psychiatry residents). 1 hour/semester, 6-8 residents.
- 1992-94 Newer Antipsychotic Drugs and Psychiatric Treatment in State Psychiatric Hospitals (Year III University of Pittsburgh medical students during Mayview State Hospital field trip). 6 hours/semester, 6-8 residents.
- 1992-93 Psychopharmacology of Treatment-Resistant Psychoses and Mood Disorders. (PGY-3 Residents doing 3 month electives at the Special Studies Center, Mayview State Hospital). 6 hours/resident during each 3 month block.
- 1992 Movement Disorders, Diagnosis and Management. Psychology & Social Work interns (University of Pittsburgh) 3 hours/semester.
- 1991-Current Psychopharmacology of the Psychoses and Movement Disorders Lectures Newer Antipsychotic Drugs. (PGY II Psychiatric Residents) Western Psychiatric Institute and Clinic, Pittsburgh, PA. 3 hours/semester, 6-8 residents.

Non-didactic Teaching at the University of Pittsburgh

- 1992-95 Preceptor to University of Pittsburgh Medical Students (Year III) assigned to the Schizophrenia Treatment and Research Center, Western Psychiatric Institute and Clinic, Pittsburgh, PA. 1 student per session.
- 1992-95 Supervise the assessment and long-term follow-up of selected patients with schizophrenia as Faculty Attending Supervisor for Year II Psychiatric Residents, Western Psychiatric Institute and Clinic, Pittsburgh, PA. 2 residents/year.

- 1992-Current Academic Coordinator (along with Dr. A. Sandman) for the University of Pittsburgh Medical Students (Year III) and Psychiatric Residents (Year II) Field Trips to Mayview State Hospital, Bridgeville, PA. 6 to 8 medical students per trip.
- 1991-Current Supervision of Psychology and Social Work interns from Western Psychiatric Institute and Clinic and the University of Pittsburgh assigned to the Special Studies Center, Mayview State Hospital, Bridgeville, PA. 1 or 2 students per semester.
- 1992-Current Residents Mock Oral Examinations in Preparation for the Boards for the Office of Residency Training, Western Psychiatric Institute & Clinic, Pittsburgh, PA. 1.5 hours per year, 1 resident.

Research Students Mentored

<i>Student</i>	<i>Research Project</i>	<i>Duration</i>
Colin Bachert (U. Pittsburgh B.S. Hons Student)	Anti-hippocampal antibodies and obstetric complications in schizophrenia	1990, 1 year
Michael Silver (Carnegie Mellon University B.S. Hons Student)	Expression of D2 receptor protein	1990, 1 year
Ketan Bulsara (Mellon Fellow, Pre-Med Student) Duke University	Anti-D2 receptor antibodies	Summer 1992
Jodi Rosenbleet (Pre-Med Student) Hahneman Medical School	Handedness and interleukin-2 production	Summer 1993
Joseph Vasile, M.D. (PGY III Resident)	Clozapine's effect on seclusion and restraints	September - December 1993
John P. John, M.D. (PGY III Resident)	Clozapine and its effects on weight and gastrointestinal symptoms	January - December 1994
Marcus Pelucio, M.D. (PGY III Resident)	Clozapine and recurrent pancreatitis	March - July 1994
Senthil Kathiresan (Pre-Med Student) University of Pittsburgh	Culture of cell-lines expressing the D4 and D2 receptors	January - June 1994
Savitha Chengappa (Pre-Med Student) WVU, Morgantown	Development of a radioreceptor assay for D4 receptor binding	September 1994 - May 1995
Al Sylvester, M.D. (PGY III Resident)	ECT use in a state hospital	September 1995 - Present
Sapna Sheth, B.S. (Pre-Med, U.Penn)	Risperidone: Clinical Outcome Study at Mayview State Hospital	June 1996 - Present

Shakil Ahmed, M.D.
(PGY I Resident)

Clozapine Withdrawal Emergent
Dyskinesias and Dystonias

August 1996 - Present

Jean Thompson
(Med Student, Year IV)
University of Pittsburgh

Clozapine Associated Hepatitis,
Pancreatitis and Nephritis

September 1996 - Present

RESEARCH:

Currently Funded Grants:

<u>Grant Number (Funded)</u>	<u>Grant Title</u>	<u>Role in Project and Percentage of Effort</u>	<u>Years Inclusive</u>	<u>Source</u>
FID-MC- HGEH \$410,558/- Pharmaceuticals	Olanzapine Vs. Placebo in the Treatment of Mania Associated with Bipolar I Disorder	Principal Investigator 15% Effort	1996-1998	Stanley Foundation/ Eli Lilly
JANSSEN: MSHRISP TDC \$12,000	Risperidone: A Clinical Outcome Study at Mayview State Hospital	Principal Investigator 5% Effort	June 1996 to Dec. 1996	Janssen Pharmaceutica & Research Foundation
1673ID TDC \$439,239	Fixed Dose Olanzapine Versus Placebo in the Treatment of Schizophrenia	Co-Principal Investigator 20% Effort and Salary Support	Aug. 1993 to Aug. 1997	Lilly Research Laboratories
M94-222 TDC \$34,125	An Open-Label Assessment of the Long-Term Safety of Sertindole	Co-Principal Investigator 2% Effort	Jan. 1995 to July 1997	Abbott Laboratories
M95-372 TDC \$250,420	A Double-Blind Randomized Comparison of the Safety and Efficacy of Sertindole and Risperidone	Co-Principal Investigator 10% Effort	July 1996 to Jan. 1999	Abbott Laboratories
M93-113 TDC \$176,612	Sertindole/Haloperidol in Schizophrenia Patients	Co-Principal Investigator	June 1994 to Dec. 1996	Abbott Laboratories
5077IL/0031:0009 TDC \$153,912	A Multi-Center, Double- Blind, Randomized Com- parison of ICI 204, 636 Seroquel and Chlorpromazine in the Treatment of Hospital- ized Subjects with Treatment- Resistant Schizophrenia and an Open Label Extension Study	Co-Investigator 10% Effort and Salary Support	Jan. 1995 to June 1996	Zeneca Pharm- aceuticals

MH46672-04 TDC \$958,875	New Antipsychotics: Clinical Trials and Naturalistic Follow-up	Co-Investigator 10% Effort and Salary Support	April 1995 to March 1999	NIMH
Funded	Inositol for the Treatment of Lithium-Induced Side Effects	Co-Investigator 5% Effort	Dec. 1995 to Nov. 1996	Stanley Foundation
Funded	Inositol for the Treatment of Breakthrough Depression During Lithium Prophylaxis	Co-Investigator 5% Effort	Dec. 1995 to Nov. 1996	Stanley Foundation

Past Grants:

<u>Grant Number (Funded)</u>	<u>Grant Title</u>	<u>Role in Project and Percentage of Effort</u>	<u>Years Inclusive</u>	<u>Source</u>
M92-762 & M92-795 TDC \$219,453	A Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of Sertindole in Schizophrenic Patients and Long-Term, Open-Label Extension	Co-Investigator 5% Effort	Oct. 1992 to April 1995	Abbott Laboratories
MH 16804-09 TDC \$61,500	National Research Service Award	Trainee 100% Clinical Research in Schizophrenia and Immunology	Jan. 1989 to Dec. 1990	NIMH
MH 41883 TDC \$1.2 million	Autoimmune Phenomena and Psychotic Relapse	Co-Investigator 20% Effort	1986 - 1993	NIMH

Pending Grants:

TBF	Olanzapine in the Treatment of Persistent Psychotic and/or Manic Symptoms in Patients with Bipolar I	Principal Investigator 10% Effort	TBF	Stanley Foundation/ Eli Lilly Pharmaceuticals
TBF	Development of a Tremor Analysis System	Co-Principal Investigator 5% Effort	1996-1998	Ben Franklin Technology Center of Western PA
TBF	The Anticholinergic Effects of Olanzapine Compared to Clozapine	Co-Principal Investigator	1997-1998	Eli Lilly

Proposed Grants:

TBF	Use of Inositol in Bipolar Depression	Principal Investigator	Future	NIMH Proposals
TBF	Use of Inositol for Lithium Induced Side Effects	Co-Investigator	Future	NIMH Proposals
TBF	Olanzapine: A Clinical Outcome Study at Mayview State Hospital	Principal Investigator 10% Effort	Future	Eli Lilly Pharmaceuticals

INVITED LECTURES and PRESENTATIONS:

- 1991 Society of Biological Psychiatry - 46th Annual Convention & Scientific Program, May 8-12, 1991. New Orleans, Louisiana. Cardiopilin Antibodies in Medicated and Never-Medicated Schizophrenic Patients.
- 1993 American Psychiatric Association - 146th Annual Meeting, May 22-27, 1993. San Francisco, California. Obstetric Complications and Autoantibodies in Schizophrenia.
- 1994 National Institute of Mental Health & Neurosciences - Medical Council of India Symposium on Methods in Biological Psychiatry Research, January 10-11, 1994. Bangalore, India. Autoimmune Mechanisms in the Pathogenesis of Schizophrenia.
- 1995 Treatment Challenges in Schizophrenia Conference, University of Pittsburgh Medical Center, Western Psychiatric Institute and Clinic. February 4, 1995. Hidden Valley, PA. Symposium on Movement Disorders.
- 1995 The Clarke Institute of Psychiatry, University of Toronto, Toronto, Canada. April 21, 1995. Talk on Changing a Predominantly Clinical Service Setting to a Clinical and Research Setting.
- 1995 Canadian Psychiatric Association 45th Annual Meeting. Victoria, British Columbia, Canada. September 19 -22, 1995. Clozapine-Associated Agranulocytosis: Treatment with G-CSF.
- 1995 Dalhousie University, Department of Psychiatry, Halifax, Nova Scotia, Canada. Academic Grand Rounds Lecturer. "Clozapine: An Antiaggressive Drug?" November 16, 1995.
- 1996 World Psychiatric Association Section Meeting on Biological Psychiatry. Bombay, India. January 8, 9, 10, 1996. Mental Health Care and Biological Psychiatry. Symposium of Newer Antipsychotic Drugs in the treatment of Schizophrenia and related disorders. "Recognition and Management of Adverse Effects Associated with Clozapine and Risperidone".
- 1996 Seventh Annual Pittsburgh Neuropsychiatry Conference, Pittsburgh, PA. Western Psychiatric Institute and Clinic, University of Pittsburgh Medical Center. April 25, 1996. "From Theory to Practice, The Clinical Application of Newer Antipsychotic Drugs in Neuropsychiatric Disorders."
- 1996 Grand Rounds by Chief Residents at Western Psychiatric Institute & Clinic, University of Pittsburgh Medical Center. July 26, 1996. "Schizoaffective Disorder."

- 1996 Treatment Advances in Mental Health Practice at Western Psychiatric Institute & Clinic, University of Pittsburgh Medical Center. October 5, 1996. "Bipolar Depression."
- 1997 Introduction to Mental Health Issues, Part II: Bipolar Disorders in Adults at the VA Medical Center, Highland Drive, Pittsburgh, PA. May 2, 1997. Sponsored by Western Psychiatric Institute & Clinic, University of Pittsburgh Medical Center.
- 1997 Effect of Clozapine on Negative Symptoms in Schizophrenic Patients with Minimal Positive Symptoms. Society of Biological Psychiatry Annual Meeting, 1997, San Diego, CA.
- 1997 A Clinical Audit of the First 142 Patients who Received Risperidone at a State Psychiatric Hospital. NCDEU 37th Annual Meeting. May 27-May 30, 1997, Boca Raton, FL.

OTHER RESEARCH RELATED ACTIVITIES:

- 1. Peer reviews for the following journals: Biological Psychiatry, Human Psychopharmacology, Life Sciences, Anxiety, Journal of Clinical Psychiatry, Psychiatry Research.
- 2. Peer reviewer for granting agencies/research committees: Western Psychiatric Institute and Clinic, Canadian Psychiatric Research Foundation

CURRENT RESEARCH INTERESTS:

- 1. **Immune Mechanisms in Schizophrenia**, Western Psychiatric Institute and Clinic, Pittsburgh, Pennsylvania. (Drs. R. Ganguli, M.D.,-Psychiatrist and B.S. Rabin, M.D., Ph.D.,-Immunopathologist, PIs on NIMH funded grants) - I was involved in examining certain immunological parameters in schizophrenia with a view to identify a subgroup of patients whose etiopathogenesis may involve an immune mechanism. During my fellowship, I obtained "wet-lab" experience in immunology, and also worked with the PIs on recruitment of subjects and execution of the various cross-sectional and longitudinal investigations. Additional didactic course-work focussed on formal clinical research methodology training and gaining knowledge of bio-statistics. During the research fellowship, and subsequent faculty appointment, I was specifically involved in the determination of the occurrence of anti-phospholipid antibodies, dopamine receptor antibodies, anti-hippocampal antibodies, and the implications of cerebral laterality for immune dysfunction in schizophrenia.
- 2. **Instrumental Quantification of Tardive Dyskinesia.** This proposal will examine the feasibility of measuring orofacial tardive dyskinesia in psychiatric patients in a standard, reliable and objective manner. A method that involves computer-assisted digitization of video recording of facial movements will be used. This data will enable the investigators not only to determine if this method is more sensitive than the available subjective clinical rating scale (AIMS), but also if it is easily applicable to an office setting. If the technique is more sensitive than the AIMS, then the potential clinical benefit of redirecting patients at high risk for this potentially irreversible neurological syndrome to receive the newer atypical antipsychotic agents, such as clozapine will be realized. Additional benefits of distinguishing between various movement disorders - such as lip tremors (Rabbit syndrome) vs. tardive dyskinesia will also be examined in pharmacological paradigms -e.g. IM Benzotropine is likely to ameliorate the Rabbit syndrome but not tardive dyskinesia. Pilot data have been gathered, and this is being done in collaboration with Mark Redfern, Ph.D. (Biomedical Engineer). Co-Investigators include: Nina Schooler, Ph.D., R. Reddy, M.D., and R. Ganguli, M.D.
- 3. **Phase III - Clinical Trials of New Antipsychotic Drugs**, Special Studies Center, Mayview State Hospital and Western Psychiatric Institute and Clinic, Pittsburgh, PA. Since, I accepted a faculty position in 1991, this 24 bed inpatient unit

is my main clinical and research responsibility, and I share the responsibility for half the patients. The unit is a joint collaborative project between the University of Pittsburgh and the Commonwealth of Pennsylvania. I am currently involved either as a Co-Principal or Co-Investigator with Dr. Nina Schooler, in various Phase III Clinical Drug Trials. This was a site in the Kane et al, 1988 Clozapine Study, and the North American Risperidone Study- Chouinard et al., 1993, and Marder & Meibach, 1994. Since my involvement in the Risperidone Study, we have also conducted trials of Olanzapine, Sertindole (two studies), in addition to having patients on long-term open label extension studies involving both drugs. We have an ongoing Seroquel study for treatment-refractory schizophrenia.

4. **New Antipsychotic Drugs: Clinical Trials and Naturalistic Follow-Up** (P.I. Dr. Nina Schooler) This NIMH funded study, is a continuation of a previous 4 year double-blind study comparing clozapine and haloperidol, except this study will compare clozapine and risperidone for patients with schizophrenia who do not meet "treatment-refractory" criteria. I am a Co-Investigator in this study which will accrue patients in 3 sites (New York - John Kane, M.D., Steve Marder, M.D.- Los Angeles and Pittsburgh) starting April 1995. In addition to traditional efficacy and adverse effect measures, the study will also focus on negative symptoms, cognitive functioning, and social adjustment outcomes.
5. **Stanley Center for the Innovative Treatment of Bipolar Disorders.** In July 1995, I started work in this project (P.I. and Director - Dr. David J. Kupfer) whose twin goals are to create a registry for Bipolar Patients in Southwestern Pennsylvania, and to undertake innovative pharmacological treatment trials of new agents for patients with Bipolar disorder. In addition to my role in expanding the recruitment and consultative aspects of the Registry, I will be involved in conducting the Stanley Clinical Trial Protocols, and designing innovative pharmacological protocols for Bipolar disorder. I helped write a protocol that has developed into a Lilly-sponsored trial comparing the atypical antipsychotic drug (olanzapine) vs. placebo for Bipolar I mania. The acute 3 week trial has a one year extension to evaluate if this drug will serve as a mood stabilizer. I am the principal investigator on this project. I am a co-investigator in two Inositol protocols: a) Inositol (up to 12 Gm/day) for breakthrough depression that occurs during lithium prophylaxis of Bipolar patients and b) Inositol (up to 12 Gm/day) for lithium-induced side effects. I am also a co-investigator on the moclobemide vs placebo in bipolar depression and citalopram vs. placebo in bipolar depression studies.
6. **Instrumental Quantification of Tremors.** Based on my collaboration with Mark Redfern, Ph.D., at the Human Motion and Balance Laboratory of the Eye and Ear Institute, we plan to develop a user-friendly, portable system of objective and reliable tremor measurement for use in psychiatric and neurologic clinics. The eventual objective is to develop a system that allows immediate analyses of the tremor using a virtual instrument interface such that the treatment of tremors, or the early recognition of tremors, or progression of diseases associated with tremor can be measured reliably and quickly. Additional collaborations will involve the Movement Disorders Clinic, UPMC (Dr. Baser), and the Department of Industrial Engineering (Dr. Biddanda). Funding is being sought from the Ben Franklin Technology Center of Western Pennsylvania.
7. **Preliminary Psychopharmacology Studies Relating to Antipsychotic Drug Trials:**

Radio-Receptor Assays: based on limited industry (Lilly Research Labs) funding, I have proposed the use of radio receptor binding assays to examine the affinity of fixed doses of olanzapine to D₂ receptors, and also to examine if these affinities predict clinical outcome in the context of a double-blind clinical trial. Clinical samples have been collected, and the assay is being optimized in the Neurochemistry and Neuropharmacology Laboratories of the VA Hospital, Highland Drive, Pittsburgh (Director: Dr. Jeff Yao, Ph.D. - is the main collaborator on this project). By using transfected cell-lines that express individual subtypes of receptor population (D₂ - cell-lines courtesy of Dr. H. van Tol, University of Toronto, Clarke Institute of Psychiatry), we may be able to minimize some of the sensitivity and specificity problems that were associated with older radioreceptor assays. If successful, we propose to extend these investigations to clozapine/risperidone studies, and to examine ratios of receptor binding, i.e. 5-HT₂/D₂, D₄/D₂ etc. to predict efficacy, and adverse effects. It is possible that "bioavailable free drug" measured by the RRA is a better indicator of specific receptor occupancy in the brain than traditional HPLC measures. Eventually the RRA measures can be correlated with

PET studies when specific ligands are available.

Norepinephrine and its relationship to positive and negative symptoms in patients receiving clozapine and risperidone. In this proposal, I hope to examine the relationship between the increases in plasma norepinephrine noted with clozapine in the context of a 6 month NIMH funded longitudinal study (see 7 above), and its relationship to primary negative symptoms. Dr. Jeffrey Yao at the VA Hospital is our main collaborator on this project too (HPLC measurements). There is impressive evidence for the interactions between norepinephrine and the dopamine neuronal systems, and the modulatory role of norepinephrine (Hornykiewicz O, 1982, and Antelman et al., 1978, 1994). We hypothesize that antipsychotic drugs with powerful effects not only on dopaminergic systems but also on the norepinephrine system are more likely to be effective in ameliorating positive and negative symptoms.

Descriptive Studies related to the use of Atypical Antipsychotic Drugs Among clozapine- treated patients, we have examined the prevalence of akathisia and tardive dyskinesia (published), obsessive-compulsive symptoms (published), weight gain and treatment of gastrointestinal symptoms (published), impact on seclusion/restraints (manuscript in preparation), use in severe self-mutilation in a patient with borderline personality disorder (published), clozapine-associated pancreatitis (published), clozapine-induced agranulocytosis and its treatment with G-CSF (published). We evaluated the impact of olanzapine on obsessive-compulsive symptoms; and on mood symptoms (published).

SERVICE:

Administrative:

1990	Member, Brain Behavior and Immunity Center, University of Pittsburgh and Carnegie Mellon University
1991	Member, Dean's Committee on Mayview State Hospital
1991	Member, WPIC/Mayview State Hospital Special Studies Center Committee for Collaborative Studies and Research
1994-96	Chair, Mayview State Hospital Committee on the Current Role of Polypharmacy in Psychiatry
1994	Member, Mayview Committee for Policy on Seclusions/Restraints
1995	Faculty Member, Stanley Center for the Innovative Treatment of Bipolar Disorders - Clinical Trials Group.
1996	Quality and Research Advisor, Committee to Restructure Mayview State Hospital Admission Units to 60 Day Length of Stay Units.
1996	Member, APA Task Force and Conference on Methods in Outcome Measurements. Section on Adverse Effects (Section Chair - Dr. Schooler).
1997	Member, Mayview State Hospital Review Board for the Protection of Human Subjects Participating in Research Studies.
1997	Member, Mayview State Hospital Pharmacy and Therapeutics Committee.

Clinical Responsibilities:

- 1990-1995 Clinical and Research Responsibility for approximately 60 patients (outpatients and partial hospital) at the Schizophrenia Treatment and Research Center, WPIC. Supervision of half the caseloads of two clinicians, and selected patients of two other clinicians
- 1991-Current Clinical responsibility for 12 patients on the 24-bed Special Studies Center at Mayview State Hospital - A joint collaborative effort of the University of Pittsburgh and the Commonwealth of Pennsylvania
- 1991-Current Clinical and Research evaluative responsibility for patients at the Special Studies Center Mayview State Hospital and at the Schizophrenia Treatment and Research Center, WPIC, enrolled in Clinical Drug Trials
- 1991-Current WPIC - 9th Floor Schizophrenia Module Inpatient coverage (weekends and holidays)
- 1991-Current Providing Second Opinions to other Psychiatrists in Mayview State Hospital, and to elected cases from other State Hospitals in Western Pennsylvania.
- 1993 WPIC - 9th Floor Schizophrenia Module Inpatient Attending for two months in 1993. Clinical responsibility for 15 patients.
- 1995-Current Clinical and Research Responsibility for participants in the Stanley Center for the Innovative Treatment of Bipolar Disorders - Inositol for Bipolar Depression, and Inositol for Lithium-Induced Side-Effects.
- 1995-Current WPIC - 7East Neuropsychiatry Inpatient Unit. Weekend coverage

Community Activities:

- 1993 Speaker at the Clozapine Update 1993 educational activity through the Office of Educational and Regional Planning (OERP), Western Psychiatric Institute and Clinic (February 11, 1993)
- 1993 Participant and Speaker in a conference organized by the National Alliance of the Mentally Ill (NAMI) entitled "We Are Not Alone", Pittsburgh, PA
- 1994 Guest Speaker: Risperidone - Theoretical Issues & Clinical Considerations. Northern Southwest Community MH/MR, Pittsburgh, PA; Aliquippa Mental Health Services, Aliquippa, PA, and Latrobe Hospital, Latrobe, PA, Westmoreland Hospital, Westmoreland, PA
- 1995 Speaker at the Antipsychotic Medications in the '90's Teleconference, Office of Educational and Regional Planning (OERP), Western Psychiatric Institute and Clinic (January 9, 1995)
- 1995 Speaker at the Treatment Challenges In Schizophrenia educational activity through the Office of Educational and Regional Planning (OERP), Hidden Valley, PA (February 4, 1995)
- 1995 Guest Speaker - Erie County Mental Health Services, Northern Southwest Communities MH/MR, Pittsburgh, Familias (Allegheny East MH/MR, Pittsburgh), Washington Hospital, Washington, PA, Mayview State Hospital - Fall Family Workshop - Re: the setting up of the Stanley Center for Bipolar Disorders (Summer and Fall 1995)

1996 Speaker at Westmoreland Hospital, Bipolar Illness, May 1996 (Providers). Speaker at New Castle, PA, Bipolar Screening Day, May 1996 (Patients and Families).

Continuing Medical Education (CME) Activities:

<i>Year</i>	<i>Activity, Sponsor, and Location</i>	<i>Category A Credits</i>
1997	Treatment from the Bedside to the Bench and Back sponsored by Mount Sinai Medical Center	24.0
1997	NCDEU 1997 sponsored by the National Institutes of Health	21.0
1997	Second International Conference on Bipolar Disorder sponsored by Western Psychiatric Institute & Clinic, University of Pittsburgh Medical Center	20.0
1997	The Neurobiology of Schizophrenia Conference sponsored by Western Psychiatric Institute & Clinic, University of Pittsburgh Medical Center	6.0
1996	13th Annual "Pittsburgh Schizophrenia" Conference sponsored by Western Psychiatric Institute & Clinic, University of Pittsburgh Medical Center	6.0
1996	Linking Mayview and the Community: The Influence of New Treatments sponsored by Western Psychiatric Institute & Clinic, University of Pittsburgh Medical Center	3.0
1996	Treatment Advances in Mental Health Practice sponsored by Western Psychiatric Institute & Clinic, University of Pittsburgh Medical Center	4.0
1996	7th Annual Neuropsychiatry Conference sponsored by Western Psychiatric Institute & Clinic, University of Pittsburgh Medical Center	6.0
1996	New Treatments in Bipolar Disorder sponsored by Western Psychiatric Institute & Clinic, University of Pittsburgh Medical Center	2.5
1996	New Clinical Drug Evaluation Unit Annual Meeting sponsored by National Institute of Mental Health	16.5
1996	Evaluating Thyroid Status sponsored by The University of Pittsburgh Medical Center	0.5
1995	Treatment Challenges in Schizophrenia sponsored by Western Psychiatric Institute & Clinic, University of Pittsburgh Medical Center	5.0
1995	Depot Neuroleptic Medications Teleconference (Mayview State Hospital) sponsored by Interactive Medical Network, Westcott Communications	1.0
1995	New Clinical Drug Evaluation Unit (NCDEU) Annual Meeting sponsored by National Institute of Mental Health	8.0

1995	Twelfth Annual Pittsburgh Schizophrenia Conference sponsored by Western Psychiatric Institute & Clinic, University of Pittsburgh Medical Center	6.0
1995	Overview of Common Medical Problems in Psychiatric Patients sponsored by Western Psychiatric Institute & Clinic, University of Pittsburgh Medical Center	6.0
1994	Methods in Biological Psychiatry Research held at NIMHANS, Bangalore, India sponsored by Western Psychiatric Institute & Clinic, University of Pittsburgh Medical Center	10.0
1994	Applications of PET in Psychiatry sponsored by Western Psychiatric Institute & Clinic, University of Pittsburgh Medical Center	1.5
1994	Extending Successful Outcomes: Deinstitutionalizing the Long-Term Patient (Mayview State Hospital) sponsored by Interactive Medical Network, Westcott Communications	1.5
1994	Advances in the Treatment of Psychosis: Clinical Management of Negatives (Mayview State Hospital) sponsored by Interactive Medical Network, Westcott Communications	1.0
1994	New Clinical Drug Evaluation Unit Program 34th Annual Meeting, Marlo Island, FL sponsored by National Institute of Mental Health	18.0
1994	First International Conference on Bipolar Disorder sponsored by Western Psychiatric Institute & Clinic, University of Pittsburgh Medical Center	14.0
1994	Advances in the Treatment of Psychoses: Medication Dosing Strategies (Mayview State Hospital) sponsored by Interactive Medical Network, Westcott Communications	1.0
1994	11th Annual Pittsburgh Schizophrenia Conference: Latest Developments in the Treatment of Schizophrenia sponsored by Western Psychiatric Institute & Clinic, University of Pittsburgh Medical Center	6.5
1994	Antipsychotic Medications in the 90s Teleconference sponsored by Western Psychiatric Institute & Clinic, University of Pittsburgh Medical Center and Mayview State Hospital	3.0
1994	Bipolar Disorder Teleconference sponsored by Interactive Medical Network, Westcott Communications	1.0

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Classification
MEDICAL PHYSICIAN AND SURGEON

Certificate Number	Certification Date	Issued	Expires
REDACTED	SEP 07 1989	OCT 12, 1996	DEC 31 1998

Signed To:

K.N. Chengappa
Signature
KADIAMADA NANALAH CHENGAPPA
REDACTED

Dorothy Childress
Commissioner of Professional and Occupational Affairs

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Classification
MEDICAL PHYSICIAN AND SURGEON

Certificate Number	Certification Date	Issued	Expires
REDACTED	SEP 07 1989	OCT 03 1998	DEC 31 2000

Issued To:

K. V. Chengappa
Signature
Dorothy Childress
Commissioner of Professional and Occupational Affairs

KADIAMADA NANALAH CHENGAPPA
REDACTED

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CURRICULUM VITAE

Kathleen A. Clegg, M.D.

Biographical

Date of Birth:	November 27, 1959
Birthplace:	Philadelphia, Pennsylvania
Citizenship:	USA
Social Security:	REDACTED
Address:	REDACTED
Telephone:	Office: 847-5461
	Home: REDACTED

Education and Training

Undergraduate

9-77-5-81	University of Michigan Ann Arbor, Michigan	B.S.N. Nursing Summa cum Laude
9-82-6-85	University of Cincinnati Cincinnati, Ohio	Pre-medical

Graduate

9-85-5-89	Case Western Reserve University	M.D.

Post-graduate

7-89-9-90	CWRU- University Hospitals of Cleveland Dept. of Psychiatry Cleveland, Ohio	Internship
10-90-1-94	CWRU- University Hospitals of Cleveland Dept. of Psychiatry Cleveland, Ohio	Residency

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Kathleen A. Clegg, M.D.

Current Position

2/94-present

CWRU/Dept. of Psychiatry

Faculty, Senior Instructor

Licensure

- State of Ohio license REDACTED
- Board eligible in Psychiatry, examination date Oct., 1994
- DEA number available on request
- Diplomate FLEX, Dec., 1990

Publications

Campbell, J., Winger, J., Mader, S., Zyzanski, S., Alptner, M., Clegg, K. Past and Present Alcoholism Assessed by the Michigan Alcoholism Screening Test in Elderly Veterans. The Southwestern Journal on Aging. 6 (1), Summer, 1990.

Professional/Teaching Activities

- Member, American Psychiatric Association
- Member, Committee on Psychiatric Resident education, 1992-93
- PGY-4 representative, Residency council, 1992-93
- Out patient medical student supervisor, 1993-94
- Co-facilitator for CWRU Mind committee small group discussions, 1993
- Participant in 'Matters of the Mind', Medical Student Psychiatry interest group
- Clinical supervisor in various community mental health agencies
- Group facilitator, Core Physician Development Program, CWRU School of Medicine 1994-95

Honors

- Graduated Summa cum laude from The University of Michigan, 1981
- Member, Sigma Theta Tau, National Nursing Honor Society
- CWRU Medical student clerkship, awarded 'Honors' in: Psychiatry, Pediatrics and Obstetrics/Gynecology

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KATHLEEN ANNE CLEGG, MD

is duly registered and entitled to practice in The State of Ohio
until the expiration date

AUDIT # : 087314

Cal K. Cohn, M.D.
7777 Southwest Freeway #1036
Houston, Texas 77074

CURRICULUM VITAE

PERSONAL HISTORY:

Date of Birth:	November 20, 1942
Birthplace:	Brooklyn, New York
Marital Status:	Married, two children
Military Service: 1969-1971	USPHS-NIH, Research Associate, Laboratory of Pharmacology, (Dr. Julius Axelrod)

EDUCATION:

M.D., 1967	Cornell University Medical College, New York, New York (1963-1967)
B.A., 1963	Columbia University, New York, NY Major: Zoology
High School, 1959	Bronx High School of Science Bronx, New York
Postgraduate Training:	
1967-1968	Internship, Internal Medicine Cornell-New York Hospital, New York, NY
1968-1969	Residency, Internal Medicine Cornell-New York Hospital New York, NY
July 1968- December 1968	Guest Investigator, Department of Metabolism and Human Behavior Rockefeller University, New York, NY (Joint-Appointment)
1973-1975	Resident, Psychiatry, University of Pennsylvania, Philadelphia, Pennsylvania

PROFESSIONAL ASSOCIATION:

1977- present Private Practice of Psychiatry
Houston, Texas

BOARD CERTIFICATION:

1976 Diplomate, American Board of Psychiatry and Neurology
(Psychiatry)

FELLOWSHIPS:

1965 Summer Fellowship, Physiology Course, Marine Biological
Laboratory, Woods Hole, Mass., (included (Supervisor Professor
Hans Kornberg, F.R.S.)

1964 National Science Foundation Summer Fellowship to Worcester
Foundation for Experimental Biology; Laboratory of Dr. Oscar
Hechter

1963 National Science Foundation Summer Fellowship to Worcester
Foundation for Experimental Biology, Shrewsbury, Mass.;
Laboratory of Dr. Oscar Hechter

ACADEMIC APPOINTMENTS

1993 - present Clinical Professor Psychiatry and Behavioral Sciences
University of Texas Medical Branch, Galveston, Texas

Clinical Professor Psychiatry
University of Texas Medical School, Houston, Texas

1977 - 1993 Clinical Associate Professor Psychiatry
University of Texas Medical School, Houston, Texas

1981 - present Clinical Assistant Professor Family Practice, University of Texas
Medical School, Houston, Texas

*Col K. Cohn, M.D.
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1986-1990	Adjunct Associate Professor of Psychiatry in Psychology, University of Houston, Houston, Texas
1977-1980	Assistant Clinical Professor, Psychiatry, Baylor College of Medicine, Houston, Texas
1975-1977	Director, Inpatient Psychiatry Unit, University of Texas Medical School, Houston, Texas
1972-1973	Assistant Professor Neuro-Chemistry, Department of Metabolism and Human Behavior, Rockefeller University, New York, NY (Dr. Jules Hirsch)
1971-1973	Senior Associate Physician, Rockefeller University New York, New York
1971-1972	Research Associate, Department of Metabolism and Human Behavior, Rockefeller University, New York, New York

OTHER APPOINTMENTS:

1996	Board of Medical Directors, Garden Village Retirement and Assisted Living Community
1993	Chairman, Psychiatry Section, Memorial Hospital Southwest Houston, Texas
1982 - present	Founder and Director, Affective Disorders Unit, Memorial Hospital Southwest, Houston, Texas
1979-1981	Chairman, Psychiatry Section Memorial Hospital Southwest, Houston, Texas
1971-1973	Seminar Associate in Appetitive Behavior Columbia University, New York, New York
1969-1971	Research Associate, Laboratory of Pharmacology, National Institute of Health, Bethesda, Maryland (Dr. Julius Axelrod) (USPHS: LT CDR)

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Revised 5-7-97*

**PROFESSIONAL
COMMITTEES:**

1993 - present	Chairman Impaired Physician Committee Memorial Hospital Southwest, Houston, Texas
1989 - 1993	Impaired Physician Committee, Memorial Hospital Southwest Houston, Texas
1989 - present	Bio-Medical Ethics Committee, Memorial Hospital Southwest Houston, Texas
1989 - present	Pastoral Care Committee, Memorial Hospital System Houston, Texas
1987-1991	Chairman, Institutional Review Committee, Memorial Hospital System, Houston, Texas

**MEMBERSHIPS AND
HONORARY SOCIETIES:**

New York Academy of Science
The Harvey Society
Sigma Xi
American Federation for Clinical Research
American Academy of Clinical Psychiatrists
Academy of Psychosomatic Medicine
Southwest Scientists Forum
American Medical Association
Harris County Psychiatric Society (1977 - 1995)
American Academy of Psychiatry and the Law

AWARDS AND MEMBERSHIPS:

Greater Houston Chamber of Commerce Nominee for Innovate Houston Award, 1988
Member, Medical Advisory Board, Depressive and Manic Depressive Association of
Harris County, 1990 Award
National Alliance for the Mentally Ill, Exemplary Psychiatrist Award, 1996

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Revised 5-7-97*

PUBLICATIONS

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- Cohn CK, Shrivastava R, Mendels J, Cohn JB, Fabre LF, Claghorn JL, Dessain EC, Itil TM, Lantin A: Double-blind, multicenter comparison of sertraline and amitriptyline in elderly depressed patients. *Journal Clinical Psychiatry* 1990: 51:12 (supplement B).
- Reimherr FW, Chouinard G, Cohn CK, Cole JO, Itil TM, LaPierre YD, Masco HL, Mendels J: Antidepressant efficacy of sertraline: a double-blind, placebo and amitriptyline-controlled, multicenter comparison study in out patients with major depression. *Journal Clinical Psychiatry* 1990: 51:12 (supplement B).
- Dunner DL, Cohn JB, Walsh T, Cohn CK, Feighner JP, Feive RR, Halikas JP, Hartford JT, Hearst ED, Settle EC, Menolascino FJ, Muller, DJ: Two combined, multicenter double-blind studies of paroxetine and doxepin in geriatric patients with major depression. *Journal of Clinical Psychiatry* 1992: 53:1(supplement).
- Shrivastva RK, Cohn CK et al: Long-term safety and clinical acceptability of venlafexine and imipramine in outpatients with major depression. *Journal of Clinical Psychopharmacology*. In press.

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Cohn CK, Robinson DS, Roberts DL, Schwiderski U, O'Brien, Ieni J et al: Responders to antidepressant drug treatment: A study comparing nefazodone, imipramine, and placebo in patients with major depression. *Journal of Clinical Psychopharmacology*. In press.

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Hechter O, Yoshinaga K, Cohn CK, Dodd P, Halkerston IDK: In vitro stimulatory effects of nucleotides and nucleosides on bio-synthetic process in castrated rat uterus. *Federation Proceedings*: April 1965.

Weiss J, Cohn CK, Chase T: Catechol-o-methyltransferase, reduction by chronic L-Dopa therapy. *The Society of Neuroscience, First Annual Meeting*, October 1971.

Cohn CK: A case of "Pseudo-Tardive Dyskinesia". *American Journal Psychiatry* 1974: 121:1045.

Cohn CK: Post Trauma Syndrome. *Third World Congress of Biological Psychiatry*, June 1981, Stockholm, Sweden.

Schwiderski U, Cohn CK, Roberts D, Copp J, Smith J, Robinson D: The Tridimensional Personality Questionnaire as a Predictor of Outcome in a Randomized Trial of Nefazodone, Imipramine and Placebo in Depression. For presentation at the American Psychiatric Association Annual Meeting on May 11-16, 1991, in New Orleans, Louisiana.

Dunner D, Boyer W, Cohn CK, Cohn J, Feighner J, Fieve R, Halikas J, Hartford J, Hearst E, Menolascino F, Muller D, Settle E, Walshe T: Paroxetine versus Doxepin in Elderly Depressed Patients: Combined Data from Two Multicenter, Double-blind Studies. For presentation at the American Psychiatric Association Annual Meeting on May 11-16, 1991 in New Orleans, Louisiana.

Cohn CK, Houston, Texas, USA, et al: Double-blind, Multicenter Comparison of Sertraline and Amitriptyline in Elderly Depressed Patients. For presentation at the Meeting of the World Congress of Biological Psychiatry, June 1991.

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Reimherr FW, Chouinard G, Cohn CK, Cole JO, Itil TM, LaPierre YD, Masco HL, Mendels J: Antidepressant efficacy of sertraline: a double-blind, placebo and amitriptyline-controlled, multi-center comparison study in out patients with major depression. For presentation at the Meeting Congress of Biological Psychiatry, June 1991.

Shrivastava RK, Cohn C, Crowder J, Davidson J, Dunner D, Feighner J, Kiev A, Patrick R: Double blind, long-term safety and clinical acceptability study of venlafaxine and imipramine in outpatients with major depression. For presentation at the ACNP meeting in Puerto Rico, December 13-18, 1992.

Cohn, C, Houston, Texas USA: Gepirone Extended Release (ER) Treatment of Outpatients with Major Depression - A Dose Response Study. For presentation at the 20th CIMP Congress, Melbourne, Australia, June 23 - June 27, 1996.

BOOKS AND CHAPTERS IN BOOKS:

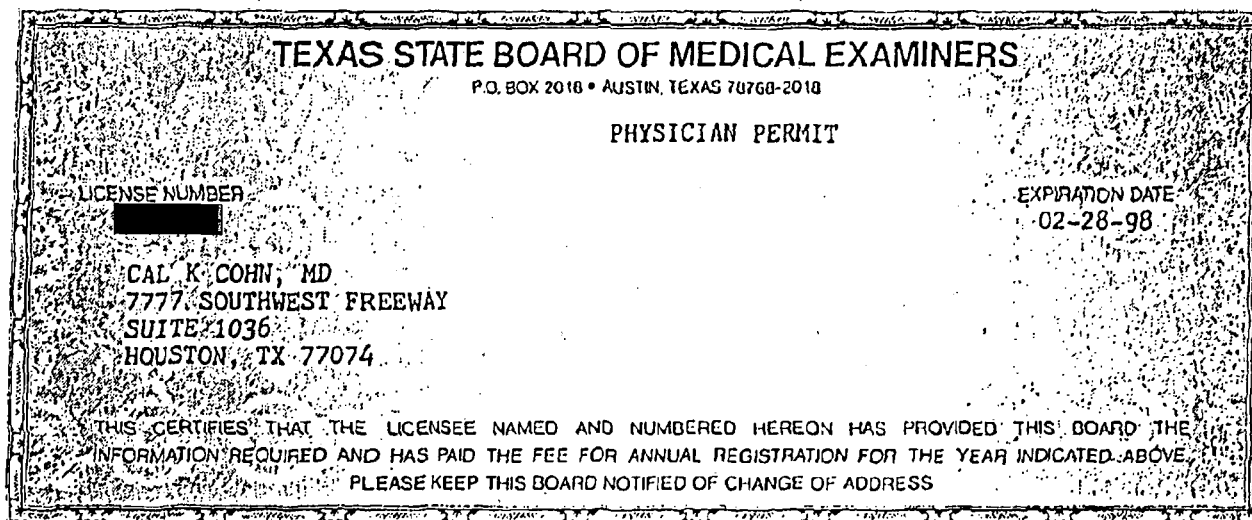
Vincent KR, Castillo I, Hauser RI, Zapata JA, Stuart HJ, Cohn CK, O'Shanick GJ: MMPI-168 Codebook, Ablex Publishing Company, Norwood, New Jersey, 1984.

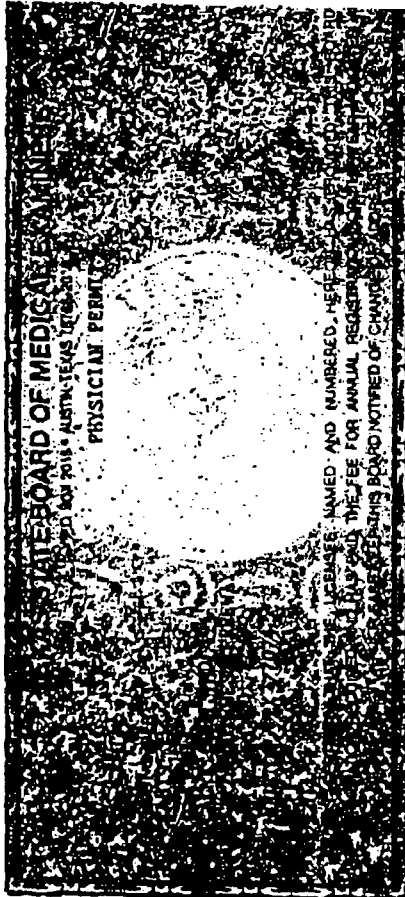
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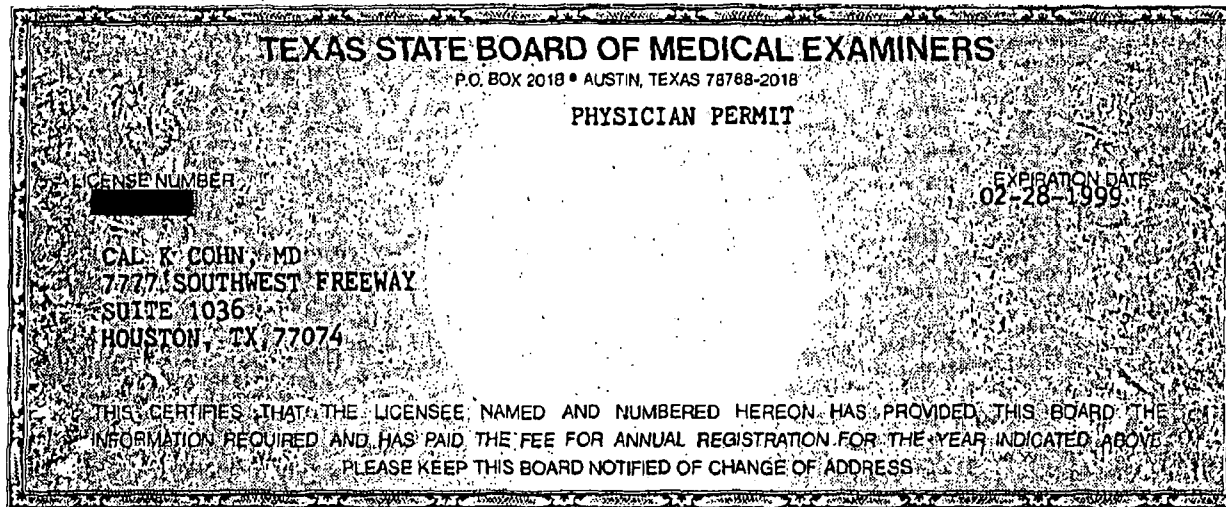


4/2/98

Jennie,

This is Dr. Colon's license - FAXED
it's illegible - I'll get
a new one @ my next
visit.

Lita



CURRICULUM VITAE

July 25, 1997

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Date of Birth: May 26, 1956

Social Security No: REDACTED

Education

Undergraduate:

9/73 - 6/77 Johns Hopkins University
Baltimore, Maryland
B.A. with General Natural Sciences and Departmental Honors

Graduate:

9/77 - 1/81 University of Maryland at Baltimore
School of Medicine
Baltimore, Maryland
John M. Dennis, M.D.
Doctor of Medicine

Post-Graduate:

6/81 - 6/82 Western Psychiatric Institute & Clinic
University of Pittsburgh
School of Medicine
Pittsburgh, Pennsylvania
Peter Henderson, M.D.
Internship/Psychiatry & Medicine

6/82 - 6/84 Western Psychiatric Institute & Clinic
University of Pittsburgh
School of Medicine
Pittsburgh, Pennsylvania
Peter Henderson, M.D.
Resident/General Psychiatry

7/84 - 7/85 Western Psychiatric Institute & Clinic
University of Pittsburgh
School of Medicine
Pittsburgh, Pennsylvania
Peter Henderson, M.D.
Chief Resident in Psychiatry

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Certification

1987 American Board of Psychiatry & Neurology

Licensure

1983 Medicine and Surgery
Commonwealth of Pennsylvania

1989 Medical Physician & Surgeon
State of Maryland

Major Research Interests

-Schizophrenia -Neuropathology
-Brain Imaging -Bioethics

Faculty Positions

7/84 - 7/85 St. Margaret's Family Practice Program
St. Margaret's Memorial Hospital
Pittsburgh, Pennsylvania
Instructor/Leader of Balint Seminar

7/85 - 11/86 Western Psychiatric Institute & Clinic
University of Pittsburgh
School of Medicine
Pittsburgh, Pennsylvania
Clinical Instructor in Psychiatry

11/86 - 11/87 Western Psychiatric Institute & Clinic
University of Pittsburgh
School of Medicine
Pittsburgh, Pennsylvania
Adjunct Instructor in Psychiatry

11/87 - 3/89 Western Psychiatric Institute & Clinic
University of Pittsburgh
School of Medicine
Pittsburgh, Pennsylvania
Assistant Professor in Psychiatry

3/89 - Present University of Maryland at Baltimore
Baltimore, Maryland
Assistant Professor

Major Academic Tasks

7/87 - 3/89 Mayview State Hospital
Bridgeville, Pennsylvania 15017
Director of Research

3/89 - Present Maryland Psychiatric Research Center
Baltimore, Maryland
Director, Treatment Research Unit

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7/93 - 6/96

Institutional Review Board
University of Maryland at Baltimore
Baltimore, Maryland
Chairman

Professional Memberships

1980 - Present	American Association for the History of Medicine
1990 - Present	Forensic Society
1994 - Present	Society For Neuroscience

Honors and Awards

1976	Elected to Alpha Omega Premedical Honor Society
1977	Honors in Biology and History of Science, The Johns Hopkins University
1977	Graduation with General Honors, The Johns Hopkins University
1980	Elected to Alpha Omega Alpha Medical Honor Society
1981	William Alexander Hammond Award for Excellence in Neurology, University of Maryland, School of Medicine
1984	Laughlin Award for Merit, National Psychiatric Endowment Fund Fellow
1987	Young Investigator Award, presented by the International Congress on Schizophrenia
1987	Medical Services Award, Mayview State Hospital
1988	Achievement Award, Pennsylvania Alliance for the Mentally Ill
1996	The Walter Weintraub Teacher of the Year, Psychiatry Resident's Association of The University of Maryland Medical System

Editorial Tasks

Reviewer, Journal of Nervous and Mental Disorders
Reviewer, Psychiatry Research
Reviewer, Psychiatric Services
Reviewer, The Journal of clinical Psychiatry
Reviewer, Archives of General Psychiatry

Major Consultantships

Local

1989 - present	University of Maryland at Baltimore, Baltimore, Maryland
1989 - present	Spring Grove Hospital Center, Baltimore, Maryland
1990 - present	Walter P. Carter Center, Baltimore, Maryland
1990 - present	Clifton T. Perkins, Baltimore, Maryland

National

1989 - Present	Sandoz Pharmaceuticals
1991 - Present	Zeneca, Inc.
1993 - Present	Robert Wood Johnson Foundation
1992 - Present	Abbott Laboratories
1992 - Present	UpJohn
1994 - Present	Janssen

Campus Activities

1989 - present	Research Committee, Spring Grove Hospital Center
1993 - 1996	Education Research Committee, University of Maryland at Baltimore
1992 - 1996	Institutional Review Board, University of Maryland at Baltimore

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Teaching Responsibilities

Current - University of Maryland at Baltimore

1989 - present	PGY I, Psychopharmacological, Introduction (18 residents)
1989 - present	PGY III, Psychopharmacological, Advanced (18 residents)
1989 - present	Clinical Case Conference

Current - Sheppard & Enoch Pratt Hospital Center

1989 - present	PGY II & III, Neuroscience (20 residents)
1989 - present	Clinical Case Conference

Current - Walter P. Carter Center

1989 - present	Clinical Case Conference

Past - University of Pittsburgh, School of Medicine

1985 - 1989	Director of Balint Seminars (50 family practice & psychiatry residents)

Grant Support

Principal Investigator

Current

Multicenter, Double-Blind, Randomized, Comparison of the Safety and Efficacy of Sertindole and Risperidone in Treatment Resistant Schizophrenic Patients, Abbott Laboratories, 5/1/96-4/30/97.

New Atypical Neuroleptic Strategies in Schizophrenia, National Institute of Mental Health, MH47311, 4/1/97-3/31/2001.

Completed

New Atypical Neuroleptic Strategies in Schizophrenia: L-745,870 (A Double-Blind, Placebo-Controlled, Safety, Tolerability Hospitalized Schizophrenic Patients), Merck Sharp & Dohme, Completed 1996.

A Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of Sertindole in Schizophrenic Patients, Abbott Laboratories, Carol Tamminga, M.D., P.I., Completed 1994.

Psychoactive Substance Use Assessment in Schizophrenia, Scottish Rite, completed 1995.

Psychoactive Substance Use Assessment in Schizophrenia, NARSAD Young Investigator Award, completed 1995.

Evaluation of Clozapine Effects on Dopamine and Serotonin Receptors, Scottish Rite, completed 1995.

Evaluation of Clozapine Effects on Dopamine and Serotonin Receptors, NARSAD Young Investigator Award, completed June 1994.

Multicenter, Placebo-Controlled, Double-Blind Safety and Efficacy Evaluation of ICI 204,636 in Hospitalized Patients with Acute Exacerbation of Chronic or Subchronic Schizophrenia, Zeneca Pharmaceutical, completed 1994.

High vs. Low Dose Remoxipride in Schizophrenia, Merck Sharp & Dohme, 2/90 - 12/93.

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Multi-Center, Randomized, Double-Blind, Positive Controlled, 4 Week, Multiple Oral Rising Dose Study to Determine Safety, Tolerability, Pharmacokinetics and Behavioral Activity of RWJ-37796 in Male Schizophrenic Subjects, The R.W. Johnson Pharmaceutical Research Laboratories, completed December 1993.

Co-Principal Investigator

Clinical Research Center: Classification and Course of the Schizophrenia, NIMH, 5P50 MH 40279, William T. Carpenter, M.D., P.I., 02/15/86 - 07/31/98.

(S)-3-(3-Hydroxyphenyl)-N-propylpiperidine Hydrochloride (-3PPP) as Treatment for Neuroleptic-induced Parkinsonism and Akathisia in Schizophrenia, Carol Tamminga, M.D., P.I., 1992-1995.

Serotonin Receptors in Teenage Suicide and Their Families, NIMH, MH 48153, Ghanshyam Pandey, Ph.D., P.I., 4/1/92 - 3/31/96.

Publications

Chapters

Tamminga CA, Shirakawa O, Conley RR: Nontarget Actions of Neuroleptics. In Brunello N, Mendlewicz J, Racagni G, eds. New Generations of Antipsychotic Drugs: Novel Mechanisms of Action. Int. Acad. Biomed. Drug Res., Basel, Karger, Vol 4, pp. 67-76, 1993.

Carpenter WT, Conley RR: "Therapeutic Approaches to Negative Symptoms". In Greden JF, Tandon R, eds. Negative Schizophrenic Symptoms: Pathophysiology and Clinical Implications. Progress in Psychiatry, Series Number 28; 205-214, 1991.

Schulz SC, Kahn EM, Baker RW, Conley RR: "Lithium and Carbamazepine Augmentation in Treatment Refractory Schizophrenia". In Angrist B, Schulz SC, eds. The Neuroleptic-Nonresponsive Patient: Characterization and Treatment. Progress in Psychiatry, Series Number 27:111-136, 1990.

Schulz, SC, Conley RR, Kahn EM, Nonresponders to neuroleptics: a distinct subtype. In: Schulz SC, Tamminga CA, eds. Schizophrenia: Scientific Progress. New York, NY: Oxford University Press; 333-340, 1989.

Cohen, RL, Conley RR, Henderson PB: Moonlighting: A Realistic Approach. In Cohen RL, Dulcan MK, eds. Basic Handbook of Training in Child and Adolescent Psychiatry. Springfield, IL: Charles C. Thomas, Publisher; 308-320, 1987.

Journal Articles

Pandey GA, Conley RR, Pandey SC, Goel S, Roberts RC, Tamminga CA, Chute D: Benzodiazepine receptors in the post-mortem brain of suicide victims and schizophrenic subjects. Psychiatry Research, in press.

Ross, DE, Thaker GK, Buchanan RW, Lahti AC, Conley RR, Medoff D: Specific measures account for most of the variance in qualitative ratings of smooth pursuit eye movements in schizophrenia. Arch of Gen Psychiatry, in press.

Kung L, Conley R, Chute DJ, Smialek J, Roberts RC: Synaptic changes in the striatum of schizophrenic cases: a controlled postmortem ultrastructural study. Synapse, in press.

Lahti RA, Roberts RC, Cochrane EV, Primus RJ, Gallager DW, Conley RR, Tamminga CA: Direct determination of dopamine D₂ receptors in normal and schizophrenic postmortem brain tissue: an [³H]NGD-94-1 study. Neuropsychopharmacology, submitted.

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- Conley RR, Carpenter WT, Tamminga CA: Time to response and response-dose in a 12-month clozapine trial. Am J Psychiatry, submitted.
- Kramer M, Last B, and the D₄ Antagonist Study Group (which includes Robert R. Conley): The effects of a selective D₄ receptor antagonist (L-745,870) in acutely psychotic schizophrenic patients. Arch of Gen Psychiatry, submitted.
- Conley R, Love R, Carpenter W: Evaluating ability to consent in psychotic inpatients. Arch of Gen Psychiatry, submitted.
- Conley R, Buchanan R: Evaluation of treatment resistant schizophrenia. Schizophrenia Bulletin, in press.
- Deckelman MC, Dixon LB, and Conley RR: Comorbid bulimia nervosa and schizophrenia. Int J Eat Disord, 22:101-105, 1997.
- Carpenter WT, Conley RR, Buchanan RW, Breier A, Tamminga CA: Clozapine conflict (Letter). Am J Psychiatry, 153(11):1505-1507, 1996.
- Lahti R, Roberts R, Conley R, Cochrane E, Mutin A, Tamminga C: D₂-type dopamine receptors in postmortem human brain sections from normal and schizophrenic subjects. Neuro Report, 7(12):1945-1948, 1996.
- Roberts R, Conley R, Kung L, Peritti F, Chute D: Reduced striatal spine size in schizophrenia: a postmortem ultrastructural study. NeuroReport, 7(6):1214-1218, April 26, 1996.
- Pandey GN, Dwivedi Y, Pandey SC, Goel S, Conley R, and Roberts R: G-proteins in the postmortem brain of suicide victims. European Neuropsychopharmacology, 6:90, 1996.
- Lahti RA, Roberts RC, Conley RR, and Tamminga CA: Dopamine D₂-family receptors in human postmortem brain: comparison of normals and schizophrenics. European Neuropsychopharmacology, 6:173, 1996.
- Carpenter WT, Conley RR, Buchanan RW, Breier A, Tamminga CA: Patient response and resource management: another view of clozapine treatment of schizophrenia. Am J Psychiatry, 152:6, June 1995.
- Lahti RA, Roberts RC, Primus RJ, Gallager DW, Conley RR, and Tamminga CA: Dopamine D₂, D₃, D₄ receptors in human postmortem brain sections: comparison between normals and schizophrenics off and on neuroleptics. American College of Neuropsychopharmacology, 34:255, 1995.
- Tamminga CA, Conley RR, Wong DF: Human Brain Receptors, IV. Human in vivo receptor imaging. Am J Psychiatry, 151(5):639, May 1994.
- Conley RR, Tamminga CA: Remoxipride in resistant schizophrenia. Letter to Editor Arch of Gen Psychiatry, 51(12):1001, 1994.
- Holcomb H, Cascella NG, Medoff DR, Gastineau EA, Loat H, Thaker GK, Conley RR, Dannals R, Wagner H, Tamminga CA: PET-FDG test-retest reliability during a visual discrimination task in schizophrenia. J Comput Assist Tomogr, 17(5):704-709; Sept-Oct 1993.
- Dixon L, DiBietz E, Myers P, Conley R, Medoff D, Lehman A: Comparison of DSM-III-R diagnoses and a brief interview substance use among state hospital patients. Hospital & Community Psychiatry, 44:8, 748-752, August 1993.
- Baker RW, Conley RR: Seizures in clozapine-treated patients (letter). Am J Psychiatry, 148:9, 1265-1266, September 1991.

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- Conley RR, Baker R: Family response to improvement by a relative with schizophrenia. Hospital and Community Psychiatry; 41:898-901, August 1990.
- Kane J, Honigfeld G, Singer J, Meltzer H and the Clozaril Collaborative Study Group (which includes Rober R. Conley): Clozapine for the treatment-resistant schizophrenic. Arch of Gen Psychiatry; 45:789-797, 1998.
- Conley, RR, Schulz SC, Baker R, Collins J, Bell J: Clozapine efficacy in schizophrenic nonresponders. Psychopharmacology Bulletin; 24:269-274, 1988.
- Pigiet VP, Robert R. Conley: Purification of thioredoxin, thioredoxin reductase, and glutathione reductase by affinity chromatography. The Journal of Biological Chemistry; 252:6367-6372, September 25, 1987.
- Pigiet VP, Robert R. Conley: Isolation and characterization of phosphothioredoxin from escherichia coli. The Journal of Biological Chemistry; 253:1910-1920, March 24, 1978.

Abstracts

- Conley R, Richardson C, Tamminga C: Treatment of primary negative symptoms. Biological Psychiatry, 42(1):S204, July 1997.
- Conley RR, Tamminga CA, Beasley C and the Maryland Study Group: Olanzapine vs. chlorpromazine in treatment-resistant schizophrenia. Biological Psychiatry, 41(7):S246, April 1997.
- Conley R, Gounaris C: Demographic differences in olanzapine responders with therapy-refractory schizophrenia. Schizophrenia Research, 24 (1,2):189, March 1997.
- Conley R, Gale E, Hirsch K: Olanzapine response in therapy-refractory schizophrenia with substance abuse (SA). Schizophrenia Research, 24 (1,2):190, March 1997.
- Conley R, Tamminga C, Beasley C: Olanzapine vs. chlorpromazine in therapy-refractory schizophrenia. Schizophrenia Research, 24 (1,2):190, March 1997.
- Lingle J, Peszke M, Kent D, Conley R: The efficacy of olanzapine treatment in patients previously treated with clozapine. Schizophrenia Research, 24 (1,2):190, March 1997.
- Richardson R, Conley R: Olanzapine response in schizophrenic subjects with neuroleptic resistant disorganization. Schizophrenia Research, 24 (1,2):191, March 1997.
- Conley R, Zaremba S, McMullen R, Love R: Evaluating ability to consent in psychotic inpatients. Schizophrenia Research, 24 (1,2):206, March 1997.
- Conley R, Tamminga C, Satterlee W and the Maryland Study Group: Olanzapine vs. Chlorpromazine in Treatment-Resistant Schizophrenia. Society For Neuroscience, 22(1):480, November 1996.
- Conley R, Zhao M, Wong D, Tamminga C: ¹¹C NMSP Receptor occupancy By Clozapine and Haloperidol in Schizophrenic Subjects. Biological Psychiatry, 39(7):514, 1996.
- Daviss S, Conley R: Density and Distribution of Labeled Sub-Populations of Mediodorsal Thalamic Neurons in Schizophrenic and Control Subjects. Schizophrenia Research, 15 (1,2):27, April 1995.

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- Pandey GN, Pandey SC, Conley RR, Roberts R, Tamminga CA: Benzodiazepine Receptors in Human Post-Mortem Brain: Effect of Schizophrenia, Suicide, and Neuroleptic Drug Treatment. Schizophrenia Research, 15 (1,2):68, April 1995.
- Conley R, Medoff D, Wong D, Tamminga C: ¹¹C NMSP Receptor Occupancy By Clozapine and Haloperidol in Schizophrenic Subjects. Schizophrenia Research, 15 (1,2):80, April 1995.
- Gale E, Hirsch K, Kent D, Conley R: Clozapine Response in Treatment Resistant Schizophrenics with Substance Abuse. Schizophrenia Research, 15 (1,2):150, April 1995.
- Conley R, Gounaris C, Zaremba S: RWJ-37796, A Novel Compound in The Treatment of Schizophrenia. Schizophrenia Research, 15 (1,2):152, April 1995.
- Richardson C, Conley R: Clozapine Response in Schizophrenic Subjects with Neuroleptic Resistant Disorganization. Schizophrenia Research, 15 (1,2):162, April 1995.
- Zaremba S, McMullan R, Dorer G, Conley R: Patient Education of Psychotic Subjects to Obtain Informed Consent. Schizophrenia Research, 15 (1,2):223, April 1995.
- Conley R, Richardson C, Kent D, Gounaris C, Zaremba S: Clozapine Response Varies in Deficit vs Non-deficit Schizophrenic Subjects. Biological Psychiatry, 35(9):746, 1994.
- Conley R, Wong D, Urbanska E, Jeffries K, Tamminga C: Striatal Receptor Occupancy with Clozapine vs Haloperidol in Schizophrenia Using PET with ¹¹C-NMSP. Society for Neuroscience, 19(1):857, 1993.
- Conley R, Carlsson A, Lahti A, Tamminga C: The Use of Preclamol (-3PPP) for Neuroleptic Induced Pseudoparkinsonism. Biological Psychiatry, 33:37A-162A, 1993.
- Conley R, Gounaris C, Wong D, Tamminga C: Clozapine vs Haloperidol Dopamine Receptor Occupancy in Schizophrenia by ¹¹C-NMSP PET. Biological Psychiatry, 33:37A-162A, 1993.
- Conley RR, Gounaris GJ, Wong DF, Tamminga CT: D₂ Receptor Occupancy with Clozapine vs Haloperidol in Schizophrenia by ¹¹C-NMSP PET. Schizophrenia Research, 9(2,3):197, 1993.
- Conley R, Schmitt R, Peretti F, Smialek J, Tamminga C: Serotonin Binding Sites in the Brain of Schizophrenic Suicide Victims. Schizophrenia Research, 9(2,3):216, 1993.
- Conley R, Tamminga C, Nguyen JA, Hain R: Remoxipride Therapy in Treatment Resistant Schizophrenia. Schizophrenia Research, 9(2,3):235, 1993.
- Hain R, Nguyen JA, Conley R: Time Course of Clozapine Response. Schizophrenia Research, 9(2,3):237, 1993.
- Dixon L, Thaker G, Conley R, Ross D, Cascella NG, Tamminga CA: Changes in Psychopathology and Dyskinesia After Neuroleptic Withdrawal in a Double-Blind Design. Schizophrenia Research, 10:267-271, 1993.
- Lahti AC, Cascella NG, Conley R, Lahti RA, Carlsson A, Tamminga CA: Pharmacologic Properties and Antipsychotic Effect of (-)-3PPP in Schizophrenic Patients. Schizophrenia Research, 9(2,3):241, 1993.

Robert R. Conley, M.D.

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- Conley R, Nguyen JA, Tamminga C: Haloperidol Kinetics and Clinical Response. Schizophrenia Research, 4(3):287, 1991.
- Dixon L, Thaker G, Cascella N, Conley R, Yablonski M, Tamminga C: Time Course of Psychopathologic and Dyskinetic Motor Changes After Blind Neuroleptic Withdrawal. Schizophrenia Research, 4(3):288, 1991.
- Conley R, Dixon L, Nguyen JA, Tamminga C, Raymond R: Remoxipride Therapy in Poorly Responsive Schizophrenics. Schizophrenia Research, 4(3):316, 1991.
- Raymond R, Conley R, Gounaris C, Medoff D: Identification of Subgroups of Poorly Responsive Schizophrenics. Schizophrenia Research, 4(3):324, 1991.
- Conley R, Peretti F, Smialek J, Stumer W, Schmitt R: Neurologic Sequelae of Psychogenic Polydipsia. Schizophrenia Research, 4(3):376, 1991.
- Conley R, Schmitt R, Pandey GS, Peretti F, Smialek J, Tamminga C: Serotonin Binding Sites and Metabolites in the Brain of Schizophrenic Suicide Victims. Schizophrenia Research, 4(3):376-377, 1991.
- Dixon L, Conley R, Schmitt R, Bartholomew M: Psychoactive Substance Abuse Assessment in Schizophrenics. Schizophrenia Research, 4(3):382, 1991.

Major Invited Speeches

Community Organizations

06/11/90	Alliance for the Mentally Ill, Catonsville, Maryland
02/16/94	National Alliance for the Mentally Ill, Baltimore, Maryland
04/27/94	Alliance for the Mentally Ill, Howard County, Maryland

Conferences

- Conley R, Tamminga C, Beasley C, and the Maryland Study Group: Olanzapine in Treatment-Resistant Schizophrenia. presented at the American College of Neuropsychopharmacology Annual Meeting, San Juan, Puerto Rico, December 1996.
- Conley R, Love R: Evaluating Ability To Consent In Psychotic Inpatients, presented at the New Clinical Drug Evaluation Unit Program, Boca Raton, Florida, May 1996.
- Conley R, Gounaris C, Zhao M, Wong D, Tamminga C: "11C NMSP Receptor Occupancy By Clozapine and Haloperidol in Schizophrenic Subjects", presented at the New Clinical Drug Evaluation Unit Program, Orlando, Florida, June 1995.
- Richardson C, Tamminga C, An Nguyen J, Conley R: "A Novel Compound in The Treatment of Schizophrenia" presented at the New Clinical Drug Evaluation Unit Program, Orlando, Florida June 1995.
- Conley R, Daviss S, Gounaris C, Tamminga C: "Cavum Septum Pellucidum (CSP) in Treatment Resistant Schizophrenia," presented at Society of Neuroscience, November 1994.
- Conley R, Beardmore C: "IRB Issues in Pharmacologic Research", presented at Foundations for Successful Clinical Pharmacy Research Symposium, September 1994.

Robert R. Conley, M.D.

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- Conley R: "New Directions in the Pharmacological Treatment of Schizophrenia", presented at Greenbrier Psychopharmacologic Symposium, March 1994.
- Conley R: "What Comes After Clozapine?", presented at the Maryland Schizophrenia Conference, December 1993.
- Conley R, Wong D, Urbanska E, Jeffries K, Tamminga C: "Striatal Receptor Occupancy with Clozapine vs Haloperidol in Schizophrenia Using PET with ¹¹C-NMSP", presented at the Society for Neuroscience, November 1993.
- Conley R, Giffels J: "How Can We Do Research with the Chronically Mentally Ill? Issues in Informed Consent", presented at Hospital and Community Psychiatry, Baltimore, Maryland, October 1993.
- Conley R, Breier A, Mallott D, Peszke M: "Treatment-Resistant Schizophrenia: Typical Problems: Practical Tips", presented at Hospital and Community Psychiatry, Baltimore, Maryland, October 1993.
- Conley R, Tamminga C, Nguyen JA, Hain R: "Remoxipride Therapy in Treatment Resistant Schizophrenia", presented at the New Clinical Drug Evaluation Unit Program, West Palm Beach, Florida, June 1993.
- Conley R: "The Treatment of Negative Symptoms" presented at the American Psychiatric Association, San Francisco, California, May 1993.
- Conley R, Carlsson A, Lahti A, Tamminga C: "The Use of Preclamol (-3PPP) for Neuroleptic Induced Pseudoparkinsonism", presented at the Biological Society, San Francisco, California, May 1993.
- Conley R, Gounaris C, Wong D, Tamminga C: "Clozapine vs Haloperidol Dopamine Receptor Occupancy in Schizophrenia by ¹¹C-NMSP PET", presented at the Biological Society, San Francisco, California, May 1993.
- Conley RR, Gounaris CJ, Wong DF, Tamminga CA: "D₂ Receptor Occupancy with Clozapine vs Haloperidol in Schizophrenia by ¹¹C-NMSP PET", presented at the International Congress on Schizophrenia Research, Colorado Springs, Colorado, April 21, 1993.
- Conley R: "Clinician's Dilemma: Successful Reintegration of The Chronic Schizophrenic Patient", presented at the Hospital & Community Psychiatry, Toronto, Canada, October 1992.
- Jeffries KH, Tamminga CA, Dubois DE, Conley RR, Wong DF, Loats HL, Shaya EK, Young LT, Gounaris CJ, Chin BB, Yung BCK, Dannals RF, Guilarte TR, Wagner HN: "Validation of Dual-Detector Probe System for Monitoring Human Dopamine D₂ Receptor Occupancy by Haloperidol in vivo", presented at Society for Neuroscience, Anaheim, California, October 29, 1992.
- Conley R: "Improving Treatment compliance in Patients with Chronic Mental Illness", presented at Statewide Physicians' Conference, Greenville, South Carolina, February 1992.
- Conley R: "Haloperidol Decanoate Therapy in Schizophrenia with Akathisia", presented at the American Psychiatric Association, New Orleans, LA, May 13, 1991.
- Tamminga CA, Cascella NG, Conley RR: Experimental Pharmacology in Schizophrenia: Partial Dopamine Agonists. Proceedings of the Fifth World Congress of Biological Psychiatry, 1991.
- Conley R, Dixon L, Thaker G, Tamminga C: "Time Course of Psychopathologic and Motor TD Changes After Blind Neuroleptic Withdrawal", presented at New Clinical Drug Evaluation Unit Program, May 29 - June 1, 1990.

Robert R. Conley, M.D.

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- Conley R: "Negative Symptoms Improve with Clozapine Therapy", presented at the Annual Meeting of the American Psychiatric Association, New York, N.Y., May 17, 1990.
- Conley R, McDermott A, Baker R, Collins J, Bell J, Schulz SC: "Neurological Abnormalities Improve in Recovering Schizophrenic", presented at The International Congress on Schizophrenia, San Diego, CA, March 1989.
- Conley R, McDermott A, Baker R, Collins J, Bell J, Schulz SC: "Neurological Abnormalities in Schizophrenics", presented at the International Congress on Schizophrenia, Clearwater, Florida, March 1987.
- Conley R, Schulz SC, Baker R, Collins J, Bell J: "Clozapine Efficacy in Schizophrenic Nonresponders", presented at Annual meeting of the American Psychiatric Association, Chicago, IL, May 1987.
- Schulz SC, Conley R, Pollock B: "Do Lithium or Carbamazepine Augment Neuroleptics?", presented at Annual meeting of the American Psychiatric Association, Washington, D.C., May 10-16, 1986.
- Conley R, Schulz SC, et. al. "Biological Characterization of Nonresponsive Schizophrenic Inpatients", presented at Group Without A Name, Toronto, Canada, November 1985.
- Conley R, Schulz SC, Pollack B, Perel JM: "Psychopharmacologic Management of 'non-responding' patients suffering from schizophrenia", presented at Group Without A Name, Toronto, Canada, November 1985.
- Conley R, Chairman "Pharmacology of Schizophrenia" Symposium World Congress of Biological Psychiatry, Philadelphia, PA, September 1985.
- Conley R, Schulz SC, et. al. "Biological Characterization of Nonresponsive Schizophrenic Inpatients" World Congress of Biological psychiatry, Philadelphia, PA, September 1985.
- Sachs M, Lomax J, Conley R: "Resident reaction to patient suicide" Workshop given at American Association of Directors of Psychiatric Residency Training, Midwinter Meeting, New Orleans, LA, January 1984.

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DEPARTMENT OF HEALTH AND MENTAL HYGIENE
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ROBERT RUSSELL CONLEY
IS AN AUTHORIZED
PHYSICIAN AND SURGEON

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Robert Russell Conley
SIGNATURE OF BEARER

Martin P. Wasserman
Martin P. Wasserman, M.D., J.D.
Secretary of Health and Mental Hygiene



DEPARTMENT OF HEALTH AND MENTAL HYGIENE

LICENSE, REGISTRATION, OR CERTIFICATION RENEWAL

THE MARYLAND STATE BOARD OF PHYSICIAN QUALITY ASSURANCE
CERTIFIES THAT ROBERT RUSSELL CONLEY
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IN ACCORDANCE WITH THE HEALTH OCCUPATIONS ARTICLE OF THE ANNOTATED CODE OF MARYLAND

LIC. REG. CERT. NO.	EXPIRATION DATE
	09/30/2000

WHERE REQUIRED BY LAW THIS MUST BE CONSPICUOUSLY DISPLAYED IN OFFICE TO WHICH IT APPLIES

Martin P. Wasserman
Martin P. Wasserman, M.D., J.D.
Secretary of Health and Mental Hygiene

CURRICULUM VITAE (updated 3/26/97)
John G. Csernansky

Identifying Data
Home address:

REDACTED

e-mail: csemanj@medicine.wustl.edu

Birthdate: February 28, 1954

Birthplace: Chicago, Illinois

Married: Wife Cynthia

Children: Son Matthew

Daughter Julia

SSN: **REDACTED**

Education

1975 BA with Honors in Chemistry, Northwestern University, Evanston, IL

1979 M.D., New York University School of Medicine, NY

1979 Visiting Medical Student, Institute of Neurology, London, England

Professional and Academic Experience

1979-1980 Internship in Psychiatry and Medicine, Stanford University Medical Center, Stanford, CA, and Santa Clara Valley Medical Center, San Jose, CA
1980-1982 Resident in Psychiatry, Stanford University School of Medicine and DVA Medical Center, Stanford, CA
1982-1983 Chief Resident in Psychiatry, DVA Medical Center, Palo Alto, CA
1983-1986 Research Associate, DVA Medical Center, Palo Alto, CA
1983-1986 Clinical Instructor in Psychiatry, Stanford University School of Medicine, Stanford, CA
1986-1989 Director, Schizophrenia Biologic Research Center, DVA Medical Center, Palo Alto, CA
1985-1990 Associate Director, Stanford Mental Health Clinical Research Center, DVA Medical Center, Palo Alto, CA
1986-1990 Assistant Professor of Psychiatry, Stanford University School of Medicine, Stanford, CA. (Also Member of Multi-department Neuroscience Faculty).
1990-1994 Gregory B. Couch Associate Professor of Psychiatry, Washington University School of Medicine, St. Louis, MO
1994-Present Associate Professor of Neurobiology, Department of Anatomy and Neurobiology, Washington University School of Medicine, St. Louis, MO
1995-Present Gregory B. Couch Professor of Psychiatry, Washington University School of Medicine, St. Louis, MO

Licensure and Certification

1980- Diplomate, National Board of Medical Examiners
1980-1991 Licensed to practice in the State of California, License # **REDACTED**
1980- DEA # **REDACTED**
1985- Diplomate in Psychiatry, American Board of Psychiatry and Neurology
1990- Licensed to practice in the State of Missouri, License # **REDACTED** Missouri BNND # **REDACTED**

Memberships

1978-Present Alpha Omega Alpha
1982-Present American Psychiatric Association - Elected to Fellowship in 1993
1982-1990 Northern California Psychiatric Society
1984-Present Society of Biological Psychiatry
1987-Present American College of Neuropsychopharmacology - Elected to Fellowship in 1996
1988-Present Society for Neuroscience
1991-Present Eastern Missouri Psychiatric Society
1992-Present Collegium Internationale Neuro-Psychopharmacologicum
1994-Present Academia, Medicinae & Psychiatriae Foundation, Inc.

Honors and Awards

- 1979 Herman Wortis Neuropsychiatric Award, New York University School of Medicine
- 1981 Mead Johnson-ACNP Psychopharmacology Travel Award
- 1983 William C. Menninger Award, Central Neuropsychiatric Association
- 1990 Alliance for the Mentally Ill Friendship Award (Napa State Hospital Chapter)
- 1991 Judith Silver Memorial Young Scientist Award-National Alliance for the Mentally Ill
- 1992 Visiting Professorship, Department of Health and the University of Queensland, State of Queensland, Australia

Teaching and Clinical Services

- 1982-1985 Assistant Chief, Mental Hygiene Clinic, DVA Medical Center, Palo Alto, CA
- 1983-Present Individual supervision of psychiatry residents, medical students, psychology interns and other trainees
- 1985-1990 Ward Chief (4B2 and 4C2), DVA Medical Center, Palo Alto, CA
- 1985-1986 Course Director for "Major Clinical Syndromes", a core seminar for Stanford University School of Medicine psychiatry residents (PGY-2)
- 1985-1990 Course Director for "Psychiatric Syndromes and Treatments", a required core course for second-year medical students, Stanford University School of Medicine
- 1990-Present Attending Psychiatrist, Barnes Hospital, Jewish Hospital, Washington University School of Medicine, St. Louis, MO
- 1991-1994 Director of Academic Development, Malcolm Bliss Mental Health Center, St. Louis, MO
- 1995-Present Medical Director, Metropolitan St. Louis Psychiatric Center (formerly Malcolm Bliss Mental Health Center), St. Louis, MO

Consultation and Committee Service

- 1983-1990 Consultant in Psychiatry, California Youth Authority
- 1985 Committee Member, APA PKSAP-VI Exam, Module on Schizophrenia
- 1986-Present *Ad hoc* reviewer, DVA Merit Review Board for Mental Health and Behavioral Sciences
- 1988 Member, DVA Career Development Award Review Committee
- 1988-Present Consultant, Biopsychiatry Treatment and Research Unit, Napa State Hospital, Napa, CA
- 1991-1993 Advisory Board of Psychiatrists, SmithKline Beecham Pharmaceuticals
- 1991 Member, NIMH Research Scientist Special Review Committee
- 1991-Present Human Subjects Committee, Washington University School of Medicine, St. Louis, MO
- 1991-Present Professional Review Committee, Department of Mental Health, State of Missouri
- 1992-1994 Member, Test Material Development Committee (Behavioral Sciences Subcommittee), National Board of Medical Examiners
- 1992-1995 Member, NIMH Clinical Centers and Special Projects Review Committee
- 1994 *Ad hoc* Member, NIMH Board of Scientific Counselors
- 1994-1995 President, Medical Staff Executive Committee, Malcolm Bliss MHC, St. Louis, MO
- 1994-Present Tissue Committee, Alzheimer's Disease and Research Center, Washington University School of Medicine, St. Louis, MO
- 1995-Present Member, National Institutes of Health Reviewers Reserve
- 1996-1999 Member, DVA Merit Review Board for Mental Health and Behavioral Sciences
- 1996-1998 Member, Center for Mental Health Services Advisory Board, Washington U. in St. Louis

Editorial Service

- 1994-1999 Associate Editor, Schizophrenia Bulletin
- 1994-1997 Editorial Board, Neuropsychopharmacology
- 1986-Present *Ad hoc* reviewer for American Journal of Psychiatry, Archives of General Psychiatry, Biological Psychiatry, Journal of Clinical Psychopharmacology, Journal of Neuropsychiatry, Journal of Nervous and Mental Disease, Journal of Psychiatric Research, Life Sciences, Neuropsychopharmacology (prior to 1994), Psychiatry Research, Psychopharmacology, Schizophrenia Research

Research Training

1974-1975	Research Assistant, Department of Chemistry, Northwestern University; member of synthetic organic chemistry group (Preceptor - James A. Marshall, Ph.D.)
1976-1977	Assistant Investigator, Marine Biology Laboratory, Woods Hole (Preceptor- Walter Troll, Ph.D.)
1977-1979	Medical Student Investigator, Millhauser Neurochemistry Laboratories, New York University School of Medicine (Preceptors - Arnold Friedhoff, M.D., and Kenneth A. Bonnet, Ph.D.)
1981-1982	Fellow in Psychopharmacology, Stanford University School of Medicine and Dept. of Veterans Affairs (Preceptor - Leo E. Hollister, M.D.)
1983-1986	Research Associate in Psychopharmacology, Stanford University School of Medicine and Dept. of Veterans Affairs (Preceptor - Leo E. Hollister, M.D.)

Publications - Refereed

1. Marshall, J.A., Schlaf, T.F., Csemansky, J.G. A convenient synthesis of diketopiperazines via aminolysis of N-pyruvyl alpha-amino esters. *Synthet. Commun.*, 5:237-244, 1975.
2. Weissman, G., Finkelstein, M.C., Csemansky, J.G., Quigley, J.P., Quinn, R.S., Techner, L., Troll, W., Dunham, P.B. Attack of sea-urchin eggs by dogfish phagocytes: A model of phagocyte-mediated cellular cytotoxicity. *Proc. Nat. Acad. Sci.*, 75:1825-1829, 1978.
3. Csemansky, J.G., Zimmerman, M., Troll, W. An elastase-like enzyme in the oocytes of *Arbacia punctulata*. *Dev. Biol.*, 70:283-286, 1979.
4. Csemansky, J.G., Grabowsky, K., Cervantes, J., Kaplan, J., Yesavage, J.A. Fluphenazine decanoate and tardive dyskinesia: A possible association. *Am. J. Psychiatry*, 138:1362-1366, 1981.
5. Yesavage, J.A., Bourgeois, M., Kraemer, H., Csemansky, J.G., Berger, P.A. Prevalence of tardive dyskinesia in 3140 French inpatients. *J. Nerv. Ment. Dis.*, 170:111-112, 1982.
6. Csemansky, J.G., Grabowsky, K., Cervantes, J., Kaplan, J., Yesavage, J.A. Fluphenazine decanoate and tardive dyskinesia (letter). *Am. J. Psychiatry*, 139:970, 1982.
7. Csemansky, J.G., Friedhoff, A.J., Bonnet, K.A. Early supersensitive changes in (3H)-spiroperidol binding in the isolated striatum. *Biochem. Biophys. Res. Commun.*, 105:117-120, 1982.
8. Magliozzi, J.R., Kanter, S.L., Csemansky, J.G., Hollister, L.E. Detection of marijuana use in psychiatric patients by determination of urinary delta-9-tetrahydrocannabinol-11-oic acid. *J. Nerv. Ment. Dis.*, 171:246-249, 1983.
9. Csemansky, J.G., Holman, C.A., Bonnet, K.A., Grabowsky, K., King, R., Hollister, L.E. Dopaminergic supersensitivity at distant sites following induced epileptic foci. *Life Sci.*, 32:385-390, 1983.
10. Csemansky, J.G., Yesavage, J.A., Maloney, W., Kaplan, J. The treatment response scale: A retrospective method of assessing neuroleptic response. *Am. J. Psychiatry*, 140:1210-1213, 1983.
11. Csemansky, J.G., Holman, C.A., Hollister, L.E. Variability and the dopamine hypothesis of schizophrenia. *Schizophr. Bull.*, 9:325-328, 1983.
12. Csemansky, J.G., Kaplan, J., Holman, C.A., Hollister, L.E. Serum neuroleptic activity, prolactin and tardive dyskinesia in schizophrenic outpatients. *Psychopharmacology*, 81:115-118, 1983.

Publications - Referenced (continued)

13. Csernansky, J.G., Csernansky, C.A., Hollister, L.E. Distinct effects of two stresses on the behavioral response to apomorphine. *Life Sci.*, 35:1513-1518, 1984.
14. Csernansky, J.G., Lombrozo, L., Gulevich, G.D., Hollister, L.E. Treatment of negative schizophrenic symptoms with alprazolam. *J. Clin. Psychopharmacology*, 4:349-352, 1984.
15. Csernansky, J.G., Kaplan, J., Hollister, L.E. Problems in classification of schizophrenics as neuroleptic responders and non-responders. *J. Nerv. Ment. Dis.*, 173:325-331, 1985. (Reprinted by APA for inclusion in PKSAP-VI).
16. Csernansky, C.A., Csernansky, J.G., Hollister, L.E. A comparison between centrifugation and filtration as a means to separate bound and unbound ligand during 3[H]-spiroperidol binding. *J. Pharmacol. Methods*, 13:497-501, 1985.
17. Csernansky, J. G., Csernansky, C.A., Bonnet, K.A., Hollister, L.E. FeC13-induced limbic seizures are accompanied by dopaminergic supersensitivity. *Biol. Psychiatry*, 20:723-733, 1985.
18. Csernansky, J.G., Csernansky, C.A., Hollister, L.E. 3[H]-Sulpiride labels mesolimbic non-dopaminergic sites that bind antidepressant drugs. *Experientia*, 41:1419-1421, 1985.
19. Csernansky, J.G., Csernansky, C.A., Glick, S.H., Hollister, L.E. Lidocaine kindling is accompanied by an increase in apomorphine stereotypy and mesolimbic D2 receptor density. *Psychopharmacology Bull.*, 21:707-711, 1985.
20. Csernansky, J.G., Csernansky, C.A., Mellentin, J.A., Hollister, L.E. Carbamazepine and dopaminergic supersensitivity. *Biol. Psychiatry*, 21(2):238-239, 1986.
21. Csernansky, J.G., Csernansky, C.A., King, R., Hollister, L.E. Oscillations in apomorphine-induced stereotypies during one year of apomorphine administration. *Biol. Psychiatry*, 21:402-405, 1986.
22. Csernansky, J.G., Prosser, E., Kaplan, J., Mahler, E., Berger, P.A., Hollister, L.E. Possible associations among plasma prolactin levels, tardive dyskinesia, and paranoia in treated male schizophrenics. *Biol. Psychiatry*, 21:632-642, 1986.
23. Vinogradov, S., Reiss, A.L., Csernansky, J.G. Clonidine in high-dose alprazolam withdrawal. (Letter) *Am. J. Psychiatry*, 143(9):1188, 1986.
24. Csernansky, J.G., Vinogradov, S., Prosser, E., Kaplan, J., Berger, P.A., Hollister, L.E. Associations among plasma prolactin levels, tardive dyskinesia, and paranoia in treated schizophrenics: Relevance to supersensitivity psychosis. *Psychopharmacology Bull.*, 22(3):897-899, 1986.
25. Whiteford, H.A., Csernansky, J.G. Psychiatric aspects of acquired immune deficiency syndrome (AIDS). *Aust. N.Z. J. Psychiatry*, 20:399-403, 1986.
26. Whiteford, H.A., Peabody, C.A., Csernansky, J.G., Berger, P.A. The severity of depression and dexamethasone nonsuppression. (Letter) *Am. J. Psychiatry*, 143(12):1634-1635, 1986.
27. Thiemann, S., Csernansky, J.G., Berger, P.A. Rating scales in research: The case of negative symptoms. *Psychiatry Res.*, 20:47-55, 1987.
28. Whiteford, H.A., Riney, S.J., Csernansky, J.G. Distinguishing depressive and negative symptoms in chronic schizophrenia. *Psychopathology*, 20:234-236, 1987.

Publications - Refereed (continued)

29. Prosser, E.S., Csemansky, J.G., Kaplan, J., Thiemann, S., Becker, T.J., Hollister, L.E. Depression, Parkinsonian symptoms, and negative symptoms in schizophrenics treated with neuroleptics. *J. Nerv. Ment. Dis.*, 175:100-105, 1987. Also abstracted in *Psychiatry Digest*, 1988.
30. Finnegan, K., Terwilliger, M., Berger, P., Hollister, L.E., Csemansky, J.G. Comparison of the neurochemical and behavioral effects of clenbuterol and desipramine. *Eur. J. Pharmacol.*, 134:131-136, 1987.
31. Csemansky, J.G., Glick, S., Mellentin, J. Differential effects of proglumide on mesolimbic and nigrostriatal dopamine function. *Psychopharmacology*, 91:440-444, 1987.
32. Whiteford, H.A., Peabody, C.A., Thiemann, S., Kraemer, H.C., Csemansky, J.G., Berger, P.A. The effect of age on baseline and postdexamethasone cortisol levels in major depressive disorder. *Biol. Psychiatry*, 22:1029-1032, 1987.
33. Beauclair, L., Vinogradov, S., Riney, S.J., Csemansky, J.G., Hollister, L.E. An adjunctive role for ascorbic acid in the treatment of schizophrenia? *J. Clin. Psychopharmacology*, 7(4):282-283, 1987.
34. Whiteford, H.A., Peabody, C.A., Csemansky, J.G., Warner, M.D., Berger, P.A. Elevated baseline and postdexamethasone cortisol levels: A reflection of severity or endogeneity? *J. Aff. Disord.*, 12:199-202, 1987.
35. Whiteford, H.A., Peabody, C.A., Warner, D., Berger, P.A., Csemansky, J.G. Maintenance therapies in schizophrenia. *Med. J. Australia*, 147:240-242, 1987.
36. Magliozzi, J.R., Csemansky, J.G., Hughes, B., Gold, A., Laubly, J.N. A reassessment of the prolactin response to haloperidol in normal males. *Res. Commun. Psychology, Psychiatry Behav.*, 12(3):187-190, 1987.
37. Csemansky, J.G., Mellentin, J., Beauclair, L., Lombrozo, L. Mesolimbic dopaminergic supersensitivity following electrical kindling of the amygdala. *Biol. Psychiatry*, 23:285-294, 1988.
38. Whiteford, H.A., Riney, S.J., Savala, R.A., Csemansky, J.G. Dexamethasone nonsuppression in chronic schizophrenia. *Acta Psychiatr. Scand.*, 77(1):58-62, 1988.
39. Csemansky, J.G., Tacke, U., Rusen, D., Hollister, L.E. The effect of benzodiazepines on tardive dyskinesia symptoms. *J. Clin. Psychopharmacology*, 8(2):154-155, 1988.
40. Uhr, S.B., Jackson, K., Berger, P.A., Csemansky, J.G. Effects of verapamil administration on negative symptoms of chronic schizophrenia. *Psychiatry Res.*, 23:351-352, 1988.
41. Csemansky, J.G., Riney, S.J., Lombrozo, L., Overall, J.E., Hollister, L.E. Double-blind comparison of alprazolam, diazepam, and placebo for the treatment of negative schizophrenic symptoms. *Arch. Gen. Psychiatry*, 45:655-659, 1988. Also abstracted in *Psychiatry Digest*, 2:27-28, 1989.
42. Csemansky, J.G., Kerr, S., Pruthi, R., Prosser, E.S. Mesolimbic dopamine receptor increases two weeks following hippocampal kindling. *Brain Res.*, 449:357-360, 1988.
43. Prosser, E.S., Csemansky, J.G., Hollister, L.E. Differences in the time course of haloperidol-induced up-regulation of rat striatal and mesolimbic dopamine receptors. *Life Sci.*, 43:715-720, 1988.

Publications - Refereed (continued)

44. Moses, J.A., Jr., Csernansky, J.G., Leiderman, D.B. Neuropsychological criteria for identification of cognitive deficit in limbic epilepsy. *Int. J. Clin. Neuropsychology*, X(3):106-112, 1988.
45. Csernansky, J.G., Faull, K.F., Pfefferbaum, A. Seasonal changes of CSF monoamine metabolites in psychiatric patients: What is the source? *Psychiatry Res.*, 25:361-363, 1988.
46. Faustman, W.O., Moses, J.A., Jr., Csernansky, J.G. Luria-Nebraska performance and symptomatology in unmedicated schizophrenic patients. *Psychiatry Res.*, 26:29-34, 1988.
47. Guelfi, G.P., Csernansky, J.G. *Plasma homovanillic acid in schizophrenia. New Trends Exp. Clin. Psychiatry*, V-N, 1:43-51, 1989.
48. Faustman, W.O., Moses, J.A., Jr., Csernansky, J.G., White, P.A. Correlations between the MMPI and the Brief Psychiatric Rating Scale in schizophrenic and schizoaffective patients. *Psychiatry Res.*, 28:135-143, 1989.
49. Guelfi, G.P., Faustman, W.O., Csernansky, J.G. Independence of positive and negative symptoms in a population of schizophrenic patients. *J. Nerv. Ment. Dis.*, 177(5):285-290, 1989.
50. Hicks, P.B., Vindogradov, S., Riney, S.J., Su, K., Csernansky, J.G. A dose-ranging study of proglumide in the treatment of schizophrenia. *J. Clin. Psychopharmacology*, 9:209-212, 1989.
51. Prosser, E.S., Pruthi, R., Csernansky, J.G. Differences in the time course of dopaminergic supersensitivity following chronic administration of haloperidol, molindone, or sulpiride. *Psychopharmacology*, 99:109-116, 1989. Also abstracted in *Psychiatry Digest*.
52. Faull, K.F., King, R., Barchas, J.D., Csernansky, J.G. CSF phenylacetic acid and hostility in paranoid schizophrenia and depression. *Psychiatry Res.*, 30:111-118, 1989.
53. Csernansky, J.G., Barnes, D.E., Bellows, E., Lombrozo, L. Interrelationships between plasma homovanillic acid and indices of dopamine turnover in multiple brain areas during haloperidol and saline administration. *Life Sci.*, 46:707-713, 1990.
54. Warner, M.D., Peabody, C.A., Csernansky, J.G. Olfactory functioning in schizophrenia and depression. *Biol. Psychiatry*, 27:456-458, 1990.
55. Faustman, W.O., Faull, K.F., Whiteford, H.A., Borchert, C., Csernansky, J.G. CSF 5-HIAA, serum cortisol, and age differentially predict vegetative and cognitive symptoms in depression. *Biol. Psychiatry*, 27:311-318, 1990.
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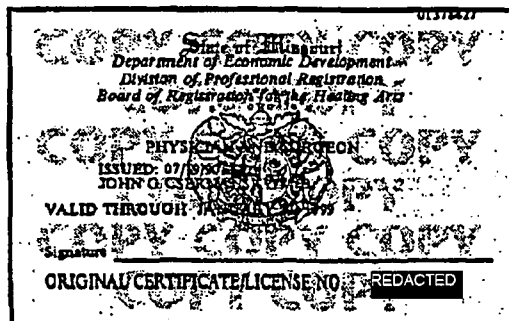
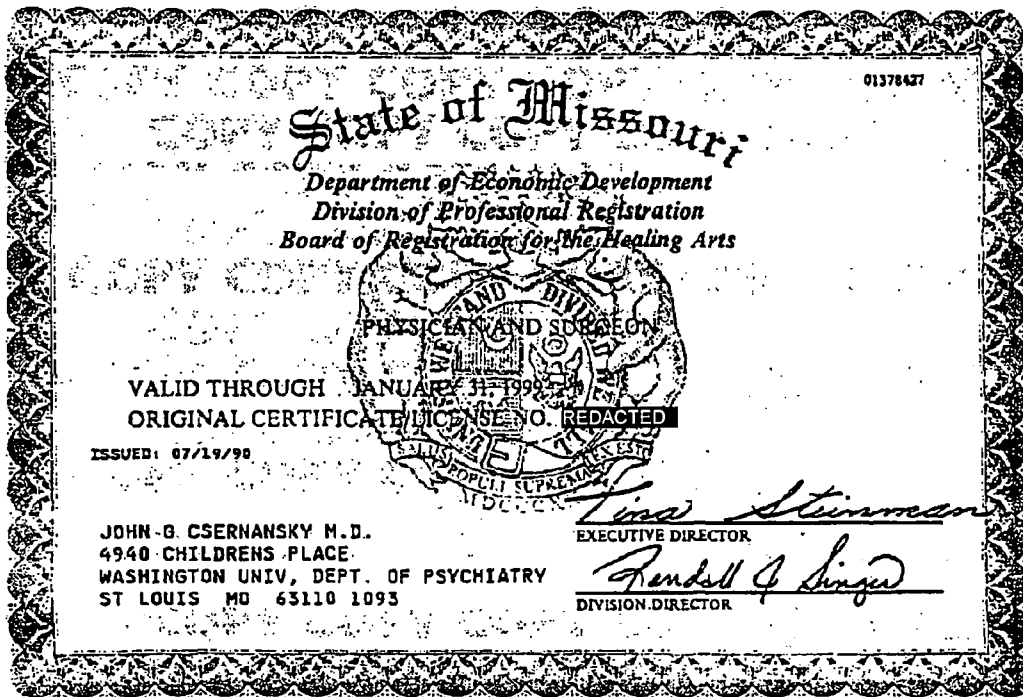
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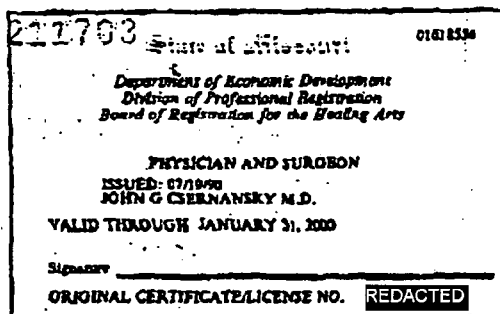
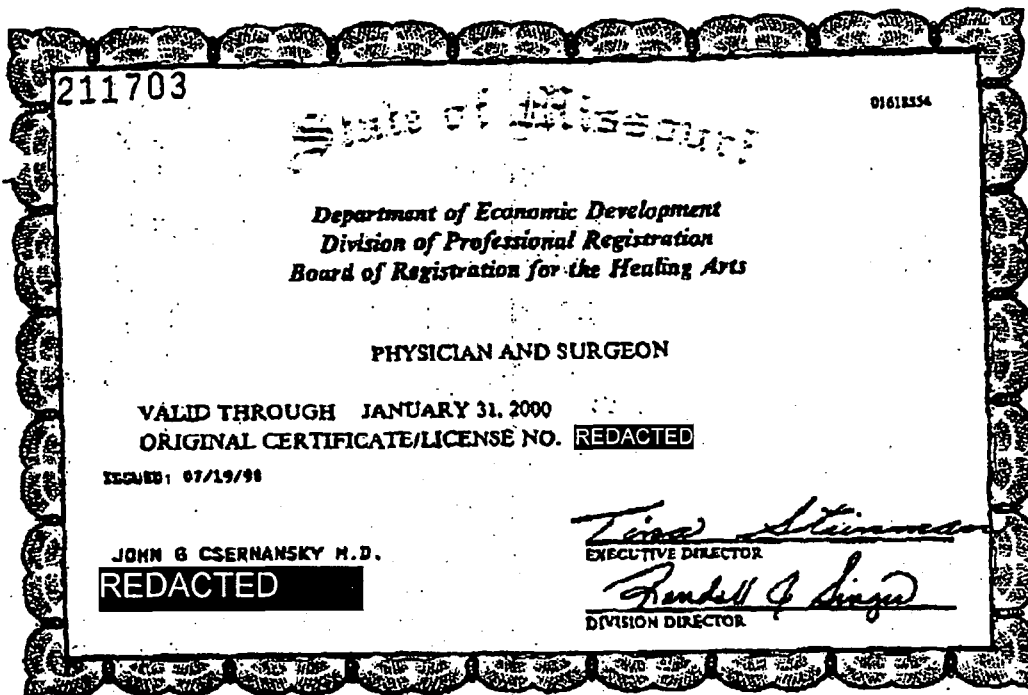
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Clinical

Private Practice of Adult and Adolescent Psychiatry in San Diego since 1981.

Academic

Assistant clinical professor of Psychiatry, University of California at San Diego Medical School.

Clinical Research

President, Damluji Bari Clinic, Inc. Founded 1992.
Conducting phase II, Phase III, and Phase IV Clinical pharmacological research.

Consultantships

Ad Hoc Committee Member in Psychiatry for CAP/MPT, Clinical review committee.

Consultant, City of San Diego. Fitness for duty evaluations.

PAST POSITIONS:

Hospital Programs

Vista Hill Hospital

A 76 bed adult, child and adolescent Not-for-Profit Psychiatric Hospital.

Medical Director 1991-1994

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PAGE 2

Alvarado Parkway Institute

An Adult, Child, and Adolescent Psychiatric
Hospital

Clinical Director, Mental Health Unit 1985-1988
Clinical Director, Depression Treatment Program
1988-1991

Chief, Continuing Medical Education 1985-1986

Chief, Psychiatry and Psychology Task Force 1985-
1986

Group Supervising Therapist for Open Unit and ICU
1985-1988

Member, Peer Review Committee 1987-1988

Vice-Chief of Staff 1985-1986

Rancho Park Hospital

An Adolescent Psychiatric Hospital & RTC

Chief of Staff 1989-1990

Vice-Chief of Staff 1985-1986 1988-1989

Chairman, Pharmacy and Therapeutics Committee
1987-1989

Chairman, Ad Hoc Drug and Alcohol Committee
1987-1988

Program Consultant for inpatient Programming
1988-1990

Day Treatment Programs

Project Enable, Neighborhood House Association
Medical Director January to August 1985

Vista Hill Behavioral Health Centers
Medical Director 1992-1994

Outpatient Programs

Mood Disorders Clinic of San Diego
Medical Director 1982-1983

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CURRICULUM VITAE - 1995
PAGE 3

Rancho Park Adolescent Outpatient Clinic
Medical Director 1989-1983

Vista Hill Behavioral Health Center
Medical Director of Outpatient Programs 1992-1994

Management

Vista Hill Foundation
Member, Senior Management Team

Clinical Research

Feighner Research Institute 1981-1988
Associate Investigator

Vista Hill Foundation
Member, Clinical Outcomes Research Committee 1991-1994

Academic

University of California, San Diego Medical School
Clinical Instructor in Psychiatry 1981-1983

Consultantships

Department of Social Services
Consultant for disability evaluation Division 1981-1993

San Diego Psychiatric Society

Member, Public Affairs Committee 1986-1987
Member, Community Liaison Committee 1986-1988
Member, Ethics Committee 1988-1991
Member, Task Force to Ensure Quality of care 1988-1990
Member, Peer Review Committee 1987-1991
Member, Private Practice Committee 1987-1988
Council Member 1992-1995

EDUCATION

High School: Baghdad College, Baghdad, Iraq
New England Jesuit's Order
Graduated June 1968, Honors List

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Medical School: Baghdad University
University of Baghdad School of Medicine
Baghdad, Iraq
Graduated June 1975, Honors List

RESIDENCY

1975-1976	Internship (Medicine/Surgery/Obstetrics & Gynecology) Baghdad University University of Baghdad Medical City Hospital Baghdad, Iraq
April-June 1977	Fellow (Neuropathology) Department of Neurology Strong Memorial Hospital University of Rochester Rochester, New York
1977-1979	Internship and Residency (PGY1 & PGY2) (Pediatrics/Neurology/Psychiatry) Department of Psychiatry Strong Memorial Hospital University of Rochester School of Medicine Rochester, New York
1979-1981	Senior Resident in Psychiatry (PGY3 & PGY4) Department of Psychiatry and Behavioral Sciences Johns Hopkins Hospital Johns Hopkins University School of Medicine Baltimore, Maryland

LICENSURE

Educational Council for Foreign Medical Graduates, 1977

Federation Licensure Examination and Licensure in the State of Maryland, 1979

Board of Medical Quality Assurance in California, Certified in 1981.

California

REDACTED

BOARD CERTIFICATION

Namir F. Damluji, M.D., FAPA
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Diplomate, American Board of Psychiatry and Neurology, 1983

Fellow, American Board of Medical Psychotherapists, 1987

HONORS AND AWARDS

High School	Testimonials and Awards in English, Mathematics, and Sciences.
Medical School	Graduated on the Honors List with awards Ranked 10th among 129 graduates.
Medical Associations	Fellow, American Psychiatric Association, 1991 Fellow, The Royal Society of Medicine, 1992

HOSPITAL STAFF AFFILIATIONS

PRESENT

1. Alvarado Parkway Institute
7050 Parkway Drive
La Mesa, California 92041
2. Mesa Vista Hospital
7850 Vista Hill Avenue
San Diego, California 92123

PAST

1. Scripps Memorial Hospital
9888 Genesee Avenue
La Jolla, California 92037
2. Harbor View Medical Center
120 Elm Street
San Diego, California 92101
3. Alvarado Hospital Medical Center
6655 Alvarado Road
San Diego, California 92120
4. Rancho Park Hospital
109 East Chase Avenue

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El Cajon, California 92020

5. Grossmont District Hospital
5555 Grossmont Center Drive
La Mesa, California 92044
6. San Luis Rey Hospital
1015 Devonshire Drive
Encinitas, California 92024
7. Vista Hill Hospital
730 Medical Center Court
Chula Vista, California 91910

SOCIETY MEMBERSHIPS

PRESENT

1. American Psychiatric Association
2. San Diego Society of Psychiatric Physicians
3. World Psychiatric Association
4. World Federation of Mental Health
5. The Royal Society of Medicine, London, England

PAST

1. American Academy of Clinical Psychiatrists
2. San Diego County Medical Society
3. Johns Hopkins Medical and Surgical Association
4. California Medical Association
5. American Medical Association

CLINICAL SPECIALITY TRAINING

University of Rochester, School of Medicine

- 1- Outpatient Affective Disorders Clinic with Dr. Richard Ciccone.
- 2- Psychodynamic Group Processing with Dr. Angelo Madonia.
- 3- Adolescent Medicine at the Inpatient Adolescent Medical

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Unit, Strong Memorial Hospital.

Johns Hopkins University, School of Medicine

- 1- Outpatient Affective Disorders Clinic with Dr. J. Raymond Depaulo.
- 2- Outpatient Psychohormonal Clinic with Dr. Frederick Berlin.
- 3- General hospital consultation and liaison service with Dr. Mark Teitlebaum and Dr. Marshall Folstein.
- 4- Outpatient and Inpatient Sickle Cell Anemia Clinic with Dr. Samuel Charache, working on a research project.
- 5- Sexual Behavior Consultation Unit with Dr. Jon Meyer and Dr. Chester Schmidt.
- 6- College Health Psychiatric Clinic, Johns Hopkins University campus with Dr. Gille D. Godenne.
- 7- Forensic Psychiatry at the Supreme Bench Court of Baltimore with Dr. Jonas Rapoport.
- 8- Outpatient Schizophrenia Disorder Clinic with Dr. Joseph Coyle and Dr. Larry Tune.
- 9- Group Process and Individual Supervision with Dr. Jerome Frank.

TEACHING AND SUPERVISORY POSITIONS

1. Medical Student Teaching and Supervision at the University of Rochester, Rochester, New York 1977-1979
2. Medical Student Teaching and Supervision at Johns Hopkins Hospital, Baltimore, Maryland 1979-1981
3. Medical Student and resident Supervision and Teaching, University of California, San Diego School of Medicine 1981 - present
4. Individual Supervision of Psychologists, MFCC's and LCSW's in private practice and in their internships.

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1982 to present

5. Project Enable, Day Treatment program supervision of individual therapists and group supervision 1985
6. Alvarado Parkway Institute, Staff Supervision of the Mental Health Unit, and Depression Treatment Program 1985-1988, 1988-1991
7. Mental Health Services Leadership Committee: Developing and Maintaining the programs and functioning of the Mental Health Services, Alvarado Parkway Institute 1985-1988
8. Vista Hill Hospital
Developing and Maintaining Diagnostic and Treatment Programs. Teaching and Supervision of staff 1991-1994

PUBLICATIONS

Tune, L., Damluji, N., Holland, T., Folstein, M., and Coyle, J. Association of Postoperative Delirium with Raised Serum Levels of Anticholinergic Drugs. Lancet, 9:26, 651-652, 1981.

Damluji, N., Cohn, R., Charache, S., Georgopoulos, A., and Folstein, M. Social Disability and Psychiatric Morbidity in Sickle Cell Anemia and Diabetes Patients. Psychosomatics, 9:23 925-931, 1982.

Mondimore, F., Damluji, N., Folstein, M., and Tune, L. Post ECT Confusional States Associated with Elevated Serum Anticholinergic Levels. Am. J. Psychiatry, 140:930-931, 1983.

Damluji, N., Feighner, J., Schuckit, M. Psychiatry, Specialty Board Review. Medical Examination Publishing Co., New York, 1983.

Damluji, N., Ferguson, J. Trazodone-Induced Delirium in Bulimic

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Patients. Am. J. Psychiatry, 141:434-435, 1984.

Feighner, J., Herbststein, J., Damluji, N. Combined MAOI, TCA, and Direct Stimulant Therapy of Treatment-Resistant Depression. J. Clin. Psychiatry, 46:206-209, 1985.

Damluji, J., Feigner J., Rosenthal, M. Recent Advances in Antidepressants, in: Pharmacotherapy of Affective Disorder: Therapy and Practice. Croom Helm Ltd., London, 1985.

Damluji, N., Ferguson, J. Three cases of Posttraumatic Anorexia Nervosa. Am. J. Psychiatry, 142:362-363, 1985.

Ferguson, J., Damluji, N. Posttraumatic Anorexia Nervosa. (A reply letter), Am. J. Psychiatry, 143:122-123, 1986.

Damluji, N., Ferguson, J. Pineal Gland Germinoma Simulating Anorexia Nervosa. Int. J. Eating Disorders, 6:4, 569 - 572, 1987.

Ferguson, J., Damluji, N. Anorexia Nervosa & Schizophrenia. Int. J. Eating Disorders, 7:3, 343-352, 1988.

Damluji, N., Ferguson, J. Paradoxical Worsening of Depressive Symptomatology caused by Antidepressants. J. Clin Psychopharmacology, 8:347-349, 1988.

Fawcett, J., Damluji, N., Orsulak, P.J., Rosenbaum, J.S. Therapeutic Monitoring of Antidepressants, Depression Dialogue, 1989...

Damluji, N. (Editor), Genett, D. The Depression Treatment Workbook. Alvarado Parkway Institute, 1988.

INVITED LECTURES & CONFERENCES

"Schizophrenia: Diagnosis and Treatment" Alvarado Parkway Institute, January 1985.

"Recent Developments in the Diagnosis and Treatment of Eating Disorders: Anorexia and Bulimia" presentation was made at an international conference in Cairo, Egypt, in February 1985.

"Crisis Intervention: Evaluation and Short-term Treatment" San Diego Navy Counseling and Family Therapy Center, April 1985.

"The Homeless and their Psychological Problems" Neighborhood House

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Association in San Diego, June 1985.

"Recent Advances in Antidepressants" Grossmont Hospital Medical Staff Meeting, September 1985.

"Eating Disorders, Phobias and Panic Attacks" sponsored by the Western Mood and Sleep Disorders Institute and Harbor View Medical Center, was the Chairman and Moderator of the program, October 1985.

"Bioavailability and Bioequivalents of Psychotropic Medication" lecture given at the Merrell-Dow Pharmaceutical Conference in San Diego, January 1986.

Inpatient Case Conference with the residents and staff of the Department of Psychiatry, Naval Hospital, Department of the Navy, San Diego, April 1986.

"Eating Disorders on Campus: Research & Clinical Considerations" keynote address presented at the fourth meeting of California Colleges Eating Disorders Consortium at San Diego State University, April 1986.

"Eating Disorders: Anorexia and Bulimia" San Diego Society for Psychiatric Physicians, at the Mental Illness Awareness Week, October 1986.

"Depression: A Practical Approach to Treatment" Scripps Clinic and Research Foundation at Rancho Bernardo, March 1987.

"An Overview on Eating Disorders: Anorexia and Bulimia" University of California, San Diego, at the VA Hospital, lecture to senior psychiatric residents, March 1987.

"Eating Disorders: Addiction or affliction?" Conference of the California Woman's Commission on Alcoholism and Drug Dependence, September 1987.

"Antidepressants in the Treatment of Depression, and Alternative Uses for Antidepressants" Scripps Memorial Hospital in Chula Vista, January 1988.

"Professional Practice After Residency: Models of Practice" lecture to senior Psychiatric Residents at University of California San Diego, February, 1988.

"Postpartum Psychiatric Disorders" Alvarado Parkway Institute, November 1988.

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"Chemical Dependency in Adolescents: The Disease Concept of Addiction" Rancho Park Hospital Staff, August 1988.

"The Depression Treatment Workbook" Lectures at Alvarado Parkway Institute on how to apply the Depression Treatment Workbook (a cognitive therapy workbook) in clinical care of patients. October, November, December, 1988.

"Cognitive Therapy in the Treatment of Couples" Alvarado Parkway Institute, October, 1989.

"Therapeutic Monitoring of Antidepressants" Castle Medical Center, Hawaii, 1990.

"Depression: Diagnosis and Treatment" Barber's Point, N.A.S. Clinic, Hawaii, 1990.

"Depression: Course and Management" Tripler Army Medical Center Grand Rounds, Hawaii, 1990.

"Depression: Diagnosis and Treatment" Pearl Harbor Outpatient Clinic, Hawaii, 1990.

"Therapeutic Monitoring of Antidepressants" Hawaii Psychiatric Society, Hawaii, 1990.

"Depression in the Elderly: Course, Diagnosis, and Treatment." Geriatric Medicine board Review, University of Hawaii at Manoa, Hawaii, 1990.

"Culture and Psychotherapy" Vista Hill Hospital, 1992

"Demonstrating Cultural Competence" Summer Clinical Institute, California Addiction Training Center, 1995.

CLINICAL PHARMACOLOGICAL RESEARCH

Associate Investigator, Buspirone Protocol 996, double-blind outpatient anxiolytic study. Bristol-Myers Company, 1981 to 1982.

Associate Investigator, Fluvoxamine Protocol 114-5510, double-blind inpatient antidepressant study. Duphar Lab, 1981 to 1982.

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Associate Investigator, Wellbutrin Protocol 16-01, double-blind outpatient antidepressant study with long-term, open-label follow-up. Burroughs Wellcome Company, 1981 to 1983.

Associate Investigator, Fluoxetine Protocols 27 & 28, double-blind outpatient antidepressant study with crossover and long-term options. Lilly Research Laboratories, 1981 to 1983.

Associate Investigator, Fluoxetine Protocols 29 & 30, double-blind inpatient antidepressant study with crossover and long-term options. Lilly Research Laboratories, 1982 to 1983.

Associate Investigator, Adinazolam Protocol 6309, double-blind outpatient antidepressant study. Upjohn Pharmaceuticals, 1982 to 1983.

Associate Investigator, LY 123508 Protocols 06 & 07, double-blind outpatient anxiolytic studies. Lilly Research Laboratories, 1982 to 1983.

Associate Investigator Adinazolam Protocols 634 & 6312, double-blind inpatient and outpatient geriatric antidepressant study with crossover and long-term options. Upjohn Pharmaceuticals, 1982 to 1983.

Associate Investigator, Fluoxetine Protocols 33 & 34, double-blind inpatient and outpatient geriatric antidepressant study with crossover and long-term extension. Lilly Research Laboratories, 1981 to 1984.

Associate Investigator, Trazodone Protocol 1368, double-blind outpatient antidepressant study with long-term follow-up. Astra Pharmaceuticals, 1982 to 1983.

Associate Investigator, BW 647U, double-blind outpatient antidepressant study. Burroughs Wellcome Company, 1982 to 1983.

Associate Investigator, Oxaprotiline Protocol 07, double-blind outpatient antidepressant study. Ciba-Geigy Pharmaceuticals, 1982 to 1983.

Associate Investigator, Zimelidine Protocol 108-303, double-blind geriatric antidepressant study with crossover and long-term options Astra Pharmaceuticals, 1982 to 1983.

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Associate Investigator, Zimelidine Protocol 108-411, double-blind outpatient antidepressant study with long-term follow-up. Astra Pharmaceuticals, 1982 to 1983.

Associate Investigator, Adinazolam Protocol 6318, double-blind outpatient antidepressant study. Upjohn Pharmaceuticals, 1983 to 1984.

Psychiatric evaluations for inclusion in the Wellbutrin Study, for sexual dysfunction, in association with the Crenshaw Clinic Burroughs Wellcome company, 1983 to 1984.

Associate Investigator, Oxaprotiline Protocol 12, double-blind outpatient antidepressant study with long-term options. Ciba-Geigy Pharmaceuticals, 1983 to 1984.

Associate Investigator, Buspirone Protocol 1604, double-blind outpatient antidepressant study with long-term options. Upjohn Pharmaceuticals, 1983 to 1985.

Associate Investigator, Fluoxetine Humanitarian Protocol 39, open-label outpatient antidepressant study. Lilly Research laboratories, 1983 to 1988.

Associate Investigator, Wellbutrin Humanitarian Protocol 39, open-label outpatient antidepressant study. Burroughs WELLCOME Company, 1983 to 1985.

Associate Investigator, Tomoxetine Protocols 05 & 10, double-blind outpatient antidepressant study with crossover and long-term options. Lilly Research Laboratories, 1983 to 1985.

Associate Investigator, Fluoxetine Protocol 62, double-blind outpatient antidepressant study, Lilly Research Laboratories, 1984 to 1985.

Associate Investigator, Estazolam Protocol M84-051, double-blind outpatient hypnotic study. Abbott Laboratories, 1985 to 1986.

Associate Investigator, Fluoxetine Protocol 79, double-blind outpatient antidepressant study. Lilly Research Laboratories, 1985 to 1986.

Associate Investigator, Adinazolam Humanitarian Protocol 6328, open-label outpatient antidepressant study. Upjohn Pharmaceuticals, 1985 to 1986.

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Associate Investigator, Paroxetine Protocol 0-01, double-blind outpatient antidepressant study. Beecham Laboratories, 1985 to 1986.

Associate Investigator, Paroxetine Protocols 03 & 04, double-blind outpatient antidepressant study with long-term extension. Beecham Laboratories, 1986 to 1987.

Associate Investigator, Mianserin Protocols 032 and 042, double-blind outpatient antidepressant study with long-term extension. Beecham Laboratories, 1986 to 1987.

Associate Investigator, Mianserin Protocols 032 and 043, double-blind outpatient antidepressant study, with long-term extension. Organon Laboratories, 1986 to 1988.

Associate Investigator, Tomoxetine Protocol B42, double-blind, fixed dosage, outpatient antidepressant study with long-term extension. Lilly Research Laboratories, 1986 to 1987.

Principal Investigator, Fluoxetine Protocol BIY-MC-HCDN, Fluoxetine vs. placebo in bulimia/parallel blind. Lilly Research Laboratories, 1986 to 1987.

Associate Investigator, WY-45, 030 Protocol 600A-203. Double-blind outpatient antidepressant study. Wyeth Laboratories, 1987.

Associate Investigator, Buspirone Protocol 03AIL-004, Comparison of Buspirone to place in Major Depressive Disorder. Bristol-Meyers Company, 1987.

Associate Investigator, Glaxo Protocol ADA - 203, Double-blind, placebo-controlled study to determine the efficacy and safety of Fluparoxan in the treatment of secondary male erectile disorder. 1992-1993.

Associate Investigator, Upjohn Protocol #M/2315/0002, Fluvoxamine vs. placebo in the treatment of Panic Disorder: a Fixed-dose, Double-blind, Dose-response study comparing efficacy and safety, 1992 to 1994.

Associate Investigator, Upjohn Protocol #M/2315/0013. Fluvoxamine vs. Placebo in the treatment of Panic disorder: a Flexible-dose, Double-blind study comparing efficacy and safety, 1993.

Associate Investigator, Syntex Protocol #15385S2280. A randomized Double-blind placebo controlled parallel study to assess the

Namir F. Damluji, M.D., FAPA
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efficacy and safety of four oral dose levels of RS-15385-197 in men with Erectile Disorder, 1994.

Associate Investigator, Bristol-Myers Squibb Protocol #CN104-127-NPRC#NEF. A prospective, multi center, open-label study of Serzone (Nefazodone) in the Management of patients with symptoms of depression in general psychiatric practices, 1994.

Associate Investigator, Upjohn Protocol #M/2315/0011. Fluvoxamine vs. Placebo in the treatment of Panic Disorder: A Long-term Maintenance, Double-blind study comparing efficacy and safety, 1993-1994.

Associate Investigator, Glaxo Protocol S3AA3009. A double-blind, placebo-controlled fixed dose evaluation of the safety and efficacy of Oral Ondansetron in the treatment of patients with panic disorder, 1995.

Associate Investigator, Hoechst Protocol #301. Forty-eight week efficacy and safety study of Propentofylline in patients with Alzheimer's Disease, 1995.

Associate Investigator, Hoechst Protocol #302. Twenty-four week efficacy and safety study of Propentofylline in patients with Vascular Dementia, 1995.

Associate Investigator, Organon Protocol #092-002. An open-label, randomized, parallel, group, comparative multi-center, safety and efficacy study of Triphasic Combination Oral Contraceptives, CTR99 and CTR77, versus, Ortho-Novum 7/7/7, 1995.

Associate investigator, Bristol-Myers Squibb CN104-127 Addendum A. A prospective, multi center, open-label study of Buspar (Buspirone HCL) augmentation therapy of Serzone (Nefazodone HCL) in the management of patients with symptoms of depression in general psychiatric practices, 1995.

Associate Investigator, Merck 057-00, a parallel, randomized, double-masked, placebo-controlled, multi center study of the effect of adding 2.0% MK-507 Ophthalmic solution to 0.5% TIMOPTIC-XE in patients with elevated intraocular pressure, 1995.

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PHYSICIAN AND SURGEON
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NAMIR FAISAL DAMLUJI
5030 CAMINO DE LA SIESTA STE #10
SAN DIEGO CA 92108

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PHYSICIAN AND SURGEON

CERTIFICATE [REDACTED] EXPIRATION 06/30/00
NAMIR FAISAL DAMLUJI
591 CAMINO DE LA REINA
SAN DIEGO CA 92108-3117

ORIGINAL
ISSUANCE DATE
04/13/91

RECEIPT NO.
00090373

Signature
PMQA 12/30/94

IMPORTANT

CUT ON DOTTED LINE

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2. Notify the Board of any name or address change in writing.
3. Report any loss immediately in writing to the Board.
4. Please sign and carry the Pocket certificate with you.
NAMIR FAISAL DAMLUJI

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December 9, 1998

MEMO TO FILE:

Please note that Dr Damluji has moved out of the United States. He has not followed patients on this study, nor shall he do so in the future. Due to his new location it has not proven possible for us to obtain a signed copy of his new M.D. licensure.

Ellen Mason
Clinical Research Coordinator

David Gordon Daniel, M.D.
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Page 1

CURRICULUM VITAE

David Gordon Daniel, M.D.

CLINICAL STUDIES WASHINGTON, DC
6066 Leesburg Pike
Falls Church, Virginia 22041
(703) 998-5850; Fax (703)998-5867

Education:

1974-78	Emory University, Atlanta, Georgia B.A. (magna cum laude)
1978-82	Vanderbilt University Medical School, Nashville, Tennessee M.D.
1982-83	Rotating Internship Vanderbilt University Medical School, Nashville, Tennessee
1983-85	Resident in Psychiatry, Vanderbilt University Medical School, Nashville, Tennessee
1985-86	Chief Resident in Psychiatry, Vanderbilt University Medical School, Nashville, Tennessee
1986-1988	Medical Staff Fellow - Clinical Brain Disorders Branch National Institute of Mental Health, Washington, D.C.
1988-1991	Senior Staff Fellow-Clinical Brain Disorders Branch National Institute of Mental Health, Washington, D.C.

Professional Experience:

1998-present	Vice President (Corporate Level) , Medical and Scientific Development, Clinical Studies, LTD
1997-present	Senior Director Clinical Studies Washington, DC, Falls Church, Virginia

David Gordon Daniel, M.D.

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Professional Experience:

(cont'd)

1997-	Founding Partner and Principal Best Practice, LLC
1991-1997	Founder, President & Director NeuroPsychiatric Services of Greater Washington (NPS) Falls Church, Virginia
1992-1997	Founder and Director Washington Clinical Research Center (WCRC), Falls Church, Virginia
1989-present	Active Privileges Columbia Dominion Hospital, 2960 Sleepy Hollow Road Falls Church, Virginia
1996-present	Courtesy Privileges Vencor-Arlington Hospital, 601 S. Carlin Springs Road Arlington, Virginia
1996-present	Courtesy Privileges Columbia-Arlington Hospital 1701 N. George Mason Drive, Arlington, Virginia
1995-1996	Director of Psychopharmacology Research Projects Northern Virginia Mental Health Institute, Falls Church, Virginia
1991-present	Director of Research & Psychopharmacology Columbia/HCA Dominion Hospital, Falls Church, Virginia
1989-1991	Medical Director NIMH Neuroscience Center at Saint Elizabeths, Washington, D.C.
1989-1991	Chairman, Medical Board NIMH Neuroscience Center at Saint Elizabeths, Washington, D.C.
1988-1989	Associate Medical Director NIMH Neuroscience Center at Saint Elizabeths, Washington, D.C.
1988-1989	Vice-Chairman, Medical Board NIMH Neuroscience Center at Saint Elizabeths, Washington, D.C.

David Gordon Daniel, M.D.

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Professional Experience:

(cont'd)

1988-1989	Chairman, Quality Assurance Committee NIMH Neuroscience Center at Saint Elizabeths, Washington, D.C.
1986-1987	Clinical Research Ward Administrator - Clinical Brain Disorders Branch National Institute of Mental Health, Washington, D.C.
1984-1986	Consultant, Geriatric Division Luton Mental Health Center, Nashville, Tennessee
1984-1985	Consultant Deberry Correctional Institute, Nashville, Tennessee

Academic Affiliations:

1995-present	Clinical Professor of Psychiatry and Behavioral Sciences George Washington University, Washington, D.C.
1991-1995	Associate Clinical Professor Department of Psychiatry and Behavioral Sciences George Washington University, Washington, D.C.
1987-1991	Assistant Clinical Professor Department of Psychiatry and Behavioral Sciences George Washington University, Washington, D.C.

Awards (Excluding Research Grants):

Magna Cum Laude- Emory University, 1978

Phi Beta Kappa-Emory University, 1978

Marc Hollender Award in Psychiatry- Vanderbilt University Medical Center, 1986

American College of Neuropsychopharmacology Travel Award, 1989

International Schizophrenia Workshop Travel Award, 1989

National Alliance for the Mentally Ill Exemplary Psychiatrist Award, 1998

David Gordon Daniel, M.D.

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Licenses/Certification:

M.D. State of Virginia
M.D. District of Columbia
M.D. Maryland

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1987-present American Board of Psychiatry and Neurology (Psychiatry)

Research Experience (Industry):

The Short and Long Term Effects of XXXXX on Positive and Negative Symptoms, Cognitive Deficits, and Motor Abnormalities in Schizophrenia

A Multicenter, Double-Blind, Placebo-Controlled, Randomized, Multiple Fixed Dose Comparison of XXX and XXX in the Treatment of Hospitalized Subjects With Acute Exacerbation of Chronic or Subchronic Schizophrenia.

An Open-Label Assessment of the Long-Term Safety of XXX in the Treatment of Schizophrenic Patients.

Phase III, Double-Blind, Multicenter, Placebo-Controlled Study Evaluating the Efficacy and Safety of Two Fixed Doses of Oral XXX in the Acute Exacerbation of Schizophrenia and Schizoaffective Disorder.

Forty-Week, Double-Blind Study Evaluating the Safety and Efficacy of Two Dose Regimens of Oral XXX and XXX in the Maintenance Treatment of Outpatients with Schizophrenia or Schizoaffective Disorder.

A 52-Week, Open Extension Study Evaluating the Safety and Outcome of XXX Daily in the Treatment of Subjects Who Have Participated in Previous XXX Clinical Trials.

A Double-Blind Comparison of XXX and XXX: An assessment of the Chronic Safety, Efficacy, Quality of Life and Relapse in Stable Schizophrenic Patients.

A Double-Blind, Placebo-Controlled, Dose-Response Comparison of the Safety and Efficacy of Three Doses of XXX and Three Doses of XXX in Schizophrenic Patients.

Clinical Evaluation of Efficacy and Safety of XXX in the treatment of Alzheimer's Disease.

XXX: A Dose Ranging study in Schizophrenic Patients.

David Gordon Daniel, M.D.

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Page 5

Research Experience:
(cont'd)

A Three-Month Open-Label Study of the Tolerability and Safety of XXX in Schizophrenic Patients.

An Open-Label Assessment of the Long-Term Safety of XXX.

Phase III, Six-Week, Double-Blind, Multicenter, Placebo-Controlled Study Evaluating the Efficacy and Safety of Three Fixed Doses of Oral XXX and XXX in the Acute Exacerbation of Schizophrenia and Schizoaffective Disorder.

XXX Dose-Finding Trial, Comparing Three Fixed Dosages of XXX to XXX and Placebo: Multicenter, Double-Blind, Parallel-Group Study.

A Study of the Efficacy of XXX and XXX Administered to Schizophrenic and Schizoaffective patients for 42 Days Followed by Open Label Treatment for One Year.

Study of XXX in Schizophrenic Patients Discontinuing Clozapine Therapy.

A Double-Blind, Randomized, Comparison of the Safety and Efficacy of XXX and XXX in Treatment Resistant Schizophrenic Patient.

A Multi-Center, Randomized, Double-Blind, Placebo and Active Controlled Study of XXX in Schizophrenic and Schizoaffective Patients.

A Multi-Center, Open-Label, Long-Term Followup, Safety Study of XXX In Schizophrenic and Schizoaffective patients Who Participated in Protocol XXX.

A Phase III, Multicenter, Open-Label Study Evaluating the Toleration and Safety of 3 Days of Treatment with Intramuscular XXX (XX to XX Daily) or XXX (up to XXX Daily) Followed by 4 Days of Treatment with Oral XXX (XX to XX Daily) or XXX in Subjects with a Diagnosis of Psychotic Disorder.

XXX Versus Placebo in the Treatment of Mania Associated with Bipolar I Disorder.

XXX Efficacy, Tolerability and Safety of XXX in the Treatment of Alzheimer's Disease.

A Phase III Randomized Study Comparing 2 Doses of Intramuscular XXX in Subjects with Psychosis and Acute Agitation.

David Gordon Daniel, M.D.

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Research Experience:

(cont'd)

An Open Extension Study Evaluating the Safety and Outcome of XX-XX Daily of Oral XXX in the Treatment of Subjects Who Have Participated in Previous XXX Clinical Trials.

The Efficacy, Safety and Tolerability of XXX Versus Placebo, Administered for One Year in Patients with Probable Alzheimer's Disease (NINCDS/ADRDA Criteria)

An Open-Label Study to Evaluate the Safety and Efficacy of XXX through XXX of XXX in Patients with Mild to Severe Probable Alzheimer's Disease in the Community Setting.

A Randomized, Double-Blind, Placebo-Controlled, Four-Arm Dose-Finding Study Investigating the Efficacy and Safety of Three doses of XXX in Patients with Alzheimer's Disease.

Double-Blind, Haloperidol-Controlled, Safety and Dose-Finding Study in the Treatment of Schizophrenia.

A Double-Blind, Placebo-Controlled, Haloperidol-Referenced Study of the Safety and Efficacy of Three doses of XXX Administered to Schizophrenic patients for 42 Days.

An Open-Label Assessment of the Long-Term Safety of XXX

Long-Term Safety and Efficacy of XXX in the Treatment of Alzheimer's Disease

An Open-label, Long-Term, Safety Study of Transdermal XXX in the Treatment of Anxious Outpatients

An Eight-Week, Multicenter Parallel-Group, Double-Blind, Placebo-Controlled study of XXX in Elderly Outpatients with DSM-IV Major Depression

A Multi-Center Pilot Study to Examine the Clinical Effects of Cross Titration of Antipsychotics with XXX in Subjects with Schizophrenia or Schizoaffective Disorder Followed by An Optional Open Extension Phase with Continued XXX Treatment

A Multi-Center Pilot Study to Examine the Clinical Effects of Cross Titration of XXX with XXX in Subjects with Schizophrenia or Schizoaffective Disorder Followed by an Optional Open Extension Phase With Continued XXX Treatment

A Multi-Center Pilot Study To Examine the Clinical Effects of Cross Titration of XXX with XXX in Subjects with Schizophrenia or Schizoaffective Disorder Followed by an Optional Open Extension Phase with Continued XXX Treatment

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Research Experience:

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The Safety and Efficacy of XXX vs placebo vs XXX as Add-on therapy to Mood Stabilizers in the Treatment of the Manic Phase of Bipolar Disorder

A Double-Blind, Placebo and Haloperidol-Controlled, Multicenter Study Evaluating the Safety and Efficacy of XXX in Schizophrenic Patients

A Six-Week, Double-Blind, Placebo- and Fluoxetine-Controlled Multicenter Study to Evaluate the Safety and Efficacy of Oral XXX in Outpatients with Major Depressive Disorder

A Prospective, Randomized, International, Parallel-Group Comparison Of XXX/XXX Vs XXX In The Reduction Of Suicidality In Patients With Schizophrenia Or Schizoaffective Disorder Who Are At Risk For Suicide

A Double-Blind, Placebo-Controlled Study of XXX in the Treatment of Signs and Symptoms of Mania in Elderly Patients with Dementia

Safety and Efficacy of Fixed Combination XXX/XXX Products As First Line Therapy in Patients With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control With Diet And Exercise

A Multicenter, Double-Blind, Randomized Study of Continuous Transdermal XXX-XXX Combinations, Compared to Continuous XXX XXX, to Examine the Safety and Effect on the Endometrium, Symptoms and Bleeding Patterns in Postmenopausal Women

Placebo-Controlled Study of the Safety and Efficacy of XXX In the Treatment of Acute Manic Or Mixed Episodes in Subjects With Bipolar I Disorder

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Selected Published Letters, Scientific Abstracts, Etc.:
(Cont'd)

34. Goldberg, T., Kleinman, J.E., Daniel, D.G., Myslobodsky, M.S., & Weinberger, D.R. (1988). Age disorientation and schizophrenic dementia. Proceedings of the Annual Meeting of the American Psychiatric Association Meeting (New Research), Montreal, Canada.
35. Suddath, R.L., Casanova, M.F., Goldberg, T.E., Daniel, D.G., Kelsoe, J.R., & Weinberger, D.R. (1988). Temporal lobe pathology in schizophrenia. Proceedings of The Annual Meeting of the American Psychiatric Association (New Research), Montreal, Canada.
36. Daniel, D.G., Berman, K.F., & Weinberger, D.R. (1988). Apomorphine and regional cerebral blood flow in schizophrenia. Proceedings of the Annual Meeting for the American Psychiatric Association (New Research), Montreal, Canada.
37. Casanova, M.F., Goldberg, T.E., Weinberger, D.R., Kleinman, J.E., Rawlings, R., Suddath, R., & Daniel, D.G. (1988). Shape analysis of the temporal lobes of schizophrenic patients. Proceedings of the Annual Meeting of the Society for Biological Psychiatry, Montreal, Canada.
38. Illowsky, B., Berman, K.F., Daniel, D.G., Suddath, R., & Juliano, D. (1988). Proceedings of the Annual Meeting of the Society for Biological Psychiatry, Montreal, Canada. May 3-7, 1988.
39. Daniel, D.G., Berman, K.F., Fawcett, R., & Weinberger, D.R. (1988). Apomorphine and cerebral blood flow in schizophrenia. Proceedings of the Annual Meeting of the Society for Biological Psychiatry, Montreal, Canada.
40. Daniel, D.G., Goldberg, T., & Weinberger, D.R. (1988). Unimodal versus bimodal distribution of ventricular size in schizophrenia. Proceedings of the Annual Meeting of the Society for Biological Psychiatry, Montreal, Canada.
41. Goldberg, T., Casanova, M.F., Suddath, R., Daniel, D.G., & Weinberger, D.R. (1987). Contrast enhancement (point process) and edge detection techniques in computer tomography and nuclear magnetic resonance brain imaging. Proceedings of the Annual Meeting of the Society for Neuroscience, New Orleans, Louisiana.

David Gordon Daniel, M.D.
Curriculum Vitae
Page 20

Selected Published Letters, Scientific Abstracts, Etc.:
(Cont'd)

42. Daniel, D.G., Myslobodsky, M.S., Coppola, R., & Weinberger, D.R. (1987). Prefrontal cortical atrophy in schizophrenia is associated with skull asymmetry. Society for Neuroscience Abstracts, New Orleans, Louisiana.
43. Coppola, R., Karson, C., Daniel, D., & Myslobodsky, M. (1987). EEG asymmetry in relation to skull asymmetry. Proceedings of the American Electroencephalographic Society Annual Meeting.
44. Daniel, D.G., Karson, C., Kirch, D., Berman, K.F., Goldberg, T., & Weinberger, D.R. (1987). Dihydroergototoxine in the treatment of the negative symptoms of schizophrenia. Proceedings of the Society for Biological Psychiatry Annual Meeting, Chicago, Illinois.
45. Daniel, D.G., Jones, D., Coppola, R., Berman, K.F., & Karson, C. (1987). Single photon emission computer tomography in psychiatry. Proceedings of the American Psychiatric Association Annual Meeting, Chicago, Illinois.
46. Karson, C.N., Coppola, R., Goldberg, T.E., & Daniel, D.G. (1987). The EEG in schizophrenia. Proceedings of the International Congress of Schizophrenia Research, Clearwater, Florida.
47. Daniel, D.G., Ban, T.A., & Wilson, W.H. (1985). Initial field testing of the diagnostic criteria or research (DCR). Proceedings of the Third Annual Vanderbilt University Medical Center Research Forum, Nashville, Tennessee.
48. Daniel, D.G., Abernethy, V., & Oliver, W.R. (1983). Sex roles and sexual function. Proceedings of the First Annual Vanderbilt University Research Forum, Nashville, Tennessee.
49. Daniel, D.G., & Abernethy, V. (1980). Sex roles and sexual function. Proceedings of the Annual Meeting of the Society for Sex Therapy and Research, Cambridge, Massachusetts.



Revised: August 26, 1998

JOHN W. HASTY
DIRECTOR

Risperidone: Clobazam: RIS-USA-113
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4th FLOOR
RICHMOND, VA 23230-1717

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DAVID G DANIEL, MD
PO BOX 4254

FALLS CHURCH, VA 22044

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Funeral Directors And Embalmers, Board of
Medicine, Board of
Nurse Aide, Registry of
Nursing, Board of
Nursing Home Administrators, Board of

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(804) 662-9907
(804) 662-9908
(804) 662-7310
(804) 662-9909
(804) 662-9111

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Pharmacy, Board of
Professional Counselors, Board of
Psychology, Board of
Social Work, Board of
Veterinary Medicine, Board of

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EXPIRES

10-31-2000

DAVID G DANIEL, MD
PO BOX 4254

FALLS CHURCH, VA 22044

REDACTED

(FOLD)

CURRICULUM VITAE

MICHAEL W. DEPRIEST, M.D.

CURRENT AS OF MARCH 1, 1997

MEDICAL DIRECTOR

License Number: **REDACTED**

Pharmacology Research Corporation • 4220 South Maryland Parkway, Suite B312 • Las Vegas,
Nevada 89119 • (702) 678-6167

EDUCATION

Undergraduate

UNIVERSITY OF TENNESSEE

Degree: B.S.N. Major: Psychology, 1985

Graduate

UNIVERSITY OF TENNESSEE

Degree: M.D., 1991

UNIVERSITY OF CINCINNATI

Psychiatry Internship, 1991 to 1992

UNIVERSITY OF CINCINNATI

Psychiatry Residency, 1992 to 1995

EXPERIENCE

PHARMACOLOGY RESEARCH CORPORATION, LAS VEGAS, NEVADA

Medical Director, July 1996 to Current Date

WEST BY NORTHWEST,

PARTIAL HOSPITALIZATION PROGRAM

Medical Director, July 1995 to May 1996

WEST BY NORTHWEST,

COMMUNITY MENTAL HEALTH CENTER

Assistant Medical Director, July 1995 to May 1996

SOUTHERN NEVADA ADULT MENTAL HEALTH SERVICES, LAS VEGAS, NEVADA

Assistant Professor of Psychiatry, May 1996 to September 1996

RESEARCH EXPERIENCE

- Assessment and evaluation of patient's involved in third and second phase studies on psychotropic medications for the following pharmaceutical companies:

Janssen
Novartis
Wyeth-Ayerst

SmithKline Beecham
Zeneca

- Certified in following psychometric instruments for pharmaceutical research:

HAM-D
PANSS
ADAS
BPRS

HAM-A
ESRS
DAD
SCID

- Assisted in conducting clinical drug trials for the following disorders:

Schizophrenia
Panic

Geriatric Depression
Alzheimer's Disease

HONORS

1985 Summa Cum Laude
University of Tennessee

1987 to 1991 Andrew Holt Academic Scholarship
University of Tennessee

LICENSURE AND ACCREDITATION

July 1992 Diplomate of the National Board of Medical Examiners

MEMBERSHIPS

1991 American Psychiatric Association

HOSPITAL AFFILIATIONS

1997-Present Montevista Hospital-5900 Rochelle Avenue, Las Vegas, Nevada 89103

1996-Present Nevada Mental Health Institute- 480 Galletti Way, Sparks, Nevada 89431

NEVADA STATE BOARD OF MEDICAL EXAMINERS

P.O. BOX 7238, RENO, NEVADA 89510



THIS CERTIFIES THAT

Michael W. DePriest, MD

License Number:



HOLDS A MEDICAL LICENSE IN THE
STATE OF NEVADA IN ACCORDANCE WITH NRS 630.

Status: ACTIVE

Expires: 6/30/99

Licensee Signature

CURRICULUM VITAE
LOUIS FERNAND FABRE, JR., M.D., Ph.D., F.C.P.

REDACTED

DATE AND PLACE OF BIRTH

September 13, 1941
Akron, Ohio

EDUCATION

Akron University, Akron, Ohio B.S., Pre-Med	1959-1962
Case-Western Reserve University, Cleveland, Ohio Ph.D., Physiology	1962-1966
Baylor College of Medicine, Houston, Texas M.D., Medicine	1965-1969
Methodist Hospital, Houston, Texas Intern, Internal Medicine	1969-1970
Baylor College Affiliated Hospitals, Houston, Texas Resident, Psychiatry	1969-1973

POSITIONS HELD**Teaching Positions**

Instructor of Science Cuyahoga Community College Cleveland, Ohio	1965
Instructor of Mental Sciences University of Texas Graduate School of Biomedical Sciences Houston, Texas	1967-1969
Assistant Professor of Mental Sciences University of Texas Graduate School of Biomedical Sciences Houston, Texas	1969-1973
Associate Lecturer Alcoholism Counselors Program University of Houston Houston, Texas	1973-1978
Clinical Assistant Professor Psychiatry Baylor College of Medicine Houston, Texas	1974-1977
Clinical Associate Professor of Psychiatry University of Texas Health Science Center Houston, Texas	1974-present
<u>Texas Research Institute of Mental Science Positions</u> Research Specialist II Texas Research Institute of Mental Sciences (TRIMS) Houston, Texas	1963-1973

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Acting Chief, Section on Neuroendocrinology
Texas Research Institute of Mental Sciences (TRIMS)
Houston, Texas 1967-1968

Chief, Section of Neuroendocrinology
Texas Research Institute of Mental Sciences (TRIMS)
Houston, Texas 1968-1972

Ward Officer, Mental Retardation and Clinical Research Ward
Center Pavilion Hospital
Texas Research Institute of Mental Sciences (TRIMS)
Houston, Texas 1970-1971

Associate Head, Mental Retardation Research Division
Texas Research Institute of Mental Sciences (TRIMS)
Houston, Texas 1970-1971

Head, Mental Retardation Research Division
Texas Research Institute of Mental Sciences (TRIMS)
Houston, Texas 1971-1973

Active Medical Staff
Texas Research Institute of Mental Sciences (TRIMS)
Houston, Texas 1971-1973

Head, Clinical Research Division
Texas Research Institute of Mental Sciences (TRIMS)
Houston, Texas 1972-1973

Chief, Alcoholism Research Section
Texas Research Institute of Mental Sciences (TRIMS)
Houston, Texas 1973

Consultant Positions

Consultant in Gas Chromatography
Veterans Administration Hospital
Houston, Texas 1967-1970

Consultant in Research and Development
Continental Group and The Vinoxin Company
Houston, Texas 1980-1981

Consultant in Research and Development
Lilly and Company
Lilly Research Laboratories
Indianapolis, Indiana 1980-1986

Consultant in Child Psychiatry
Texas City Independent School District
Texas City, Texas 1975-1989

Clinic Ownerships and Directorships

Owner-Director
Champions Clinic
Houston, Texas 1973-1979

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Owner-Director Portland Clinic Houston, Texas	1974-1975
Owner-Director Fabre Research Clinics, Inc. 5503 Crawford Houston, Texas 77004	1975-present
Owner-Director Fabre Research Clinics, Inc. 4503 Austin Houston, Texas 77004	1975-present
Owner-Director The Fabre Clinic at Austin 504 W. 17th Street Austin, Texas	1978-1983
Owner-Director The Fabre Clinic at Dallas 3601 Swiss Avenue Dallas, Texas	1990-1992
<u>Other Executive Positions</u>	
Owner, Director and President Fabre Enterprises, Inc. 5503 Crawford Houston, Texas	1978-present
<u>Medical Research Executive Positions</u>	
Director - President Fabre Research Clinics, Inc. 5503 Crawford Houston, Texas	1973-present
Chairman of the Board Research Testing of the Northeast A Delaware Corporation	1978-1981
Director - President Clinical Evaluations, Inc. 5503 Crawford Houston, Texas	1980-present
Chairman of the Board Fabre-Kramer Pharmaceuticals, Inc. 5847 San Felipe, Suite 3147 Houston, Texas 77057	1992-Present
Chairman of the Board Fabre-Kramer Pharmaceuticals, Inc. 731/733 Ormskirk Road Pemberton, Wigan Lancashire, England	1992-Present

Hospital Appointments

Active Staff Member
Psychiatry Department
St. Joseph's Hospital
Houston, Texas 1973-1975
Active Courtesy Staff Member 1975-present

Active Staff Member
Park Plaza Hospital
Houston, Texas 1978-1980
Active Courtesy Staff Member 1980-present

Active Staff Member
Psychiatry Department
Hermann Hospital
Houston, Texas 1974-1975
Active Courtesy Staff Member 1975-present

Courtesy Staff Member
Houston International Hospital
Houston, Texas 1974-1990

Assistant Attending in Psychiatry Service
Harris County Hospital District Medical & Dental Staff
Houston, Texas 1974-present

BOARD CERTIFICATION AND LICENSURE

Certified Proficient in the Basic Sciences
Texas State Board of Medical Examiners
Austin, Texas 1968

Licensed to Practice Medicine in the State of Texas
Texas State Board of Medical Examiners
Number REDACTED
August 27, 1969

Licensed to Practice Medicine in the State of Arkansas
Number REDACTED
April 30, 1974

Licensed to Practice Medicine in the State of Virginia
Number REDACTED
November 18, 1982

Diplomat of the American Board of Psychiatry and Neurology, Inc.
Number REDACTED
Certified in Psychiatry, January 1976

Clinical Laboratory Director
Certified by American Board of Bioanalysts
Certificate REDACTED
April, 1978

HONORARY

Associate Scholarship Award, University of Akron
B.S. with Distinction, University of Akron
Phi Sigma Alpha, Liberal Arts, Honorary Fraternity

National Institute of Health Travel Fellow to the Third International Congress of Endocrinology, Mexico	
A.M.A. Physicians Recognition Award	1972
Who's Who in Texas	1973-1974
American Men and Women of Science	1973-1974
Men of Achievement Volume II, Cambridge, England	1974
Who's Who in the South and Southwest	1974
National Register of Prominent American and International Notables	1974-1975
Fellow Intercontinental Biographical Association Cambridge, England	1975
International Platform Association	1975-1976
A.M.A. Physicians Recognition Award	1977
A.M.A. Physicians Recognition Award	1980
A.M.A. Physicians Recognition Award	1983
A.M.A. Physicians Recognition Award	1986
A.M.A. Physicians Recognition Award	1989
A.M.A. Physicians Recognition Award	1992
Who's Who Worldwide	1993

SOCIETY MEMBERSHIPS

Aerospace Medical Association
 American Academy of Child Psychiatry
 American Association of Bioanalysis
 American Association of Sex Educators, Counselors and Therapists
 American Association for Social Psychiatry, Fellow
 American College of Clinical Pharmacology, Fellow
 American College for Clinical Pharmacology and Therapeutics
 American Federation for Clinical Research
 American Group Psychotherapy Association
 American Medical Association
 American Physiological Society
 American Psychiatric Association
 Collegium International Neuro-Psychopharmacologium
 The Endocrine Society
 Federation of American Societies for Experimental Biology
 Flying Physicians Association
 Harris County Medical Association
 International Association for Social Psychiatry, Fellow
 New York Academy of Sciences
 Research Society on Alcoholism
 Royal Society of Medicine, Affiliate
 Texas Commission on Alcohol
 Texas Medical Association
 Texas Research Society of Alcoholism
 American College Neuro Pharmacology

WORLD CONGRESS MEMBERSHIPS

Third International Congress of Endocrinology
 Fourth International Congress of Endocrinology
 Fifth International Congress of Pharmacology
 Fifth World Congress of Pharmacology
 Fifth World Congress of Psychiatry
 Sixth World Congress of Social Psychiatry
 Sixth World Congress of Psychiatry
 Seventh International Congress of Pharmacology
 Seventh World Congress of Social Psychiatry
 Tenth International Collegium Internationale Neuro-Psychopharmacologium

Eleventh International Collegium Internationale Neuro-Psychopharmacologium
Twenty-Third International Congress of Aviation and Space Medicine
International Symposium of Psychopharmacology
Asociacion Argentina De Psiquiatria Biologica
Eighth World Congress of Psychiatry

MEETINGS ATTENDED - CME HOURS AND CEU CREDITS

(from July, 1974)

1. Brook Lodge Conference Hypnotics. Sponsored by the Upjohn Company, Kalamazoo, Michigan, July 24-27, 1974. 10 Hours Category II/1.0 CEU Credits
2. Texas Medical Association, 108th Annual Session. San Antonio, Texas May 1-4, 1975. 12 Hours Category II/1.2 CEU Credits
3. Aerospace Medical Association. International Congress of Aviation and Space Medicine. Acapulco, Mexico. September 20-October 2, 1975. 10 Hours Category II/1.0 CEU Credits
4. American Society for Clinical Pharmacology and Therapeutics. 77th Annual Meeting. Seattle, Washington. March 18-19, 1976. 13 Hours Category I/1.3 CEU Credits
5. Collegium International Psychopharmacologium (CINP). Quebec, Canada, July 2-9, 1976. 18 Hours Category I/1.8 CEU Credits
6. International Society for Social Psychiatry. Meeting the Future of the Family. Opatija, Yugoslavia, October 4-10, 1976. 20 Hours Category I/2.0 CEU Credits
7. American College of Neuropsychopharmacology. 1976 Annual Meeting. New Orleans, Louisiana, December 13-17, 1976. 17 Hours Category I/1.7 CEU Credits
8. American Society for Clinical Pharmacology and Therapeutics. 78th Annual Meeting. Dallas, Texas, March 23-25, 1977. 16 Hours Category I/1.6 CEU Credits
9. American Association of Sex Educators, Counselors and Therapists. San Francisco, California, April 20-23, 1977. 20 Hours Category II/2.0 CEU Credits
10. American College of Clinical Pharmacology. Washington, D.C., April 28-30, 1977. 12 Hours Category I/1.2 CEU Credits
11. American Association of Social Psychiatry. Minor Tranquilizers in Everyday Practice sponsored by McAllen Hospital. Toronto, Canada, May 1-2, 1977. 3 Hours Category I/ .3 CEU Credits
12. American Psychiatric Association Toronto, Canada, May 3-5, 1977. 10 Hours Category I/1.0 CEU Credits
13. NCDEU. Key Biscayne, Florida, May 18-22, 1977. 20 Hours Category II/2.0 CEU Credits
14. VI World Congress of Psychiatry. Honolulu, Hawaii, August 28-September 3, 1977. 10 Hours Category I. 8 Hours Category II/1.8 CEU Credits
15. Masters Course in Hypnotics. New Orleans, Louisiana, September 23-25, 1977. 24 Hours Category II/2.4 CEU Credits

16. Phenomenology and Treatment of Anxiety. Shamrock Hilton Hotel, Houston, Texas, December 1-2, 1977. 8 Hours Category I/.8 CEU Credits
17. The Use of Psychotherapeutic Drugs in the Treatment of Mental Illness. Columbia University, New York, New York. 17 Hours Category I/1.7 CEU Credits
18. 79th Annual Meeting American Society for Clinical Pharmacology and Therapeutics. Peachtree Plaza Hotel, Atlanta, Georgia, March 29-31, 1978. 18 Hours Category I/1.8 CEU Credits
19. Seventh Annual Meeting American College of Clinical Pharmacology. Sheraton Place Hotel, San Francisco, California, April 27-28, 1978. 12 Hours Category I/1.2 CEU Credits
20. 131st Annual Meeting American Psychiatric Association. Atlanta, Georgia, May 7-10, 1978. 6 Hours Category I/.6 CEU Credits
21. NCDEU Annual Meeting. Key Biscayne, Florida, May 23-25, 1978. 16 Hours Category I/1.6 CEU Credits
22. Symposium, Treatment of Anxiety: Diagnostic and Symptomatic Considerations. Atlanta, Georgia, May 7, 1978. 3 Hours Category I/.3 CEU Credits
23. 11th Congress Collegium Internationale Neuropsychopharmacologium. Vienna, Austria, July 9-16, 1978. 12 Hours Category II/1.2 CEU Credits
24. 7th International Congress of Pharmacology. Paris, France, July 16-21, 1978. 18 Hours Category II/1.8 CEU Credits
25. 7th International Congress of Social Psychiatry. Lisbon, Portugal, October 8-14, 1978. 8 Hours Category II/.8 CEU Credits
26. American College of Neuropsychopharmacology 19th Annual Meeting, Maui, Hawaii, December 11-14, 1978. 18 Hours Category I/1.8 CEU Credits
27. Eightieth Annual Meeting American Society for Clinical Pharmacology and Therapeutics. Crown Center Hotel in Kansas City, Missouri, March 21-23, 1979. 20 Hours Category I/2.0 CEU Credits
28. Symposium, Review of Protocol: Diagnostic Criteria and Hamilton Depression Rating Scale Training Session. November 13, 1979. 6 Hours Category I/.6 CEU Credits
29. Eighth Annual Meeting of the American College of Clinical Pharmacology. Washington, D.C., May 3-5, 1979. 10 Hours Category I/1.0 CEU Credits
30. 132nd Annual Meeting of the American Psychiatric Association. Chicago, Illinois, May 12-18, 1979. 10 Hours Category I/1.0 CEU Credits
31. NCDEU Annual Meeting. Key Biscayne, Florida, May 21-24, 1979. 16 Hours Category I/1.6 CEU Credits
32. American College of Neuropsychopharmacology - 20th Annual Meeting. San Juan, Puerto Rico, December 11-14, 1979. 20 Hours Category II/2.0 CEU Credits
33. 19th Annual International Industrial Pharmacy Conference. Austin, Texas, February 24-29, 1980. 12 Hours Category I/1.2 CEU Credits
34. American Society for Clinical Pharmacology and Therapeutics. Fairmont San Francisco, California, March 19-21, 1980. 18 Hours Category I/1.8 CEU Credits
35. 132nd Annual Meeting American Psychiatric Association. San Francisco, California, May 5-8, 1980. 6 Hours Category I/.6 CEU Credits

36. Symposium, Progress in the Pharmacotherapy of Depression. San Francisco, California, May 5, 1980. 3-1/2 Hours Category I/3.5 CEU Credits
37. Ninth Annual Meeting of the American College of Clinical Pharmacology. Washington, D.C., May 14-16, 1980. 14 Hours Category I/1.4 CEU Credits
38. NCDEU Annual Meeting. Key Biscayne, Florida, May 27-29, 1980. 16 Hours Category I/1.6 CEU Credits
39. Symposium, Therapeutic Progress in Cannabinoid Research. University of Connecticut, Groton, Connecticut, October 20-21, 1980. 14 Hours Category II/1.4 CEU Credits
40. Symposium, Pharmacotherapy of Depression, Mead Johnson Co., San Juan, Puerto Rico, December 15, 1980. 3-1/2 Hours Category I/3.5 CEU Credits
41. American College of Neuropsychopharmacology, 21st Annual Meeting. San Juan, Puerto Rico, December 16-18, 1980. 18 Hours Category I/1.8 CEU Credits
42. American Society for Clinical Pharmacology and Therapeutics. New Orleans, Louisiana, March 18-21, 1981. 18 Hours Category I/1.8 CEU Credits
43. Symposium, Depression: Current Management/Future Directions, Sponsored by the American Psychiatric Association. New Orleans, Louisiana, May 10, 1981. 3-1/2 Hours Category I/3.5 CEU Credits
44. Symposium, The Many Faces of Anxiety: Diagnosis, Therapy and Recent Advances, Sponsored by the American Psychiatric Association, May 10, 1981. 8 Hours Category I/8 CEU Credits
45. NCDEU Annual Meeting. Key Biscayne, Florida, May 25-29, 1981. 16 Hours Category I/1.6 CEU Credits
46. Annual Meeting of American College of Neuropsychopharmacology. San Diego California, December 16-18, 1981. 27 Hours Category I/2.7 CEU Credits
47. Symposium, An Approach to Dilemmas in the Pharmacotherapy of Depression: A New Generation Antidepressant. Sponsored by Duke University Medical Center. Orlando, Florida, February 4-5, 1982. 12 Hours Category I/1.2 CEU Credits
48. NCDEU Annual Meeting, Sponsored by the National Institute of Mental Health. Key Biscayne, Florida, June 1-3, 1982. 12 Hours Category I/1.3 CEU Credits
49. Symposium, Endocrinological Aspects of Ethanol Tolerance and Dependence, Sponsored by NIAAA and Washington University. St. Louis, Missouri, September 14-15, 1982. 8 Hours Category II/8 CEU Credits
50. International Symposium on Receptors and the Upper GI Tract, Sponsored by the University of Alabama School of Medicine, UAB, Scottsdale, Arizona, December 10-11, 1982. 15 Hours Category I/1.5 CEU Credits
51. Symposium, Psychiatric Perspectives "83", Sponsored by Orlando Regional Medical Center and the University of Florida. Orlando, Florida, March 11-12, 1983.
52. NCDEU Annual Meeting. Key Biscayne, Florida, May 31, 1983. 7 Hours Category I/7 CEU Credits
53. II World Conference on Clinical Pharmacology and Therapeutics, Washington, D.C., August 3, 1983. 5 Hours Category I/5 CEU Credits
54. American Academy of Family Physicians, Miami, Florida, October 10, 1983.
55. Symposium, 1984 and Beyond: Psychiatry Encounters the Future, Sponsored by the American Psychiatric Association. Los Angeles, California, May 5-11, 1984. 3 Hours Category I/3 CEU Credits
56. NCDEU Annual Meeting. Key Biscayne, Florida, May 21-23, 1984. 17 Hours Category I/1.7 CEU Credits

57. NCDEU Annual Meeting. Key Biscayne, Florida, May 1-3, 1985. 17 Hours Category I/1.7 CEU Credits
58. American College of Neuropsychopharmacology 1985 Annual Meeting. Maui, Hawaii, December 10-13, 1985.
59. American Psychiatric Association 1986 Annual Meeting. Washington, D.C., May 11, 1986. 3 Hours Category I/3 CEU Credits
60. NCDEU Annual Meeting. Key Biscayne, Florida, May 27-29, 1986. 20 Hours Category I/2.0 CEU Credits
61. Symposium, Serotonin in Affective Disorders: Anatomic, Pharmacologic and Clinical Perspectives, Sponsored by Dista Products Company. Cambridge, Massachusetts, April 4, 1987. 5 Hours Category I/5 CEU Credits
62. American Psychiatric Association. 1987 Annual Meeting. Chicago, Illinois, May 9-15, 1987. 3 Hours Category I/3 CEU Credits
63. NCDEU Annual Meeting. Key Biscayne, Florida, May 26-28, 1987. 12 Hours Category I/1.2 CEU Credits
64. Symposium, Clinical and Cognitive Aspects of Anxiety, Sponsored by Laboratories Substantia and Warner-Lambert Company, Paris, France, January 28, 1988
65. American Psychiatric Association 1988 Annual Meeting. Montreal, Quebec, Canada, May 7-12, 1988. 33 Hours Category I/3.3 CEU Credits
66. NCDEU Annual Meeting. Key Biscayne, Florida, May 31-June 3, 1988. 12 Hours Category I/1.2 CEU Credits.
67. Buspirone Symposium, sponsored by Bristol-Myers Company and Boryung Pharmaceuticals, Seoul and Pusan Korea, June 24-25, 1988
68. XVth Collegium Internationale Neuro-Psychopharmacologicum Congress. Munich, West Germany, August 15-19, 1988. 24 Hours Category I/2.4 CEU Credits
69. Symposium on Trazodone An Antidepressant With Adrenolytic Activity, sponsored by Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A., Munich, West Germany, August 15, 1988. 4 Hours Category II/4 CEU Credits.
70. American Psychiatric Association 1989 Annual Meeting. San Francisco, California, May 6-11, 1989. 4 Hours Category I/4 CEU Credits
71. NCDEU Annual Meeting. Key Biscayne, Florida, May 30-June 2, 1989. 12 Hours Category I/1.2 CEU Credits
72. VIIIth World Congress of Psychiatry. Athens Greece, October 12-19, 1989. 20 Hours Category I/2.0 CEU Credits
73. American Psychiatric Association 1990 Annual Meeting. New York, New York, May 12-17, 1990. 6 Hours Category I/6 CEU Credits
74. NCDEU 30th Annual Meeting. Key Biscayne, Florida, May 29-June 1, 1990. 12 Hours Category I/1.2 CEU Credits
75. XVIIth Collegium Internationale Neuro-Psychopharmacologicum Congress. Kyoto, Japan, September 10-14, 1990. 20 Hours Category I/2.0 CEU Credits
76. American Psychiatric Association 1991 Annual Meeting. New Orleans, Louisiana, May 11-16, 1991. 8 Hours Category I/8 CEU Credits

77. NCDEU 31st Annual Meeting. Key Biscayne, Florida, May 28-31, 1991. 12 Hours Category I/1.2 CEU Credits.
78. 5th World Congress of Biological Psychiatry. Florence, Italy, June 9-14, 1991. 5 Hours Category I/5 CEU Credits
79. American College of Neuropsychopharmacology (ACNP) 30th Annual Meeting. San Juan, Puerto Rico, December 8-11, 1991
80. American Psychiatric Association 1992 Annual Meeting. Washington, DC, May 2-7, 1992. 10 Hours Category I/1.0 CEU Credits
81. NCDEU 32nd Annual Meeting. Boca Raton, Florida, May 26-29, 1992. 12 Hours Category I/1.2 CEU Credits
82. XVIIIth Collegium Internationale Neuro-Psychopharmacologicum Congress. Nice, France, June 28-July 2, 1992. 20 Hours Category I/2.0 CEU Credits
83. American College of Neuropsychopharmacology (ACNP) 31st Annual Meeting. San Juan, Puerto Rico, December 14-19, 1992
84. International Congress of Schizophrenia Research, Colorado Springs, Colorado, April 7-21, 1993
85. NCDEU 33rd Annual Meeting. Boca Raton, Florida, June 1-4, 1993. 12 Hours Category I/1.2 CEU Credits
86. American Psychiatric Association 1993 Annual Meeting. San Francisco, California May 22-27, 1993.
87. Visiting Faculty Meeting (BuSpar), Orlando, Florida, March 3-6, 1994.
88. American Psychiatric Association (APA) Annual Meeting. Philadelphia, PA. May 21-26, 1994,
89. NCDEU 34th Annual Meeting. Marco Island, Florida, May 31-June 3, 1994. 12 Hours Category I/1.2 CEU Credits.
90. American College of Neuropsychopharmacology. Honolulu, Hawaii. Dec. 12-17, 1994
91. CNS Distinguished Faculty In Anxiety Conference. Palm Desert, California. March 2-5, 1995
92. NCDEU 35th Annual Meeting. Orlando, Florida, May 31-June 3, 1995
12 Hours Category I/1.2 CEU Credits.
93. CNS Distinguished Faculty In Depressive Disorders Conference. (Serzone) Washington, D.C. June 9-11, 1995
94. Rhone-Poulenc Rorer Research and Development Investigators Meeting. Paris, France. July 6 -7, 1995
95. CNS Distinguished Faculty in Anxiety Conference, San Diego, California, Feb. 22-25, 1996
96. CNS Distinguished Faculty in Anxiety Conference, Orlando, Florida, Feb. 29 - March 3, 1996
97. NCDEU 36th Annual Meeting, Boca Raton, Florida May 28-June 1, 1996
12 Hours Category I/1.2 CEU Credits.
98. Quintiles(Wyeth-Ayerst) Investigators Training Meeting, Del Mar, California

June 10-13, 1996

99. C.I.N.P Congress Collegium Internationale Neuro-Psychopharmacologicum Meeting, Melbourne, Australia June 23-27, 1996- 24 Hours Category 1/2.4 CEU Credits
100. Serzone Opinion Leaders Training Conference, Princeton, New Jersey July 24-25, 1996
101. NorAge/IPA Congress, Reykjavik, Iceland, October 4-6, 1996
102. Strategies in the Treatment of Resistant Depression, Menninger Clinic, Topeka, Kansas, October 25-26, 1996 (3 hours CME credits)
103. Third Annual Psychiatric Symposium Focus on Depression, Great Falls, Montana, October, 1996.
104. ACNP Meeting (American College of Neuropsychopharmacology) San Juan, Puerto Rico, Dec. 9-13, 1996.
105. Wellbutrin Speakers Education Program, Phoenix, Arizona, Dec. 13-15, 1996.
106. Serzone Opinion Leaders Training Conference, Dallas, Texas, February 7-9, 1997.
107. American Psychiatric Association, Annual Meeting, Poster Presentation Gepirone Extended Release (ER) and Placebo Treatment of Outpatients with Major Depression. C. Cohn and Louis F. Fabre. May 17-22, 1997 - San Diego
108. NCDEU 37th Annual Meeting, Boca Raton, Florida May 28-June 1, 1997
12 Hours Category 1/1.2 CEU Credits.
109. ACNP Meeting (American College of Neuropsychopharmacology) Kamula, Hawaii. Dec, 1997.
110. Eli Lilly & Co. Investigator's Meeting B Indianapolis, Indiana, January 13-14, 1998
111. Hoechst Marion Roussel Phase III Study M100907 Investigators Meeting, Ft. Lauderdale, Florida, April 3-4, 1998.
112. Otsuka America Pharmaceutical, Inc. Investigators Meeting Protocol #31-98-217
A Multicenter, Randomized, Double-Blind, active-Controlled Study to Compare the Long-Term Maintenance Effects and Safety of Aripiprazole and Haloperidol following Acute Relapse in Schizophrenic patients, plus an open-label follow-on study (protocol #31-98-218) for patients as they exit from the double-blind trial. May 14-16, 1998, San Diego, California.
113. Iloperidone Protocol ILP2001 Multicenter Investigator's Meeting Novartis Pharmaceuticals Corporation June 24-25, 1998, Palm Beach, Florida
114. NCDEU 38th Annual Meeting, Boca Raton, Florida June 9-June 13 1998
19 Hours Category 1/1.2 CEU Credits.
115. Aripiprazole Investigator Meeting Otsuka Pharmaceutical Co., June 25-27, 1998, Washington, D.C.
116. Eli Lilly/Scirex Coordinators/Investigators Meeting, July 29-July 31, 1998 San Diego, California.
117. Novartis Pharmaceuticals Corporation Investigators Meeting, Protocol ILP2001 on Iloperidone, June 24, 1998. Palm Beach, Florida.
118. Otsuka Investigator Meeting on Aripiprazole, June 25 and June 26, 1998, Washington, D.C.

119. Eli Lilly/Scirex Coordinators/Investigators Meeting. July 29-July 30, 1998, San Diego, CA.
120. 14th Congress of the European Sleep Research Society. Sept. 9-12, 1998. Madrid, Spain
21 hrs.
121. Glaxo Wellcome AK1A4006/4007 Investigator Meeting. September 13-15, 1998. Washington, D.C.
122. Wyeth-Ayerst Laboratories Venlafaxine XR Investigators Meeting. October, 16-18, 1998. Colorado Springs, CA.
123. Ziprasidone Phase II and Phase III Investigator Meeting, New York, New York. Nov. 12-14, 1998
124. ACNP Meeting (American College of Neuropsychopharmacology) San Juan, Puerto Rico, Dec. 12-19-1998.

PUBLICATIONS

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- *4. DETERMINATION OF ALDOSTERONE AND TETRAHYDROALDOSTERONE IN BLOOD BY ELECTRON CAPTURE GAS CHROMATOGRAPHY. Fabre, L.F., Jr., Fenimore, D.C., Farmer, R.W., Davis, H.W. and Farrell, G.L., Journal of Chromatographic Science, 7:632-638, 1969.
- *5. QUANTITATIVE ANALYSIS OF ALDOSTERONE AND CORTISOL FROM BLOOD BY GAS CHROMATOGRAPHY AND C 14 TRACERS. Fabre, L.F., Jr., Fenimore, D.C., Farmer, R.W., Davis, H.W. and Farrell, G.L., Atomlight, 70:1-12, 1969.
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- *9. EFFECT OF ETHANOL ON ADRENOCORTICAL STERIOD SECRETION. Fabre, L.F., Jr., Farmer, R.W. and Davis, H.W., Advances in Mental Science III, Biological Aspects of Alcohol, M. K. Roach, W. M. McIsaac and P. J. Creaven, Eds., University of Texas Press, Austin, TX, 418-445, 1970.
- *10. COMPUTER ASSISTED COLUMN CALIBRATION FOR GAS-LIQUID CHROMATOGRAPHY OF BIOLOGICAL COMPOUNDS. Talbot, P., Pellizzari, E.D., Brown, J.H., Farmer, R.W. and Fabre, L.F., Jr., Advances in Chromatography, 6:86, 1970.
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- *40. PILOT OPEN LABEL STUDY WITH ALPRAZOLAM (U-31, 889) IN OUT-PATIENTS WITH NEUROTIC DEPRESSION. Fabre, L.F., Jr., Current Therapeutic Research, 19(6):661-667, June, 1976.
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- 75. AN OPEN TRIAL OF LOFEXIDINE IN PATIENTS WITH SYMPTOMS OF ALCOHOL WITHDRAWAL. Fabre, L.F., Jr., Reed, N. and Cawein, M., Clin. Res., 1983.
- 76. THE EFFECT OF ALCOHOL ON ALDOSTERONE SECRETION AND METABOLISM. Fabre, L.F., Jr., Symposium Endocrinological Aspects of Ethanol Tolerance and Dependence, sponsored by NIAAA and Washington University, Kansas City, Missouri, September 13, 1982.
- 77. CURRENT RESEARCH: ANTIANXIETY AGENTS. Louis F. Fabre, M.D. Ph.D., Psychiatric Perspectives "83", sponsored by Orlando Regional Medical Center and the University of Florida, March 11-12, 1983.
- 78. CURRENT RESEARCH: NEW ANTIDEPRESSANT AGENTS. Louis F. Fabre, M.D., Ph.D., Psychiatric Perspectives "83", sponsored by Orlando Regional Medical Center and the University of Florida, March 11-12, 1983.
- 79. DROWSINESS-SEDATION LEVELS IN ANXIOUS NEUROTIC OUTPATIENTS. NCDEU Annual Meeting, sponsored by the National Institute of Mental Health, May 30 - June 2, 1983.
- *80. DROWSINESS-SEDATION LEVELS IN ANXIOUS NEUROTIC OUTPATIENTS. Fabre, L.F., Jr., Johnson, P.A. and Greenblatt, D.J., II World Conference on Clinical Pharmacology & Therapeutics, Washington, D.C., August 3, 1983.
- 81. A COMPARISON OF THREE-TIMES DAILY AND SINGLE NIGHTTIME DOSAGE OF PRAZEPAM IN ANXIOUS NEUROTIC OUTPATIENTS. Fabre, L.F., Jr., Johnson, P.A. and Greenblatt, D.J., American Academy of Family Physicians, Miami, Florida, October 10, 1983.
- 82. TRAZODONE TREATMENT OF CHRONIC DEPRESSION. Louis F. Fabre, Jr., M.D., Ph. D., Asociacion Argentina De Psiquiatria Biologica, Buenos Aires, Argentina, September 2, 1985.
- 83. ANXIETY: DIAGNOSIS AND CURRENT TREATMENT PERSPECTIVES. Louis F. Fabre, M.D., Ph. D., Texas Academy of Physician Assistants, Corpus Christi, Texas, September 14, 1985.
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85. DIFFERENTIAL DIAGNOSIS AND CURRENT TREATMENT OF ANXIETY. Louis F. Fabre, M.D., Ph.D. Buspirone Symposium sponsored by Bristol-Myers Company and Boryung Pharmaceuticals. Seoul Korea, June 24, 1988 and Pusan Korea, June 25, 1988.
- *86. A STUDY OF PAROXETINE, IMIPRAMINE, AND PLACEBO IN THE TREATMENT OF DEPRESSED OUTPATIENTS. Louis F. Fabre, M.D., Ph.D. XVIth Collegium Internationale Neuro-Psychopharmacologicum Congress. Munich, West Germany, August 15-19, 1988.
- *87. UNITED STATES EXPERIENCE AND PERSPECTIVES WITH TRAZODONE. Louis F. Fabre, M.D., Ph.D. Symposium on "Trazodone An Antidepressant With Adrenolytic Activity" sponsored by Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A. Munich, West Germany, August 15, 1988.
- *88. TRAZODONE DOSING REGIMEN - EXPERIENCE WITH SINGLE DOSING ADMINISTRATION. Louis F. Fabre, M.D., Ph.D. Symposium on "Insights in the Use of Trazodone in Depressed Patients". VIIIth World Congress of Psychiatry. Athens Greece, October 12-19, 1989.
- *89. BUSPIRONE IN THE SYMPTOMATIC TREATMENT OF ACUTE ALCOHOL WITHDRAWAL (ABSTRACT). Louis F. Fabre, M.D., Ph.D., Julie Powers Vettraino, RN, MSN, Allison Stephens, RN and David McLendon, Ph.D. VIIIth World Congress of Psychiatry. Athens Greece, October 12-19, 1989.
90. SERTRALINE TREATMENT OF GERIATRIC MAJOR DEPRESSION COMPARED WITH AMITRIPTYLINE. Louis F. Fabre, M.D., Ph.D. Symposium on "Serotonin Reuptake Inhibition in the Management of Depression". VIIIth World Congress of Psychiatry. Athens Greece, October 12-19, 1989.
- *91. DOUBLE-BLIND, MULTICENTER COMPARISON OF SERTRALINE AND AMITRIPTYLINE IN ELDERLY DEPRESSED PATIENTS. Cohn CK, Shrivastava R, Mendels J, Cohn JB, Fabre LF, Claghorn JL, Dessain EC, Itil TM and Lautin A. Symposium on "Serotonin Reuptake Inhibition in the Management of Depression". VIIIth World Congress of Psychiatry. Athens Greece, October 12-19, 1989.
- *92. THE TREATMENT OF ANXIETY. Louis F. Fabre, M.D., Ph.D. Symposium on "New Horizons in Anxiety Therapy", sponsored by Science & Medicine Canada. Vancouver, British Columbia, November 18, 1989.
- *93. GEPIRONE IN THE TREATMENT OF MAJOR DEPRESSION. Jenkins SW, Robinson DS, Fabre LF, Andary JJ, Messina ME and Reich LA. American College of Neuropsychopharmacology (ACNP) 1989 Annual Meeting. Maui, Hawaii, December 10-15, 1989.
- *94. USE OF BUSPIRONE IN DEPRESSION WITH AND WITHOUT MELANCHOLIA (ABSTRACT). Louis F. Fabre, M.D., Ph.D. Symposium, Mead Johnson Pharmaceuticals' Visiting Faculty Program Meeting. Scottsdale, Arizona, March 9-10, 1990.
- *95. BUSPIRONE'S UTILITY IN DEPRESSION AND MELANCHOLIA. Louis F. Fabre, M.D., Ph.D., "The Wallingford CNS Academy" meeting, Bristol-Myers Squibb Company. New York, New York, May 11, 1990.
- *96. COMBINED BUSPIRONE-FLUOXETINE IN SEVERE DEPRESSION (ABSTRACT). Louis F. Fabre, M.D., Ph.D., Julie Powers Vettraino, RN, MSN and Cynthia Saucedo, M.D. American Psychiatric Association 143rd Annual Meeting. New York, New York, May 12-17, 1990.
97. A DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY OF CITALOPRAM IN MAJOR DEPRESSIVE DISORDER (ABSTRACT). Joseph Mendels, Louis Fabre, and Ari Kiev. NCDEU 30th Annual Meeting. Key Biscayne, Florida, May 29-June 1, 1990.
- *98. VENLAFAXINE IN DEPRESSED OUTPATIENTS (ABSTRACT). Arif Khan, Louis Fabre, Stephen

- Dager and David Dunner. NCDEU 30th Annual Meeting. Key Biscayne, Florida, May 29-June 1, 1990.
99. DEPRESSION IN THE ELDERLY. Louis F. Fabre, M.D., Ph.D. Scientific Session, Recent Advances in Psychopharmacology. Ontario Medical Association 110th Annual Meeting, sponsored by Pfizer Canada Inc. Toronto, Ontario Canada, June 4-8, 1990.
 100. ICI 204,636, A NOVEL ATYPICAL ANTIPSYCHOTIC: EARLY INDICATION FOR SAFETY AND EFFICACY IN MAN (ABSTRACT). L. Fabre, V. Slotnick, V. Jones, G. Murray and J. Malick. 17th Collegium Internationale Neuro-Psychopharmacologicum Congress. Kyoto, Japan, September 10-14, 1990.
 - *101. 5HT1A AGONISTS IN THE TREATMENT OF MAJOR DEPRESSION (ABSTRACT). Louis Fabre. "Serotonin and Depression: Neuropharmacology and New Dimensions in Treatment" Satellite Symposium. Bristol-Myers Squibb Company. Kyoto, Japan, September 13, 1990.
 - *102. COMPARATIVE EFFICACY AND SAFETY OF NORTRIPTYLINE AND FLUOXETINE IN THE TREATMENT OF MAJOR DEPRESSION: A CLINICAL STUDY. LF Fabre, MB Scharf, and TM Itil. "The Clinician's Challenge: Strategies for Treatment of Depression in the 1990's" Symposium, sponsored by Sandoz Pharmaceuticals Corporation. Phoenix, Arizona, February 15, 1991.
 103. THE DIAGNOSIS AND TREATMENT OF ANXIETY AND RELATED DISORDERS. Louis Fabre. Symposium sponsored by Bristol-Myers Squibb (Pty) Limited South Africa. Eastern Transvaal, South Africa. February 22-23, 1991.
 104. THE PSYCHOPHARMACOLOGIC TREATMENT OF DEPRESSION. Louis Fabre. Symposium sponsored by Bristol-Myers Squibb (Pty) Limited South Africa. Eastern Transvaal, South Africa, February 22-23, 1991.
 105. ZALOSPIRONE: A NEW SEROTONIN-1A PARTIAL ANTAGONIST - PHASE I STUDIES (ABSTRACT). LF Fabre, S Troy, and AT Derivan. NCDEU 31st Annual Meeting. Key Biscayne, Florida, May 28-31, 1991.
 - *106. SERTRALINE AND THE ELDERLY (ABSTRACT). Louis Fabre. "Serotonin and Psychiatry: The Role of Sertraline" Satellite Symposium, Pfizer International. Florence, Italy, June 9, 1991.
 - *107. A DOUBLE-BLIND MULTICENTER STUDY COMPARING THE SAFETY AND EFFICACY OF SERTRALINE WITH PLACEBO IN MAJOR DEPRESSION (ABSTRACT). Louis F. Fabre. 5th World Congress of Biological Psychiatry. Florence, Italy, June 10-14, 1991.
 108. BUSPIRONE IN THE TREATMENT OF MIXED ANXIETY-DEPRESSION. Symposium "New Trends in the Treatment of Anxiety," Louis F. Fabre, M.D., Ph.D. Sponsored by Bristol-Myers Squibb of Portugal. Oporto and Lisbon, Portugal, November 22-23, 1991.
 109. THE TREATMENT OF ANXIETY, DEPRESSION AND RELATED DISORDERS WITH SPECIAL REFERENCE TO THE EFFICACY OF BUSPIRONE. Louis F. Fabre, M.D., Ph.D. Symposium sponsored by Bristol-Myers Squibb. Abu Dhabi, Dubai, and Al Ain, United Arab Emirates, December 15-17, 1991.
 - *110. AUGMENTATION OF ANTIDEPRESSANT RESPONSE AND IMPLICATIONS FOR COMBINATION THERAPY. Louis F. Fabre, M.D., Ph.D. Symposium, Mead Johnson Pharmaceuticals' Visiting Faculty Program Meeting. Tuscon, Arizona, February 20-23, 1992.
 111. EFFICACY AND SAFETY OF BID DOSES OF VENLAFAXINE IN A DOSE-RESPONSE STUDY (ABSTRACT). J Mendels, R Johnson, J Mattes, R Riesenber, L Fabre, et al. NCDEU 32nd Annual Meeting. Boca Raton, Florida, May 26-29, 1992.
 112. ASCENDING SINGLE-DOSE SAFETY AND TOLERANCE OF WY-47,791 HCL, A NOVEL POTENTIAL ANTIPSYCHOTIC (ABSTRACT). L. Fabre, S Leventer, L Goodman, M Welch, A Baker.

- and A Derivan. XVIII Collegium Internationale Neuro-Psychopharmacologicum Congress. Nice, France. June 28-July 2, 1992.
113. FLUVOXAMINE IN THE TREATMENT OF DEPRESSION. A DOUBLE-BLIND COMPARISON WITH IMIPRAMINE AND PLACEBO IN OUTPATIENTS WITH MAJOR DEPRESSION (ABSTRACT). L Fabre, J Vettraino, L Birkhimer, and V Houser. XVIII Collegium Internationale Neuro-Psychopharmacologicum Congress. Nice, France, June 28-July 2, 1992.
 - *114. COMPOSITE EVALUATION OF PLACEBO CONTROLLED STUDIES IN PATIENTS WITH GENERALIZED ANXIETY DISORDERS (DSM III) AND COEXISTING DEPRESSIVE SYMPTOMS. RE Gammans, AJ Hvizdos, RJ Seidehamel, JB Cohn, CS Wilcox, LF Fabre, JC Peckhold, WT Smith, and K Rickels. XVIII Collegium Internationale Neuro-Psychopharmacologicum Congress. Nice, France, June 28-July 2, 1992.
 115. A MULTICENTER, OPEN PILOT TRIAL OF ICI 204,636 IN HOSPITALIZED PATIENTS WITH ACUTE PSYCHOTIC SYMPTOMATOLOGY (ABSTRACT). LF Fabre and L Arvanitis. International Congress on Schizophrenia Research. Colorado Springs, Colorado, April 17-21, 1993.
 116. A DOUBLE-BLIND MULTICENTER TRIAL OF A LOW DOSE RANGE AND A HIGH DOSE RANGE OF GEPIRONE-ER COMPARED TO PLACEBO IN THE TREATMENT OF DEPRESSED OUTPATIENTS. (ABSTRACT) LF Fabre, C Wilcox, J Dale, J Ferguson, & J Cohn. NCDEU 35th Annual Meeting, Orlando, Florida, May 31-June 3, 1995. Psychopharmacology Bulletin, 1995, Vol. 31, No. 3, Page. 631
 117. MULTIPLE DOSE PHARMACOKINETICS AND DOSE PROPORTIONALITY STUDY OF SEROQUEL™ (ICI 204,636 IN MALE SCHIZOPHRENIC PATIENTS. (ABSTRACT) Y. WJ Wong, BJ Ewing, LF Fabre, PT Thynum & C Yeh. CNP Meeting, San Juan, Puerto Rico, Dec. 11 - 15, 1995.
 118. BIOEQUIVALENCE OF CLOZAPINE IN HEALTHY SUBJECTS. RG Buice, V. Subramanian, KL Duchin, J. Whisnant, LF Fabre, IVAX Corporation and Fabre. Clinics, Inc. (POSTER) AAPS Meeting, Miami, Florida, November 9, 1995
 - *119. MULTIPLE DOSE PHARMACOKINETICS AND DOSE PROPORTIONALITY STUDY OF SEROQUEL (ICI 204,636) IN MALE SCHIZOPHRENIA PATIENTS. Fabre, LF, Wong, James, JC. Ewing, Barbara J, Thynum Per, Yeh, Chiao (POSTER) presented at the ACNP Annual Meeting in San Juan, Puerto, Rico, Dec. 10-13, 1995.
 - *120. MULTIPLE DOSE PHARMACOKINETICS OF ICI 204,636 IN SCHIZOPHRENIC MEN AND WOMEN (ABSTRACT) Feigner, A., and Fabre, LF. NCDEU Meeting, Boca Raton, Florida, May 28-31, 1996.
 - *121. GEPIRONE EXTENDED RELEASE (ER) TREATMENT OF OUTPATIENTS WITH MAJOR DEPRESSION-A DOSE RESPONSE STUDY. COHN, C., FABRE, LF (POSTER) presented at the XX C.I.N.P. Congress Collegium International Neuropsychopharmacologicum Congress, Melbourne, Australia, June 23-27, 1996. The Journal of the European College of Neuropsychopharmacology, Volume 6, Supplement 3, June 1996. (Page 49)
 122. LONG TERM GEPIRONE EFFICACY IN THE TREATMENT OF MAJOR DEPRESSION PREVENTION OF RELAPSE (ABSTRACT) Fabre, L.F., and Claghorn, J. presented at the NorAge/IPA Congress, Reykjavik, Iceland, October 4-5, 1996.
 123. GEPIRONE SAFETY AND EFFICACY IN THE TREATMENT OF GENERALIZED ANXIETY DISORDER (ABSTRACT) Fabre, LF. and Kramer, SJ. presented at the NorAge/IPA Congress, Reykjavik, Iceland, October 4-5, 1996.
 124. OVERVIEW OF TREATMENT-RESISTANT DEPRESSION, PSYCHOPHARMACOLOGY (INCLUDING THE DIFFERENCES SEEN IN THE GERIATRIC POPULATIONS, AUGMENTATION

STRATEGIES: THYROID AUGMENTATION, LITHIUM, PSYCHOSTIMULANTS, ESTROGEN, ETC. AND DEPRESSION IN SUBSTANCE ABUSERS, ADOLESCENTS AND OTHER SUBPOPULATIONS Louis F. Fabre, M.D., Ph.D., presented at the Third Annual Psychiatric Symposium: Focus on Depression, Great Falls, Montana, Oct. 11, 1996.

125. STRATEGIES IN THE TREATMENT OF RESISTANT DEPRESSION Louis F. Fabre, M.D., Ph.D., presented at the Menninger Clinic (Secly Conference Center) Topeka, Kansas, Oct. 25-26, 1996.
126. GEPİRONE EXTENDED RELEASE (ER) COMPARED TO PLACEBO IN THE TREATMENT OF OUTPATIENTS WITH MAJOR DEPRESSION. ABSTRACT NR562 Cohn C., and Fabre, LF presented at the American Psychiatric Association Meeting, San Diego, CA, May, 1997.
127. CITALOPRAM IN THE TREATMENT OF MODERATE TO SEVERE DEPRESSION. Mendels, J., Kiev, A., Fabre, LF, and Schwartz, G presented at the American Psychiatric Association Meeting, San Diego, CA, May, 1997.

CLINICAL STUDIES PERFORMED WITH LOUIS. F. FABRE, JR., M.D., PH.D. AS PRINCIPAL INVESTIGATOR

1. Amoxapine Capsules. To evaluate the therapeutic efficacy and side effects of amoxapine in comparison with placebo and imipramine in patients with depressive illness. (Lederle Laboratories)
2. U-33,030 and placebo comparison in patients with insomnia (14 day study). (The UpJohn Company)
3. U-33,030 and placebo comparison in patients with insomnia (2 day study). (The UpJohn Company)
4. U-33,030 and flurazepam comparison in patients with insomnia (single-dose cross-over study). (The UpJohn Company)
5. Double-Blind placebo controlled study of U-28,774 in anxiety. (The UpJohn Company)
6. U-33,030 and flurazepam comparison in patients with insomnia (7 day study) (The UpJohn Company)
7. Triazolam and placebo comparison in psychiatric patients with insomnia (single-dose cross-over study). (The UpJohn Company)
8. Triazolam and placebo comparison in geriatric patients with insomnia (single-dose cross-over study). (The UpJohn Company)
9. Triazolam and placebo comparison in psychiatric patients with insomnia (7 day study). (The UpJohn Company)
10. Triazolam (U-33,030) open label efficacy study in insomniac alcoholic patients after withdrawal from alcohol (28 day study). (The UpJohn Company)
11. Triazolam open label efficacy study in patients with insomnia (7 day study). (The UpJohn Company)
12. Triazolam and flurazepam comparison in patients with insomnia (single-dose cross-over study). (The UpJohn Company)
13. Comparison of alprazolam, Valium and placebo in the treatment of anxiety. (The UpJohn Company)
14. Efficacy of Alprazolam in the treatment of anxiety in recovering alcoholic subjects. (The UpJohn Company)
15. Efficacy of alprazolam in the treatment of neurotic depression. (The UpJohn Company)
16. Comparison of ketazolam, diazepam and placebo in once a day vs. TID dosing. (The UpJohn Company)

17. Open label evaluation of minimum effective dosage and tolerance of graded oral doses of nomifensin in depressed outpatients. (Hoechst)
18. Open-label study to investigate the efficacy of AHR-2277 in the alleviation of anxiety and improvement in everyday functioning in anxious subjects. (A. H. Robins Co.)
19. Triazolam and chloral hydrate comparison in-patients with insomnia (single-dose cross-over study). (The UpJohn Company)
20. Triazolam and flurazepam comparison in patients with insomnia. (The UpJohn Company)
21. Comparison of lenperone (AHR-2277), diazepam and placebo, 28-day, double-blind study. (A. H. Robins Co.)
22. Double-Blind comparative evaluation of efficacy and safety of a specific dose range of oral dose of HOE 984, imipramine and placebo in depressed outpatients. (Hoechst)
23. Double-Blind, comparative evaluation of efficacy and safety of a specific dose range of oral doses of WIN 27,147-2, imipramine and placebo in depressed outpatients. (Sterling-Winthrop)
24. Comparison of therapeutic effect, tolerance and safety of ketazolam and diazepam administered for six months to outpatients with chronic anxiety neurosis. (The UpJohn Company)
25. Comparison of triazolam and placebo in the treatment of insomnia and anxiety in anxious outpatients. (The UpJohn Company)
26. Comparison of ketazolam, clorazepate dipotassium and placebo in once a day vs. multiple daily dosing. (The UpJohn Company)
27. Open rising dose efficacy/safety study of SCH 12679 in anxiety. (Schering Corp.)
28. Evaluation of trazodone in the treatment of endogenous depression. (Mead-Johnson Pharmaceuticals)
29. Wellbutrin phase II placebo controlled proof of efficacy. Multi-clinic (Burroughs-Wellcome Co.)
30. A comparative clinical trial of ripazepam, diazepam and placebo in the treatment of anxiety states. (Parke-Davis)
31. Comparison of the anti-anxiety efficacy of alprazolam and chlordiazepoxide hydrochloride in the chronic withdrawal period from alcohol. (The UpJohn Company)
32. Halazepam, SCH 12041, an anti-anxiety agent. (Schering Corp.)
33. Alprazolam, imipramine and placebo in the treatment of neurotic depression. (The UpJohn Company)
34. Phase II open study of MCN-3377 to establish efficacy in the treatment of non-psychotic patients with manifest anxiety. (McNeil Laboratories)
35. A 14-28 day efficacy, safety and toleration study of SAH 48-104 to 75 mg BID vs. placebo in hospitalized depressed patients. (Sandoz)
36. The Safety and effectiveness of long term oral administration of trazodone in depressive illness. (Mead-Johnson Pharmaceuticals)
37. Comparison of triazolam, diazepam and placebo in the treatment of insomnia and anxiety in outpatients with anxiety neurosis. (The UpJohn Company)
38. Phase II double-blind controlled study of McN3377 fenobam preparation and placebo to establish efficacy

- in the treatment of non-psychotic outpatients with manifest anxiety. (McNeil Laboratories)
39. Phase II open label controlled study of nabilone in anxiety. (Eli Lilly and Company)
 40. A comparative clinical trial of trenbenzomine, chlordiazepoxide and placebo in the treatment of mixed affective-anxious disorders. (Parke-Davis)
 41. Phase II pilot open label study of brofexine in anxiety. (Adria Labs)
 42. Comparison of Halcion and placebo in the treatment of insomnia in depressed patients on tricyclic anti-depressants. (The Upjohn Company)
 43. Phase IV outpatient comparison of Prazepam against placebo, diazepam and clorazepate in anxiety. (Warner Chilcott)
 44. Evaluation of anti-anxiety and anti-anginal effects of peritrate 80 mg sustained action tablets with phenobarbital. (Warner Chilcott)
 45. Phase II double-blind comparison of WY-23,409 and placebo in depression. (Wyeth-Ayerst Laboratories)
 46. Maintenance study of bromperidol in chronic schizophrenia. (Ortho Pharmaceutical Group)
 47. Double-blind controlled study of McN-2453 Azepindole preparation and placebo to establish efficacy in the treatment of outpatients with depression. (McNeil Laboratories)
 48. A double-blind study of the anxiolytic activity and safety of brofexine in outpatients using a placebo controlled randomized parallel group design. (Adria Laboratories)
 49. Comparison of alprazolam and placebo in the treatment of anxiety. (The Upjohn Company)
 50. Double-blind evaluation of the safety and efficacy of two dose ranges of Wellbutrin vs. placebo in depressed outpatients. (Burroughs-Wellcome Co.)
 51. Comparison of moban and placebo in the treatment of neurotic depression. (Endo Laboratories)
 52. Comparison of alprazolam, oxazepam (Serax) and placebo in the treatment anxiety. (The Upjohn Company)
 53. A phase I safety study of VI-100 in small single doses administered to human subjects. (Vinoxen)
 54. A phase I safety study of VI-100 in maximal single doses administered to human subjects. (Vinoxen)
 55. A phase I safety study of VI-100 in multiple doses administered to human subjects over a five day trial period. (Vinoxen)
 56. A phase I safety study of VI-200 in small single doses administered to human subjects. (Vinoxen)
 57. Phase I safety study of VI-200 in multiple doses administered to human subjects over a five day trial period. (Vinoxen)
 58. Phase I safety study of VI-200 in maximal single doses administered to human subjects. (Vinoxen)
 59. Double-blind randomized parallel controlled study of nabilone, diazepam or placebo in patients exhibiting symptoms of anxiety. (Eli Lilly and Company)
 60. Safety and efficacy of DL-262 in outpatients with endogenous depression. (Dow Chemical)
 61. Outpatient comparison of prazepam against placebo diazepam and clorazepate in anxiety. (Warner

Chilcott)

62. A dose ranging study of melperone in anxious patients. (Merrell-National)
63. Evaluation of buspirone as an anti-anxiety agent as compared to diazepam. (Mead-Johnson Pharmaceuticals)
64. A controlled multicenter clinical trial of zometapine in the treatment of major depressive disorders. (Warner Lambert/Parke-Davis)
65. Comparison of the anti-anxiety efficacy of alprazolam (U-31,889) and chlordiazepoxide hydrochloride and placebo in the chronic withdrawal period from alcohol. (The UpJohn Company)
66. Double-blind comparison of bromperidol and haloperidol in newly admitted schizophrenics. (Ortho Pharmaceuticals Group)
67. Double-blind comparison of VI-100 and VI-200 and placebo in the treatment of alcohol withdrawal syndrome in recently admitted alcoholic inpatients. (Vinoxen)
68. A short term clinical study comparing the efficacy and safety of quazepam 15 mg with flurazepam 30 mg and placebo for the treatment of insomnia in hospitalized patients. (Schering Co.)
69. A multicenter controlled clinical trial of trebenzomine, thioridazine and placebo in the treatment of newly admitted schizophrenic inpatients. Warner- Lambert/Parke-Davis)
70. Phase I single dose tolerance test of EN-207. (Endo Laboratories)
71. Bioequivalency of kanamycin with the standard kanamycin in normal subjects. (Beecham Laboratories)
72. Phase IV inpatient comparison study of prazepam vs. placebo in the treatment of anxiety associated with the acute phase of alcohol withdrawal. Warner-Lambert)
73. Phase I multiple dose tolerance test of EN-207. (Endo Laboratories)
74. A controlled multicenter clinical trial of vivalan (ICI 58,834) in the treatment of psychogeriatric patients with a clinical diagnosis of endogenous depression. (ICI Pharmaceuticals)
75. Evaluation of buspirone as an anti-anxiety agent, buspirone vs. diazepam. (Mead-Johnson Pharmaceuticals)
76. Alprazolam efficacy in the treatment of schizophrenia symptoms and behavior. (The UpJohn Company)
77. A multicenter, controlled clinical trial of trebenzomine, doxepin and placebo in the treatment of depressed-anxious outpatients. (Warner-Lambert)
78. A controlled study of the treatment of major depressive disorders with fluoxetine HCl. (Eli Lilly and Company)
79. Moban bioequivalency study in outpatient schizophrenics. (Endo Laboratories)
80. A double blind multicenter study to compare the efficacy and safety of fluotracen vs. placebo in depressed patients. (Sandoz)
81. Open label emergency use of nomifensine maleate for the treatment of depression. (Hoechst)
82. Multicenter double-blind randomized parallel comparison of naproxen sodium and a compound of aspirin, phenacetin, caffeine and codeine phosphate in patients with moderate to severe pain due to tennis elbow or frozen shoulder. (Syntex Laboratories)

83. Multicenter double-blind randomized parallel comparison of naproxen sodium and propoxyphene napsylate with acetaminophen in patients with moderate to severe lumbosacral pain, tenosynovitis, fibrositis or spondylitis. (Syntex Laboratories)
84. A phase II short term efficacy study comparing estazolam with flurazepam and placebo. (Abbott)
85. A double blind comparison of VI-100 with placebo in the treatment of tobacco withdrawal and cigarette craving in outpatients. (Vinoxen)
86. An initial safety and efficacy study of SAH 52-522 vs. placebo in neurotic outpatients. (Sandoz)
87. A long term double blind clinical study comparing the safety and acceptance of quazepam 30 mg with flurazepam 30 mg for the treatment of chronic insomnia in outpatients. (Schering-Plough)
88. Phase IV outpatient comparison study of prazepam once daily vs. three times daily dosage. (Parke-Davis)
89. Double-blind, controlled evaluation of pyrilamine maleate and placebo in insomniac patients suffering primarily from difficulties falling asleep.
90. Zometapine treatment of depressed outpatients. (Warner-Lambert/Parke-Davis)
91. A multi-clinic double blind parallel study of praxilene (Nafrolyl) vs. placebo in the alleviation of symptoms associated with dementia. (Lipha Chemicals, Inc.)
92. Open label study of zometapine in the treatment of major depressive disorders. (Warner-Lambert/Parke-Davis)
93. The bioavailability of phenacetin free Fiorinal: a comparison of the tablet and capsule to a reference solution. (Sandoz)
94. Clobamine (RMI 81,182 EF) in the treatment of depression. (Merrill-Dow)
95. Bioavailability of phenacetin free Fiorinal with codeine. (Sandoz)
96. A multicenter efficacy and safety evaluation of SAH 52-522 vs. diazepam (Valium) and placebo in anxious outpatients. (Sandoz)
97. An inpatient phase II dose ranging study of DL-588. (Merrill-Dow)
98. Bupropion: A determination of abuse liability.
99. Phase I multiple dose double-blind tolerance test of EN-207. (Endo Laboratories)
100. Open trial of lofexidine in inpatients with symptoms of alcohol withdrawal. (Merrill-Dow)
101. Phase II open label multidose study of EN-207 in endogenous depression. (Endo Laboratories)
102. A placebo controlled randomized double-blind trial of lofexidine in inpatients with symptoms of alcohol withdrawal. (Merrill-Dow)
103. Amoxapine and maprotiline in the treatment of depressive illness: A controlled comparison in outpatients using the dexamethasone suppression test as a neuroendocrine marker.
104. Multicenter phase II double-blind placebo controlled study of EN-207 in depressed outpatients - utilizing fixed dose ranges. (Endo Laboratories)
105. Phase II open label multiple dose study of EN-207 in depressed patients for six weeks. (Endo Laboratories)

106. Double-blind evaluation of the safety and tolerance of 106-689-2i - multiple doses for seven days in healthy volunteers. (Sandoz)
107. A study of the effect of antacid and anticholinergic medication on ranitidine absorption. (Glaxo, Inc.)
108. An outpatient phase II dose ranging study of napactadine.
109. The steady state bioavailability Mellaril tablets, suspension and concentrate. (Sandoz)
110. Multiple oral dose tolerance study of tracazolate (ICI 136,753) 40 mg QID in normal subjects. (ICI Pharmaceuticals)
111. Multiple oral dose tolerance study of tracazolate (ICI 136,753) 80 mg QID in normal subjects. (ICI Pharmaceuticals)
112. An open label multicenter study to determine the safety and efficacy of a total daily dose of 6 mg ergoloid mesylates (Hydergine) plus 60 mg nortriptyline HCl (Pamelor) in depressed outpatients. (Sandoz)
113. Multiple oral dose tolerance study of tracazolate (ICI 136,753) 20 mg QID in normal subjects. (ICI Pharmaceuticals)
114. CGS7135A in moderate depression. (Ciba-Geigy)
115. An open label dose-ranging trial of synaptamine outpatients with anxiety neurosis. (Ciba-Geigy)
116. Continued treatment of depressed hypertensive patients who have benefited from trazodone in a clinical trial. (Mead-Johnson Pharmaceuticals)
117. Comparison of trazodone and amitriptyline in the treatment of depressed patients with stable, controlled hypertension. (Mead-Johnson Pharmaceuticals)
118. Amoxapine and maprotiline in the treatment of depressive illness: A controlled comparison in outpatients using dexamethasone suppression test as a neuroendocrine marker.
119. Tolerance to repeated intravenous infusions of ranitidine HCl at two dose levels. (Glaxo, Inc.)
120. Phase I/II CP-51,974 in the treatment of depressed inpatients double-blind, multiple dose, multicenters protocol. (Pfizer, Inc.)
121. Long-term safety and efficacy of CGS-7135A in moderate depression (humanitarian protocol). (Ciba-Geigy)
122. Synaptamine (CGS-7525A) antidepressant open label, single vs. multiple dosing trial. (Ciba-Geigy)
123. Long-term safety and efficacy of CGS-7525A in anxiety neurosis. (Ciba-Geigy)
124. Rechallenge of normal subject who developed diarrhea during I.V. administration of ranitidine HCl. (Glaxo, Inc.)
125. The steady state bioavailability of Mellaril sustained release tablets. (Sandoz)
126. CGS-7575A double-blind trial comparing CGS-7525A with diazepam and placebo in outpatients with anxiety neurosis. (Ciba-Geigy)
127. Tolerance to repeated intravenous infusions of ranitidine HCl at two dose levels comparison with cimetidine and saline infusions. (Glaxo, Inc.)
128. Double-blind trial comparing CGS-7135A with desipramine HCl and placebo in patients with moderate

- depression. (Ciba-Geigy)
129. Oxaprotiline Hydrochloride double-blind comparative efficacy and tolerability study with placebo in known alcoholic patients with a depressive episode of moderate severity. (Ciba-Geigy)
130. Long-term use of oxaprotiline hydrochloride in patients with a depressive disorder. (Ciba-Geigy)
131. An open long-term study of sertraline (CP-51,974) in the treatment of depressive illness. (Pfizer, Inc.)
132. CGS-7135A onset of action study in patients with moderate depression. (Ciba-Geigy)
133. Oxaprotiline hydrochloride comparative efficacy and tolerability study with amitriptyline hydrochloride and placebo in major depressive disorder. (Ciba-Geigy)
134. A controlled study of the treatment of generalized anxiety disorder comparing twice a day dosing of lorazepam and diazepam or placebo. (Eli Lilly and Company)
135. CP-529,74 Double-blind. (Pfizer, Inc.)
136. Long-term use of oxaprotiline hydrochloride in alcoholic patients with a depressive disorder. (Ciba-Geigy)
137. Comparison of buspirone, alprazolam and lorazepam in the treatment of anxiety. (Mead-Johnson Pharmaceuticals)
138. A double-blind placebo controlled cross-over study to compare two initial dosage regimens of labetalol (Trandate) in patients with mild or moderate hypertension. (Glaxo, Inc.)
139. Multicenter double-blind placebo controlled randomized comparative study of clovoxamine fumarate and imipramine hydrochloride in patients with major depressive episode. (Kali-Duphar)
140. Tomoxetine vs. placebo in depression (parallel: blind). (Eli Lilly and Company)
141. Phase II/III sertraline (CP51-974) in the treatment of patients with major depression (double-blind, multiple dose protocol). (Pfizer, Inc.)
142. Double-blind parallel comparison of citalopram and placebo in patients with major depression or bipolar disorder, depressed. (Pfizer, Inc.)
143. Buspirone in the symptomatic treatment of acute alcohol withdrawal. (Bristol-Myers)
144. Open-label, dose-ranging, safety and efficacy trial of CGS-10746B in subchronic and chronic schizophrenics with acute exacerbations requiring institutionalization. (Ciba-Geigy)
145. A multicenter, double-blind, parallel, placebo-controlled dose ranging study evaluating the safety and efficacy of suriclone in patients with a generalized anxiety disorder. (Ives Laboratories)
146. Double-blind, multiple dose, sertraline/placebo controlled trial in major depressive disorder - protocol extension. (Pfizer, Inc.)
147. Tomoxetine in depression - extension study. (Eli Lilly and Company)
148. Open label, dose-ranging, safety and efficacy trial of CGS-10746B given every 12 hours in subchronic and chronic schizophrenics with acute exacerbations. (Ciba-Geigy)
149. Pharmacokinetics of labetalol (Trandate) in elderly and younger patients with hypertension. (Glaxo, Inc.)

150. Buspirone in the long-term treatment of chronic anxiety. (Mead-Johnson Pharmaceuticals)
151. A multicenter non-blind, dose ranging study evaluating the safety and efficacy of suriclone in patients with generalized anxiety disorder. (Ives Laboratories)
152. Fluvoxamine Maleate: A multicenter placebo-controlled comparison of two dosage regimens in outpatients with major depression. (Kali Duphar)
153. A parallel study to compare the pharmacodynamic profile of lebetalol to that of hydrochlorothiazide in patients with mild to moderate hypertension. (Glaxo, Inc.)
154. MDS-509 A multicenter, two phase, dose ranging study evaluating the safety and efficacy of suriclone in patients with generalized anxiety disorder. (Wyeth-Ayerst Laboratories)
155. CGS-9896 single-blind, dose-ranging trial of BID and TID dosing of CGS-9896 or placebo in outpatients with generalized anxiety disorder. (Ciba-Geigy)
156. Nitrendipine (BAY e 5009) bioequivalency of various formulations in healthy volunteers. (Miles, Inc.)
157. Nitrendipine (BAY e 5009) bioequivalency of various formulations in healthy volunteers: stable isotope technique. (Miles, Inc.)
158. Fluvoxamine Maleate: A humanitarian protocol for continuation of treatment up to six months. (Kali-Duphar)
159. Fluoxetine in the treatment of major depressive disorder (compassionate use). (Eli Lilly and Company)
160. Clovoxamine in the treatment of anxiety and depression in anxious, depressed outpatients: A multicenter double-blind placebo-controlled randomized comparative study of clovoxamine fumarate and imipramine hydrochloride. (Kali Duphar)
161. A multicenter, double-blind, placebo controlled, fixed-dose response study evaluating the efficacy and safety of minaprine in patients with major depression. (Ives Laboratories)
162. A double-blind, imipramine and placebo controlled study of paroxetine in depressed outpatients. (Beecham Laboratories)
163. A multicenter, double-blind, placebo controlled, fixed-dose response study evaluating the efficacy and safety of minaprine in patients with dysthymic disorder. (Ives Laboratories)
164. A multicenter, double-blind, placebo controlled fixed dose evaluation of four doses of paroxetine. (Beecham Laboratories)
165. Minaprine MDS 536,537 extended treatment amendment. (Ives Laboratories)
166. Fluoxetine vs. placebo: Fixed low dose in depression. (Eli Lilly and Company)
167. A double-blind extension of protocol PAR03-04. (Beecham Laboratories)
168. A double-blind extension of protocol PAR03-06. (Beecham Laboratories)
169. Ascending single dose tolerance study of WY-45,030 tablets. (Wyeth-Ayerst Laboratories)

170. Pamelor Study #4-1-OP Comparative evaluation of nortriptyline vs. trazodone in depressed geriatric outpatients. (Sandoz)
171. Double-blind, placebo-controlled, multiple dose tolerance study of WY-45,030 tablets. (Wyeth-Ayerst Laboratories)
172. Tomoxetine/Placebo fixed dose depression. (Eli Lilly and Company)
173. A phase III double-blind, multisite comparison of sertraline and amitriptyline in the treatment of geriatric patients with major depression or bipolar disorder depressed. 36(Pfizer, Inc.)
174. A phase III long term, double-blind, multisite continuation of the comparison of sertraline and amitriptyline in the treatment of geriatric patients with major depression or bipolar disorder depressed. (Pfizer, Inc.)
175. Extension of protocol B4Z-MC-HFA6 tomoxetine/placebo fixed dose depression. (Eli Lilly and Company)
176. Open-label study of WY-45,030 tablets in depressed outpatients. (Wyeth-Ayerst Laboratories)
177. The comparative steady state bioavailability of Mellaril. (Sandoz)
178. Double-blind placebo controlled study in patients with generalized anxiety disorder SL80.0342. (Lorex)
179. An open label multicenter evaluation of the efficacy and safety of orally administered GR-C507/75 in patients with a generalized anxiety disorder. (Glaxo, Inc.)
180. A parallel, dose-blind, placebo-controlled, pilot dose-ranging, multicenter study to evaluate the efficacy and tolerability of BTS 54524 in outpatients with major depression. (The Boots Company)
181. Double-blind, placebo-controlled, parallel-group dosage-determination study of WY-45,030 tablets in depressed patients. (Wyeth-Ayerst Laboratories)
182. Compassionate use of sertraline (CP-51,974) for major depression. (Pfizer, Inc.)
183. Evaluation of ICI 169,369 in patients with generalized anxiety. (Stuart)
184. Intermediate-term safety and clinical acceptability study in WY-45,030 tablets in depressed patients. (Wyeth-Ayerst Laboratories)
185. Double-blind, placebo-controlled, long term study of alpidem in patients with anxiety disorders. (Lorex)
186. A double-blind, multicenter trial of two dose ranges of gepirone vs. placebo in the treatment of depressed outpatients. (Bristol-Myers)
187. Comparison of buspirone to placebo in major depressive disorder. (Bristol-Myers)
188. The steady state bioequivalence of Mellaril 100 mg, 200 mg, and 400 mg sustained release tablets. (Sandoz)
189. Ascending single dose safety and tolerance study of WY 47,384 capsules. (Wyeth-Ayerst Laboratories)
190. A phase II, parallel-group, placebo-controlled study to evaluate the efficacy and safety of ipsapirone HCl in outpatients with generalized anxiety disorder during a four week treatment period. (Miles,

Inc.)

191. Double-blind parallel comparison of sertraline and placebo in obese outpatients with mild hypertension. (Pfizer, Inc.)
192. Tomoxetine/placebo modified fixed dose depression. (Eli Lilly and Company)
193. Double-blind parallel comparison of sertraline and placebo in obese patients with mild hypertension - an extension. (Pfizer, Inc.)
194. Extension of protocol B4Z-MC-HFAH tomoxetine/placebo modified fixed dose. (Eli Lilly and Company)
195. Double-blind parallel comparison of SM-3997 and placebo in outpatients with generalized anxiety disorder. (Pfizer, Inc.)
196. Single blind pilot study of SM-3997 in outpatients with generalized anxiety disorder. (Pfizer, Inc.)
197. A double-blind, multicenter trial of two dose ranges of gepirone (1 mg and 5 mg) versus placebo in the treatment of anxious outpatients (including long-term extension). (Bristol-Myers)
198. An open-label multicenter trial to evaluate the safety and tolerability of dothiepin in doses of 200-300 mg/day for a 6 week period in patients with depression. (The Boots Company)
199. An open-label, long-term, extension study of dothiepin BPI 1003 study. (The Boots Company)
200. A placebo-controlled study to assess a concurrent usage schedule for switching patients from diazepam, clorazepate, or chlordiazepoxide to buspirone. (Bristol-Myers)
201. A placebo-controlled, multicenter evaluation of the efficacy and safety of orally administered GR-C507/75 in (S3A-206) patients with a generalized anxiety disorder. (Glaxo, Inc.)
202. A double-blind, parallel group comparison of idazoxan and placebo in patients with major depressive disorder. (Reckitt & Coleman)
203. A placebo-controlled study to assess a concurrent usage schedule for switching patients from alprazolam to buspirone. (Bristol-Myers)
204. A placebo-controlled study to assess a concurrent usage schedule for switching patients from lorazepam to buspirone. (Bristol-Myers)
205. A multicenter, randomized, double-blind parallel group dose response study of milacemide in patients with mood disorders currently in a major depressive episode. (Searle)
206. An open-label extension study of milacemide in patients with mood disorders currently or recently in a major depressive episode. (Searle)
207. A placebo-controlled, dose response multicenter evaluation of the safety and efficacy of orally administered GR-C507/75 in patients with generalized anxiety disorder. (Glaxo, Inc.)
208. Dose finding study of the efficacy and safety of moclobemide compared with placebo in the treatment of outpatients with major depressive disorder. (Hoffman LaRoche)
209. A double-blind, parallel group, multicenter study to evaluate antidepressant efficacy, safety and tolerability of dothiepin, doxepin and placebo in outpatients with major depression. (The Boots

Company)

210. A multicenter, double-blind, placebo controlled trial of CP-76,593 in the treatment of outpatients with a major depressive disorder. (Pfizer, Inc.)
211. Milacemide dose response study in major depressive episode. (Searle)
212. Double-blind, placebo-controlled, parallel group dose determination study of enciprazine tablets in anxious patients. (Wyeth-Ayerst Laboratories)
213. A double-blind trial of nefazodone, imipramine, and placebo in the treatment of depressed outpatients. (Bristol-Myers)
214. A multicenter, double-blind, placebo-controlled, parallel group study of the efficacy of ipsapirone HCl (Bay Q 7821) in outpatients with generalized anxiety disorder. (Miles, Inc.)
215. Double-blind, placebo-controlled, parallel-group dosage-determination study of low doses of venlafaxine in depressed patients. (Wyeth-Ayerst Laboratories)
216. A multicenter, double-blind, placebo-controlled, parallel group comparison study of the safety and efficacy of ipsapirone HCl (Bay Q 7821) versus placebo in outpatients with major depressive disorder. (Miles, Inc.)
217. Fliperidone: Efficacy and safety in outpatients with major depression. (McNeil Pharmaceuticals)
218. A double-blind, placebo-controlled, comparative trial of sertraline and fluoxetine in the treatment of outpatients with major depressive disorder. (Pfizer, Inc.)
219. Multicenter, placebo-controlled, double-blind study of ICI 170,809 in non-hospitalized patients with depression. (Stuart)
220. A double-blind, randomized comparison of Pamelor (nortriptyline HCl) with fluoxetine HCl in subjects with major depressive disorder. (Sandoz)
221. Ascending single dose safety and tolerance study of LAD 2691. (Delegrange)
222. A double-blind multicenter trial of gepirone, imipramine and placebo in the treatment of depressed outpatients. (Bristol-Myers)
223. Pilot safety, tolerability and plasma level evaluation of ICI 204,636 in hospitalized patients with schizophrenic symptomatology. (ICI Pharmaceuticals)
224. An open multi-center trial of buspirone in the long term treatment of depressed outpatients. (Bristol-Myers)
225. Clinical protocol: BPI 1009 (dothiepin versus doxepin). (The Boots Company)
226. Tomoxetine/desipramine/placebo trial in major depressive disorder. (Eli Lilly and Company)
227. Long term extension of a double-blind, placebo-controlled, parallel-group dosage determination study of low doses of venlafaxine in outpatients with major depression. (Wyeth-Ayerst Laboratories)
228. Double-blind comparison of 3 doses of SM-3997 and placebo in outpatients with major depression. (Pfizer, Inc.)

229. Ascending single dose safety, tolerance and preliminary pharmacokinetic study of WY 47,846 tablets in normal male volunteers. (Wyeth-Ayerst Laboratories)
230. A double-blind, placebo-controlled, multicenter study to evaluate the efficacy, safety and tolerability of sibutramine hydrochloride (5, 10 and 20 mg daily) versus desipramine HCl (150 mg daily) in outpatients with major depression. (The Boots Company)
231. Fluvoxamine in the treatment of depression: A single center double-blind placebo-controlled comparison with imipramine in outpatients. (Reid-Rowell)
232. Ascending multiple oral dose safety and tolerance study of LAD 2691 in normal subjects. (Delagrange)
233. A second multicenter double-blind dose response study of zacopride and placebo in anxious outpatients. (Wyeth-Ayerst Laboratories)
234. Efficacy and safety of SC-48274 at 1 mg or 25 mg BID in generalized disorder. (Searle)
235. Open pilot, multicenter, safety and efficacy evaluation of ICI 204,636 in hospitalized patients with acute psychotic symptomatology. (ICI Pharmaceuticals)
236. Open-label evaluation of WY 47,846 hydrochloride tablets in outpatients with major depression. (Wyeth-Ayerst Laboratories)
237. Open-label evaluation of WY 47,846 hydrochloride tablets in outpatients with generalized anxiety disorder. (Wyeth-Ayerst Laboratories)
238. A double-blind, placebo-controlled, TID dose determination study of WY 47,846 hydrochloride tablets in outpatients with generalized anxiety disorder. (Wyeth-Ayerst Laboratories)
239. Double-blind, placebo-controlled, TID dose determination study of WY 47,846 hydrochloride tablets in outpatients with major depression. (Wyeth-Ayerst Laboratories)
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240. Double-blind, placebo-controlled, dose ranging evaluation of ondansetron (GR 38032F) versus diazepam in the treatment of generalized anxiety disorder. (Glaxo, Inc.)
241. A second multicenter, double-blind dose response study of zacopride and placebo in anxious patients. (Wyeth-Ayerst)
242. Double-blind parallel comparison of three dose ranges of CGS-18102A versus placebo in patients with major depressive disorder. (Ciba-Geigy)
243. Ascending single dose safety, tolerance, and preliminary pharmacokinetic study of WY-50,324 hydrochloride capsules in normal male volunteers. (Wyeth-Ayerst)
244. A multicenter, randomized, double-blind, placebo-controlled comparison of paroxetine and fluoxetine in the treatment of major depressive disorder (Smith-Kline)
245. Disposition and metabolism of radiolabeled ICI 204,636 in patients with schizophrenic symptomatology. (ICI Pharmaceuticals)
246. Ascending single-dose safety, tolerance, and preliminary pharmacokinetic study of WY 47,791 hydrochloride capsules in normal male volunteers. (Wyeth-Ayerst)
247. A prospective randomized, double-blind, placebo-controlled, multicenter, parallel-groups comparison of the efficacy and safety of abecarnil low dose (7.5 mg), high dose (15 mg), and diazepam (21 mg) in outpatients with generalized anxiety disorder. (Sandoz)

248. An open, multicenter trial of gepirone extended-release in the treatment of patients with mood disorders. (Bristol-Myers Squibb)
249. A phase I, double-blind, placebo-controlled study of safety, tolerance, and pharmacokinetics of single and multiple doses of RP-62203 capsules in healthy male volunteers. (Rhone-Poulenc Rorer)
250. Double-blind, placebo-controlled, parallel-group, dosage determination study of BID and TID doses of venlafaxine in outpatients with major depression. (Wyeth-Ayerst)
251. A prospective randomized, double-blind, placebo-controlled, multicenter, parallel-groups comparison of the efficacy and safety of abecarnil (3.0-9.0 mg) and lorazepam (1.5-4.5 mg) in elderly outpatients with anxiety symptoms. (Sandoz)
252. A prospective multicenter, open-label study of the safety of abecarnil (5.0-17.5 mg) in outpatients with generalized anxiety disorder. (Sandoz)
253. A double-blind, placebo-controlled, multicenter trial comparing 30 mg of BuSpar given two times daily versus three times daily in patients with generalized anxiety disorder. (Bristol-Myers Squibb)
254. A multicenter evaluation of the safety and efficacy of 150 mg/day and 300 mg/day of Bupropion HCl sustained-release versus placebo in depressed outpatients. (Burroughs-Wellcome Co.)
255. LY237733 in patients with generalized anxiety disorder. (Lilly)
256. LY170053 versus placebo/haloperidol in the treatment of schizophrenia. (Lilly)
257. A study of the efficacy of 4mg and 8 mg of HP873 administered to schizophrenic patients for 42 days. (Hoechst-Roussel)
258. Safety surveillance study for Wellbutrin sustained release (Burroughs Wellcome Co.)
259. Fixed Dose Olanzapine versus Placebo in the Treatment of Schizophrenia (Lilly)
260. A multicenter, double-blind, randomized, controlled, multiple fixed-dose and dose regiment comparison of Seroquel (TM) (ICI 204,636) and Haloperidol in the prevention of psychotic relapse in outpatients with chronic or subchronic schizophrenia. (Zeneca Pharmaceuticals)
261. FID-MD-HGAP- Fixed Dose Olanzapine Versus Placebo in the Treatment of Schizophrenia (Lilly Research Laboratories)
262. A multicenter evaluation of the safety and efficacy of two flexible doses of Wellbutrin 7 sustained-release versus placebo in depressed outpatients (Burroughs Wellcome Company)
263. Forty-week, double-blind study evaluating the safety and efficacy of two dose regiments of oral ziprasidone (CP-88, 059-1 (80-120mg, QD, and 40-80mg, BID) and haloperidol (5-20mg daily) in the maintenance treatment of outpatients with schizophrenia or schizoaffective disorder (Pfizer)
264. A clinical evaluation of Risperdal (TM) in the treatment of schizophrenia (Parxel Int. Corp.)
265. A study for the evaluation of safety, tolerance and steady-state pharmacokinetics of HP 873 up to 16mg/day administered to hospitalized schizophrenic patients (Hoechst-Roussel Pharmaceuticals, Inc.)

266. Phase III, six week, double-blind, multicenter, placebo controlled study evaluating the efficacy and safety of two oral fixed doses of oral ziprasidone CP-88, 059-1 (40 mg, BID and 80mg, BID) in the acute exacerbation of schizophrenia and schizoaffective disorder (Pfizer)
267. A single-dose, two-way crossover evaluation to determine the bioavailability of a trifluoprazine HCL tablet, 10mg, (Stelazine, J, SKB) and trifluoperazine HCL tablet, 10mg, (Invamed) in a test population of 38 healthy fasted male volunteers (Invamed, Inc.)
268. Flecinoxan in the treatment of generalized anxiety disorder. A single-center, double-blind, parallel, placebo controlled comparison with diazepam in outpatients. (Solvay)
269. A 156 week (3 year) Open extension study evaluating the safety and outcome of 40-200 mg, daily of oral Ziprasidone or 1-8 BID of oral Ziprasidone daily in the treatment of subjects who have participated in previous Ziprasidone (CP-88-059-1) Clinical Trials. (Pfizer)
270. Effect of ICI 205,636 (Seroquel J) on Antipyrine Metabolism in Subjects with Psychotic Disorders (Zeneca)
271. Bioequivalency of Clozapine Tablets 25 mg (Zenith)
272. A multiple-dose, steady-state study assessing the relative bioequivalence of Clozapine (Zenith Laboratories, Inc.) and Clozaril 7 (Sandoz). (Zenith)
273. An eight subject pilot study assessing the negative bioequivalence of Clozapine (Zenith Laboratories) and Clozaril 7 (Sandoz). (Zenith)
274. Acute bioequivalence study with 200mg tablet formulations of Fluconazole in fasted healthy normal men. (Novopharm Limited)
275. A bioequivalence trial comparing ICI 204,636 (Seroquel J) sales tablets (1 x 200 mg.) and ICI 204,636 clinical trial tablets (2 x 100 mg) in men with selected psychotic disorders. (Zeneca)
276. A multicenter, multinational, double-blind, dose-rising placebo-controlled study of Fananserine in inpatients with schizophrenia. (Rhône-Poulenc Rorer)
277. Bioequivalence of clozapine tablets 25 mg in schizophrenic subjects. (Novopharm)
278. A prospective, randomized, multi-center, double-blind, parallel-group study of the efficacy and safety of SDZ-MAR 327 (200-400 mg/day) as compared to haloperidol (10-20mg/day) and placebo in institutionalized patients with chronic schizophrenia. (Sandoz)
279. Double-blind, placebo-controlled study of Venlafaxine ER and Fluoxetine in outpatients with major depression. (Wyet)
280. Single dose two-way crossover bioequivalence study of Invamed, Clomipramine hydrochloride 25 mg capsules and anafartil 7 25 mg in healthy male volunteers. (Invamed)
281. Phase III, Six week, double blind, multicenter placebo-controlled study of evaluating the efficacy and safety of three fixed doses of oral Ziprasidone (20 mg, BID, 60 mg, BID and 100 mg, BID) and Haloperidol in the acute exacerbation of schizophrenia and schizoaffective disorder. (Pfizer)
282. Mazapertine dose-finding trial, comparing three fixed doses of Mazapertine to Risperidone and placebo: Multicenter, double blind, parallel group study. (Janssen)
283. The tolerability and safety of switching to and subsequently withdrawing from ICI 204,636 (Seroquel) in subjects with selected psychotic disorders. (Zeneca)

284. A two-way single-dose, fasting bioavailability study of Clozapine 25 mg given as a 12.5 mg dose in normal healthy male-volunteers (Novopharm)
285. The Pharmacokinetics, Tolerability and Safety of ICI 204,636 (Seroquel (TM) When Co-administered with Fluoxetine or Imipramine in Subjects with Selected Psychotic Disorder (Zeneca)
286. A Phase II, Multicenter Double Blind Parallel Randomized Comparison of Oral Fananserin and Placcho over 28 days in inpatients with Schizophrenia (Rhône-Poulenc)
287. Open Label Trial for ICI 204,636 (Seroquel) (Zeneca)
288. Double-Blind Placebo Controlled Study of Venlafaxine and Fluoxetine in in patients with Major Depression and Melancholia (Wyeth-Ayerst)
289. Bioequivalence of Clozapine Tablets 25 mg in Schizophrenia patients (Novopharm)
290. A Pilot Two Way Single Dose, Food Effect, Comparative Bioavailability Study of Nifedipine ER Tablets (30 mg) versus Adalat CC Tablets (30 mg) in twelve Normal, Healthy, Non-Smoking Male Volunteers (Biovail Corporation International)
291. A Multicenter Double-Blind Placebo Controlled Comparison of the Effects on Sexual Functioning of Wellbutrin (Bupropion HCl) Sustained Release and Sertraline in Outpatients with Moderate to Severe Recurrent Major Depression (Glaxo Wellcome)
292. A pilot bioavailability study with a single 75 mg tablet of Permoline (Cylett) in fasted healthy, normal men. (Bioassay Laboratory Inc.)
293. A relative bioavailability pilot study of bupropion HCL 100 mg tablets under fasting conditions. (Glaxo Wellcome) (Bioassay)
294. Comparative single dose Bioequivalence study of Clozapine tablets in schizophrenic patients. (Mylan Pharmaceuticals, Inc.)
295. A relative bioavailability pilot study of Omerprazole 20 mg delayed-release capsules. (Vigi Hyuma, Ph.D.)
296. Tolerability and pharmacokinetics of once daily dosing of quetiapine (Seroquel TM) in men and women with selected psychotic disorders. (Zeneca)
297. Strategies for switching from conventional antipsychotic drugs to Olanzapine (Eli Lilly Company)
298. Risperidone vs. Olanzapine in the treatment of Schizophrenia (Janssen Research Foundation)
299. Risperidone vs. Olanzapine in the treatment of Schizophrenia (Janssen Research Foundation)
300. A Double-blind, Placebo-Controlled, Multicenter Study Evaluating the Efficacy and Safety of SR 46349B in outpatients with Major Depression. (Sanofi)
301. A Phase III double-blind placebo controlled study of Aripiprazole in the treatment of Psychosis, with Risperidone as active control. (Otsuka)
302. A open-label follow up study of the long-term safety of Aripiprazole in patients with psychosis (Otsuka)
303. Double-blind placebo controlled 14 day treatment study of the safety and tolerability of SR 48692 in patients with Schizophrenia (Sanofi)

304. A Multi-center, placebo-controlled study of Wellbutrin (Bupropion Hydrochloride) sustained release (2R) for the prevention of relapse recurrence in subjects whose depression responded to treatment with Wellbutrin SR. (Glaxo Wellcome)
305. Olanzapine alone and in corporation with Fluoxetine versus placebo in Major Depressive disorder with psychotic features. (Eli Lilly)
306. Multi-center, open label, long-term follow-up safety study of M100907 tablets in Schizophrenia and Schizoaffective subjects who participated in Protocol M100907/3001 or M100907/3002. (Hoechst Marion Roussel)
307. A multi-center, placebo and active control double-blind randomized study of the efficacy and safety of M100907 (10 and 20 mg/day) in schizophrenics and schizoaffective patients (Hoechst Marion Roussel)
308. The pharmacokinetics of Geppar 20 mg MR tablets (Sidmak) in male Asians compared to male Caucasians and males of African Descent (Blacks). (Fabre-Kramer Pharmaceuticals, Inc.)
309. Effect of Food on the bioavailability of Geppar 20 mg MR Tablets (Sidmak). (Fabre-Kramer Pharmaceuticals, Inc.)
310. Bioequivalence of Bristol-Myers Squibb's Gepirone 20 mg ER tablets and Fabre-Kramer Pharmaceuticals, Inc. Geppar 20 mg MR tablets (Sidmak). (Fabre-Kramer Pharmaceuticals, Inc.)
311. Olanzapine versus Placebo in the treatment of bipolar disorder, manic or mixed.
312. A pilot study to evaluate the pharmacokinetic profile after a single dose (1 x 20 mg) of Geppar MR (Sidmak) tablets in healthy male volunteers under fasting and non fasting conditions. (Fabre-Kramer Pharmaceuticals, Inc.)
313. Multiple-dose Pharmacokinetics and the Effect of Food in Sustained-Release (SR) Quetiapine Fumarate (Seroquel) (Zeneca Pharmaceuticals)
314. An Open Label Comparison of the Neurocognitive Effects of Aripiprazole to Olanzapine Administered Orally in Patients With Stable Psychosis (Otsuka Pharmaceuticals)
315. An Open-Label Follow-on Study of the Long-Term Safety of Aripiprazole Administered Orally in Patients with Psychosis (Otsuka Pharmaceuticals)
316. A Multi-Center, Double-Blind, Placebo-Controlled Comparison of the Safety and Efficacy and Effects on Sexual Functioning of Wellbutrin (bupropion HCl) Sustained Release (SR) and Fluoxetine in Outpatients with Moderate to Severe Recurrent Major Depression (Glaxo Wellcome)
317. Rising Single and Multiple Dose Tolerance Study of DAB-452 in Patients with Schizophrenia and Schizoaffective Disorder (Wyeth Ayerst Pharmaceuticals)
318. A Randomized, Multicenter, Double-Blind, Placebo-Controlled, Fixed-Dose, 7-Week Evaluation of the Efficacy and Safety of Lamotrigine in Treatment of a Depressive Episode in Unipolar Depressed Patients (Glaxo Wellcome Pharmaceuticals)
319. The Pharmacokinetics, Safety, Tolerability and Pharmacodynamics of Alprazolam Given Before and During Treatment with Quetiapine Fumarate (SEROQUEL™) in Men and Women with Selected Psychotic Disorders (Zeneca Pharmaceuticals)
320. A Placebo-Controlled Study of Pregabalin in Patients with Acute Mania (Parke-Davis Pharmaceuticals)

321. Striatal Dopamine-D2 Receptor Binding of DAB-452 Using Positron Emission Tomography (PET) in Patients with Schizophrenia or Schizoaffective Disorder (Wyeth Ayerst Pharmaceuticals)
322. A Multi-Center, Randomized, Double-blind, Active-Controlled Study to Compare the Long-term Maintenance Effects and Safety of Aripiprazole and Haloperidol Following Acute Relapse in Schizophrenic Patients (Otsuka America Pharmaceuticals, Inc.)
323. An Open-Label Follow-on Study of the Long-Term Safety of Aripiprazole in Patients with Chronic Schizophrenia (Otsuka America Pharmaceuticals, Inc.)
324. A Usual Use, Open Label, Randomized, 3 Month Cohort, Outcomes Study in Persistent Back Pain Comparing OxyContin® Q12H (Controlled Release Oxycodone) vs. Hydrocodone/APAP Q4-6 PRN (Purdue Pharma, L.P.)
325. A Three Year, Open Label, Analgesic Efficacy, Safety, Acceptability, Tolerability and Quality of Life Registry of Controlled-Release Oxycodone Tablets (OxyContin®) in Chronic Non-Cancer Pain (Purdue Pharma, L.P.)
326. Prevalence of Hyperprolactinemia in Schizophrenic Patients Treated With Antipsychotic Drugs (Eli Lilly and Company)
327. Olanzapine in the Reduction of Hyperprolactinemia and Associated Morbidity in Schizophrenic Patients (Eli Lilly and Company)
328. Allelic Variation in Schizophrenia (Eli Lilly and Company)
329. A Study to Examine the Tolerance and Pharmacokinetics of Short-Acting Intramuscular Olanzapine in Patients with Chronic Schizophrenia (Eli Lilly and Company)
330. Risperidone depot (microspheres) in the treatment of subjects with schizophrenia or schizoaffective disorder. (Janssen Research Foundation)
331. Double-Blind, Placebo-Controlled, Comparative Efficacy Study of Venlafaxine ER and Sertraline in Producing Remission in Outpatients with Major Depressive Disorder (Wyeth-Ayerst Research)
332. A Multicenter, parallel, double-blind, placebo controlled, randomized comparison of a flexible dose of GW650250A (8 to 16 mg) and placebo for the outpatient treatment of moderate to severe recurrent depression. (GlaxoWellcome)
333. A Double-Blind, Placebo and Paroxetine Controlled, Multicenter, Dose-Ranging Study Evaluating the Efficacy and Safety of SR142801 in Outpatients with Major Depressive Disorder (Sanofi-Synthelabo)
334. Placebo-Controlled Olanzapine Monotherapy in the Treatment of Bipolar I Depression (Eli Lilly and Company)
335. A Controlled Trial of the Efficacy of Rapid Initial Dose Escalation of Olanzapine to Treat Acute Behavioral Agitation in Schizophrenia and Bipolar I Disorder (Eli Lilly and Company)
336. A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Trial of the Safety and Efficacy of SEROQUEL™ (Quetiapine Fumarate) as Add-on Therapy with Lithium or Divalproex in the Treatment of Acute Mania (AstraZeneca)
337. Duloxetine Versus Placebo and Paroxetine in the Acute Treatment of Major Depression (Eli Lilly and Company)
338. A Three-Week, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group,

Safety and Efficacy Study of Extended-Release Carbamazepine in Patients with Bipolar Disorder
(Shire Laboratories)

- 339. A Six-Month, Open Label, Multicenter Study of Extended-Release Carbamazepine in Patients With Bipolar Disorder - An Extension of Protocols 105.301 and 105.302 (Shire Laboratories)
- 340. A Double-Blind, Placebo and Haloperidol-Controlled, Multicenter Study Evaluating the Safety and Efficacy of SR46349B in Schizophrenic Patients (Sanofi-Synthelabo)
- 341. A Double-Blind, Placebo and Haloperidol-Controlled, Multicenter Study Evaluating the Safety and Efficacy of SR48692 in Schizophrenic Patients (Sanofi-Synthelabo)
- 342. A Multi-Center, Randomized, Double-Blind, Active-Controlled Study to Compare the Long-Term Maintenance Effects and Safety of Aripiprazole and Haloperidol Following Acute Relapse in Schizophrenic Patients (Otsuka America Pharmaceuticals)
- 343. An Open-Label, Follow-on Study of the Long-Term Safety of Aripiprazole in Patients with Chronic Schizophrenia (Otsuka America Pharmaceuticals)
- 344. A Study to Assess the Safety, Tolerability and Pharmacokinetics of Single and Multiple Doses of an Intramuscular Formulation of Depot Olanzapine (Pamoate Salt) in Stable Schizophrenic Subjects (Eli Lilly and Company)
- 345. The efficacy and safety of single dosage ranges of risperidone vs placebo in the treatment of manic episode associated with Bipolar I Disorder. (Janssen Research Foundation)
- 346. A 9-week, open-label, multi-center, safety trial of flexible dose ranges of risperidone in the treatment of manic episodes associated with Bipolar I Disorder. (Janssen Research Foundation)
- 347. A Multicenter, Double-Blind, Randomized Comparison of the Efficacy and Safety of Sustained-release Formulation Quetiapine Fumarate (SEROQUEL™) and Placebo in the Treatment of Patients with Schizophrenia (AstraZeneca Pharmaceuticals)
- 348. A Multiple-Dose Steady-State Study Assessing the Relative Bioequivalence of Clozapine (Zenith Goldline Pharmaceuticals) and Clozaril® 100 mg (Novartis) Tablets (Zenith Goldline Pharmaceuticals)
- 349. The Assessment of Sibutramine for the Treatment of Olanzapine-Associated Weight Gain in Patients with Schizophrenia, Schizophreniform Disorder, Schizoaffective Disorder, and Bipolar I Disorder (Eli Lilly and Company)

Curriculum Vitae for David Feifel, M.D., Ph.D.

Personal Data:

D.O.B: October 5, 1962
Place of Birth: Toronto, Canada
Wife: Maria C. Feifel
Children: Ariel Jacob Feifel (1/1/93)
Natania Tova Feifel (12/30/94)

Academic Degrees:

Bachelor of Science (B.Sc.), University of Toronto, 1985 (Neuroscience)
Medical Degree (M.D.) University of Toronto, 1991
Masters of Arts (M.A.) University of Toronto, 1989 (Physiological Psychology)
Doctor of Philosophy (Ph.D.), University of Toronto, 1992 (Neuroscience)

Clinical Training:

Internal Medicine Internship, Toronto General Hospital July 1991 - June 1992
Psychiatry Residency, University of California, San Diego, July 1992 - June 1995

Professional Positions

Chief Resident, UCSD Outpatient Psychiatric Services, July 1994 - July 1995
Assistant Professor, Department of Psychiatry, UCSD, July 1995 - present
Attending Physician, Inpatient Psychiatry, UCSD Medical Center, July 1995 - present
Founder and Director, Adult ADHD Program, UCSD, July 1995 - present
Attending Psychiatrist, Huntingtons Disease Clinic, July 1995 - present
Co-Founder and Director, UCSD Mindfulness-Based Stress Management Clinic
Lecturer, "Psychopharmacology" third year medical students, UCSD School of Medicine,
January 1996- present
Faculty in Residence, SDSU-UCSD Joint Psychology Doctorate Program

Awards and Scholarships:

- ◆ Hospital for Sick Children, Undergraduate Research Fellowship, 1983, 1985
- ◆ University of Toronto, School of Medicine, Summer Research Scholarship, 1986, 1987
- ◆ George Brown Memorial Award for Research Accomplishments, University of Toronto, School of Medicine 1987
- ◆ Gertrude Evans Estate Award for Research in Psychiatry, University of Toronto, School of Medicine, 1990.
- ◆ Medical Research Council of Canada, Research Scholarship, 1987, 1988, 1989, 1990
- ◆ Eli Lilly, U.S. Congress of Psychiatry Travel Fellowship, 1993
- ◆ Dista, Society for Biological Psychiatry Travel Fellowship, 1994
- ◆ Scottish Rite Schizophrenia Research Program Grant, "Preclinical evaluation of neuropeptide-based treatments for psychosis" (July 1994 -July 1996)
- ◆ American Psychiatric Association Resident Research Award, 1994/1995

- ♦ National Alliance for Research on Schizophrenia and Depression (NARSAD) Young Investigator Award, "The role of midbrain neuropeptides in sensorimotor gating" (effective July 1995 - July 1997)
- ♦ Chairman's Award for Research Excellence, June 1995
- ♦ Central Neuropsychiatry Association, Resident Paper Award, 1995
- ♦ American Psychiatric Association, Young Faculty Investigator Award, December 1996
- ♦ Society For Biological Psychiatry, A.E. Bennet Award Commendation for Research, May 1997

Organizational Memberships and Affiliations

Society for Neuroscience, 1986 - present
International Brain Research Organization, 1986 - present
American Neuropsychiatric Association, 1996- present

Selected Research Presentations and Lectures

- *International Brain Research Organization meeting, Budapest, Hungary, August 1987
- *Society for Neuroscience meeting, New Orleans, LA, October, 1987
- *Society for Neuroscience meeting, Toronto, Canada, November, 1988
- *Society for Neuroscience meeting, Phoenix, AZ, November, 1989
- *Society for Neuroscience meeting, St. Louis, MO, November, 1990
- *North American Medical Student Research meeting, Galveston TX, November, 1991(invited)
- *American Psychiatric Association, 46th Institute on Hospital & Community Psychiatry, San Diego, CA, October, 1994** (invited)
- *California Psychiatric Association, La Jolla, CA, October, 1994 (invited)
- *Grand Rounds, Dept. Of Psychiatry, UCSD, October, 1994 (invited)
- *Grand Rounds, Combined Dept. of Psychiatry and Neurology, UCSD, January, 1994 (invited)
- *Central Neuropsychiatry Association, Ohio Psychiatric Association, October 1995 (invited)
- *Society for Neuroscience meeting, San Diego, CA, November, 1995
- * Society for Biological Psychiatry, New York, NY, May, 1996
- * NARSAD, 10th Annual Scientific Symposium, New York, NY October, 1996 (invited)

Other

Referee for:
Neuroscience and Biobehavioral Reviews
Pharmacology Biochemistry and Behavior
Neuropharmacology,
Critical Reviews in Neurobiology

Grant Reviewer for:
Canadian Psychiatric Association

*Founder and Editor of, *The Gifford Beacon*, The newsletter for staff and clients of UCSD Outpatient Psychiatric Services

*Author of, "Acute stabilization of manic inpatients using oral loading of valproate" guidelines for the County of San Diego, Mental Health Services (Commissioned by San Diego County mental health and supported by Abbot Pharmaceuticals).

Academic/Clinical Committees

General Educational Committee, Dept. of Psychiatry, UCSD

Resident Recruitment Committee, Dept. of Psychiatry, UCSD

Resident Advisory Committee, Journal of Clinical Psychiatry (1993- 1995)

Publications (abstracts not listed):

Vaccarino F.R., Feifel D., Vale W., Rivier J. and Koob G. Centrally administered hypothalamic growth hormone-releasing factor stimulates food intake in free-feeding rats, Peptides, 1988, 9(Suppl 1): 35-38.

Feifel D., Vaccarino F.J., Vale W. and Rivier J. Feeding effects of growth hormone-releasing factor in rats are photoperiod sensitive, Behavioral Neuroscience, 1989, 103:824-830.

Feifel D. and Vaccarino F.J. Central Injections of growth hormone-releasing factor increase operant responding for food reward, Progress in Neuropsychopharmacology and Biological Psychiatry, 1990, 525:189-194.

Feifel D. and Vaccarino F.J. Central Somatostatin: a re-examination of its effects on feeding, Brain Research, 1990, 535:189-194.

Vaccarino F.J., Feifel D., Vale W. and Rivier J. Antagonism of central growth hormone-releasing factor activity selectively attenuates dark-onset feeding in rats, The Journal of Neuroscience, 1991, 11(12):3924-3927.

Feifel D., Vaccarino, F.J., Vale W. and Rivier J. Evidence for a common neural mechanism mediating growth hormone-releasing factor-induced and somatostatin-induced feeding, Neuroendocrinology, 1993, 57:299-305.

Feifel D. and Vaccarino F.J. Growth hormone regulatory peptides (GHRH and Somatostatin) and Feeding: a model for the integration of central and peripheral function. Neuroscience and Biobehavioral Reviews, 1994, 18:421-33.

Coscina D.V., Feifel D., Nobrega J.N. and P.J. Currie Intraventricular but not intra-PVN metergoline elicits feeding in satiated rats. American Journal of Physiology, 1994, 266:R1562-7.

Dickinson P.R., Feifel D. and Vaccarino F.J. Blockade of endogenous GRF at dark-onset selectively suppresses protein intake. Peptides, 1995, 16(1):7-9.

Feifel D. Parallels of Psychoanalytic Theory and Quantum Mechanics (letter). Harvard Review of Psychiatry, 1996, 4:58,

Feifel D. Diagnosis of attention deficit disorder in adults. Postgraduate Medicine, 1996 100(3):207-218,

Feifel D. and Young C. Iron overload in an outpatient psychiatric clinic, Journal of Clinical Psychiatry, 58(2):74-78, 1997

Feifel D. and Swerdlow NR. Injections of CCK into the nucleus accumbens potentiate apomorphine-induced disruption of prepulse inhibition. Neuroscience Letters, 227: 5-8, 1997

Feifel, D., Minor LK, Delawa S and Swerdlow NR. The effects of intra-accumbens neurotensin on sensorimotor gating, Brain Research, In Press

Feifel D. and Minor LK. Somatostatin depletion reverses amphetamine-induced deficits in sensorimotor gating. Pharmacology Biochemistry, and Behavior , In Press

Feifel D. Neurotransmitters and Neuromodulators in frontal-subcortical circuits. In: Cummings J, and Miller B, The Human Frontal Lobes: Function and Dysfunction, In Press

Feifel D. and Reza, T.L. and Robeck S.L. Prodomamine effect of intra-accumbens on sensorimotor gating deficits. Peptides, In Press

Feifel D. and Reza, T.L. and Robeck S.L. Do CCK-based treatment have potential as antipsychotic? An assesment using the prepulse inhibition model. Biological Psychiatry, Submitted

Feifel D. and Reza, T.L.. Sensorimotor Gating Effects Of Selective CCK-Antagonists. Psychopharmacology, Submitted

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Signature *David Feifel*
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**Curriculum Vitae
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Personal: DOB: 12/2/53, Mineola, New York
Social Security Number: REDACTED
Married: Lauren Reece, 6/21/86
Children: Georgia Reece Flaum (DOB 3/02/89)
Chester Reece Flaum (DOB 10/07/91)

Employment and post-graduate training:

'95 - present: Associate Professor of Psychiatry
Co-director, Mental Health Clinical Research Center,
Department of psychiatry, University of Iowa, Iowa City, Iowa

'90 - '95: Assistant Professor of Psychiatry
Clinical director, Mental Health Clinical Research Center,
Department of psychiatry, University of Iowa, Iowa City, Iowa

'88 - '90: Post-doctoral Fellow in Clinical Neurobiology/Schizophrenia Research
Department of psychiatry, University of Iowa, Iowa City, Iowa

'86 - '88 Assistant Clinical Professor of Psychiatry
State University of New York, Health Science Center at Brooklyn
Brooklyn, New York

'85 - '86 Chief resident and Clinical Instructor in Psychiatry
New York University Medical Center, New York, New York

'82 - '85 Resident in Psychiatry
New York University Medical Center, New York, New York

Education:

7/78 - 6/82 State University of New York, Health Science Center at Stony Brook
College of Medicine, Stony Brook, New York
Degree: M.D., 6/82

Michael Flaum, M.D.

1/76 - 6/78 Columbia University, College of Basic Studies; New York, New York
Degree: B.S., 6/78
Magna Cum Laude, Phi Beta Kappa

Licensure and Certification:

Licensure: Iowa: July, 1988 - Permanent REDACTED
New York: April, 1989 - Permanent REDACTED
Certification: American Board of Psychiatry and Neurology - April, 1989 REDACTED

Professional Affiliations:

American Psychiatric Association
International Society for Neuroimaging in Psychiatry

Editorial Activities:

Reviewer for: *American Journal of Psychiatry*, *Archives of General Psychiatry*,
Schizophrenia Bulletin, *Schizophrenia Research*, *Psychiatry Research: Neuroimaging*,
Journal of Neuropsychiatry and Clinical Neurosciences, *American Journal of Geriatric Psychiatry*

Areas of Research Interest:

Neuroimaging (structural and functional MRI, PET)
Diagnosis and classification of schizophrenia and other psychotic disorders
Diagnostic and phenomenological assessment methods in clinical and research settings
Nicotine and caffeine abuse/dependence in schizophrenia

Current Research Projects:

Use of functional MRI as a measure of brain activity in normals and schizophrenics
Predictors of outcome in recent onset psychosis
Effects of cigarette smoking on attention and cerebral blood flow
Clinical correlates of brain morphology in schizophrenia (MRI)

Current Teaching Activities:

Director of third and fourth year medical student education in psychiatry (approximately 190 students/class/year)

BIBLIOGRAPHY
A. Manuscripts published or in press:

1. Menza M, Easton J, Flaum M, et al: Approaches to the treatment of lithium-resistant mania. *Psychiatric Medicine*, 6:73-87, 1988.
2. Andreasen NC, Flaum M, Swayze VW, et al: Positive and negative symptoms in schizophrenia: A critical reappraisal. *Archives of General Psychiatry*, 47:615-621, 1990.
3. Flaum M: Neuroleptics and schizophrenia. *Iowa Medicine*, 80:60-62, 1990.
4. Andreasen NC, Swayze VW, Flaum M, et al: Ventricular abnormalities in affective disorder: Clinical and demographic correlates. *American Journal of Psychiatry*, 147:893-900, 1990.
5. Andreasen NC and Flaum M: DSM-IV in progress: Schizophrenia and related disorders. *Hospital and Community Psychiatry*, 41: 954-956, 1990.
6. Flaum M, Arndt SV, and Andreasen NC: The role of gender in studies of ventricular enlargement in schizophrenia: A predominantly male effect. *American Journal of Psychiatry*, 147: 1327-1332, 1990.
7. Andreasen NC, Swayze VW, Flaum M, et al: Ventricular enlargement in schizophrenia evaluated with computed tomographic scanning: Effects of gender, age, and stage of illness. *Archives of General Psychiatry*, 47: 1008-1015, 1990.
8. Nopoulos P, Flaum M, Miller DD: Clozapine induced NMS without rigidity. *Annals of Clinical Psychiatry*, 2: 251-254, 1990.
9. Flaum M, Arndt, SV and Andreasen NC: The reliability of "bizarre" delusions. *Comprehensive Psychiatry*, 32:59 - 65, 1991.
10. Andreasen NC and Flaum M: Schizophrenia: The characteristic symptoms. *Schizophrenia Bulletin*, 17:25-49, 1991.
11. Flaum M and Andreasen NC: Diagnostic criteria for schizophrenia and related disorders: Options for DSM-IV. *Schizophrenia Bulletin*, 17:133-142, 1991.
12. Andreasen NC, Flaum M, and Arndt, SV: The Comprehensive Assessment of Symptoms and History (CASH): An instrument for assessing psychopathology and diagnosis. *Archives of General Psychiatry*, 49:615-623, 1992.
13. Arndt SV, Tyrrell G, Flaum M and Andreasen NC: Comorbidity of substance abuse and schizophrenia: The role of pre-morbid adjustment. *Psychological Medicine*, 22:379-388, 1992.
14. Andreasen NC, Rezai K, Alliger RJ, Swayze VW, Flaum M. et al: Hypofrontality in neuroleptic-naïve patients and in patients with chronic schizophrenic: Assessment with Xenon-133 SPECT and the Tower of London. *Archives of General Psychiatry*, 49: 943-958, 1992.

15. **Flaum M**, Andreasen NC and Arndt SV: The Iowa prospective longitudinal study of recent onset psychoses. *Schizophrenia Bulletin*, 18:481-490, 1992.
16. Andreasen NC, **Flaum M**, Swayze VW, O'Leary DS et al.: Intelligence and brain structure in normal individuals. *American Journal of Psychiatry*, 150:130-134, 1993.
17. Amador XF, Strauss DH, Yale SA, **Flaum M**, Endicott J, and Gorman JM: Assessment of insight in psychosis. *American Journal of Psychiatry*, 150:873-879, 1993.
18. Andreasen NC, Harris G, Cizadlo T, Arndt S, O'Leary DS, Swayze VW, and **Flaum M**. Techniques for measuring sulcal/gyral patterns in the brain as visualized through MR scanning: Brainplot and Brainmap. *Proceedings for National Academy of Sciences*, 90:93-97, 1994.
19. Houlihan DJ, **Flaum M**, Arnold SE, Keshavan M, Alliger A: Further evidence for olfactory identification deficits in schizophrenia. *Schizophrenia Research*, 12:179-182, 1994.
20. Miller DD, **Flaum M**, Arndt SV, Fleming F, and NC Andreasen. The effect of antipsychotic withdrawal on negative symptoms in schizophrenia. *Neuropsychopharmacology*, 11:11-20, 1994.
21. Amador XF, **Flaum M**, Andreasen NC, Strauss DH, Yale SA, Clark S, and Gorman JM: Awareness of illness in schizophrenia, schizoaffective and mood disorders. *Archives of General Psychiatry*, 51:826-836, 1994.
22. Andreasen NC, Arndt S, Swayze VS, Cizadlo T, **Flaum M**, O'Leary DS, Ehrhardt J, Yuh WTC: Thalamic abnormalities in schizophrenia visualized through magnetic resonance image averaging. *Science*, 266:294-298, 1994.
23. Roy MA, **Flaum M**, Gupta S, and NC Andreasen. Epidemiological and clinical correlates of familial and sporadic schizophrenia. *Acta Psychiatrica Scandinavica*, 89: 324-328, 1994.
24. Andreasen NC, Nopoulos P, Schultz S, Miller DD, Swayze VW, and **Flaum M**: Positive and negative symptoms of schizophrenia: Past, present and future. *Acta Psychiatrica Scandinavica*, 90(Suppl 384): 51-59, 1994.
25. Andreasen NC, Flashman L, **Flaum M**, Arndt S, Swayze VW, O'Leary DS, Ehrhardt JC, Yuh WTC: Regional brain abnormalities in schizophrenia measured with magnetic resonance imaging. *JAMA*, 242: 1763-1769, 1994
26. **Flaum M**, Andreasen NC, Swayze VW, O'Leary DS, and Alliger RJ: IQ and brain size in schizophrenia. *Psychiatry Research*: 53:243-357, 1994
27. Nopoulos PC, Flashman LA, Hubbard W, **Flaum M**, Arndt SV, O'Leary DS, and NC Andreasen. Stability of cognitive functioning early in the course of schizophrenia. *Schizophrenia Research*, 14:29-37, 1994.
28. Strakowski SM, **Flaum M**, Tohen M: Substance abuse in psychotic disorders: associations with affective syndromes. *Schizophrenia Research*, 14:73-81, 1994.

29. Arndt SV, Tyrrell G, Woolson R, Flaum M, Andreasen, N.C. Effects of errors in a multicenter medical study: Preventing misinterpreted data. *Journal of Psychiatry Research*, 28:447-459, 1994.
30. Roy MA, Flaum M, Arndt SV, Crowe RR, and NC Andreasen. Magnetic resonance imaging in familial vs. sporadic cases of schizophrenia: *Psychiatry Research*, 54: 25-36, 1994
31. Andreasen NC, Arndt SV, Miller, DD, Flaum M, Nopoulos PC: Correlational studies of the scale for the assessment of negative symptoms (SANS) and the scale for the assessment of positive symptoms (SAPS): An overview and update. *Psychopathology*. 28:7-17, 1995.
32. McGorry PD, Mihalopoulos C, Henry L, Dakis J, Jackson HJ, Flaum M, Harrigan S, McKenzie D, Kulkarni J, and Karoly R: Spurious Precision: Procedural validity of diagnostic assessment in psychotic disorders. *American Journal of Psychiatry*, 152:220-223, 1995.
33. Gupta S, Andreasen NC, Arndt S, Flaum M, Schultz SK, Hubbard WC, and Smith M: Neurological soft signs in neuroleptic-naïve and neuroleptic-treated schizophrenic patients and in normal comparison subjects. *American Journal of Psychiatry*, 152:191-196, 1995.
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35. Andreasen NC, Arndt SV, Alliger RJ, Miller DD and Flaum M. Symptoms of schizophrenia: Methods, meanings and mechanisms. *Archives of General Psychiatry*, 52:341-351, 1995.
36. Arndt SV, Andreasen NC, Flaum M, Miller DD and Nopoulos P. A longitudinal study of symptom dimensions in schizophrenia: Prediction and patterns of change. *Archives of General Psychiatry*, 52:352-360, 1995.
37. Nopoulos PC, Flaum M, Andreasen NC and Swayze VW. Gray matter heterotopias in schizophrenia. *Psychiatry Research: Neuroimaging*, 61:11-14, 1995.
38. Flaum M, O'Leary DS, Swayze VW, Miller DD, Arndt S, and Andreasen NC: Symptom dimensions and brain morphology in schizophrenia and related psychotic disorders. *Journal of Psychiatric Research*, 29:261-276, 1995.
39. Gupta S, Rajaprabhakaran R, Arndt SV, Flaum M, Andreasen NC: Premorbid adjustment as a predictor of phenomenological and neurobiological indices in schizophrenia. *Schizophrenia Research*, 16:189-197, 1995.
40. Flaum M and NC Andreasen: The reliability of distinguishing "primary" vs. "secondary" negative symptoms. *Comprehensive Psychiatry*, 36:421-427, 1995.
41. Roy MA, Flaum M and NC Andreasen. No difference found between winter- and non-winter-born schizophrenic cases. *Schizophrenia Research*, 17:241-248.

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42. Nopoulos P, Torres I, Flaum M, Andreasen NC, Ehrhardt JC, and WTC Yuh: Brain Morphology in first episode schizophrenia. *American Journal of Psychiatry*, 152:1721-1723, 1995.
 43. Andreasen NC, Swayze VS, O'Leary DS, Nopoulos P, Cizadlo T, Harris G, Arndt S, and Flaum M: Abnormalities in midline attentional circuitry in schizophrenia: Evidence from magnetic resonance and positron emission tomography. *European Neuropsychiatry* (Supplement) 37-41, (1995).
 44. Flashman LA, Flaum M, Gupta S, Andreasen NC: Soft signs and neuropsychological performance in schizophrenia. *American Journal of Psychiatry*, 153:526-532, 1996.
 45. Flaum M and SK Schultz. When does amphetamine-induced psychosis become schizophrenia? *American Journal of Psychiatry*, 153:812-815, 1996.
 46. Amador XF, Harkavy Friedman J, Kasapis C, Yale SA, Flaum M and JM Gorman. Suicidal behavior in schizophrenia and its relationship to awareness of illness. *American Journal of Psychiatry*, 153:1185-1188, 1996.
 47. Strakowski SM, Flaum M, Amador XF, Bracha HS, Pandurangi AK, Robinson D, Tohen M: Racial bias and differences in the diagnosis of psychosis. *Schizophrenia Research*, 21:117-124, 1996.
 48. Flaum M: Making sense of schizophrenia. *Hospital Practice*, 31:51-79, 1996
 49. Kirkpatrick B, Amador XF, Flaum M, Yale SA, Gorman JM, Carpenter WT, Tohen M, Mcglashan T: The deficit syndrome in the DSM-IV Field Trial .1. Alcohol and other drug abuse. *Schizophrenia Research*. 20: 69-77, 1996
 50. Flaum M and SK Schultz. The core symptoms of schizophrenia. *Annals of Medicine*, 28:525-531, 1996.
 51. Nopoulos P, Swayze VW, Flaum M, Yuh WTC, Ehrhardt JC, Arndt SV and NC Andreasen. Cavum septi pellucidi in normals and patients with schizophrenia as detected by MRI. *Biological Psychiatry*, 41:1002-8, 1997.
 52. Gupta S, Andreasen NC, Arndt S, Flaum M, Hubbard W, and S Ziebell: The Iowa longitudinal study of recent onset psychosis: one-year follow-up of first episode patients. *Schizophrenia Research*, 23: 1-13, 1997.
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 54. Andreasen NC, O'Leary DS, Flaum M, Nopoulos P, Watkins GL, Ponto LLB and R Hichwa: Hypofrontality in schizophrenia: distributed dysfunctional circuits in neuroleptic-naive patients. *Lancet*, 349:1730-34, 1997.
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 56. Nopoulos P, Flaum M and NC Andreasen: Brain morphology in schizophrenia: Sex differences. *Am J Psychiatry*, in press.
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B. Book Chapters:

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