The UNIVERSITY OF CHICAGO
The Division of the Biological Sciences • The University of Chicago Medical Center

CONSENT/AUTHORIZATION BY SUBJECT FOR PARTICIPATION IN A RESEARCH PROTOCOL

Protocol Number: IRB16-0834 Name of Subject: _____

STUDY TITLE: Effects of Pregnenolone on Perceived Social Isolation

Doctors Directing Research: Dr. Stephanie Cacioppo & Dr. Jon Grant
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Department of Psychiatry
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You are being asked to participate in a research study. A member of the research team will explain what is involved in this study and how it will affect you. This consent form describes the study procedures, the risks and benefits of participation, as well as how your confidentiality will be maintained. Please take your time to ask questions and feel comfortable making a decision whether to participate or not. This process is called informed consent. If you decide to participate in this study, you will be asked to sign this form.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to investigate the effects of pregnenolone on perceived social isolation, such as feelings of loneliness. Pregnenolone is a hormone that we believe might work to alleviate loneliness because of the way it works in the brain. It interacts with a neurosteroid called allopregnanolone, which, when impaired, has been associated with aspects of perceived social isolation. Another purpose of this study is to investigate how other feelings (such as life satisfaction and anxiety) change after a one time intake of pregnenolone (400mg) or after a one time intake of a placebo (sugar pill).

Pregnenolone is being used as an experimental drug for this study. This means that pregnenolone is not approved by the Food and Drug Administration for reducing the symptoms of perceived social isolation.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 224 people with high perceived social isolation and 12 people with low perceived social isolation will take part in this study at the University of Chicago.

WHAT IS INVOLVED IN THE STUDY?

The study will last about 4 to 4 ½ hours and includes one office visit. During the visit, if you have high perceived social isolation, you will be randomly assigned to a study drug

administration group (a group who takes pregnenolone 400mg) or the control group (group who takes the placebo). Whether you receive the study drug or the placebo is based on a 50/50 chance, like flipping a coin. In all, 112 subjects will receive pregnenolone 400mg, and 112 subjects will receive the placebo.

During the visit, you will be asked to fill out a series of questionnaires (e.g., demographics, questions about perceived social isolation, and questions about your mood) and do a behavioral visual task on a computer while your responses and reaction times will be recorded.

During the visit, the following will occur:

- The study will be discussed with you and you will be asked to sign this consent form.
- A review of your medical history and your medications will be completed.
- A review of your family history, a review of family medical issues and psychiatric issues will be discussed with you.
- You will be asked to give a urine sample that will be tested for illegal drug use (including marijuana). This test must be negative in order to participate in the study.
- You will complete several questionnaires, including questions about perceived social isolation and questions about your mood.
- You will do a visual task on a computer.
- If you have high perceived isolation, the study drug will be given to you (either pregnenolone 400mg, or placebo) and you will be instructed on how to take it 30 minutes after you arrive at the high-performance electrical neuroimaging (HPEN) laboratory.
- You will be asked to provide blood samples throughout the visit so that we can see how your blood hormones change at different times after taking the pregnenolone or placebo. The experimenter will draw your blood from your arm three times: 1) 30 minutes before you take the study drug, 2) 2 hours and 30 minutes after taking the study drug, and 3) again an hour later. About 1 teaspoon of blood will be taken each time.
- You will also be asked to provide saliva samples during the study at the same three times. About 1 teaspoon of saliva will be taken each time. We ask you to provide saliva samples so that we can see how the samples are related to behavioral tasks and how you are feeling at different times in the study.
- You will watch a 2 hour-long relaxing movie in a quiet and relaxing environment.

Two hours after you take the pill (drug or placebo) , the following will occur:

- You will do the exact same behavioral visual task on a computer
- You will complete the same questionnaires again.
- You will wait for 30 minutes in a relaxing and quiet environment.
- **Estimated Duration of Visit: 4 to 4 1/2 Hours**

Behavioral visual task: You will be shown some images and/or words on a computer. No pictures involving nudity will be presented. However, some of these images may be stressful, but should not be overwhelming. If you feel uncomfortable at any time, please alert the study staff immediately.

During this study, Dr. Stephanie Cacioppo and her research team will collect information about you for the purposes of this research. This information includes name, date of birth, telephone number, e-mail address, demographic information, and the results of your study-related tests. Your behavioral data will be represented by a code number in the data field where a name would ordinarily go. Data from this study may be used in research publications or presentations. Your name and other identifying information will NOT be part of this data set.

In the event suicidal ideation or similar events take place during the study, you will be removed from the study and referred to the appropriate clinical resources.

HOW LONG WILL I BE IN THE STUDY?

We think you will be in the study for 4 to 4 ½ hours, where you will take the study drug or placebo once. There is no long-term follow-up after you stop the study.

Dr. Cacioppo may decide to take you off the study without your consent if:

- You are unable to meet the requirements of the study;
- Your medical condition changes;
- The study drug is no longer available;
- New information becomes available that indicates that participation in this study is not in your best interest; or
- If the study is stopped.

WHAT ARE THE RISKS OF THE STUDY?

The most common side effects observed in people taking the study drug pregnenolone include:

- Anxiety
- Insomnia
- Irritability
- Headaches
- Acne
- Scalp hair loss

There is a possibility that you may have heart palpitations or an irregular heart rhythm. If this happens, please let the study doctor know immediately. If you have a history of any heart problems, you are not eligible to participate in this study.

The study team will also ask you questions about your mood and behaviors. These

questions may make you feel uncomfortable. If at any time you would like to stop the interview, please let a member of the study staff know.

There may be other risks that could arise which are not reasonably foreseeable. If new information becomes available which could influence your willingness to continue, this new information will be discussed with you.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct medical benefit to you. We hope the information learned from this study will benefit other individuals with high perceived social isolation in the future.

WHAT OTHER OPTIONS ARE THERE?

Participation in this study is voluntary. An alternative option to participating in the study is psychotherapy for perceived social isolation. The decision whether or not you wish to participate in this study will not affect your care at the University of Chicago Medical Center**.**

WHAT ARE THE COSTS?

Clinical services provided during a clinical trial are either research-related or related to usual medical care. Research-related services are done to complete the research and the costs are not the responsibility of you or your insurance.

The costs that are considered research-related for this study may include any additional laboratory tests, the study drug and placebo, physician visits, imaging, procedures or other clinical services that are dictated by the research protocol and only required because you are part of this study.

Usual medical care costs include any and all services that are considered medically necessary for your disease and would be done even if you were not part of this research study. This may include laboratory tests, physician visits, imaging, procedures, and other clinical services that your physician orders for your routine care. The cost of this usual, ongoing medical care will be the responsibility of you or your insurance, and may include deductibles and co-payments. Similarly, this care will be subject to all the same requirements and restrictions of your insurance.

If you have questions about whether specific clinical services are research related or usual medical care, please speak to your physician or research contact person.

If you suffer an unanticipated injury as a direct result of this research and require emergency medical treatment, the University of Chicago Medical Center will provide such treatment at the University of Chicago Medical Center at no cost to you. You must notify Dr. Cacioppo or Dr. Grant as promptly as possible after your injury in order to receive this care. An injury is “unanticipated” if it is not one of the known effects of a study drug, medical device or procedure, and is not the result of your disease or

condition. The costs of any non-emergency care for such an injury will be billed to you or your insurance in the ordinary manner. If you think that you have suffered a research related injury, you must let Dr. Cacioppo or Dr. Grant know right away.

WILL I BE PAID FOR MY PARTICIPATION?

You will receive $60 monetary compensation for your participation in the study at the end of the visit. You will also receive a parking voucher or $5 for public transportation at the end of the visit. If the study has to be interrupted before the end of your visit, your compensation will be pro-rated at $15 per hour.

WHAT ABOUT CONFIDENTIALITY?

Study records that identify you will be kept confidential. All of the data will be kept in a secure computer server and in locked filing cabinets only accessible to the research team. The data collected in this study will be used for the purpose described in the form. By signing this form, you are allowing the research team access to your medical records, which include Protected Health Information. Protected Health Information (PHI) consists of any health information that is collected about you, which could include your medical history and new information collected as a result of this study. The research team includes the individuals listed on this consent form and other personnel involved in this study at the University of Chicago. However, our study records will not include any identifiers. Your data will be thus de-identified using a coding system. Your behavioral data and EEG scan will be performed with a code number in the data field where a name would ordinarily go. Data from this study may be used in research publications or presentations or a registry shared between University of Chicago investigators. Your name and other identifying information will NOT be part of this data set.

Your records may be reviewed by federal agencies whose responsibility is to protect human subjects in research including the Food and Drug Administration (FDA) and Office of Human Research Protections (OHRP). In addition, representatives of the University of Chicago, including the Institutional Review Board, a committee that oversees the research at the University of Chicago, may also view the records of the research. If your research record is reviewed by any of these groups, they may also need to review your entire medical record.

If health information is shared outside the University of Chicago, the same laws that the University of Chicago must obey may not protect your health information.

During your participation in this study, you will have access to your medical record. Dr. Cacioppo is not required to release to you research information that is not part of your medical record.

This consent form will be kept by the research team for at least five years. The study results will be kept in your research record and be used by the research team indefinitely. At the time of study completion, either the research information not already in your medical record will be destroyed or information identifying you will be removed from

study results. Any research information in your medical record will be kept indefinitely.

Data from this study may be used in medical publications or presentations. Your name and other identifying information will be removed before this data is used. If we wish to use identifying information in publications, we will ask for your approval at that time.

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.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. If you choose not to participate in this study, your care at the University of Chicago/University of Chicago Medical Center will not be affected. You may choose not to participate at any time during the study. Leaving the study will not affect your care at the University of Chicago/University of Chicago Medical Center.

If you choose to no longer be in the study and you do not want any of your future health information to be used, you must inform Dr. Cacioppo in writing at the address on the first page. Dr. Cacioppo may still use your information that was collected prior to your written notice.

We will tell you about significant new information that may affect your willingness to stay in this study.

You will be given a signed copy of this document. This consent form document does not have an expiration date.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

You have talked to a member of the study team about this study and you had the opportunity to ask questions concerning any and all aspects of the research. If you have further questions about the study, you may call Dr. Cacioppo at (773) 702-6983.

If you have a research related injury, you should immediately contact Dr. Cacioppo at (773) 702-6983 or Dr. Grant at (773) 834-1325.

If you have any questions concerning your rights in this research study you may contact the Institutional Review Board, which is concerned with the protection of subjects in research projects. You may reach the Committee office between 8:30 am and 5:00 pm, Monday through Friday, by calling (773) 702-6505 or by writing: Institutional Review Board, University of Chicago, 5841 S. Maryland Avenue, MC7132, I-625 , Chicago, Illinois, 60637.

CONSENT

SUBJECT

The research project and the procedures associated with it have been explained to me. The experimental procedures have been identified and no guarantee has been given about the possible results. I will receive a signed copy of this consent form for my records.

I agree to participate in this study. My participation is voluntary and I do not have to sign this form if I do not want to be part of this research study.

Signature of Subject: _____
Date: _____ Time: _____ AM/PM (Circle)

PERSON OBTAINING CONSENT

I have explained to_____ the nature and purpose of the study and the risks involved. I have answered and will answer all questions to the best of my ability. I will give a signed copy of the consent form to the subject.

Signature of Person Obtaining Consent: _____
Date: _____ Time: _____ AM/PM (Circle)

PRINCIPAL INVESTIGATOR/PHYSICIAN:

Signature of Investigator/Physician _____
Date: _____ Time: _____ AM/PM (Circle)