INFORMED CONSENT FORM

Official Title: **A Neurosteroid Intervention for Menopausal and Perimenopausal Depression**

NCT Number: NCT03505905

IRB Approved Date: January 30, 2024

The University of Texas Southwestern Medical Center

CONSENT TO PARTICIPATE IN RESEARCH

Title of Research:	A Neurosteroid Intervention for Menopausal and Perimenopausal Depression
Funding Agency/Sponsor:	National Institute of Aging (NIA)
Study Doctor:	E. Sherwood Brown, M.D., Ph.D. (Principal Investigator)

You may call the study doctor or research personnel during regular office hours at 214-645-6950. At other times, you may call them at 214-648-5555.

Instructions:
Please read this consent form carefully and take your time making a decision about whether to participate. As the researchers discuss this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. The purpose of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. If you decide to participate, you will be given a copy of this form to keep.

Why is this study being done?
This study is being done to find out whether an investigational (non-FDA approved) drug called pregnenolone can help with lowering depressive symptoms and physical symptoms associated with menopause in women. The word “investigational” means that pregnenolone is not currently approved by the U.S. Food and Drug Administration (FDA) for the treatment of depression in women undergoing menopausal transition.

Why is this considered research?
This is a research study because pregnenolone is currently classified as an over-the-counter nutritional supplement by the FDA, and is currently not approved by the FDA for other indications, including perimenopausal and menopausal depression.

The following definitions may help you understand this study:

- Double-blind means neither you nor the researchers will know which drug you are receiving (study drug pregnenolone or placebo).
- Placebo-controlled means that some participants will get a placebo. A placebo looks like the investigational drug but it includes no active ingredients.
- Randomization means you will be placed by chance (like a flip of a coin) in one of the study groups (study drug pregnenolone or placebo).
- Standard medical care means the regular care you would receive from your personal doctor if you choose not to participate in this research.

- Researchers means the study doctor and research personnel at the University of Texas Southwestern Medical Center at Dallas and its affiliated hospitals.

Why am I being asked to take part in this research study?
You are being asked to take part in this study because you have indicated that you have symptoms associated with depression and menopause.

Do I have to take part in this research study?
No. You have the right to choose whether you want to take part in this research study. If you decide to participate and later change your mind, you are free to stop participation at any time.

If you decide not to take part in this research study it will not change your legal rights or the quality of health care that you receive at this center.

How many people will take part in this study?
About 72 people will be enrolled in this study at UT Southwestern. This study also is taking place at another medical facility in the country (Massachusetts General Hospital, Boston, MA). There will be 144 people enrolled in this research study throughout Boston, MA and Dallas, TX.

What is involved in the study?
If you volunteer to take part in this research study, you will be asked to sign this consent form and will have the following tests and procedures. All procedures in this study are being done solely for the purpose of this study (research).

Screening Procedures
To help decide if you qualify to be in this study, the researchers will ask you questions about your health, including past and present medical and psychiatric history, any medications you take and any surgical procedures you have had.

You may also have to fill out certain forms or have the following exams, tests or procedures:

- Psychiatric evaluation;
- Physical exam and medical history;
- Vital signs;
- Blood tests;
- Urine pregnancy test and urine drug screen;
- Mood scales and psychiatric history (including substance use history);
- Demographic information (age, sex, ethnic origin).

Group Assignment
If the researchers believe you can take part in this study, you will be assigned randomly (like a flip of a coin) to receive either pregnenolone or placebo during your participation in the study. At some point in the study, you have about a 50% chance of receiving pregnenolone.

The group you will be in is decided by a statistician using a specialized computer program. Neither you nor the researchers will be allowed to choose which group you are assigned to. Neither you nor the researchers will know which group you are in. However, a staff member not involved in the study conduct will have access to your group assignment, and will release the information about your assignment to the researchers if it is needed for your safety.

Study Medication/Intervention

If you decide to participate in this study you may be taking one of the following:

- Pregnenolone:
  - Baseline: 50 mg twice a day (total: 100 mg/day) for one week
  - Week 1: 150 mg in the morning and 150 mg in the evening for one week (total: 300 mg/day) for one week
  - Week 2: 250 mg in the morning and 250 mg in the evening (total: 500 mg/day) for the remainder of the study
  - A clinician may adjust your dosing depending on any side effects you may experience in the study.
- Placebo: the same number of capsules as in the active study drug group will be taken throughout the study.

  The placebo capsules will be made to look exactly like the same as the pregnenolone capsules. Neither you, nor the researchers, will be able to see any difference.

Procedures and Evaluations during the Research

	Visit 1	**Visit 2**	**Visit 3**	**Visit 4**	**Visit 5**	**Visit6**	**Visit 7**	**Visit 8**	**Visit 9**	**Visit 10**	**Visit 11**	**Visit 12**	**Visit 13**
Instrument	**Wk 0 BL & R**	**48-96 hrs Post baseline (phone)**	**Wk 1**	**Wk 2**	**Wk 4**	**Wk 6 (Phone)**	**Wk 8**	**48-96 hrs Post Wk 8 visit (phone)**	**Wk 9**	**Wk 10**	**Wk 12**	**Wk 14 (Phone)**	**Wk 16**
SCID, HRSD, TII, RLHQ (Module 1)	X												
MADRS	X	X	X	X	X	X	X	X	X	X	X	X	X
HRSA, PSQI, RLHQ (Module 3)	X		X	X	X		X		X	X	X		X
GCS	X		X	X	X		X		X	X	X		X
Cognitive tasks: RAVLT, TMT, CPFQ	X						X						X
MEN-QOL	X						X						X
Safety Assessments: SAFTEE, C-SSRS, Vital signs,	X		X	X	X		X		X	X	X		X
UPT, UDS	X				X		X				X		X
Safety Assessments: Physical Exam	X						X						X

IRB Approved Date: 1/30/2024

Safety Assessments: Routine labs, weight	X						X						X
Blood draw (Neurosteroid levels)	X						X						X
Psychiatric evaluation/check-in	X		X	X	X		X		X	X	X		X
Exit survey													X
Approximate visit duration	*3hr*	*20 mins*	*1.5hr*	*1.5hr*	*1.5hr*	*20min*	*2hr*	*20 mins*	*1.5hr*	*1.5hr*	*1.5hr*	*20min*	*2hr*

During the Baseline visit (approximately a 3 hour visit), you will be given the following:

- Structured Clinical Interview for DSM-5 Clinician Version (SCID-CV) - brief structured interview used to help diagnose psychiatric illnesses
- Montgomery Asberg Depression Scale (MADRS) – a measure of depressive symptoms designed for use in clinical trials
- Hamilton Rating Scale for Depression (HRSD) – a measure of severity of depressive symptoms
- Hamilton Rating Scale for Anxiety (HRSA) – a measure of how anxious you've been feeling in the past week
- Pittsburgh Sleep Quality Index (PSQI) – a measure of how well you've been sleeping during the past week
- Greene Climacteric Scale (GCS) – a checklist of any mood changes and physical symptoms as related to menopause
- Menopause Specific Quality of Life (MEN-QOL) – a measure of how bothersome menopausal symptoms have been for you
- Female Reproductive Lifecycle and Hormones Questionnaire (RLQH) Modules 1 and 3 – Module 1 is a questionnaire to evaluate your childbearing potential, menopausal status, and menstrual cycle. Module 3 is a menstrual cycle and symptom tracker.
- Treatment Impressions Inventory (TII) – a measure of your feelings and impressions towards your medical treatment
- Systematic Assessment for Treatment Emergent Events (SAFTEE) – a side effects symptom scale
- Columbia-Suicide Severity Rating Scale (C-SSRS) – a brief interview to assess any suicidal thoughts and acts you may have had in your lifetime
- Rey Auditory Verbal Learning Test (RAVLT) – a word memory test
- Trail Making Test (TMT) – a test to measure your attention, speed, and accuracy
- Cognitive and Physical Functioning Questionnaire (CPFQ) – is a short self-report scale that assesses possible cognitive and physical side effects.
- Blood draw – approximately 2.5 tablespoons of blood will be drawn from your arm to check routine clinical values, neurosteroid levels (brain chemicals) and an additional blood panel may also be conducted to assess Follicle Stimulating Hormone (FSH) levels to confirm menopause status. Additional 1.5 tablespoons will be drawn if you opted-in for DNA testing.
- Vital signs (blood pressure, temperature, heart rate, respiratory rate, weight) will be obtained from you
- Urine sample will be obtained from you to conduct a Urine Drug Screen (UDS)

and a Urine Pregnancy Test (UPT)
- Physical Examination will be performed by a study clinician
- Psychiatric evaluation will be performed by a study clinician to assess your psychiatric history, safety and health, and discuss study medication tolerability and side effects

During Weeks 1, 2, 4, 9, 10, 12 (approximately 1.5-hour visit), the following information will be collected from you:
- MADRS, HRSA, PSQI, GCS, RLHQ Module 3, SAFTEE, C-SSRS,medication adherence, check-in with a study clinician to assess your safety and go over medication tolerability and any side effects.

During Weeks 8 and 16 (approximately 2-hour visit), the following information will be collected from you:
- MADRS, HRSA, PSQI, GCS, RAVLT, TMT, CPFQ, MEN-QOL, SAFTEE, C-SSRS, UDS, vital signs, blood draw (2.5 tablespoons to check clinical values and neurosteroid levels), medication adherence, physical exam, and check-in with a study clinician to assess your safety and go over medication tolerability and any side effects and provide referrals for future care.

During Weeks 4, 8, and 16, a urine pregnancy test (UPT) and urine drug screen (UDS) will be administered to you.

Following 48-96 hours after your first visit (baseline), weeks 6, 48-96 hours after your week 8 visit and at week 14, you will receive a phone call (approximately 20 minutes) from a research coordinator and MADRS will be completed over the phone. At week 16 (or your last study visit if you decide to stop your study participation early), you will also complete an exit survey regarding your perception of in-person vs. virtual research visits.

At Week 17, you will have a safety follow-up phone call that will last approximately 10 minutes to check on any ongoing side effects and see if you've utilized treatment referrals.

All the assessments and tests in this study are designed for research, not for medical purposes. They are not useful for finding problems or diseases. Even though the researchers are not looking at your assessments and tests to find or treat a medical problem, you will be told if they notice something unusual. You and your regular doctor can decide together whether to follow up with more tests or treatment. Because the assessments and tests done in this study are not for medical purposes, the research results will not be sent to you or to your regular doctor.

OPTIONAL Blood Sample for DNA (genetic) Analysis

In addition to other activities and procedures for which you have been asked to consent, you are also able to provide an OPTIONAL blood sample to look at your genes, which are often called "DNA".

If you agree to this study component, then up to 1.5 tablespoons of blood will be drawn from a vein in your arm with a small sterile needle. This is the standard method used to obtain blood for routine hospital tests. We may ask for a second blood sample if the research laboratory cannot process the first sample.

How will my DNA samples be stored and identified?
Your sample will be marked with a coded identifier and will not be personally identifiable. Neither your name nor any identifying information will be given to the researchers who receive your samples. Your samples will be shipped to and stored at UT Southwestern McDermott Center for Human Growth and Development in a secure freezer with coded identification that will not include any personal identifiers, such as your name or date of birth.

What is DNA?
DNA means *deoxyribonucleic acid*. DNA is the substance in our cells which contains information we inherited from our parents and other family members. Your DNA contains "genes" which predict things like physical characteristics (eye color, hair color, height, etc.) and may also be a factor in whether you develop or are at risk of developing certain illnesses or disorders.

What is genetic testing?
Genetic tests look for naturally occurring differences in a person's genes, or the effects of specific genes. These differences could indicate an increased chance of getting a disease or condition. Genetic testing includes gene tests (DNA testing) and sometimes biochemical tests (protein testing) if it relates to a specific gene.

In gene tests, DNA in cells taken from a person's blood, body fluids or tissues is examined for differences. The differences can be relatively large - a piece of a chromosome, or even an entire chromosome, missing or added. Sometimes the change is very small - as little as one extra, missing or altered chemical within the DNA strand. Genes can be amplified (too many copies), over-expressed (too active), inactivated, or lost altogether. Sometimes pieces of chromosomes become switched, turned over or discovered in an incorrect location.

How is DNA obtained? Cells from blood or other body materials are processed in a laboratory that has special equipment that can extract DNA and identify genes.

What will happen to the samples collected for this research? Dr. E. Sherwood Brown, M.D., Ph.D. and Dr. Marlene Freeman, M.D. (Principal Investigator at the MGH site) will compare information about the health of participants with the results of research tests using their DNA.

How long will my samples be kept? Dr. E. Sherwood Brown, M.D., Ph.D. and Dr. Marlene Freeman, M.D. will keep your sample in a research laboratory at this medical center until it is all gone, becomes unusable or until they decide to discard the sample. If

your sample remains stored beyond your lifetime, your sample will be used as described in this document.

May other researchers use my sample?
When you provide a sample for purposes of this study your sample becomes the property of The University of Texas Southwestern Medical Center and may be used for future studies or provided to other investigators at other medical research facilities without any identifiers.

Who decides which research scientists may receive samples of my DNA?
Dr. E. Sherwood Brown and Dr. Marlene Freeman decide which researchers at this medical center and at other medical centers may receive samples of your DNA. Your samples may be used in other research only if the other research has been reviewed and approved by an Institutional Review Board (IRB).

Could my sample be used for other purposes?
No. Your samples or your DNA will only be used for research. Research tests using your sample may possibly result in inventions or procedures that have commercial value and are eligible for protection by a patent. Compensation for any future commercial developments is not available from the University of Texas Southwestern Medical Center at Dallas, its researchers or other facilities or researchers whose research may benefit from the use of your sample.

By agreeing to the use of your sample in research, you are giving your sample without expectation of acknowledgment, compensation, interest in any commercial value or patent, or interest of any other type. However, you retain your legal rights during your participation in this research.

Will the results of research tests be reported to me?
No. Drs. Brown and Freeman will use samples of your DNA only for research. The samples will not be used to plan your health care.

Permission to share samples for genetic testing

You have the option to elect to share your samples for the purpose of genetic research as described above. (A "no" answer will not disqualify you from participating in the main study.)

Yes _____ initials. I do allow the use of my samples for genetic research
No_____ initials. I do not allow the use of my samples for genetic research.

How long can I expect to be in this study?
The study will last 16 weeks, with a safety follow-up phone call (non-data collection) at Week 17. You can choose to stop participating for any reason at any time. However, if you decide to stop participating in the study, we encourage you to tell the researchers. You may be asked if you are willing to complete some study termination tests.

What are the risks of the study?

Study Procedure/Intervention

Because of your participation in this study, you are at risk for the following side effects. You should discuss these with the researchers and your regular health care provider.

Pregnenolone may cause some, all or none of the side-effects listed below.

	Frequent 20% or more of subjects	Occasional 15% or less of subjects	Rare Less than 1% of subjects
Serious	None	None	None
Less Serious	None	None	None
Minor	Mild Restlessness	Mild Muscle Pain/Stiffness, Mild Cold Hands/Feet	None

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.

Risks to Embryo, Fetus or Breast-fed Infant

Females: If you are part of this study while pregnant or breast-feeding an infant, it is possible that you may expose the unborn child or infant to risks. For that reason, pregnant and breast-feeding females cannot participate in the study. If you can become pregnant, a urine pregnancy test will be done, and it must be negative before you participate in this study. If you take part in this study and you are sexually active, you and any person that you have sex with must use medically-acceptable birth control (contraceptives) during the study. Medically-acceptable birth control (contraceptives) includes:

(1) surgical sterilization (such as hysterectomy or “tubes tied”),

(2) barrier methods (such as condom or diaphragm) used with a spermicide (a substance that kills sperm), or

(3) an intrauterine device (IUD).

If you do become pregnant during this study, you must tell the researchers immediately.

Risks of Blood Drawing

You will have 2.5 tablespoons of blood collected because you are in this research study. You will also have an option to provide additional 1.5 tablespoons of blood for genetic testing as outlines above. 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.

Placebo
If you receive a placebo, you will not receive active medication for your health problem. If your problem becomes worse, your participation in the research will stop. If this happens, your study doctor can discuss alternative care with you.

Other Risks
There may possibly be other side effects that are unknown at this time. If you are concerned about other, unknown side effects, please discuss this with the researchers.

How will risks be minimized or prevented?
During the study, you will have a follow-up at every visit with the study doctor. During these follow-ups, the doctor will review any side effects that you may have and check in with your symptoms are not worsening, to make sure there are no problems with the study medication and to ensure it is safe for you to remain in the study.
Pregnancy tests will be done every visit in women who can have children to ensure safety. Study staff and doctors will be available outside of office hours if you need to contact them in an emergency.

The study will also include a Data and Safety Monitoring Board (DSMB). This is an independent group of doctors and professionals familiar with the study, who will meet at least twice a year to review all safety data in the study. This board will provide its independent review of the study procedures and make recommendations to ensure the highest safety precautions for you.

What will my responsibilities be during the study?
While you are part of this study, the researchers will follow you closely to determine whether there are problems that need medical care. It is your responsibility to do the following:

- Ask questions about anything you do not understand.
- Keep your appointments.
- Follow the researchers' instructions.
- Let the researchers know if your telephone number or address changes.
- Store study materials (pills, pill bottles) a secure place at home away from anyone who is unable to read and understand labels, especially children.
- Tell the researchers before you take any new medication, even if it is prescribed by another doctor for a different medical problem or something purchased over the counter.
- Tell your regular doctor about your participation in this study.
- Carry information about pregnenolone in your purse or wallet.
- Report to the researchers any injury or illnesses while you are on study even if you do not think it is related.

If I agree to take part in this research study, will I be told of any new risks that

may be found during the course of the study?
Yes. You will be told if any new information becomes available during the study that could cause you to change your mind about continuing to participate or that is important to your health or safety.

What should I do if I think I am having problems?
If you have unusual symptoms, pain, or any other problems while you are in the study, you should report them to the researchers right away. Telephone numbers where they can be reached are listed on the first page of this consent form.

If you have a sudden, serious problem, like difficulty breathing or severe pain, go to the nearest hospital emergency room, or call 911 (or the correct emergency telephone number in your area). Tell emergency personnel about any medications you are taking, including any medications you are taking for this study.

What are the possible benefits of this study?
If you agree to take part in this study, there may or may not be direct benefits to you. The researchers cannot guarantee that you will benefit from participation in this research. We hope the information learned from this study will benefit other women with menopausal depression in the future. Information gained from this research could lead to better treatment for women experiencing depression during the menopausal transition.

What options are available if I decide not to take part in this research study?
You do not have to participate in this research to receive care for your medical problem. Instead of being in this study, you have the following options:

- Outpatient pharmacological (medication) treatment, psychotherapy, or counseling for depression with a provider of your choice

Please talk to the researchers or your personal doctor about these options.

Will I be paid if I take part in this research study?
Yes. You will be paid the following:

- $100 at Baseline (if you complete the entire visit and are eligible for the study), Weeks 8, 16
- $50 at Weeks 1, 2, 4, 9, 10, 12
- $25 at Weeks 6 and 14 (phone calls)

Payments will not be prorated, and you will need to complete all procedures during the visit to receive compensation.

DART passes will be available (2 passes at Baseline 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., cab fare), lost time away from work and other activities, lost wages, or child care expenses.

How will I be paid?
You will be issued a UT Southwestern Greenphire ClinCard, which can be used as a credit or debit card. You will also receive instructions on how to use the card. In order to receive study payments, your name, address, date of birth and Social Security Number (SSN) will be collected from you by the research staff. All information will be stored in a secure fashion and will be deleted from the UT Southwestern Greenphire ClinCard system once the study has been completed.

Important Information about Study Payments
1. Your SSN is needed in order to process your payments. Should you decide not to provide your SSN, your study participation payment will be decreased at the current IRS tax rate. Study payments are considered taxable income and are reportable to the IRS.
2. An IRS Form 1099 will be sent to you if your total payments are $600 or more in a calendar year.
3. Your ClinCard payment information will not be shared with any third parties and will be kept completely confidential

This information will remain confidential unless you give your permission to share it with others, or if we are required by law to release it.

UT Southwestern, as a State agency, will not be able to make any payments to you for your participation in this research if the State Comptroller has issued a “hold” on all State payments to you. Such a “hold” could result from your failure to make child support payments or pay student loans, etc. If this happens, UT Southwestern will be able to pay you for your taking part in this research 1) after you have made the outstanding payments and 2) the State Comptroller has issued a release of the “hold.”

Will my insurance provider or I be charged for the costs of any part of this research study?
No. Neither you, nor your insurance provider, will be charged for anything done only for this research study (i.e., the Screening Procedures, Experimental Procedures, or Monitoring/Follow-up Procedures described above).

However, the standard medical care for your condition (care you would have received whether or not you were in this study) is your responsibility (or the responsibility of your insurance provider or governmental program). You will be charged, in the standard manner, for any procedures performed for your standard medical care.

What will happen if I am harmed as a result of taking part in this study?
It is important that you report any illness or injury to the research team listed at the top of this form immediately. Compensation for an injury resulting from your participation in this research is not available from the University of Texas Southwestern Medical Center at Dallas. You retain your legal rights during your participation in this research.

Can I stop taking part in this research study?
Yes. If you decide to participate and later change your mind, you are free to stop taking part in the research 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 decide to stop your study participation, you may be asked by the research staff to come to the research office for a final visit and complete assessments designed for Weeks 8 or 16 as outlined above.

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

If I agree to take part in this research study, can I be removed from the study without my consent?
Yes. The researchers may decide to take you off this study if:

- Your medical problem remains unchanged or becomes worse.
- The researchers believe that participation in the research is no longer safe for you.
- The researchers believe that other treatment may be more helpful.
- The sponsor or the FDA stops the research for the safety of the participants.
- The sponsor cancels the research.
- You are unable to keep appointments or to follow the researcher's instructions.

Will my information be kept confidential?
All the information collected in the study is for research purposes only, and will not become a part of your medical record.

You should know that certain organizations that may look at and/or copy your research records for research, quality assurance, and data analysis including:

- National Institute of Aging (NIA)
- Massachusetts General Hospital, Boston, MA
- Representatives of government agencies, like the U.S. Food and Drug Administration (FDA), involved in keeping research safe for people; and
- The UT Southwestern Institutional Review Board.
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law).

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.

Authorization for Use and Disclosure of Health Information for Research Purposes

What is the purpose of this form?
This authorization describes how information about you and your health will be used and shared by the researcher(s) when you participate in the research study: *Neurosteroid Intervention for Perimenopausal and Menopausal Depression, a study investigating effectiveness of pregnenolone as a treatment for depression in women undergoing menopausal transition* ("Research Project"). Health information is considered "protected health information" when it may directly identify you as an individual. By signing this form you are agreeing to permit the researchers and other others (described in detail below) to have access to and share this information. If you have questions, please ask a member of the research team.

Who will be able to use or share my health information?
UT Southwestern Medical Center may use or share your health information with *E. Sherwood Brown, M.D., Ph.D.* and his staff at UT Southwestern Medical Center ("Researchers") for the purpose of this research study.

Will my protected health information be shared with someone other than the Researchers?
Yes, the Researchers may share your health information with others who may be working with the Researchers on the Research Project ("Recipients") for purposes directly related to the conduct of this research study or as required by law. These other people or entities include:

- *NIH – National Institute of Aging:* 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.

- *Massachusetts General Hospital, Boston, MA:* These are other research facilities that are working with UT Southwestern on the Research Project.

- *Quest Diagnostic Laboratories, Inc.:* The laboratory will need access to your health information to assist the Researchers in the Research Project. This laboratory will only have access to your year of birth, not the full date of birth and will not have access to your name.

- *The UT Southwestern Institutional Review Board (IRB):* This is a group of people who are responsible for assuring that the rights of participants in research are respected. Members and staff of the IRB at UT Southwestern may review the records of your participation in this research. A representative of the IRB may

contact you for information about your experience with this research. If you do not want to answer their questions, you may refuse to do so.

- 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.

How will my health information be protected?
Whenever possible your health information will be kept confidential as required by law. Federal privacy laws may not apply to other institutions, companies or agencies collaborating with UT Southwestern on this research project. There is a risk that the Recipients could share your information with others without your permission. UT Southwestern cannot guarantee the confidentiality of your health information after it has been shared with the Recipients.

Why is my personal contact being used?
Your personal contact information is important for the UT Southwestern Medical Center research team to contact you during the study. However, your personal contact information will not be released without your permission.

What health information will be collected, used and shared (disclosed)?
The Researchers will collect, use, and share the following de-identified (e.g., no name, address, or date of birth) information for research purposes only: demographics (age, gender, ethnicity, etc.), blood analyses results, including DNA collection, psychiatric, medical, and surgical history (including substance use history), scores on psychiatric rating scales, current medications you are taking, physical exam (including vital signs, such as height, weight, blood pressure, pulse, respiratory rate, body mass index (BMI)), results of urine drug screen and urine pregnancy tests, scores on cognitive assessments, scores on cognitive tests, and any side effects, medical emergencies, or other adverse events you may experience during your participation in the study.

Will my health information be used in a research report?
Yes, the research team may fill out a research report. (This is sometimes called “a case report”.) The research report will not include your name, address, or telephone or social security number, date of birth, or initials. The published results will be presented as a group summary, which means that no individual participant may be identified in a research report. The research report will also include information the research team collects for the study.

Will my health information be used for other purposes?
Yes, the Researchers and Recipients may use your health information to create research data that does not identify you. Research data that does not identify you may be used and shared by the Researchers and Recipients in a publication about the results of the Research Project or for other research purposes not related to the Research Project.

Do I have to sign this authorization?
No, this authorization is voluntary. Your health care providers will continue to provide you with health care services even if you choose not to sign this authorization. However, if you choose not to sign this authorization, you cannot take part in this Research Project.

How long will my permission last?
This authorization has no expiration date. You may cancel this authorization at any time. If you decide to cancel this authorization, you will no longer be able to take part in the Research Project. The Researchers may still use and share the health information that they have already collected before you canceled the authorization. To cancel this authorization, you must make this request in writing to: E. Sherwood Brown, M.D., Ph.D., Department of Psychiatry, UT Southwestern Medical Center, 5323 Harry Hines Blvd., Dallas, TX, 75390-8849; Tel: (214) 645-6950.

Are there procedures I should follow after stopping participation in this research?
Yes. If you, the researchers, or the sponsor stops your participation in the research, you may be asked to do the following:

- Let the researchers know immediately that you wish to withdraw from the research.
- Return to the research center for tests that may be needed for your safety.
- Return any unused study materials, including empty containers.
- Discuss your future medical care, if any, with the researchers and/or your personal doctor.

Whom do I call if I have questions or problems?
For questions about the study, contact E. Sherwood Brown, M.D., Ph.D. at 214-645-6950 during regular business hours and at 214-648-5555 after hours and on weekends and holidays.

For questions about your rights as a research participant, contact the UT Southwestern Institutional Review Board (IRB) Office at 214-648-3060.

SIGNATURES:

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP.

Your signature below certifies the following:

- You have read (or been read) the information provided above.
- You have received answers to all of your questions and have been told who to call if you have any more questions.
- You have freely decided to participate in this research.
- You understand that you are not giving up any of your legal rights.

_____

Name of Participant (Printed)

_____ _____ _____ AM / PM

Signature of Participant Date Time

_____

Name of Person Obtaining Consent (Printed)

_____ _____ _____ AM / PM

Signature of Person Obtaining Consent Date Time