



FORM: Application for Human Research

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UACCESS EDOC NUMBER (FOR PROJECTS REQUIRING AN IRB FEE) _____

PROJECT TITLE: Association of Familial Handedness and Cerebral Asymmetry in Healthy Subjects

INVESTIGATOR

Principal Investigator Name, Degree(s): Thomas G. Bever, PhD

Principal Investigator UA netID



Status/Rank:

Regents' Professor

Center:

Section:

Department:

Department of Linguistics

College:

Social and Behavioral Sciences

Contact phone:

520-626-6366

Official University Email:

tgb@email.arizona.edu

ADVISOR CONTACT INFORMATION (REQUIRED FOR ALL STUDENTS AND RESIDENTS)

Name, Degree(s), UA NetID:

Contact phone:

Official University Email:

ALTERNATE/COORDINATOR CONTACT INFORMATION

Name, UA NetID:

Nicholas Breitborde, PhD

Contact phone:

520-874-7531

Official University Email:

breitbor@email.arizona.edu




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SECTION 1: REQUIRED SIGNATURES

1. PRINCIPAL INVESTIGATOR

I will conduct my research according to the University of Arizona HSPP Investigator Manual.

	2/28/14	Thomas G. Bever
Signature	Date	Print Name

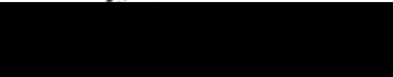
2. ADVISOR (FOR ALL STUDENTS AND RESIDENTS ACTING AS THE PI)

I will oversee the student researcher according to the University of Arizona HSPP Investigator Manual.

Signature	Date	Department
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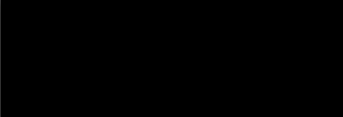
3. SCIENTIFIC/SCHOLARLY REVIEW (CANNOT BE ASSOCIATED WITH THE PROJECT)

I have examined the proposal cited above, and find that the information contained therein is complete and that the scientific or scholarly validity of the project appears appropriate.

	2/28/14	Natasha Warner
Signature	Date	Print Name
nwarner@email.arizona.edu	626-5591	
Official University Email	Phone number	

4. DEPARTMENT/CENTER/SECTION REVIEW

I have reviewed this application and determined that all departmental requirements are met and that the investigator has adequate resources to conduct the Human Research.

	3/3/14	Ofelia Zepeda
Signature	Date	Print Name
ofelia@email.arizona.edu	621-8294	
Official University Email	Phone number	



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SECTION 2: GENERAL INFORMATION

1. Not including this project submission, how many:
 - a. Human Research studies is the PI involved in as [key personnel](#)? 0
 - b. Active subjects are there in the PI's open Human Research study/ies? 0
 - c. Investigators are involved on the PI's open Human Research studies? 0
 - d. Research coordinators are involved on the PI's open Human Research studies? 0
2. What is the expected length of this project? up to 5 years
3. Retention of study materials before, during, and after completion of the project:
 - a. Where will the original signed consent and PHI Authorization documents be stored (building name and room)? N/A
 - b. How long will the data/consents be kept after conclusion of the project?
 - 6 years
 - Other: indefinitely
4. If the Human Research project is funded, identify all sponsoring entity(ies): N/A
5. If funding support is from a federal agency (such as a training grant, infrastructure grant, salary support, project grant, etc.), list federal agency and grant number _____
6. Total funding amount **OR** per subject amount: _____
7. The Principal Investigator hereby affirms that ALL individuals who meet the definition of "investigator" for this project in the current "Policy on Investigator Conflict of Interest in Research" have completed the mandatory Conflict of Interest training (<http://www.orcr.arizona.edu/coi/training>) Yes
8. Will this project be registered on ClinicalTrials.gov because ...? Yes No
 - a. the local PI is the sponsor of the clinical trial (including NIH-funded clinical trials where the local PI is the funding recipient OR IND holder);
 - OR**
 - b. The PI has been designated by a sponsor, contractor, grantee, or awardee to register the clinical trial to ClinicalTrials.gov, as the [Responsible Party](#) (responsible for conducting the trial, and has sufficient data rights)

If yes, please check the appropriate box:

 - ClinicalTrials.gov "NCT" number for this trial (define):
 - Registration pending



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Clinical trial does not require registration (click above to see what studies qualify)

SECTION 3. PROJECT NARRATIVE

1) Background

Cerebral asymmetry is a strong predictor of a number of negative health and functional outcomes, including schizophrenia, dyslexia and language disorders, autism, and immune diseases. The majority of people have left-dominant activation during language use and other activities. Although the likelihood of any of these particular disorders is low, it is higher on average among people with “reversed” asymmetry, i.e. people with right-dominant brains. Unfortunately, cerebral asymmetry is infrequently examined in clinical and healthy populations as it often requires the use of costly assessment strategies (e.g., functional and structural neuroimaging). Consequently, there is a need to in develop easily implemented measures of cerebral asymmetry.

Recently, Bever and colleagues have developed a questionnaire designed to assess genetic loading for familial non-right-handedness (having a close blood relative who is left-handed or ambidextrous). Familial non-right-handedness correlates with cerebral asymmetry. As such, the Handedness Questionnaire may be a potential cheap and easily-implemented proxy measure of cerebral asymmetry. Thus, the goal of this study is to examine the association between familial handedness, cerebral asymmetry, and the course of psychotic disorders.

2) Lay Summary (approximately 400 words)

Cerebral asymmetry is a strong predictor of a number of negative health and functional outcomes, including schizophrenia, dyslexia and language disorders, autism, and immune diseases. The risk of these disorders is low, but is higher on average in individuals with right-dominant brains. Unfortunately, measurement of this variable requires use of expensive assessments (e.g., brain imaging). For this study, we will examine whether scores on a cheap and easily implemented questionnaire (i.e., the Handedness Questionnaire) may be associated with cerebral asymmetry. This assessment may allow for the more frequent assessment of an important clinical construct.

3) Setting of the Human Research

This research will be conducted in Thomas Bever’s Language and Cognition Lab, rooms 304, 306, and 308 in the Communication Building. Participants will be briefed before and after their participation in these same rooms.

4) Resources available to conduct the Human Research

High quality audio playback equipment will be used to maximize the perceptual effects under study. The laboratory in which the experiment will take place contains an electroencephalogram (EEG) machine connected to an Apple computer to record EEG output, with a PC computer to run the behavioral experimental software by which the stimuli will be presented to the participants and by



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which the participants will overtly respond. This equipment is dedicated to use by the Bever Lab, and access will be effectively unlimited.

Thomas Bever has experience designing and conducting dichotic listening experiments as well as numerous other behavioral and EEG experiments. Research assistant Dane Bell has undergone practical training in EEG measurement and analysis from the manufacturer of the equipment to be used in the human research. On the basis of this expertise, all other personnel will be trained to ensure safety, accuracy, and consistency in measurement. This training will include modeling correct application of EEG nets, use of the collection and presentation software, and participant rights, as well as regular evaluation and review.

Research assistants Elizabeth Fowler and Dane Bell have undergone formal training in screening subjects for symptoms of psychosis using the Structured Clinical Interview for the DSM-IV by Nicholas Breitborde.

A large pool of potential research participants will be available for recruitment in the Department of Psychology's subject pool, which is made up of undergraduate students enrolled in PSY 101 and PSY 150 each semester. These students have the option to participate in experiments or to write a paper to fulfill course credit. Relevant demographic information including familial handedness will be available in advance of recruitment, allowing a balanced distribution according to participant sex and familial handedness.

5) Study Population

Participants will be recruited from the University of Arizona Department of Psychology Research Subject Pool. Eligibility criteria include:

- Ages 18-35
- No evidence of a past or present diagnosis of a psychotic illness as determined by the Structured Clinical Interview for the Diagnostic and Statistical Manual of Mental Disorders-IV (SCID-IV, Attachment 7).
- No first-degree relative with a past or present diagnosis of a psychotic illness as determined by the Family Interview for Genetic Studies
- No history of traumatic brain injury or organic neurological impairment per self-report
- No known hearing impairment
- Native (first-language) speakers of English

Subjects participating in the EEG version of the study will be restricted in membership above and beyond subjects in the behavioral version, in that individuals with open head wounds are to be excluded, along with individuals with hairstyles that would prevent good electrode contact, such as dreadlocks and tight braids and individuals whose hair is dyed with certain red dyes known to stain electrode nets.

The subject pool is not made up of any vulnerable population, and although subjects will be students, they will not be the students of any study personnel. Because women of childbearing age are included in the population, it is possible that some subjects could be pregnant at the time of the study.

However, because of the entirely non-medical nature of this study, pregnant women are not a vulnerable population for this research. EEG equipment and use poses no risk to pregnant women.



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Both men and women will be equally encouraged to participate in the study. The racial/ethnic distribution of subjects will reflect the characteristics of students enrolled in introductory Psychology courses at the UA.

6) Recruitment Methods and Consenting Process

Participants will be recruited from Psychology courses via a website hosted by the Department of Psychology, or via direct emails from study personnel to subjects meeting handedness criteria. Students will participate in experiments for partial course credit. Alternatively, students have the option of writing a paper for equivalent credit. The web recruitment information (Attachment 4) will be provided on the website. All subject pool members will be able to view the descriptions in Attachment 4 and self-identify by emailing the PI to request the study password. Interested students will then be contacted using the prescreening templates (Attachment 4). Participants meeting inclusion criteria will then be sent a second email (Attachment 4) with a study password allowing them to sign up for the study.

This recruitment process will also provide enough time for potential subjects to consider whether to participate, and because of the minimal-risk nature of the experiment, this is expected to provide enough time to consider participation.

Up to 150 subjects will be recruited in the course of the whole study.

Subjects will be informed of the study aims and methods prior to giving consent through a Consent Form (Attachment 5) and an oral summary of the consent form. Subjects will be informed orally that they can stop participation at any time. Research personnel will provide answers to any questions potential subjects may have prior to consent. Consenting will take place in the Communication building room 304 or 308 with only study personnel and the subject present. Since a written consent form would be the only identifying information among the otherwise anonymous data gathered in the course of the research, informed oral consent will be secured prior to any data collection.

Following the experimental task, research personnel will debrief each subject roughly following the script in Attachment 6 for the purposes of answering any questions the subject may have, noting any problems the subject experienced, and to reiterate the aims of the research.

7) Procedures involved in the Human Research

After providing informed consent, all participants will complete a single research visit lasting no longer than 1 hour. The presence of gross hearing impairment will be checked by playing pure tones into each ear at 500, 1000, 2000, and 3000 Hz at a volume of 20 dB. Subjects will be asked to respond when they hear a tone, and periods of silence will serve as controls.

At this visit, participants will complete a series of questionnaires and interviews. The Structured Clinical Interview for the DSM-IV (Attachment 4) will be used to confirm no diagnosis of a psychotic disorder. The Family Interview for Genetic Studies will be used to confirm that there is no family history of a psychotic illness (Attachment 8). Demographic information will be collected via the demographics form (Attachment 9). Genetic loading for left-handedness will be assessed using the Handedness Questionnaire (Attachment 10). Presence of subthreshold psychotic symptoms will be assessed using the Community Assessment of Psychic Experiences (Attachment 11).



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Next, participants will complete the Dichotic Fused Word Task. In this task, subjects listen to a dual channel recording of simultaneously spoken rhyming words (e.g., the word “pill” played through the left channel, and the word “dill” played through the right channel). A non-exhaustive but representative list of the words to be played can be found in Attachment 12. In the behavioral version of the study, subjects indicate on a sheet of paper what word they heard during this simultaneous speech.

In addition to the behavioral version of the study, the neural activation of some subjects will be measured using an EEG collection system comprising specialized hardware and software.

The risk associated with participation in this study is no greater than that in daily life.

8) Risks to subjects

Risks to subjects in this study are minimal. They include a potential loss of privacy (e.g., if non-study staff were to get access to research data) and feeling uncomfortable when answering personal questions included in study assessments. With regard to the former, we will minimize this risk by storing all research data in locked file cabinets that are only accessible to research staff, and no identifying information will be associated with the research data. Since the names will not be connected to the sensitive information such as the mental health of their relations, it will not be possible for this information to negatively impact the participant or their relations if the participant’s responses were revealed to non-research personnel by accident. With regard to the latter, subjects will be allowed to take breaks during the completion of study assessments to minimize discomfort, as well as to stop participation at any time.

Subjects may be fitted with an EEG net to noninvasively measure their brain activity. Researchers will be present during the experiment and will stop the experiment and remove the electrode net in the event of participant discomfort. As with any electronic device, there is a very small risk of electric shock from the equipment used in this study. The risk of electric shock is no greater than during the use of any electronic equipment, such as a personal computer. The equipment will be tested on a monthly basis to ensure proper functioning.

In the unlikely event of electric shock, the power to the EEG system and associated equipment will be cut off. The system will not be used until repaired and recertified by the manufacturer.

Appropriately sized EEG nets (small, medium or large) will be used to minimize discomfort. Discomfort can be immediately resolved by removing the net. All EEG equipment was designed under ISO 13485 quality system procedures, and has received FDA clearance for use with humans. Additionally, all electronic equipment is plugged into isolation transformers to isolate the equipment from the power supply. Nets will be disinfected after every use.

The subjects’ hair may be slightly damp and salty after the experiment if their brain activity was measured, and they may want to wash your hair after participating. A few electrodes placed on their faces may leave visible impressions. These will disappear 5-10 minutes after the net is removed.

9) Potential benefits to subjects and/or society

There are no direct benefits to society. However, validating an easy and cheap strategy to assess cerebral asymmetry (i.e., Handedness Questionnaire, Attachment 10) may have societal benefits.



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More specifically, it could simplify early detection of psychosis and other asymmetry-related disorders and make other testing efforts more targeted by indicating individuals who are more likely to eventually exhibit symptoms.

10) Provisions to protect the privacy of subjects and the confidentiality of data

Protection of subject privacy: Identifying information for subjects will not be collected as part of this study. Neither the names of the participants nor of their relations will be recorded with the experimental data or elsewhere. No ID numbers will be collected or recorded. No audio or video recordings of the subjects will be made, and it is not possible to identify individuals by their EEG recordings.

Protection of data confidentiality: All data will be stored in lock file cabinets that are only accessible by research staff. Electronic copies of the data will be stored on password protected files on the hard drives of the research personnel and on back-up optical disks kept locked in the Communication building, rooms 304, 306, and 308, and to which only research personnel will have access, unless otherwise required by law. Data will not be destroyed because if it were, and such data were needed again, new subjects would have to be inconvenienced to re-collect the data, and the data presents no danger to subjects even if it were to become public.

11) Cost to subjects

The only cost to subjects is up to 1 hour of their time.

12) Subject compensation

Subjects will receive course credit for participating in this study.

13) Withdrawal of subjects

If it is learned that a subject provided incorrect information with regard to his or her eligibility for the study (e.g., initially reporting no symptoms of psychosis but later acknowledging symptoms of psychosis), this subject will be removed from the study. We anticipate no increased risk associated with this withdrawal procedure.

14) Sharing of results with subjects

Subjects can learn about the results of the study by contacting the PI following the completion of the study.

15) Drugs, Devices, and Gases

This project will employ Electric Geodesic, Inc.'s Geodesic Electroencephalographic System with a HydroCel Geodesic Sensor Net (GSN).

This medical equipment is certified to EN 60601-1, CAS 22.2 No. 601.1, CSA 22.2 No. 601.2.26, UL 2601, and IEC 60601-2.26. The Geodesic EEG System, of which the GSN is a part, carries the US FDA Pre-market 510k Clearance K012079 (Attachment 13).

Only research personnel qualified by training materials furnished by the device manufacturer will control the device's use at all times. The device will be used, cleaned, and stored in Communication



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304 in accordance with recommended practice by the device manufacturer. Only qualified research personnel will use and have access to the device, since Communication 304 is locked at all times. The device is not to be disposed of, but regular cleaning and minor repairs will be carried out by qualified research personnel. Major maintenance and replacement of the device is carried out by the manufacturer on a yearly basis.

APPENDIX 4

SAMPLE RECRUITMENT MATERIALS

The following are sample texts that will be used for recruiting subjects. It is possible that the actual texts will vary slightly from what is written below. However, the main ideas in each text will remain the same.

A. RECRUITMENT/PRESCREENING EMAIL:

[Included for participants recruited from the mass survey]

You are being invited to participate in studies of cognitive processing based on information you provided on the mass survey in your PSY 150A1/101 course.

[Included for self-selecting participants]

Thank you for your interest in participating in experiment #<experiment number>.

[Included for all potential participants]

The experiment consists of one session that will last up to 1 hour. During the experiment, you will listen to English words and choose which word you heard from a list of options. During these tasks, your brainwaves may be recorded through an electrode net worn on your head. You will receive course credit for your participation.

To determine your eligibility, please reply with your answers to the questions below. A researcher will review your responses and contact you if needed. If you do not wish to participate, simply ignore this email.

If you have questions about the study, please contact a researcher by replying to this e-mail or calling 520-626-6593. You may also contact the principal investigator, Thomas G. Bever, directly at tgb@email.arizona.edu.

This study involves the use of EEG recordings, a non-invasive way of measuring the activity of your brain. During the study, you may be fitted with an electrode cap soaked in an electrolyte solution. Certain conditions may make the study procedures difficult or increase your risk of being irritated by the electrolyte solution. To ensure that you are eligible to complete the study, please answer the questions below. If you do not want to answer a question, you may state that or decline to return the questionnaire. This information will be used only for screening purposes.

1. When is your birthday? Please give month, day, and year.
2. What is your first/native language?
3. Do you have any hearing impairment?
4. Do you have any history of head trauma or neurological problems (e.g. loss of consciousness, epilepsy)?
5. Have you ever been diagnosed with a psychological/psychiatric disorder? If so, what was the diagnosis and are you currently being treated?

6. Do you currently have an open head wound?
7. Are you currently taking any prescription psychopharmacological medications? These are drugs that are prescribed for or may affect psychiatric conditions, such as Ritalin or other drugs for ADHD/ADD, anti-depressants, anti-anxiety drugs, beta blockers (also used for blood pressure regulation) and anti-psychotics.
8. Do you have a tightly braided (e.g. cornrows) or other hairstyle that would make contact with the scalp difficult that you would be unwilling or unable to take down for the study?
9. Is your hair dyed? If so, what color is it dyed?

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Language and Cognition Lab
Communication 304
520-626-6593

B. INFORMATION TO APPEAR ON THE EXPERIMENT WEBSITE MAINTAINED BY THE PSYCHOLOGY DEPARTMENT

The experiment consists of one session that will last up to 1 hour. During the experiment, you will listen to English words and choose which word you heard from a list of options. During these tasks, your brainwaves may be recorded through an electrode net worn on your head. You will receive course credit for your participation.

If you have questions about the study, please contact a researcher by sending an email to dane@email.arizona.edu or calling 520-626-6593. You may also contact the principal investigator, Thomas G. Bever, directly at tgb@email.arizona.edu.

C. FOLLOW-UP EMAIL SCRIPT (ELIGIBLE):

Thank you for your interest in our studies.

To participate, please log on to <http://experiments.psychology.arizona.edu> and select our study.

You may sign up for experiment # [website experiment number] using the password '[study password]' (do not include the quotes).

If you do not wish to participate, simply ignore this email.

If you have questions about the study, please contact a researcher by replying to this e-mail or calling 520-626-6593. You may also contact the principal investigator, Thomas G. Bever, directly at tgb@email.arizona.edu.

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Language and Cognition Lab
Communication 304
520-626-6593

D. FOLLOW-UP EMAIL SCRIPT (INELIGIBLE):

Thank you for your interest in our studies. Unfortunately, we cannot accommodate your participation at this time.

If you have questions about the study, please contact a researcher by replying to this e-mail or calling 520-626-6593. You may also contact the principal investigator, Thomas G. Bever, directly at tgb@email.arizona.edu.

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Language and Cognition Lab
Communication 304
520-626-6593

1
2 **The University of Arizona Consent to Participate in Research**
3
4

Study Title: Association of Familial Handedness and Cerebral Asymmetry in Healthy Subjects

Principal Investigator: Thomas G. Bever

5
6 **This is a consent form for research participation.** It contains important information about
7 this study and what to expect if you decide to participate. Please consider the information
8 carefully. Feel free to discuss the study with your friends and family and to ask questions
9 before making your decision whether or not to participate.

10 **You will not directly benefit as a result of participating in this study.** Also, as explained
11 below, your participation may result in minor unintended or harmful effects the risk of which
12 is no greater than that of everyday life.

13 **1. Why is this study being done?**
14

15 Cerebral asymmetry, the relative strength of the right and left hemispheres of the brain, is
16 a predictor of a number of disorders, including schizophrenia, dyslexia and language
17 disorders, autism, and immune diseases. Most people have left-dominant activation
18 during language use and other activities. Although the likelihood of any of these
19 particular disorders is low, it is higher on average among people with “reversed”
20 asymmetry, i.e. people with more right-dominant brains than average. Unfortunately,
21 measuring asymmetry is expensive because it involves brain imaging. For this study, we
22 are trying to discover whether a questionnaire about the handedness of blood relatives is
23 a good predictor of cerebral asymmetry. If it is, then more people will be able to be
24 tested, and more attention and care can be devoted to people with higher risk of the
25 diseases mentioned above.
26

27 **2. How many people will take part in this study?**
28

29 Up to 150 people will take part in this study.
30

31 **3. What will happen if I take part in this study?**
32

33 You will first be checked for hearing impairment that could affect your ability to complete
34 the task. This will consist of listening for tones and responding when you hear one.
35 Following this, you will complete a series of questionnaires and interviews. The
36 Structured Clinical Interview for the Diagnostic and Statistical Manual of Mental
37 Disorders (DSM-IV) will be used to confirm that you do not have any psychotic disorders,
38 and the Community Assessment of Psychic Experiences (CAPE). The Family Interview
39 for Genetic Studies may be used to confirm that there is no family history of a psychotic
40 illness. Demographic information will be collected via a demographics form. A

41 Handedness Questionnaire will be used to determine how likely you were to have been
42 left-handed, based on how many left-handed people there are among your relations.

43
44 Finally, you will listen to recordings of single-syllable English words through headphones
45 and indicate from a set of similar words which word you heard. For example, you may
46 hear “pill” and have to choose it from the set “mill fill pill will”.

47
48 You may be fitted with an electrode net to noninvasively record your brain activity while
49 you listen to the words and give your responses. The electrode net consists of small
50 sponges wired together in an elastic cap. Caps are of three sizes to comfortably fit a range
51 of head sizes. Prior to fitting the net, the net is soaked in an electrolyte solution and then
52 patted dry. Electrical contact is made through the conductivity of wet sponges touching
53 the scalp. Fitting and testing the net will take about 10-20 minutes.

54

55 **4. How long will I be in the study?**

56

57 Your participation will be limited to a single visit lasting no longer than 1 hour.

58

59 **5. Can I stop being in the study?**

60

61 **Your participation is voluntary.** You may refuse to participate in this study. If you
62 decide to take part in the study, you may leave the study at any time. No matter what
63 decision you make, there will be no penalty to you and you will not lose any of your usual
64 benefits. Your decision will not affect your future relationship with The University of
65 Arizona. If you are a student or employee at the University of Arizona, your decision will
66 not affect your grades or employment status.

67

68 **6. What risks, side effects or discomforts can I expect from being in the study?**

69

70 **The risks of participating are minimal.** You may experience discomfort in answering
71 study-related questions that are of a personal nature. If you do experience discomfort, you
72 will be allowed to take breaks during the completion of study assessments to minimize
73 discomfort, and as always, you may discontinue participation in the study at any time with
74 no loss of benefits to which you are otherwise entitled. You do not have to answer any
75 questions you do not want to.

76

77 If you choose to participate, you will be in contact with electrical equipment, which as in
78 everyday life carries a small risk of electric shock. The risk of shock is no greater than
79 during the use of any electronic equipment, such as a personal computer. Also, all
80 electronic equipment is plugged into medical-grade isolation transformers to prevent a
81 power surge or other problem with the building electrical supply from reaching you.

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83 If your scalp’s electrical activity is measured using an electrode net, your hair may be
84 slightly damp and salty after the experiment and you may want to wash your hair after

85 participating. A few electrodes placed on your face may leave visible impressions. These
86 will disappear 5-10 minutes after the net is removed.

87

88 **7. What benefits can I expect from being in the study?**

89

90 No direct benefits are anticipated from being in the study.

91

92 **8. What other choices do I have if I do not take part in the study?**

93

94 The alternative to participating in this study is to choose another eligible study to
95 participate in or to complete an alternative assignment as described in your course
96 syllabus. You may choose not to participate without penalty or loss of benefits to which
97 you are otherwise entitled.

98

99 **9. Will my study-related information be kept confidential?**

100

101 Efforts will be made to keep your study-related information confidential. However, there
102 may be circumstances where this information must be released. For example, personal
103 information regarding your participation in this study may be disclosed if required by state
104 law.

105

106 Also, your records may be reviewed by the following groups (as applicable to the
107 research):

108

- 109 • Office for Human Research Protections or other federal, state, or international
regulatory agencies
- 110 • The University of Arizona Institutional Review Board or Office of Responsible
111 Research Practices
- 112 • The sponsor supporting the study, their agents or study monitors

113

114 Your name and other identifying information will not be linked to study data at any time.
115 Research personnel for the study will have access to your name on the Psychology
116 Department's Experiment Scheduling and Tracking System website for the purpose of
117 assigning course credit, but every identifying record of your participation will be
118 automatically expunged at the end of the current semester.

119

120 **10. What are the costs of taking part in this study?**

121

122 There are no costs of taking part in this study apart from your time.

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124 **11. Will I be paid for taking part in this study?**

125

126 No, you will not be paid for taking part in this study. You will receive 1 course credit for
127 each half hour of participation up to 2 course credits.

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12. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should seek treatment. The University of Arizona has no funds set aside for the payment of treatment expenses for this study.

13. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The University of Arizona reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact the principal investigator, Thomas G. Bever, at tgb@email.arizona.edu.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Human Subjects Protection Program at 520-626-6721 or online at <http://ocr.arizona.edu/hssp>.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact principal investigator, Thomas G. Bever, at tgb@email.arizona.edu.

By continuing with this research project you are allowing your data to be used for research purposes.

1
2
3 **APPENDIX 6**

4 The script below is an example of what would be said during the debriefing. Because of the
5 natural variation in conversation, the actual utterances may vary. However, the key ideas
6 expressed in this example will be present in every variation on the script.

7 **SAMPLE SCRIPT FOR DEBRIEFING SUBJECTS AFTER THE EXPERIMENT**
8

9 Most people’s brains are asymmetrical so that portions of the left half (in particular, the planum
10 temporale) are slightly bigger than analogous portions of right half, and that certain left
11 hemisphere regions, in particular the inferior frontal lobe and superior temporal lobe, are more
12 active than similar regions of the right hemisphere when people do language-related activities.
13 This is called cerebral asymmetry, and the amount of asymmetry varies from person to person. It
14 seems to be related to how most people are right-handed, but some are ambidextrous or left-
15 handed – the more leftward cerebral asymmetry you have, the more likely you are to be right-
16 handed (because the left hemisphere more or less controls the right half of the body).
17

18 Cerebral asymmetry is a strong predictor of a number of negative health and functional outcomes,
19 including schizophrenia, dyslexia and language disorders, autism, and immune diseases.
20 Unfortunately, measurement of asymmetry requires use of expensive assessments like brain
21 imaging. In this study, we are examining the possibility that the family handedness questionnaire
22 you filled out may act as a reliable but inexpensive measure of cerebral asymmetry by helping
23 determine your genetic load for left-handedness (roughly, the likelihood that you would have been
24 left-handed). Our hope is that this questionnaire will make it possible to find more people who are
25 at risk for the disorders I mentioned, so we can test the right people.
26

27 The task you performed in the study is called dichotic listening, and it works by playing different
28 sounds in each ear. In particular, it was “fused” dichotic listening, because the sounds were both
29 single-syllable words that rhymed, so that your left ear might be played ‘pill’ and your right ear
30 ‘fill’ at the same time. In normal life, it would be safe to assume that only one of them is right, so
31 you only think you hear one or the other. For most people, there’s a preference for hearing the
32 word that’s played in their right ear, because it’s connected to the dominant left hemisphere. The
33 amount of the time the right-ear word is reported is used to show the degree of dominance of the
34 left hemisphere, so that someone with no cerebral dominance would be equally likely to hear the
35 left-ear word as they would the right-ear word.
36

37 If the amount of right-ear advantage corresponds (inversely) to the genetic load for left-
38 handedness, then the family handedness questionnaire may be a useful and inexpensive tool for
39 assessing risk of several health problems.

MANUAL FOR THE FIGS
by M. Elizabeth Maxwell

Clinical Neurogenetics Branch, Intramural Research Program
National Institute of Mental Health

PURPOSE

The Family Interview for Genetic Studies (FIGS) is a guide for gathering diagnostic information about relatives in the pedigrees being studied. This diagnostic information becomes part of a pool of data on each individual relative, to be added to data from the completed Diagnostic Interview for Genetic Studies (DIGS) and from medical records.

The FIGS becomes particularly important when reliance on direct information from a subject becomes impossible. There are always relatives who are deceased or unavailable, and some who do not provide true or adequate information about themselves or who are too ill to be interviewed directly.

WHO PROVIDES FIGS DATA

Generally, the FIGS is done as the second part of the interview package, the first part being the Diagnostic Interview for Genetic Studies (DIGS). FIGS data should be collected from everyone interviewed about all known members of the extended family. This recommendation is backed by extensive experience, confirmed in a study by Gershon and Guroff (Information from relatives. Arch Gen Psychiatry, Vol. 41, February 1984) which states:

"Only 15% of the (1,093) interview-diagnosed relatives were identified as having a major affective disorder by one informant alone, going up to 64% agreement with four or more informants."

Another reason for collecting FIGS data from everybody interviewed about all known family members is that you never know in advance which relative has information that will enable you to determine bilineality or extenders or pointers.

COMPARISON OF TECHNIQUES BETWEEN FIGS AND DIGS

Whereas the DIGS is designed to be used verbatim (with relatively few item exceptions), the FIGS is meant to be only a guide for the interviewer. For example, the Face Sheet Question One requires a probe as to whether or not the subject has ever had any psychiatric or personality problems. The interviewer is free to word the probe in a way that will best elicit the information. The

interviewer may say, "Tell me about him. What was he like? Was he a moody person?" With practice and with clinical judgment the interviewer knows what to ask, how to ask it, how much to ask, when to push, and when to use restraint. It is the interviewer's responsibility to obtain as much data relevant to the study as possible, with the minimum number of questions. Because each individual and his/her family are unique, no interview instrument could cover the range of possible questions to be asked.

THE PEDIGREE DRAWING

A pedigree is usually drawn as part of the initial ascertainment to determine whether a particular family is suitable for study. If the proband cannot provide the information to draw the pedigree, another family member can provide the data. If it has not been drawn prior to the interview it should be done as part of the interview before beginning the FIGS.

At a minimum the pedigree includes the proband and his/her parents, grandparents, siblings, aunts, uncles, offspring, and spouse.

The pedigree may indicate the presence of bilineality. When a proband's relatives include affected individuals on both the mother's and the father's side, the family is said to be bilineal. In such a family the relationship of the affected relatives to the proband might be parents, grandparents, aunts or uncles. The limits of degree of relationship that would mark a family as bilineal are determined by the study design.

Bilineality may also be in a sibship other than the proband's, perhaps making that sibship ineligible for the study.

With regard to screening for bilineality, a general rule is that in any generation, when there are one or more affected offspring, the parent relative's spouse and the spouse's first degree relatives should be screened by the FIGS.

The pedigree may also indicate extenders. Extenders are any of the proband's second degree relatives (grandparent, uncle or aunt, half-sib, niece or nephew, or grandchild) who are affected. An extender expands the pedigree insofar as the first degree relatives of an extender are included in the pedigree for study. For example, if the proband's uncle is affected, the uncle's sibship and offspring are studied and if one of the offspring is found to be affected, the uncle's spouse and her family will be checked for bilineality. The interviewer should ask for information regarding pathology in any of them.

The pedigree may also indicate pointers. Pointers are relatives who are not affected but who have offspring who are affected. For example, if the proband's aunt is not affected but she has a daughter who is affected, the daughter's sibship is studied, and the aunt's spouse and his family will be checked for bilineality. The interviewer should ask for information regarding pathology in any of them.

THE THREE PARTS OF THE FIGS

There are three parts of the FIGS: the General Screening Questions, the Face Sheet, and the symptom checklists.

The most general information is gathered by using the General Screening Questions about all known relatives in the pedigree, regardless of how distantly related. The Face Sheet is for each of the informant's first degree relatives, and also for any affected relatives about whom the informant can provide information. The various symptom checklists are used to ferret out the diagnostic details that help make possible a best estimate diagnosis. There are checklists for these disorders: depression, mania, alcohol/drug abuse, psychosis, and paranoid/schizoid/schizotypal personality.

HOW TO USE THE FIGS

There are three steps to using the FIGS: 1) review the pedigree with the informant; 2) ask the General Screening Questions; and 3) complete a Face Sheet and symptom checklists with selected relatives.

1) Review the Pedigree

Before you begin the FIGS you will need a clean copy of the pedigree diagram without diagnostic information. (The pedigree diagram is drawn at the time of the first FIGS interview, and a clean copy should go to each subsequent interviewer.) A completed, clean pedigree provides the following for each person: name, number within the family, sex, age at the time of pedigree drawing, marital status, role in the family, whether living or dead, and if dead, age at the time of death. Persons about whom there is already sufficient information on a major diagnosis, such as schizophrenia or bipolar I, should be indicated so that unnecessary repetition can be avoided. The clean pedigree itself is identified by family name, number, date of the FIGS interview, and the name and number of the informant.

Show the pedigree to the informant and ask if anyone is missing, or if he/she can supply missing pieces of information (names, ages, and so on). At a minimum the pedigree includes the proband's parents, grandparents, siblings, aunts, uncles, cousins, offspring, spouse (and parents and siblings of the married-in spouse if there are affected offspring). If the informant's first degree relatives are not on the pedigree, expand the pedigree to include them.

2) Ask the General Screening Questions.

Ask the informant to keep in mind all of the relatives on the pedigree as he/she listens to the questions you will read.

When you get a positive response to one of the questions, record it directly on the pedigree by the name of the person being described. At this point you are receiving overall, general information and writing notes on the pedigree, being careful to pick up any hints of pathology. Probing for more detail can come later with the Face Sheets and symptom checklists.

- 3) Ask about individual relatives, using a Face Sheet and symptom checklists.

Having completed the General Screening Questions and having noted the responses directly on the pedigree, complete a Face Sheet for each of the informant's first degree relatives, e.g., the informant's parents, siblings, and offspring, as well as the informant's spouse. Ask about each one, using a separate Face Sheet for each, whether or not there is any hint of pathology reported by the informant. In addition, complete a Face Sheet as follow up on any hints from the informant of pathology anywhere in the pedigree, even if the person is not someone in the group described above. Otherwise, extenders and pointers may be missed.

The birthdate need not be asked if it is already in the data.

Write on the Face Sheet any narrative that may have significance for diagnosis, including that of "normal". The narrative can be one or two sentences describing what the person was like, and if there were any psychiatric or personality problems. If the informant offers nothing and you feel it would help, you could do some prompting from the General Screening Questions to refresh his/her memory on what information is being sought, at your own discretion.

If there is any known pathology, you should have detected it while going through the General Screening Questions with the pedigree. As you do a Face Sheet, immediately examine those hints and explore them further by asking questions on the pertinent checklists. The checklists ask details of symptoms, number of episodes, duration, age of onset, treatment, and impairment rating.

Complete a symptom checklist for any suspected depression, mania, alcohol or drug abuse, psychosis, or paranoid/schizoid/schizotypal personality. Symptom checklists for depression, mania or psychosis may be omitted for persons already assigned a major diagnosis such as schizophrenia or bipolar I.

Should you learn of a disorder other than those for which there are checklists, go to question five on the Face Sheet, which allows space for a description and has questions on the age of onset, treatment and impairment.

Use a checklist only if you have reason to believe that the informant can tell you something. You will know this either by responses to the General Screening Questions or by the narrative you get when doing the Face Sheet. If you start a checklist and find the informant cannot provide details stop using the checklist. If you find that the informant knows only about

treatment and onset but nothing else, get whatever information you can. If the informant may have "heard about" a problem, or may have rarely seen the subject, or for any reason simply doesn't have any knowledge, there is no point in even beginning a checklist. Use your own discretion, but note as narrative on the Face Sheet your observations regarding the reasons for the dearth of information.

If you already have enough information in a subject's data pool for a positive diagnosis, there is no need to use a checklist. For example, suppose you are doing the FIGS and you are beginning the Face Sheet on a proband with schizophrenia. The study already has confirming information from two other informants for the core diagnosis of schizophrenia. On the pedigree diagram it is indicated that two confirming FIGS reports would be sufficient evidence in this case to warrant omission of the psychosis checklist. Nonetheless you will still want to complete a Face Sheet narrative giving that informant's unique perspective, even though you do not need to complete a checklist on psychosis. On the other hand, if the informant gives information not previously revealed in the data, you will want to record it as fully as possible. Examples might be evidence of depression or alcoholism not disclosed previously by other relatives or in the DIGS.

To avoid the problem of a false negative, however, you may go ahead and collect information from at least four or five informants or until you get a report of a core diagnosis when pathology is suspected.

Even if a DIGS has been completed on the subject you can never be certain of its reliability, and the FIGS can help corroborate or expand the information. Notes jotted down as the informant speaks about the subject may turn out to be important pieces of the diagnostic picture as a whole.

Suppose the informant knows something significant about a family member on the pedigree who is not someone on whom you would normally do a Face Sheet (that is, not a first degree relative). In each case such as this, complete a Face Sheet and relevant checklists, the same as you would for a first degree relative.

DATA COLLECTION

As each informant completes a FIGS, the body of data about a single relative is increased with each FIGS completed. There may be many pages of data from various informants about a single subject.

Each completed FIGS page (whether General Screening Questions, Face Sheet or symptom checklist page carries identification: family name and number, informant name and number, subject name and number, and the date the information was obtained. Without this identification the page has little value. Thus, each page must stand on its own. This is necessary because for the best estimate diagnosis each page will be part of the subject's data pool entry, combined with FIGS pages from other relatives about the subject, the

subject's DIGS if completed, and the subject's medical records, if any. (The above does not apply to coded information.)

Additional FIGS pages will be needed during the course of the study as new information is acquired. Relatives who were not ill before may become ill, relatives in remission may have a relapse, or a previously not located relative may be found who can provide information. New information is recorded on a FIGS Face Sheet (with checklists as needed and as possible) and added to the pool of information about that subject.

TYPES OF PEDIGREE DRAWINGS

Hand-drawn pedigrees

1. Clean pedigree

A clean pedigree has everything but diagnostic information. It is essential for doing the FIGS. (Make several copies of this clean pedigree for use in interviews. Information from each informant should be recorded on a separate copy of the clean pedigree.)

2. Pedigree with FIGS information

This copy has new information from the informant, written onto the clean pedigree. The new information may be in terms of filling in missing persons, names, and so on, or of expanding the pedigree to include additional beginning. Write the responses to the General Screening Questions on this copy. Be sure to write the date and the name and number of the informant on the pedigree used when doing a FIGS. With each FIGS done there will be a pedigree with input from a single informant.

3. Master pedigree

A single pedigree with cumulative information from each of the FIGS informants. If it is kept up-to-date throughout the study by recording new information as it is collected, it provides detailed information at a glance. Used as a basis for the computer-drawn pedigree, the master pedigree is hand-drawn and gives the following information:

- a) who has been interviewed, as each interview is completed; who has refused or is unable or deceased;
- b) diagnostic highlights (in abbreviations) as each relative reveals details of family history (extracted from their FIGS);
- c) diagnostic status, whether provisional (DIGS only), and then final best estimate diagnoses; or revised after new information;

- d) who has given a blood sample, and whether that sample is in culture;
- e) new marriages, births, deaths, and
- f) the master record of numbers assigned (no two relatives will have the same number).

Computer-drawn Pedigree

Drawn by means of a computer program, this can provide information on the final diagnosis of all affected beginning as well as the status of cell lines. The computer may draw pedigrees with or without diagnoses, with or without a record of cell line status, and with or without genotypes.

ADDRESSES AND TELEPHONE NUMBERS

In general the best time to ask for addresses and telephone numbers is not during the scheduled interview time. The information can be forwarded by telephone or by mail.

Probands and relatives who are well disposed to the study will generally provide addresses and telephone numbers of other relatives, but sometimes they may wish to contact a relative for permission before giving you access.

An ongoing record of current addresses and telephone numbers is conveniently kept in numerical or alphabetical order in a loose leaf binder so that additional pages of relatives or new families can be added to the study.

Continuing contacts, with probands and relatives as well as changes in name/address/telephone number are recorded on these pages in such a way that any of the research staff will be able to pick up the work at any point, knowing what has been done.

FIGS: FACE SHEET

**FAMILY INTERVIEW FOR GENETIC STUDIES
(FIGS)**

Interview date: – –
Month Day Year

Family last name: _____ Family ID Number:

Informant name: _____
First Middle Last
Informant ID:

Person being described name: _____
First Middle Last
Person being described ID:

Relationship to Informant: _____

Birthdate of person described, if known: – –
Month Day Year
No Yes Unk

Is person being described living? 0 1 9
Age in Year
Age and Year when last seen or known about, or died: in

If deceased, cause of death: _____
No Yes Unk

Suicide? 0 1 9

INTERVIEWER: Refer to General Screening Questions if necessary.

1. **(Probe:** has he/she had any psychiatric or personality problems like those we mentioned earlier?) 0 1 9
Write narrative:

FIGS: FACE SHEET

FIGS
11-Feb-1999

Continue Narrative:

FIGS: OTHER DISORDERS

1. Indicate any disorder not in the checklists and complete questions 1.a-f for the disorder.
Specify: _____

	Code Response						
1.a) Code and describe professional treatment:	0 1 2 3 4 9						
0. None							
1. Inpatient: _____							
2. Outpatient: _____							
3. ECT: _____							
4. Medication: _____							
9. Unknown							
1.b) Age of onset	<table style="margin: auto; border-collapse: collapse;"> <tr> <td colspan="2" style="text-align: center;">Age</td> </tr> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> </tr> </table>	Age					
Age							
1.c) Number of episodes	<table style="margin: auto; border-collapse: collapse;"> <tr> <td colspan="3" style="text-align: center;">Episodes</td> </tr> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> </tr> </table>	Episodes					
Episodes							
1.d) Duration of longest episode in weeks	<table style="margin: auto; border-collapse: collapse;"> <tr> <td colspan="3" style="text-align: center;">Weeks</td> </tr> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> </tr> </table>	Weeks					
Weeks							
1.e) Rate and code impairment or incapacitation:	0 1 2 9						
0. None							
1. Impaired							
2. Incapacitated							
9. Unknown							
1.f) Interviewer judgement on reliability of this information:	1 2 3						
1. Good							
2. Fair							
3. Poor							

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Interview date: — —
Month Day Year

Use One Per Informant

Family last name: _____ Family ID Number:

Informant name: _____ ID:
First MI Last

INTERVIEWER: Before you begin, you need to generate or obtain a pedigree on which to record all of the responses to the following General Screening Questions. (See FIGS Manual for details.)

Step 1: *Let's go over your family tree.* (Include spouse and his/her parents and siblings, offspring, parents, siblings, aunts, uncles, cousins, grandparents, as well as any other relatives the informant can recall.)

Step 2: *Now I am asking you to keep in mind all those in your family tree as I go through this list of questions.* (Note all positive responses on the pedigree.)

Was anyone adopted?

Was anyone mentally retarded?

Did anyone:

Have problems with their nerves or emotions? Take medicine or see a doctor for it? Take lithium?

Feel very low for a couple of weeks or more, or have a diagnosis of depression?

Attempt or complete suicide?

Seem overexcited (or manic) day and night, or have a diagnosis of mania?

Have visions, hear voices, or have beliefs that seem strange or unreal?

Have unusual or bizarre behavior, or have a diagnosis of schizophrenia?

Have trouble with the police, with completing school, or with keeping a job?

Have alcohol or drug use that caused problems (with health, family, job, or police)? Go to AA or NA, or have treatment for this?

(Was anyone) hospitalized for psychiatric problems, or for drug or alcohol problems?

Have inherited medical diseases such as Huntington's disease or seizure disorder or any other disorders of the brain or nervous system?

(Did anyone) have few friends, or seem to be a loner?

(Did anyone) seem odd or eccentric in behavior or appearance?

(Was anyone) extremely jealous, or suspicious, or believe in magic, or see special meanings in things that no one else saw?

Step 3: Complete a Face Sheet for each of the informant's first degree relatives and spouse. If he/she knows well other affected relatives, also complete a Face Sheet for them. In addition, for each of these given a positive response in the General Screening, complete the symptom checklist for any suspected: Depression/Mania, Alcohol/Drug Abuse, Psychosis, or Paranoid/Schizoid/Schizotypal Personality.

FIGS: DEPRESSION CHECKLIST

Interview date:

--	--	--

 –

--	--

 –

--	--	--	--

Month Day Year

Family last name: _____ Family ID Number:

--	--	--	--

Informant name: _____ ID:

--	--	--	--	--

First MI Last

Person being described name: _____ ID:

--	--	--	--	--

First MI Last

Code for a single episode (best recalled, worst episode if possible).

	<u>No</u>	<u>Yes</u>	<u>Unk</u>	
1. <i>During depression...</i>				
1.a) <i>...was he/she depressed most of the day, nearly every day, for as long as a week or more?</i>	0	1	9	
1.b) <i>...did he/she lose interest in things or become unable to enjoy most things, for as long as a week?</i>	0	1	9	
1.c) <i>...did he/she have a change in appetite or weight without trying to?</i>	0	1	9	
1.d) <i>...did he/she have a change in sleep patterns (either too much or too little)?</i>	0	1	9	
1.e) <i>...did he/she become unable to work, go to school, or take care of household responsibilities?</i>	0	1	9	
If yes: Describe: _____ _____				
<table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td style="padding: 2px;">Discontinue this checklist</td></tr></table> ←	Discontinue this checklist			
Discontinue this checklist				
1.f) <i>...did he/she move or speak more slowly than usual?</i>	0	1	9	
1.g) <i>...did he/she pace or wring his/her hands?</i>	0	1	9	
1.h) <i>...did he/she have less energy or feel tired out?</i>	0	1	9	
1.i) <i>...did he/she feel guilty, worthless or blame himself/herself?</i>	0	1	9	
1.j) <i>...did he/she have trouble concentrating or making decisions?</i>	0	1	9	
1.k) <i>...did he/she talk of death or suicide? Or try suicide?</i>	0	1	9	
1.l) <i>...did he/she have visions, or hear voices, or have beliefs or behavior that seem strange or unusual, at the same time as (symptoms above)? (If YES, complete a Psychosis Checklist after this one.)</i>	0	1	9	

FIGS: DEPRESSION CHECKLIST

	Code Response						
<p>2. Code and describe professional treatment:</p> <p style="margin-left: 20px;">0. None</p> <p style="margin-left: 20px;">1. Inpatient: _____</p> <p style="margin-left: 20px;">2. Outpatient: _____</p> <p style="margin-left: 20px;">3. ECT: _____</p> <p style="margin-left: 20px;">4. Medication: _____</p> <p style="margin-left: 20px;">9. Unknown</p>	<p>0 1 2 3 4 9</p>						
<p>3. Age of onset</p>	<table style="margin-left: auto; margin-right: auto;"> <tr> <td colspan="2" style="text-align: center;">Age</td> </tr> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> </tr> </table>	Age					
Age							
<p>4. Number of episodes</p>	<table style="margin-left: auto; margin-right: auto;"> <tr> <td colspan="3" style="text-align: center;">Episodes</td> </tr> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> </tr> </table>	Episodes					
Episodes							
<p>5. Duration of longest episode in weeks</p>	<table style="margin-left: auto; margin-right: auto;"> <tr> <td colspan="3" style="text-align: center;">Weeks</td> </tr> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> <td style="border: 1px solid black; width: 20px; height: 20px;"></td> </tr> </table>	Weeks					
Weeks							
<p>6. Rate and code impairment or incapacitation:</p> <p style="margin-left: 20px;">0. None</p> <p style="margin-left: 20px;">1. Modified RDC Impairment</p> <p style="margin-left: 20px;">2. Modified RDC Incapacitation</p> <p style="margin-left: 20px;">3. RDC Minor Role Dysfunction</p> <p style="margin-left: 20px;">4. Change from previous functioning</p> <p style="margin-left: 20px;">9. Unknown</p>	<p>0 1 2 3 4 9</p>						
<p>7. Interviewer judgement on reliability of this information:</p> <p style="margin-left: 20px;">1. Good</p> <p style="margin-left: 20px;">2. Fair</p> <p style="margin-left: 20px;">3. Poor</p>	<p>1 2 3</p>						

FIGS: MANIA CHECKLIST

Interview date: — —
Month Day Year

Family last name: _____ Family ID Number:

Informant name: _____ ID:
First MI Last

Person being described name: _____ ID:
First MI Last

	<u>No</u>	<u>Yes</u>	<u>Unk</u>
1. <i>For most of the time day and night over several days, did he/she (more than usual)...</i>			
1.a) <i>...seem too happy/high/excited?</i>	0	1	9
1.b) <i>...become so excited or agitated it was impossible to converse with him/her?</i>	0	1	9
1.c) <i>...act very irritable or angry?</i>	0	1	9
1.d) <i>...need less sleep without feeling tired?</i>	0	1	9
1.e) <i>...show poor judgement (e.g., spending sprees, sexual indiscretions?)</i>	0	1	9
If yes: Describe: _____ _____			
Discontinue this checklist ←			
1.f) <i>...behave in such a way as to cause difficulty for those around him/her (obnoxious/manipulative)?</i>	0	1	9
1.g) <i>...feel that he/she had special gifts or powers?</i>	0	1	9
1.h) <i>...become more talkative than usual?</i>	0	1	9
1.i) <i>...jump from one idea to another?</i>	0	1	9
1.j) <i>...become easily distracted?</i>	0	1	9
1.k) <i>...get involved in too many activities at work or school?</i>	0	1	9
1.l) <i>...have visions? hear voices? have beliefs or behavior that seem strange or unusual? at the same time as (above symptoms)? (If YES, complete a Psychosis Checklist after this one.)</i>	0	1	9

FIGS: MANIA CHECKLIST

	Code Response						
<p>2. Code and describe professional treatment:</p> <p style="margin-left: 20px;">0. None</p> <p style="margin-left: 20px;">1. Inpatient: _____</p> <p style="margin-left: 20px;">2. Outpatient: _____</p> <p style="margin-left: 20px;">3. ECT: _____</p> <p style="margin-left: 20px;">4. Medication: _____</p> <p style="margin-left: 20px;">9. Unknown</p>	<p>0 1 2 3 4 9</p>						
<p>3. Age of onset</p>	<table style="margin-left: auto; margin-right: auto;"> <tr><td colspan="2" style="text-align: center;">Age</td></tr> <tr><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td></tr> </table>	Age					
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<p>4. Number of episodes</p>	<table style="margin-left: auto; margin-right: auto;"> <tr><td colspan="3" style="text-align: center;">Episodes</td></tr> <tr><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td></tr> </table>	Episodes					
Episodes							
<p>5. Duration of longest episode in weeks</p>	<table style="margin-left: auto; margin-right: auto;"> <tr><td colspan="3" style="text-align: center;">Weeks</td></tr> <tr><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td></tr> </table>	Weeks					
Weeks							
<p>6. Rate and code impairment or incapacitation:</p> <p style="margin-left: 20px;">0. None</p> <p style="margin-left: 20px;">1. Impaired</p> <p style="margin-left: 20px;">2. Incapacitated</p> <p style="margin-left: 20px;">9. Unknown</p>	<table style="margin-left: auto; margin-right: auto;"> <tr><td colspan="2" style="text-align: center;">Code Response</td></tr> <tr><td style="border: 1px solid black; width: 20px; height: 20px;"></td><td style="border: 1px solid black; width: 20px; height: 20px;"></td></tr> </table> <p>0 1 2 9</p>	Code Response					
Code Response							
<p>7. Interviewer judgement on reliability of this information:</p> <p style="margin-left: 20px;">1. Good</p> <p style="margin-left: 20px;">2. Fair</p> <p style="margin-left: 20px;">3. Poor</p>	<p>1 2 3</p>						

FIGS: ALCOHOL & DRUG ABUSE CHECKLIST

Interview date: — —
 Month Day Year

Family last name: _____ Family ID Number:

Informant name: _____ ID:
 First MI Last

Person being described name: _____ ID:
 First MI Last

ALCOHOLISM

Code for a single episode (best recalled, worst episode if possible).

	No	Yes	Unk
1. <i>Because of drinking, did he/she ever have problems such as...</i>			
1.a) <i>...being unable to stop or cut down on drinking?</i>	0	1	9
1.b) <i>...spending a lot of time drinking or being hung over?</i>	0	1	9
1.c) <i>...being unable to work, go to school, or take care of household responsibilities?</i>	0	1	9
1.d) <i>...being high from drinking when he/she could get hurt?</i>	0	1	9
1.e) <i>...accidental injuries?</i>	0	1	9
1.f) <i>...reducing or giving up important activities?</i>	0	1	9
1.g) <i>...objections from the family or friends, at work or school?</i>	0	1	9
1.h) <i>...legal problems more than once (DWIs, arrests)?</i>	0	1	9
1.i) <i>...blackouts more than once?</i>	0	1	9
1.j) <i>...binges or benders more than once?</i>	0	1	9
1.k) <i>...physical health problems (liver disease, pancreatitis)?</i>	0	1	9
1.l) <i>...emotional or psychological problems (uninterested, depressed, suspicious/paranoid, having strange ideas)?</i>	0	1	9
1.m) <i>...withdrawal symptoms (shakes, seizures/convulsions, DTs)?</i>	0	1	9

Code Response

	0	1	2	3	4	9
2. <i>Did he/she go to AA or have any kind of treatment? (Code and describe all that apply)</i>						
0. None						
1. Inpatient: _____						
2. Outpatient: _____						
3. AA or other self-help: _____						
4. Medication: _____						
9. Unknown						

Describe details and/or other treatment:

	No	Yes	Unk
3. <i>Does he/she currently have a problem with alcohol?</i>	0	1	9

FIGS: ALCOHOL & DRUG ABUSE CHECKLIST

4. Record age he/she began to have alcohol-related problems.

Ons Age	

5. Record age he/she stopped drinking heavily.

Rec Age	

DRUG ABUSE/DEPENDENCE

6. Which drugs did he/she have trouble with?

Specify: _____

7. Because of his/her drug use, did he/she have...

- 7.a) ...physical health problems (hepatitis, overdose, withdrawal symptoms, accidental injuries)?
- 7.b) ...emotional or psychological problems (uninterested, depressed, suspicious/paranoid, having strange ideas)?
- 7.c) ...legal problems (arrests for possessing, selling, or stealing drugs)?
- 7.d) ...problems with family or friends?
- 7.e) ...troubles at work or school?

<u>No</u>	<u>Yes</u>	<u>Unk</u>
0	1	9
0	1	9
0	1	9
0	1	9
0	1	9

Code Response

8. Did he/she go to NA or have any kind of treatment? (Code and describe all that apply)

- 0. None
- 1. Inpatient: _____
- 2. Outpatient: _____
- 3. NA or other self-help: _____
- 4. Medication: _____
- 9. Unknown

0	1	2	3	4	9
---	---	---	---	---	---

Describe details and/or other treatment:

9. Does he/she currently have a problem with drugs?

<u>No</u>	<u>Yes</u>	<u>Unk</u>
0	1	9

10. Record age he/she began to have drug-related problems.

Ons Age	

11. Record age he/she stopped using drugs heavily.

Rec Age	

Code
Response

12. Interviewer judgement on reliability of this information:

- 1. Good
- 2. Fair
- 3. Poor

1	2	3
---	---	---

FIGS: PSYCHOSIS CHECKLIST

Interview date: — —
Month Day Year

Family last name: _____ Family ID Number:

Informant name: _____ ID:
First MI Last

Person being described name: _____ ID:
First MI Last

PSYCHOSIS

Code for a single episode (best recalled, worst episode if possible).

1. *What were his/her unusual beliefs or experiences?*

Specify: _____

<i>Did he/she ever...</i>	<u>No</u>	<u>Yes</u>	<u>Unk</u>
1.a) <i>...believe people were following him/her, or that someone was trying to hurt or poison him/her?</i>	0	1	9
1.b) <i>...believe someone was reading his/her mind?</i>	0	1	9
1.c) <i>...believe he/she was under the control of some outside person or power or force?</i>	0	1	9
1.d) <i>...believe his/her thoughts were broadcast, or that an outside force took away his/her thoughts or put thoughts into his/her head?</i>	0	1	9
1.e) <i>...have any other strange or unusual beliefs?</i>	0	1	9
If yes: Describe: _____ _____			
1.f) <i>...see things that were not really there?</i>	0	1	9
1.g) <i>...hear voices or other sounds that were not real?</i>	0	1	9

If yes: Describe: _____

Skip to question 1.h ←

FIGS: PSYCHOSIS CHECKLIST

	<u>No</u>	<u>Yes</u>	<u>Unk</u>
1.g.1) (Code YES if: voice with content having no relation to depression or elation, or voice keeping up running commentary on subject's behavior or thoughts, or two or more voices conversing.)	0	1	9
1.h) <i>...speak in a way that was difficult to make sense of?</i>	0	1	9

If yes: Describe: _____

1.i) <i>...seem to be physically stuck in one position, or move around excitedly without any purpose?</i>	0	1	9
1.j) <i>...appear to have no emotions, or inappropriate emotions?</i>	0	1	9

Weeks

--	--	--

2. How long did the longest of these experiences last?

INTERVIEWER: If less than 1 week (unless successfully treated), STOP HERE. Otherwise continue, if informant is knowledgeable about this person.

INTERVIEWER: If subject did NOT have any episode of Major Depression or Mania (by FIGS checklists from this informant), skip to question 6.

	<u>No</u>	<u>Yes</u>	<u>Unk</u>
3. When any (SX above) happened, did he/she also have the mood disturbance we discussed before, <u>at the same time</u> ?	0	1	9

Skip to question 6

INTERVIEWER: For the rest of this checklist, "illness duration" refers to total time of illness, including active and prodromal and/or residual symptoms and/or treatment (include time on medication).

	<u>No</u>	<u>Yes</u>	<u>Unk</u>
4. (Probe and code YES if mania and/or depression lasted at least 30% of <u>total</u> duration of illness described above, or medication for it.)	0	1	9

5. (Probe and code YES if illness described above, or medication for it, was ever present for as long as one week, <u>without</u> depression and/or mania.)	0	1	9
--	---	---	---

Skip to question 6

5.a) (Code YES if the above was true for as long as two weeks.)	0	1	9
--	---	---	---

FIGS: PSYCHOSIS CHECKLIST

- | | Code Response |
|---|---------------|
| 6. Code and describe professional treatment (Code and describe all that apply): | 0 1 2 3 4 9 |
| 0. None | |
| 1. Inpatient: _____ | |
| 2. Outpatient: _____ | |
| 3. ECT: _____ | |
| 4. Medication: _____ | |
| 9. Unknown | |

Describe details and/or other treatment:

- | | | | | | | | | | | |
|--|---|----|----------|---|---|--|--|---|--|--|
| 7. Age of onset | | | Age | <table border="1" style="margin: auto;"> <tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr> </table> | | | | | | |
| | | | | | | | | | | |
| 8. Number of episodes (Code 001 if chronic symptoms and/or treatment since onset) | | | Episodes | <table border="1" style="margin: auto;"> <tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr> </table> | | | | | | |
| | | | | | | | | | | |
| 9. <u>Total</u> illness duration (<u>all</u> episodes, includes active and prodromal and/or residual symptoms and/or treatment. | Weeks | OR | Years | Code Response | | | | | | |
| | <table border="1" style="margin: auto;"> <tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr> </table> | | | | <table border="1" style="margin: auto;"> <tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr> </table> | | | <table border="1" style="margin: auto;"> <tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr> </table> | | |
| | | | | | | | | | | |
| | | | | | | | | | | |
| | | | | | | | | | | |

- | | |
|---|---------|
| 10. Rate and code impairment or incapacitation: | 0 1 2 9 |
| 0. None | |
| 1. Impaired | |
| 2. Incapacitated | |
| 9. Unknown | |
| 11. Interviewer judgement on reliability of this information: | 1 2 3 |
| 1. Good | |
| 2. Fair | |
| 3. Poor | |

INTERVIEWER: If informant apparently does not know subject well enough to give information on Prodromal/Residual symptoms, STOP HERE.

If duration criterion for DSM III-R Schizophrenia, Chronic Type, already met, (question 9, total illness duration > 2 years), STOP HERE.

FIGS: PSYCHOSIS CHECKLIST

INTERVIEWER: Use this page only if Schizo-affective is ruled out (by questions 3 to 5 above), or if the psychosis symptoms lasted at least one week (or shorter duration if successfully treated).

Establishing the Prodromal Period:

16. Now I would like to ask you about the year before his/her **(psychotic symptoms)** started. During that time did he/she...

(Ask after completing question 16.a-n for the Prodromal period:)

Establishing the Residual Period:

Now I would like to ask you about the year after his/her **(psychotic symptoms)** stopped. During that time did he/she...

	Prodromal Period			Residual Period		
	<u>No</u>	<u>Yes</u>	<u>Unk</u>	<u>No</u>	<u>Yes</u>	<u>Unk</u>
16.a) ...stay away from family and friends, become socially isolated?	0	1	9	0	1	9
16.b) ...have trouble doing his/her job, going to school, or doing work at home?	0	1	9	0	1	9
16.c) ...do something peculiar like talking to self in public?	0	1	9	0	1	9
16.d) ...neglect hygiene and grooming?	0	1	9	0	1	9
16.e) ...appear to have no emotions or inappropriate emotions?	0	1	9	0	1	9
16.f) ...speak in a way that was hard to understand, or was he/she at a loss for words?	0	1	9	0	1	9
16.g) ...have unusual beliefs or ideas?	0	1	9	0	1	9
16.h) ...have unusual perceptions, like sensing the presence of a person not actually present?	0	1	9	0	1	9
16.i) ...have no interests, no energy?	0	1	9	0	1	9
16.j) ...find special meaning in TV, radio, or newspaper articles?	0	1	9	0	1	9
16.k) ...feel nervous with other people?	0	1	9	0	1	9
16.l) ...worry that people were out to get him/her?	0	1	9	0	1	9
17.a) How long did he/she have these experiences?	Weeks					

INTERVIEWER: Return to top of question 16 to establish the Residual period and code in Residual Column.

17.b) How long did he/she have these experiences after his/her (Active psychotic features) stopped?	Weeks					
	<u>No</u>	<u>Yes</u>	<u>Unk</u>			
18. Was he/she always this way?	0	1	9			

**FIGS: PARANOID/SCHIZOID/SCHIZOTYPAL
PERSONALITY CHECKLIST**

SITE OPTIONAL

Interview date: – –

Month Day Year

Family last name: _____ Family ID Number:

Informant name: _____ ID:

Person being described name: _____ ID:

First MI Last First MI Last

PARANOID PERSONALITY

Code for a single episode (best recalled, worst episode if possible).

	<u>No</u>	<u>Yes</u>	<u>Unk</u>
1. <i>Does he/she...</i>			
1.a) <i>...often keep an eye out to stop people from taking advantage of him/her?</i> Expects, without sufficient basis, to be exploited/harmed by others.	0	1	9
1.b) <i>...get concerned that friends or co-workers are not really loyal or trustworthy?</i> Questions, without justification, loyalty of friends or associates.	0	1	9
1.c) <i>...often pick up hidden threats or put-downs from what people say or do?</i> Reads hidden demeaning or threatening meanings into benign remarks or events.	0	1	9
1.d) <i>...take a long time to forgive someone if they have insulted or hurt him/her?</i> Bears grudges or unforgiving of insults/slightings.	0	1	9
1.e) <i>...seem to believe it is best not to let other people know much about him/her?</i> Reluctant to confide in others because of unwarranted fear that information will be used against him/her.	0	1	9
1.f) <i>...often get angry about being insulted or slighted?</i> Easily slighted, quick to react with anger or counterattack.	0	1	9
1.g) <i>...seem to be a jealous person? Ever suspected that his/her spouse/partner was unfaithful?</i> Questions, without justification, fidelity of spouse or sexual partner.	0	1	9

SCHIZOID PERSONALITY

	<u>No</u>	<u>Yes</u>	<u>Unk</u>
2. <i>Does he/she...</i>			
2.a) <i>...seem not to want or enjoy close relationships, like with family or friends?</i> Neither desires nor enjoys close relationships, including family.	0	1	9
2.b) <i>...prefer to do things alone rather than with other people?</i> Almost always chooses solitary activities.	0	1	9
2.c) <i>...hardly ever seem to have strong feelings, like being very angry or very happy?</i> Rarely, if ever, claims or appears to experience strong emotions, anger/joy.	0	1	9
2.d) <i>...seem uninterested in being sexually involved with another person?</i> Little if any desire to have sexual experiences with another person (age taken into account).	0	1	9

**FIGS: PARANOID/SCHIZOID/SCHIZOTYPAL
PERSONALITY CHECKLIST**

SITE OPTIONAL

		<u>No</u>	<u>Yes</u>	<u>Unk</u>
2.e)	<i>...seem not to care if people praise or criticize him/her?</i> Indifferent to praise and criticism from others.	0	1	9
2.f)	<i>...have no one to be really close to or confide in, or just one person, outside of the immediate family?</i> No close friends or confidants, or only one, other than first-degree relatives.	0	1	9
2.g)	<i>...act cold or distant, hardly ever smile or nod back at people?</i> Constricted affect, aloof, cold, rarely reciprocates gestures or expressions.	0	1	9

SCHIZOTYPAL PERSONALITY

3.	<i>Does he/she...</i>			
3.a)	<i>...wonder if people talking to each other are talking about him/her? Say that a common event or object is a special sign for him/her?</i> Ideas of reference (not delusions of reference).	0	1	9
3.b)	<i>...often act nervous in a group of unfamiliar people?</i> Excessive social anxiety.	0	1	9
3.c)	<i>...reports experiences with the supernatural? Believe in astrology, seeing the future, UFOs, ESP or a "sixth sense"?</i> Odd beliefs or magical thinking, influencing behavior and inconsistent with subcultural norms.	0	1	9
3.d)	<i>...mistake objects or shadows for people, or noises for voices? Have a sense that some invisible person or force is around? See faces change before his/her eyes?</i> Unusual perceptual experiences.	0	1	9
3.e)	<i>...behave in odd or eccentric ways? Look peculiar or untidy, have unusual mannerisms, talk to him/herself?</i> Odd, eccentric, peculiar behavior or appearance.	0	1	9
3.f)	<i>...sometimes make it hard to follow what he/she is saying? Ramble off the subject, talk in vague or abstract terms?</i> Odd speech (without loosened associations or incoherence).	0	1	9
3.g)	<i>...sometimes act silly, not in keeping with the situation? Or tend not to show any feelings in response to people?</i> Inappropriate or constricted affect (e.g., silly or aloof).	0	1	9

INTERVIEWER: If any **YES** to any Personality Disorders, ask the following questions (to be used for research, not diagnosis).

IMPAIRMENT/DISTRESS

4.	<i>Does he/she have problems because of this behavior or thinking or feeling—either with the family or socially, or at work or school?</i> Significant social or occupational impairment.	0	1	9
5.	<i>Does this behavior or thinking or feeling cause the person unhappiness?</i> Significant subjective distress.	0	1	9
6.	Interviewer judgement on reliability of this information:	Code Response		
	1. Good	1	2	3
	2. Fair			
	3. Poor			

APPENDIX 9

Demographics

Race: American Indian or Alaska Native
African American or Black
Asian
Caucasian
Native Hawaiian or other Pacific Islander
Two or More Races
Other

Ethnicity: Hispanic or Latino
Not Hispanic of Latino

Age: _____

Years of Education: _____

Sex (M/F): _____

Parents' occupations: _____

Please read and follow these directions carefully. On the following page is a family tree. It shows your father's side of the family on the left and your mother's side on the right. For each relation in the tree, think carefully about your BLOOD relatives. In the center of the box, write in the TOTAL number of people related to you in that position. Then write in the NUMBER of relatives who are Left-handed, Right-handed or Ambidextrous (use both hands about equally well) in the spaces provided.

Uncles
(Father's brothers)

L	<u>1</u>	R	__
<u>2</u>			
A	__		

For example, I have three uncles, all on my father's side. Only two of my uncles are blood relatives (my father's brothers); the third is married to my father's sister and so is not a blood relative. Of the two uncles, I know one is left-handed and am unsure of the other's hand preference.

I would fill in the Uncles on the left of the page (my father's side of the family) as shown here.

The boxes with diagonal lines correspond to one person in your family tree. For these boxes, write in that person's hand preference (L, R or A). Leave the box empty if you are unsure of their hand preference. For example, my grandfather on my mother's side is right-handed, so I would fill in the box like this:

Grandfather
(Mother's father)

R

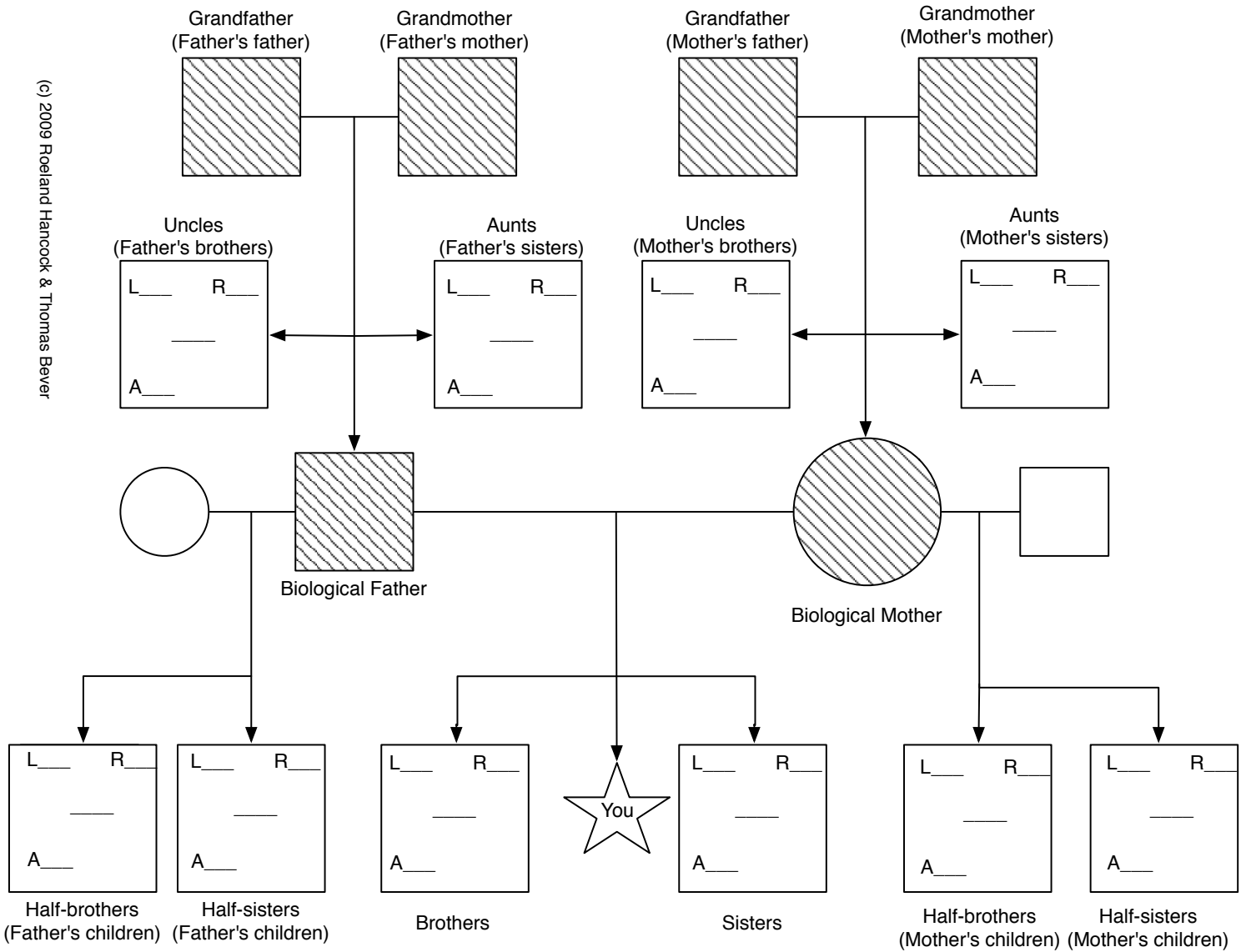
There are also spaces for half-siblings, the biological children of one, but not both, of your biological parents. For example, my mother has a male child from a previous partnership. I know my half-brother is right handed, so I would fill in the box like this:

L	__	R	<u>1</u>
<u>1</u>			
A	__		

Half-brothers
(Mother's children)

Please let the experimenter know if you have any questions.

(c) 2009 Roeland Hancock & Thomas Bever



Subject ID _____ Sex _____ Initials _____ Date _____

Identical Twins: _____

CAPE, J. van Os, H. Verdoux en M. Hanssen
Maastricht University, Department Psychiatry and Neuropsychology

CAPE

The CAPE has three dimensions: a positive, a depressive and a negative dimension score. The CAPE provides an overall score and a total score per dimension by adding up the number of positive answers to the frequency question, and it provides a distress score by adding up the scores of the distress questions.

In order to account for partial non-response, scores were weighted for the number of valid answers per dimension. The weighted score per dimension is the sum score per dimension divided by the amount of items filled in by the subject. CAPE positive, negative and depression scores can be expressed as units standard deviation (standardized scores) in order to remove scale difference.

First of all, the scores 0-3 of the CAPE have to be recoded to 1-4 (frequency: never-sometimes-often-nearly always; distress: not distressed-a bit distressed-quite distressed-very distressed)!

The three weighted frequency and distress scores are calculated by adding up the item-scores in Column A and B, respectively, that belong to the specific factor divided by the amount of items filled in.

The positive dimension frequency score consists of the following questions in column A:
 $a2+a5+a6+a7+a10+a11+a13+a15+a17+a20+a22+a24+a26+a28+a30+a31+a33+a34+a41+a42$
The positive dimension distress score consists of the accompanying questions in column B:
 $b2+b5+b6$ etc.

The depressive dimension frequency score consists of the following questions in column A:
 $a1+a9+a12+a14+a19+a38+a39+a40$
The depressive dimension distress score consists of the accompanying questions in column B:
 $b1+b9+b12$ etc.

The negative dimension frequency score consists of the following questions in column A:
 $a3+a4+a8+a16+a18+a21+a23+a25+a27+a29+a32+a35+a36+a37$
The negative dimension distress score consists of the accompanying questions in column B:
 $b3+b4+b8$ etc.

Total score CAPE: items 1-42.

1. Do you ever feel sad?
(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 2

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:
(please tick)

Not distressed A bit distressed Quite distressed Very distressed

2. Do you ever feel as if people seem to drop hints about you or say things with a double meaning?
(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 3

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:
(please tick)

Not distressed A bit distressed Quite distressed Very distressed

3. Do you ever feel that you are not a very animated person?
(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 4

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:
(please tick)

Not distressed A bit distressed Quite distressed Very distressed

4. Do you ever feel that you are not much of a talker when you are conversing with other people?
(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 5

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:
(please tick)

Not distressed A bit distressed Quite distressed Very distressed

5. Do you ever feel as if things in magazines or on TV were written especially for you?
(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 6

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:

(please tick)

Not distressed A bit distressed Quite distressed Very distressed

6. Do you ever feel as if some people are not what they seem to be?

(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 7

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:

(please tick)

Not distressed A bit distressed Quite distressed Very distressed

7. Do you ever feel as if you are being persecuted in some way?

(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 8

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:

(please tick)

Not distressed A bit distressed Quite distressed Very distressed

8. Do you ever feel that you experience few or no emotions at important events?

(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 9

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:

(please tick)

Not distressed A bit distressed Quite distressed Very distressed

9. Do you ever feel pessimistic about everything?

(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 10

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:

(please tick)

Not distressed A bit distressed Quite distressed Very distressed

10. Do you ever feel as if there is a conspiracy against you?

(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 11

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:

(please tick)

Not distressed A bit distressed Quite distressed Very distressed

11. Do you ever feel as if you are destined to be someone very important?

(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 12

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:

(please tick)

Not distressed A bit distressed Quite distressed Very distressed

12. Do you ever feel as if there is no future for you?

(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 13

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:

(please tick)

Not distressed A bit distressed Quite distressed Very distressed

13. Do you ever feel that you are a very special or unusual person?

(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 14

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:

(please tick)

Not distressed A bit distressed Quite distressed Very distressed

14. Do you ever feel as if you do not want to live anymore?
(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 15

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:

(please tick)

Not distressed A bit distressed Quite distressed Very distressed

15. Do you ever think that people can communicate telepathically?
(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 16

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:

(please tick)

Not distressed A bit distressed Quite distressed Very distressed

16. Do you ever feel that you have no interest to be with other people?
(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 17

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:

(please tick)

Not distressed A bit distressed Quite distressed Very distressed

17. Do you ever feel as if electrical devices such as computers can influence the way you think?
(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 18

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:

(please tick)

Not distressed A bit distressed Quite distressed Very distressed

18. Do you ever feel that you are lacking in motivation to do things?
(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 19

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:
(please tick)

Not distressed A bit distressed Quite distressed Very distressed

19. Do you ever cry about nothing?
(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 20

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:
(please tick)

Not distressed A bit distressed Quite distressed Very distressed

20. Do you believe in the power of witchcraft, voodoo or the occult?
(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 21

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:
(please tick)

Not distressed A bit distressed Quite distressed Very distressed

21. Do you ever feel that you are lacking in energy?
(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 22

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:
(please tick)

Not distressed A bit distressed Quite distressed Very distressed

22. Do you ever feel that people look at you oddly because of your appearance?
(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 23

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:

(please tick)

Not distressed A bit distressed Quite distressed Very distressed

23. Do you ever feel that your mind is empty?

(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 24

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:

(please tick)

Not distressed A bit distressed Quite distressed Very distressed

24. Do you ever feel as if the thoughts in your head are being taken away from you?

(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 25

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:

(please tick)

Not distressed A bit distressed Quite distressed Very distressed

25. Do you ever feel that you are spending all your days doing nothing?

(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 26

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:

(please tick)

Not distressed A bit distressed Quite distressed Very distressed

26. Do you ever feel as if the thoughts in your head are not your own?

(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 27

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:

(please tick)

Not distressed A bit distressed Quite distressed Very distressed

27. Do you ever feel that your feelings are lacking in intensity?

(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 28

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:

(please tick)

Not distressed A bit distressed Quite distressed Very distressed

28. Have your thoughts ever been so vivid that you were worried other people would hear them?

(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 29

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:

(please tick)

Not distressed A bit distressed Quite distressed Very distressed

29. Do you ever feel that you are lacking in spontaneity?

(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 30

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:

(please tick)

Not distressed A bit distressed Quite distressed Very distressed

30. Do you ever hear your own thoughts being echoed back to you?

(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 31

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:

(please tick)

Not distressed A bit distressed Quite distressed Very distressed

31. Do you ever feel as if you are under the control of some force or power other than yourself?
(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 32

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:

(please tick)

Not distressed A bit distressed Quite distressed Very distressed

32. Do you ever feel that your emotions are blunted?
(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 33

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:

(please tick)

Not distressed A bit distressed Quite distressed Very distressed

33. Do you ever hear voices when you are alone?
(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 34

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:

(please tick)

Not distressed A bit distressed Quite distressed Very distressed

34. Do you ever hear voices talking to each other when you are alone?
(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 35

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:

(please tick)

Not distressed A bit distressed Quite distressed Very distressed

35. Do you ever feel that you are neglecting your appearance or personal hygiene?

(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 36

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:

(please tick)

Not distressed A bit distressed Quite distressed Very distressed

36. Do you ever feel that you can never get things done?

(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 37

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:

(please tick)

Not distressed A bit distressed Quite distressed Very distressed

37. Do you ever feel that you have only few hobbies or interests?

(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 38

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:

(please tick)

Not distressed A bit distressed Quite distressed Very distressed

38. Do you ever feel guilty?

(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 39

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:

(please tick)

Not distressed A bit distressed Quite distressed Very distressed

39. Do you ever feel like a failure?

(please tick)

Never Sometimes Often Nearly always

If you ticked "never", please go to question 40

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:

(please tick)

Not distressed A bit distressed Quite distressed Very distressed

40. Do you ever feel tense?

(please tick)

Never Sometimes Often Nearly always

If you ticked "never", you are now ready

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:

(please tick)

Not distressed A bit distressed Quite distressed Very distressed

41. Do you ever feel as if a double has taken the place of a family member, friend or acquaintance?

(please tick)

Never Sometimes Often Nearly always

If you ticked "never", you are now ready

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:

(please tick)

Not distressed A bit distressed Quite distressed Very distressed

42. Do you ever see objects, people or animals that other people cannot see?

(please tick)

Never Sometimes Often Nearly always

If you ticked "never", you are now ready

If you ticked "sometimes" , "often" or "nearly always" please indicate how distressed you are by this experience:

(please tick)

Not distressed A bit distressed Quite distressed Very distressed

1. pill

2. bill

3. coat

4. goat

5. pig

6. dig

7. tear

8. deer

9. cage

10. page

11. pan

12. can

13. car

14. bar

15. tail

16. pail

17. kit

18. pit

19. pier

20. beer

21. ten

22. pen

23. cook

24. book

25. keg

26. peg

27. toy

28. boy

29. curl

30. pearl

1.	page	cage	gage	rage
2.	coat	tote	goat	boat
3.	curl	girl	pearl	burl
4.	deer	beer	pier	tear
5.	pail	gale	tail	bale
6.	fit	pit	bit	kit
7.	pit	bit	kit	fit
8.	till	bill	pill	gill
9.	gale	bale	hale	tail
10.	bar	tar	car	par
11.	pan	tan	can	man
12.	boy	toy	coy	roy
13.	took	cook	rook	book
14.	cook	rook	book	took
15.	pier	tear	deer	beer
16.	den	ken	ten	pen
17.	tar	bar	par	car
18.	curl	pearl	burl	girl
19.	pill	gill	till	bill
20.	dig	big	pig	rig
21.	beer	tear	pier	deer
22.	ken	pen	den	ten
23.	roy	coy	toy	boy
24.	rig	dig	pig	big
25.	keg	beg	peg	leg
26.	tote	coat	boat	goat
27.	leg	peg	beg	keg
28.	man	pan	tan	can
29.	rage	cage	gage	page
30.	tear	deer	beer	pier

NAME _____

DATE _____

RED ON _____

Page 2b

1.	burl	girl	pearl	curl
2.	coat	boat	goat	tote
3.	gill	bill	pill	till
4.	tail	pail	bale	gale
5.	den	ken	ten	pen
6.	rook	book	took	cook
7.	tan	can	pan	man
8.	dig	rig	big	pig
9.	coy	boy	toy	roy
10.	tear	pier	deer	beer
11.	beg	leg	keg	peg
12.	ten	ken	pen	den
13.	kit	fit	bit	pit
14.	coat	tote	goat	boat
15.	bale	tail	pail	gale
16.	roy	coy	toy	boy
17.	par	tar	bar	car
18.	pill	till	gill	bill
19.	pier	deer	beer	tear
20.	page	rage	gage	cage
21.	tan	pan	man	can
22.	pig	beer	pier	tear
23.	deer	beer	pier	tear
24.	peg	keg	leg	beg
25.	tar	par	car	bar
26.	girl	burl	curl	pearl
27.	pier	tear	beer	deer
28.	bit	pit	kit	fit
29.	cage	gage	page	rage
30.	book	cook	took	rook

1.	coy	boy	toy	roy
2.	page	gage	cage	rage
3.	goat	boat	tote	coat
4.	den	ten	ken	pen
5.	deer	tear	pier	beer
6.	fit	kit	pit	bit
7.	deer	tear	pier	beer
8.	gale	bale	tail	pail
9.	cook	took	book	rook
10.	gill	till	pill	bill
11.	pan	tan	man	can
12.	boat	coat	tote	goat
13.	pit	kit	bit	fit
14.	man	can	tan	pan
15.	pill	gill	till	bill
<hr/>				
16.	dig	big	pig	rig
17.	tar	bar	par	car
18.	leg	peg	keg	beg
19.	pearl	curl	burl	girl
20.	pier	deer	tear	beer
21.	toy	coy	roy	boy
22.	gale	pail	bale	tail
23.	cage	rage	page	gage
24.	pig	dig	big	rig
25.	pier	tear	beer	deer
26.	cook	rook	book	took
27.	leg	keg	peg	beg
28.	den	ten	ken	pen
29.	girl	burl	curl	pearl
30.	car	tar	par	bar

1. den	ken	ten	pen
2. tear	deer	pier	beer
3. kit	bit	pit	fit
4. gill	bill	till	pill
5. man	tan	can	pan
6. coat	boat	tote	goat
7. bar	car	tar	par
8. ken	pen	ten	den
9. cage	rage	page	gage
10. leg	beg	peg	keg
11. coat	tote	goat	boat
12. leg	keg	beg	peg
13. rook	took	cook	book
14. cage	rage	gage	page
15. big	pig	dig	rig
16. bill	till	gill	pill
17. tan	pan	can	man
18. car	bar	tar	par
19. coy	boy	roy	toy
20. roy	toy	boy	coy
21. tail	bale	gale	pail
22. rig	big	dig	pig
23. fit	kit	pit	bit
24. cook	book	took	rook
25. bale	tail	pail	gale
26. pier	tear	deer	beer
27. burl	pearl	girl	curl
28. curl	girl	burl	pearl
29. tear	beer	deer	pier
30. beer	pier	tear	deer

1. tar	bar	par	car
2. beer	pier	tear	deer
3. gill	pill	bill	till
4. can	man	tan	pan
5. gale	pail	tail	bale
6. coat	boat	goat	tote
7. rook	cook	took	book
8. keg	beg	leg	peg
9. can	tan	man	pan
10. coy	roy	toy	boy
11. fit	kit	pit	bit
12. pearl	girl	curl	burl
13. tear	pier	deer	beer
14. pail	gale	tail	bale
15. roy	toy	coy	boy
16. cage	rage	page	gage
17. ken	pen	ten	den
18. book	took	cook	rook
19. cage	gage	page	rage
20. pill	bill	till	gill
21. tar	par	bar	car
22. keg	peg	beg	leg
23. fit	bit	pit	kit
24. ken	pen	den	ten
25. coat	goat	boat	tote
26. pearl	girl	burl	curl
27. rig	big	dig	pig
28. big	pig	rig	dig
29. tear	deer	pier	beer
30. beer	pier	tear	deer

1. peg	leg	beg	keg
2. pail	tail	gale	bale
3. kit	bit	pit	fit
4. pen	ken	ten	den
5. took	rook	book	cook
6. rig	big	pig	dig
7. gage	cage	page	rage
8. till	bill	gill	pill
9. page	rage	gage	cage
10. beg	keg	peg	leg
11. pig	big	rig	dig
12. tan	pan	man	can
13. den	ken	ten	pen
14. gill	till	bill	pill
15. tail	pail	bale	gale
16. curl	burl	girl	pearl
17. tear	pier	beer	deer
18. can	pan	man	tan
19. beer	tear	deer	pier
20. coy	toy	roy	boy
21. girl	pearl	curl	burl
22. roy	toy	boy	coy
23. goat	coat	boat	tote
24. tar	par	bar	car
25. pier	beer	deer	tear
26. pier	tear	beer	deer
27. fit	bit	pit	kit
28. rook	book	cook	took
29. car	tar	par	bar
30. coat	tote	goat	boat

1.	coy	boy	toy	roy
2.	page	gage	cage	rage
3.	goat	boat	tote	coat
4.	den	ten	ken	pen
5.	deer	tear	pier	beer
6.	fit	kit	pit	bit
7.	deer	tear	pier	beer
8.	gale	bale	tail	pail
9.	cook	took	book	rook
10.	gill	till	pill	bill
11.	pan	tan	man	can
12.	boat	coat	tote	goat
13.	pit	kit	bit	fit
14.	man	can	tan	pan
15.	pill	gill	till	bill
16.	dig	big	pig	rig
17.	tar	bar	par	car
18.	leg	peg	keg	beg
19.	pearl	curl	burl	girl
20.	pier	deer	tear	beer
21.	toy	coy	roy	boy
22.	gale	pail	bale	tail
23.	cage	rage	page	gage
24.	pig	dig	big	rig
25.	pier	tear	beer	deer
26.	cook	rook	book	took
27.	leg	keg	peg	beg
28.	den	ten	ken	pen
29.	girl	burl	curl	pearl
30.	car	tar	par	bar

SEP 1 9 2001

K012079

510(k) SUMMARY

Submitter's name: Electrical Geodesics, Inc.
1850 Millrace Drive
Eugene, OR 97403
541-687-7962

Date summary prepared: June 25, 2001

Device name:

Proprietary name: Geodesic EEG System™
Common or usual name: EEG machine
Classification name: Electroencephalograph, 84 GWQ
Class II, 21 CFR 882.1400.

The product includes the Geodesic Sensor Net® which has the following identifiers:

Common name: EEG electrode
Classification name: Cutaneous electrode, 84 GXY
Class II, 21 CFR 882.1320.

Legally marketed device for substantial equivalence comparison:

For the Geodesic EEG System it is the Bio-Logic Ceegraph 128-Channel Recording System submitted by Bio-Logic Systems Corporation and cleared for marketing under 510(k) #K973883. For the Geodesic Sensor Net, the predicate device is the Electro-Cap VII System submitted by Electro-Cap Inc. and cleared for marketing under 510(k) #K780045.

Description of the device:

The Geodesic EEG System is a digital electroencephalography system (EEG) with a dense sensor array of 32 to 256 channels. Like existing digital EEG systems, the Geodesic EEG System is computer controlled and capable of acquiring, storing, and displaying data. It includes scalp conductive electrodes, amplifiers, a central processing unit, and software. The Geodesic Sensor Net is a dense array of scalp electrodes designed to allow rapid application in an even distribution across the head. The Net Amps™ consists of multiple amplifiers for physiological signals that are fully software controlled. Net Station® is the software package that provides control of the Geodesic EEG System, digital data storage, and operator-selected waveform displays. The software does not perform any data analysis. Additional components of the system are an articulated arm with extended cable, rack system, various cables, standard components of personal computer (monitor, keyboard, mouse), electrolyte solution, and disinfectant.

The Geodesic EEG System is a new device that has not previously been submitted to FDA. It has features similar to other digital EEG devices on the market.

Intended use of device:

The Geodesic EEG System is intended to measure and record the electrical activity of the patient's brain. It can be used on adults, children, and infants.

Technological characteristics:

The technological characteristics of the Geodesic EEG System are similar to those of other digital EEG systems, including the predicate device, the Ceegraph 128-Channel Recording System. Each product is an EEG machine that is software controlled, can accommodate a variable number of electrodes, and can acquire, display, and record EEG data. Some differences in electrical parameters are described. Differences in the software include that the products use different operating systems and that Net Station does not analyze the data. Another difference is that the Geodesic EEG System has dedicated electrodes, the Geodesic Sensor Net.

The Geodesic Sensor Net is compared to the Electro-Cap VII System. Each product consists of a structure that links a number of electrodes so that they can be easily applied to the patient. The Geodesic Sensor Net uses a geodesic array of electrodes with equal distribution across the head. The Electro-Cap uses the 10-20 array. The Geodesic Sensor Net can accommodate a larger number of electrodes. Finally, the Geodesic Sensor Net does not require scalp abrasion for use.

Testing conducted:

Testing was conducted to ensure compliance with international standards related to electroencephalographs. The general safety standards used were: CAN/CSA C22.2 No. 601.1-M90 including Supplement 1 and Amendment 2 and UL Std. No. 2601-1 (2nd Edition). The electromagnetic compatibility standard was EN60601-1-2(1993). The electroencephalograph standards were IEC 60601-2-26 and CAN/CSA C22.2 No. 601.2.26. The biocompatibility standard was ISO 10993. The Geodesic EEG System passed all testing.

Performance testing:

Comparative performance testing and clinical evaluations were not submitted as part of this 510(k).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 19 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Electrical Geodesics, Inc.
c/o Mr. Robert S. McQuate
R. S. McQuate & Associates, Inc.
3636 E. Columbine Drive
Phoenix, Arizona 85032

Re: K012079
Trade/Device Name: Geodesic EEG System™
Regulation Number: 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GWQ
Dated: June 29, 2001
Received: July 3, 2001

Dear Mr. McQuate:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Mr. Robert S. McQuate

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>


Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): 

Device name: Geodesic EEG System™


Indications for Use:

The Geodesic EEG System is intended to measure and record the electrical activity of the patient's brain. It can be used on adults, children, and infants.

(Please do not write below this line)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use OR Over-The-Counter Use


(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number 