INFORMED CONSENT FORM

Official title: Exploring the Effects of Corticosteroids on the Human Hippocampus using Neuroimaging

NCT number: NCT03896659

IRB Approved date: June 14, 2023

Consent to be part of a Research Study
To be conducted at

The University of Texas Southwestern Medical Center

Information about this form

You may be eligible to take part in a research study. This form gives you important information about the study.

Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Please tell the researchers or study staff if you are taking part in another research study.

Voluntary Participation - You do not have to participate if you don't want to. You may also leave the study at any time. If you decide to stop taking part in this research study, it will not affect your relationship with the UT Southwestern staff or doctors. Whether you participate or not will have no effect on your legal rights or the quality of your health care.

If you are a medical student, fellow, faculty, or staff at the Medical Center, your status will not be affected in any way.

General Information – "Who is conducting this research?"

Principal Investigator
The Principal Investigator (PI) is the researcher directing this study; the PI is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is E. Sherwood Brown, M.D., Ph.D., Department of Psychiatry at UT Southwestern Medical Center.

Funding
National Institute of Mental Health (NIMH), a federal agency that promotes scientific research, is funding this study. This organization is providing money to UT Southwestern Medical Center so that the researchers can conduct the study.

Purpose – "Why is this study being done?"

The purpose of this research is to study the effects of a stress hormone called cortisol on mood, memory, and the brain in people with and without depression. When cortisol is used in a medication form (for example, tablet), it is called hydrocortisone.

This study is not designed to treat depression. The researchers hope to learn whether the brain of people with and without depression is affected differently by hydrocortisone. The researchers are also interested if these effects differ between men and women.

Investigational Use of Drug or Device
This study involves the use of an investigational drug called hydrocortisone (cortisol). "Investigational" means that the drug has not yet been approved by the U.S. Food & Drug Administration (FDA) for studying hydrocortisone-induced changes associated with memory and the brain in depressed and healthy people. Hydrocortisone is approved by the U.S. Food & Drug Administration (FDA) for the human use.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web

site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Information about Study Participants – "Who is participating in this research?"

You are being asked to be a participant in this study because you have indicated you may be experiencing symptoms of depression, or you are a healthy volunteer.

How many people are expected to take part in this study? This study will enroll approximately 188 study participants.

Information about Study Procedures – "What will be done if you decide to be in the research?"

While you are taking part in this study, you will be asked to attend 5 visits with the researchers or study staff across approximately 9 weeks. For your convenience, you will have the option of completing some procedures remotely through secure video conferencing software (e.g. Zoom, Teams). Procedures which must be conducted in-person include physical examinations, the RULIT assessment, blood draws, urine pregnancy tests, electrocardiograms, and MRI procedures. All study procedures are summarized below.

You consent to complete some procedures virtually. Yes ____ No ____ _____
Subject Initials

Study Procedures – as a research participant, you will complete the following visits and procedures:

Baseline Screening Visit (Visit 1) – After you sign this consent to participate, exams, tests, and/or procedures may be done as described below to find out if you can continue in the study (if you are "eligible" for the study); this will take place at the Baseline Screening Visit. All procedures in this study are done for "**research only**" purpose and will include:

- Psychiatric history – you will meet with a study clinician to go over your past and present psychiatric history, including diagnoses, medications, hospitalization, and treatment history.
- Medical history – you will meet with a study clinician to go over your past and present medical and surgical history.
- Concomitant medications – you will be asked about any medications you are currently taking or have taken in the last month.
- Physical examination – A clinician will conduct a routine physical exam to determine your general health. Vital signs will be collected as part of the physical exam and include your height, weight, blood pressure, respiratory rate, pulse, and body mass index (BMI).
- Structured Clinical Interview for DSM 5 (SCID) – an interview used to help diagnose psychiatric illness.
- Rey Auditory Verbal Learning Test (RAVLT) – a word memory test.
- Ruff Light Trail Learning (RULIT) – a test of visual and spatial learning and memory.
- Quick Inventory of Depressive Symptomatology (QIDS-C) – an interview that measures depressive symptoms.
- Young Mania Rating Scale (YMRS) – an interview that measures manic symptoms.
- Perceived Stress Scale (PSS-10) – a questionnaire you will fill out that measures your stressful feelings and thoughts in the past month.
- Childhood Trauma Questionnaire (CTQ) – a questionnaire you will fill out to measure how much stress and childhood adversity you have experienced.
- Prodromal Questionnaire – Brief Version (PQ-B) – a questionnaire you will fill out to measure any unusual experiences you have experienced over the past month and how much distress they have caused you.
- Treatment Impressions Inventory (TII) – a questionnaire you will out to measure how you feel about your treatment and how you feel about certain things around you.
- Columbia Suicide Severity Rating Scale (C-SSRS) – an interview that assesses any suicidal thoughts you

may have experienced in your lifetime or are experiencing at the present time.
- Systematic Assessment for Treatment Emergent Event (SAFTEE) – a checklist you will fill out that measures any side effects you may be experiencing.
- International Physical Activity Questionnaire (IPAQ) – a short form you will fill out to evaluate your physical activity.
- Blood draw – Blood will be taken from a vein in your arm (50 mL (approximately 3.5 tablespoons) of blood collected) to evaluate your health and also to test metabolic health, your complete blood count, and morning cortisol levels, and for epigenetics testing.
- Electrocardiogram (ECG) – an ECG will be performed to check the condition of your heart.
- Urine Pregnancy Test (UPT) – If you are capable of becoming pregnant, a pregnancy test will also be done before you receive study treatment.

This visit will take approximately 3 hours.

The results of the screening exams, tests, and/or procedures will be reviewed to determine whether you will be allowed to continue in the study. If you are not allowed to continue in the study, the researcher will discuss the reasons with you.

Assignment to Study Groups
When it is determined that you are eligible for the study, you will be assigned by chance (like flipping a coin) to one of 2 study groups to receive either hydrocortisone or placebo first. You will receive both hydrocortisone and placebo during your participation in the study, but the order in which you receive hydrocortisone or placebo will be determined at random. Placebo is an inactive, harmless substance that looks like the other study drugs.

Specifically, you will receive either hydrocortisone (1 tablet twice a day for a total of 160 mg/day) or placebo for 3 days, then receive no medication for 25 days, and then receive hydrocortisone or placebo (depending to which order you are assigned). The possible group assignments are:
1. Hydrocortisone (3 days) → no study medication ("washout", 25 days) → placebo (3 days)
2. Placebo (3 days) → no study medication ("washout", 25 days) → hydrocortisone (3 days)

Neither you nor the researchers will know whether you are receiving the study drug or a placebo. In the event of an emergency, there is a way for the researcher to find out which you are receiving.

Visit 2 (approximately 45 minutes) – at this visit, you will complete the following:
- Quick Inventory of Depressive Symptomatology (QIDS-C) – an interview that measures depressive symptoms.
- Young Mania Rating Scale (YMRS) – an interview that measures manic symptoms.
- Clinician follow-up – you will also meet with a study clinician to monitor your general health and wellness.
- Actigraphy – You will be asked to wear a wrist actigraphy monitor on your non-dominant wrist during each 3-day period of study drug administration. You will need to press the event marker before and after sleep each day. The actigraph will record bed time, get up time, time in bed, total sleep time, how long it takes you to fall asleep, how well you sleep, and when you wake after you've fallen sleep.
- You will receive either hydrocortisone or placebo at this visit and begin taking it the next day for 3 days. On day 3, you will take it in the morning and come back for your Visit 3 as described below.

Visit 3 (approximately 3.5 hours) – at this visit, you will complete the following:
- Rey Auditory Verbal Learning Test (RAVLT) – a word memory test.
- Ruff Light Trail Learning (RULIT) – a test of visual and spatial learning and memory.
- Quick Inventory of Depressive Symptomatology (QIDS-C) – an interview that measures depressive symptoms.

- Young Mania Rating Scale (YMRS) – an interview that measures manic symptoms.
- Prodromal Questionnaire – Brief Version (PQ-B) – a questionnaire you will fill out to measure any unusual experiences you have experienced over the past month and how much distress they have caused you.
- Columbia Suicide Severity Rating Scale (C-SSRS) – an interview that assesses any suicidal thoughts you may have experienced in your lifetime or are experiencing at the present time.
- Systematic Assessment for Treatment Emergent Event (SAFTEE) – a checklist you will fill out that measures any side effects you may be experiencing.
- Internal Status Scale – a questionnaire you will fill out that asks about how you are feeling on the day of your study visit.
- Blood draw – Blood will be taken from a vein in your arm (32.5 mL (approximately 2 tablespoons) of blood collected) to evaluate your health and also to test metabolic health, your complete blood count, and cortisol levels. At this visit specifically, we will also test for the level of progesterone if you are a woman with an active menstrual cycle.
- Electrocardiogram (ECG) – an ECG will be performed to check the condition of your heart.
- Clinician follow-up – you will also meet with a study clinician to monitor your general health and wellness.
- Urine Pregnancy Test (UPT) – If you are capable of becoming pregnant, a pregnancy test will also be done before you receive study treatment.
- You will have an MRI of your brain. For this procedure, you will lie still inside a large, doughnut-shaped magnet, also called the MRI scanner. The MRI technologist can see and hear you during the procedure. You will also be given a squeeze ball to use for communication. You will be inside the MRI scanner for approximately 75 minutes. In addition to taking pictures of your brain, you will complete the following tasks while you are inside the scanner:

1. Novelty Detection Task:
    a. You will be asked to view a series of indoor and outdoor images during the practice task. Then, during the actual task, you will be presented with a set of images and asked to select whether you have seen a certain image before or if it is a new image.
2. Mnemonic Discrimination Task:
    a. You will be asked to view a series of images during a practice task. Then, during the actual task, you will be presented with a set of images and will be asked to choose whether each image is something you have seen before, an image you have not seen before, or an image that is similar to an image you have seen before.

Washout Period (25 days)

- A “washout” period will take place between Visit 3 and Visit 4 and will last 25 days. During this period, you will not receive either hydrocortisone or placebo and will remain free of study medication.

Visit 4 (approximately 45 minutes) – at this visit, you will complete the following:

- Quick Inventory of Depressive Symptomatology (QIDS-C) – an interview that measures depressive symptoms.
- Young Mania Rating Scale (YMRS) – an interview that measures manic symptoms.
- Clinician follow-up – you will also meet with a study clinician to monitor your general health and wellness.
- Actigraphy – You will be asked to wear a wrist actigraphy monitor on your non-dominant wrist during each 3-day period of study drug administration. You will need to press the event marker before and after sleep each day. The actigraph will record bed time, get up time, time in bed, total sleep time, how long it takes you to fall asleep, how well you sleep, and when you wake after you’ve fallen sleep.
- You will receive either hydrocortisone or placebo at this visit and begin taking it the next day for 3 days. On day 3, you will take it in the morning and come back for your Visit 3 as described below.

Visit 5 (approximately 3.5 hours) – at this visit, you will complete the following:

- Rey Auditory Verbal Learning Test (RAVLT) – a word memory test.
- Ruff Light Trail Learning (RULIT) – a test of visual and spatial learning and memory.
- Quick Inventory of Depressive Symptomatology (QIDS-C) – an interview that measures depressive symptoms.
- Young Mania Rating Scale (YMRS) – an interview that measures manic symptoms.
- Prodromal Questionnaire – Brief Version (PQ-B) – a questionnaire you will fill out to measure any unusual experiences you have experienced over the past month and how much distress they have caused you.
- Columbia Suicide Severity Rating Scale (C-SSRS) – an interview that assesses any suicidal thoughts you may have experienced in your lifetime or are experiencing at the present time.
- Systematic Assessment for Treatment Emergent Event (SAFTEE) – a checklist you will fill out that measures any side effects you may be experiencing.
- Internal Status Scale – a questionnaire you will fill out that asks about how you are feeling on the day of your study visit.
- Blood draw – Blood will be taken from a vein in your arm (32.5 mL (approximately 2 tablespoons) of blood collected) to evaluate your health and also to test metabolic health, your complete blood count, and cortisol levels. At this visit specifically, we will also test for the level of progesterone if you are a woman with an active menstrual cycle.
- Electrocardiogram (ECG) – an ECG will be performed to check the condition of your heart.
- Clinician follow-up – you will also meet with a study clinician to monitor your general health and wellness.
- Urine Pregnancy Test (UPT) – If you are capable of becoming pregnant, a pregnancy test will also be done before you receive study treatment.
- You will have an MRI of your brain. For this procedure, you will lie still inside a large, doughnut-shaped magnet, also called the MRI scanner. The MRI technologist can see and hear you during the procedure. You will also be given a squeeze ball to use for communication. You will be inside the MRI scanner for approximately 75 minutes. In addition to taking pictures of your brain, you will complete the Novelty Detection Task and the Mnemonic Discrimination Task as described above in Visit 3.
- Exit survey – you will be asked to complete an exit survey about your experiences with in-person vs. virtual research visits. If you choose to stop study participation prior to Visit 5, we may ask you to complete this survey at your last study visit.

Could your participation end early? There are several reasons why the researchers may need to end your participation in the study (early withdrawal). Some reasons are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is stopped.

Risks – "What are the risks of participation in the research?"

Risks from the specific research procedures (hydrocortisone side effects)

There are risks to taking part in this research study. One risk is that you may have side effects while on the study. You will take hydrocortisone for 3 days. Any side effects should go away once you stop taking the medication.

Everyone taking part in the study will be watched carefully for any side effects. However, the study doctors don't know all the side effects that may happen. Be sure to tell your study doctor immediately, about any side effect that you have while taking part in the study.

The following section will describe the risks related to your participation in this research study. You should talk to your study doctor about any side effects or other problems that you have while taking part in the study.

Side effects can range from mild to serious. Serious side effects are those that may require hospitalization, are life threatening or fatal (could cause death). The frequency that people experience a certain side effect can range from many (likely), few (less likely) or only one or two (rarely).

Risks and side effects related to the hydrocortisone include those which are:

Likely, some may be Serious
In 100 people, approximately 20 – 100 may have:

- Increased appetite, headache, fever, nausea, diarrhea, restlessness, difficulty sleeping, stomach pain, light-headedness, irritability, confusion.

Less Likely, some may be Serious
In 100 people, approximately 1 – 20 may have:

- Depression, anxiety.
- Rash, loss of appetite, acne, chills, increased urination.

For more information about risks and side effects, ask one of the researchers or study staff.

We will tell you about any significant new findings which develop during the course of this research which may relate to your willingness to continue taking part.

Risks from the specific research procedures (MRI)
There are no known risks from exposure to magnetic fields. You may experience nervousness and/or anxiety due to the loud banging made by the machine while it is taking pictures and from confinement in a tight space (claustrophobia). If you become anxious, you can stop the procedure at any time. You may also experience some discomfort and fatigue from lying still during imaging.

If you have any metal clips or plates in your body, if you are pregnant or are trying to become pregnant, or you have permanent eyeliner or eyebrows or any pieces of metal in your body you should tell the investigator as an MRI may not be appropriate.

MRI may not be appropriate if you have any of the following:

- heart pacemaker, heart valve replacement, or aortic clips
- metal fragments in your eyes, skin, or elsewhere in your body
- brain clips or pieces of metal used in aneurysm surgery or intercranial bypass
- venous umbrella
- pieces of metal in the body resulting from work as a sheet-metal worker or welder
- clips placed in an internal organ
- prosthetic devices, such as middle ear, eye, joint, or penile implants
- joint replacement
- hearing aid that cannot be removed
- neurostimulator
- insulin pump
- shunts or stents
- metal mesh or coil implants
- metal plate, pin, screws, or wires, or any other metal implants

If you have a history of an implanted device or clips in your pelvis (involving your uterus or fallopian tubes) or under your skin, acting as a contraceptive to prevent pregnancy, the MRI technologist will obtain specific information about

the make and model of your implanted device to determine if it is safe for you to receive the MRI examination.

Risks from the specific research procedures (blood draw)
Risks associated with drawing blood from your arm include minimal discomfort and/or bruising. Infection, excess bleeding, clotting, and/or fainting also are possible, although unlikely.

Are there Risks related to withdrawing from the study?

If you decide to withdraw from this study early, please discuss your decision with the principal investigator. The researcher may ask you to complete study withdrawal procedures at a final study visit. This visit includes meeting with a study clinician. There is no risk to you if you do not complete the final withdrawal procedures and you can choose not to participate in them.

Reproductive Risks:

Concerns for sexually active men and women: Women should not become pregnant and men should not father a baby while taking part in this study because we do not know how the study drugs/procedures could affect a man's sperm (for some drugs/procedures, the concern may be that the sperm might be affected and in some cases, drugs could being carried by the semen into the vagina and cause harm) or a fetus, if a woman becomes pregnant during the study. It is important that you talk to your study doctor about avoiding pregnancy during this study. If you think you might have become pregnant or if you believe your female partner has become pregnant while you are in this study, you must tell one of the study doctors right away so that management of the pregnancy and the possibility of stopping the study can be discussed.

If you are a woman who is pregnant or could be pregnant, you cannot take part in this study because we do not know how the hydrocortisone might affect a developing fetus. We will do a pregnancy test before you start treatment to make sure you are not pregnant.

Risks to babies who are being breastfed: Women who are breastfeeding cannot take part in this study because we do not know what effect the drugs/procedures might have on their breast milk.

Are there risks if you also participate in other research studies?
Being in more than one research study at the same time may increase the risk to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers.

Other risks:

Placebo
When receiving a placebo, you are not receiving active medication for a health problem. The use of a placebo in this study is not designed to intervene in any medical problem. However, if a medical problem you have becomes worse or you develop a problem, your participation in the research may stop. If this happens, your study doctor can discuss alternative care with you.

Psychological Stress
Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions, take a break or stop your participation in this study at any time.

Loss of Confidentiality
Any time information is collected; there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

Risk of Untreated Depression
You will meet with a clinician at each study visit to go over any depressive symptoms you may be experiencing and to see how you have been feeling. If your symptoms worsen significantly while you are participating in the study, your study participation may stop and a clinician will discuss the appropriate arrangements for your care with you.

Genetic Informational Risks
This research study includes genetic testing. Human tissue contains genes that determine many of a person's physical characteristics, such as the color of eyes and hair. In some cases, genetic testing of tissues can be used to indicate a risk for the development of certain diseases. Genetic information is unique to each individual and could potentially be used to discover possible changes in a person's future health status or life expectancy, or that of his/her children and family members.

Releasing this information to you could cause psychological distress, anxiety or family problems. Releasing this information to others, such as including it in your medical record, may pose a possible risk of discrimination, or increase difficulty in obtaining or maintaining disability, long-term care, or life insurance.

These risks would occur if your information is released by mistake. The measures being taken to protect your privacy are discussed below and make this possibility unlikely.

Even though the results of genetic testing may not be linked to you, it is possible that people of your ethnic background may be found to be at more risk for certain diseases based on future genetic research and this information might harm you in the future as a member of the group. Also, there may be unknown risks of genetic testing in the future.

What if a research-related injury occurs?
The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even though the researchers are careful to avoid them. In the event of a research-related injury or if you experience an adverse reaction, please immediately contact your study doctor. See the section "Contact Information" for phone numbers and additional information. You may also need to tell your regular doctors.

If you are injured or made sick from taking part in this research study, medical care will be provided. This care may be billed to you or your insurance. Depending on the circumstances, this care may be provided at no cost to you. We have no plans to give you money if you are injured. The investigator can provide you with more information.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

Benefits – "How could you or others benefit from your taking part in this study?"
The possible benefit of your participating in this study is receiving ongoing assessment for any depressive symptoms you may be experiencing, getting blood work, ECG and physical exam. Should any significant clinical results (blood work or ECG) arise as a result of monitoring, they will be shared with you. We hope the information learned from this study will benefit other people with similar conditions in the future.

Alternative procedures or course of treatment – "What other options are there to participation in this study?"
This is not a treatment study. This study is not designed to treat your depressive symptoms. There are other options available to you. Your other choices may include: getting treatment or care without being in a study from a clinical provider of your choice or taking part in another study designed to treat depression.

Payments – Will there be any payments for participation?

You will receive the following payment for you study participation at the completion of each visit:

- Baseline visit: $60
- Visit 3: $100
- Visit 5: $100
- Each time you bring back the actigraphy monitor (two possible times), you will receive $20 for a total of $40.

The total possible compensation for completing all study visits is $300. No payments will be prorated.

You will be issued a UT Southwestern Greenphire ClinCard, which can be used as a credit or debit card. Compensation will be credited to the card after completion of Baseline, Visit 3, Visit 5, and each time you return the actigraphy monitor (maximum of two times). Your name, address, date of birth and social security number will be shared with a third-party solely for the purposes of compensation processing. All information will be stored in a secure fashion.

Please note that if you are on record as owing money to the State of Texas, such as for back child support or a delinquent student loan, the payment may be applied to that debt.

An IRS Form 1099 will be sent to you if your total payments are $600 or more in a calendar year, unless it's a reimbursement.

DART passes will be available (2 passes at Baseline if eligible, and 1 pass at the remaining visits) throughout your participation in the study.

There are no funds available to pay for parking expenses, transportation to and from appointments (e.g., taxi expenses), lost time away from work and other activities, lost wages, or child care expenses.

Confidentiality – How will your records be kept confidential?

Information we learn about you in this study will be handled in a confidential manner, within the limits of the law. If we publish the results of the study in a scientific journal or book, we will not identify you. The Institutional Review Board and other groups that have the responsibility of monitoring research may want to see study records which identify you as a subject in this study.

Certificate of Confidentiality:

To help us further protect your information, the investigators will obtain a Certificate of Confidentiality from the U.S. Department of Health and Human Services (DHHS). This Certificate adds special protections for research information that identifies you and will help researchers protect your privacy.

With this Certificate of Confidentiality, the researchers cannot be forced to disclose information that may identify you in any judicial, administrative, legislative, or other proceeding, whether at the federal, state, or local level. There are situations, however, where we will voluntarily disclose information consistent with state or other laws, such as:

- to DHHS for audit or program evaluation purposes;
- information regarding test results for certain communicable diseases to the Texas Department of State Health Services, including, but not limited to HIV, Hepatitis, Anthrax, and Smallpox;
- if you pose imminent physical harm to yourself or others;
- if you pose immediate mental or emotional injury to yourself;
- if the researchers learn that a child has been, or may be, abused or neglected; or
- if the researchers learn that an elderly or disabled person has been, or is being, abused, neglected or exploited.

The Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing

information about your involvement in this research study. In addition, the researchers may not use the Certificate to withhold information about your participation in this research study if you have provided written consent to anyone allowing the researchers to release such information (including your employer or an insurance company). This means that you or your family must also actively protect your privacy.

A Certificate of Confidentiality does not represent an endorsement of this research project by the Department of Health & Human Services or any other Federal government agency.

Research policies require that private information about you be protected and this is especially true for your health information. However, the law sometimes allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study. All information collected in this study is solely for research purposes. Medical information collected during this study and the results of any test or procedure that may affect your medical care will not be included in your medical record. None of the information collected in this study will be available to health care providers (unless you specifically authorize the research to share information with your provider) and authorized persons including your insurance company.

What is Protected Health Information (PHI)?
Protected Health Information is information about a person's health that includes information that would make it possible to figure out who's it is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for this research study. In carrying out this research, the health information we will see and use about you will include:

- your medical history and psychiatric treatment history, any medications you are currently using or have used in the past month, results of your blood work, ECG findings, MRI findings, information you give us during interviews or from questionnaires, demographic information like your age, marital status, the type of work you do and the years of education you have completed.

We will get this information by asking you.

How will your PHI be shared?
Because this is a research study, we will be unable to keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- the Sponsor, National Institute of Mental Health (NIMH), funding the study. The sponsor includes any people, entities, groups or companies working for or with the sponsor or owned by the sponsor. The sponsor will receive written reports about your participation in the research. The sponsor may look at your health information to assure the quality of the information used in the research.
- the committee that checks the study data on an ongoing basis, to determine if the study should be stopped for any reason.
- the members of the local research team.
- The Institutional Review Board, Human Research Protection Program Office and the Compliance Office of the University of Texas Southwestern Medical Center, and other groups that oversee how research studies are carried out.
- the Food and Drug Administration (FDA) and other U.S. and international governmental regulatory agencies involved in overseeing drug or device research.
- Representatives of domestic and foreign governmental and regulatory agencies may be granted direct access to your health information for oversight, compliance activities, and determination of approval for new medicines, devices, or procedures.

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect,

use and share your health information. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in the research study.

Parts of your PHI may be photocopied and sent to a central location or it may be transmitted electronically, such as by e-mail or fax. The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here.

The Genetic Information Nondiscrimination Act (GINA) is a Federal law that will protect you in the following ways:

- Health insurance companies and group plans may not request genetic information from this research;
- Health insurance companies and group plans may not use your genetic information when making decisions regarding your eligibility or premiums;
- Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote, or fire you or when setting the terms of your employment.

GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease

How will your PHI be protected?
In an effort to protect your privacy, the study staff will use code numbers instead of your name, to identify your health information. Initials and numbers will be used on any photocopies of your study records, and other study materials containing health information that are sent outside of the Psychoneuroendocrine Research Group for review or testing (for example, to UC Irvine or Johns Hopkins – both collaborating universities). If the results of this study are reported in medical journals or at meetings, you will not be identified.

Do you have to allow the use of your health information?
You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties but you will not be allowed to participate in the study.
After you enroll in this study, you may ask the researchers to stop using your health information at any time . However, you need to say this in writing and send your letter to E. Sherwood Brown, M.D., Ph.D. at The University of Texas Southwestern Medical Center, Department of Psychiatry, 5323 Harry Hines Blvd, MC 8849, Dallas, TX 75390-8849. If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?
The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study.

How long will your PHI be used?
By signing this form, you agree to let us use and disclose your health information for purposes of the study until the end of the study. This permission to use your personal health information expires when the research ends and all required study monitoring is over.

Contact Information – Who can you contact if you have questions, concerns, comments or complaints?

If you have questions now, feel free to ask us. If you have additional questions, concerns, comments or complaints later or you wish to report a problem which may be related to this study please contact:

E. Sherwood Brown, M.D., Ph.D. can be reached at 214-645-6950 during regular business hours. If this number is

not available, then contact 214-648-5555, including after hours and on weekends and holidays.

The University of Texas Southwestern Medical Center Human Research Protection Program (HRPP) oversees research on human subjects. HRPP and Institutional Review Board (IRB) representatives will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the HRPP by calling the office at 214-648-3060.

Research Consent & Authorization Signature Section

If you agree to participate in this research and agree to the use of your protected health information in this research, sign this section. You will be given a copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE FOLLOWING STATEMENTS ARE TRUE:

- You have read (or been read) the information provided above.
- Your questions have been answered to your satisfaction about the research and about the collection, use and sharing of your protected health information.
- You have freely decided to participate in this research or you are voluntarily giving your consent for another person to participate in this study because you believe this person would want to take part if able to make the decision and you believe it is in this person's best interest.
- You understand that a copy of this signed consent document, information about this study, and the results of any test or procedure that may affect your medical care, will not be included in your medical record. Information in your medical record will not be available to health care providers (unless you authorize the release of your information) and authorized persons including your insurance company.
- You authorize the collection, use and sharing of your protected health information (another person's protected health information) as described in this form.

Adult Signature Section

Printed Name of Participant	Signature of Participant	Date	Time AM PM
Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date	Time AM PM