Consent Form
And
Authorization to Use and Disclose Protected Health Information

Sponsor / Study Title:	**NIDA / "Intracranial Stimulation Mapping In Epilepsy –The InStim Study"**
Protocol Number:	**30271**
Principal Investigator:	**Alexander Herman, M.D., Ph.D.**
Telephone:	**612-625-1194** **612-946-1424 (24-Hours)**
Address:	**University of Minnesota Medical Center** **420 Delaware St. SE** **Minneapolis, MN 55455**

If your doctor is also the person responsible for this research study, please note that s/he is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Supported By: This research is supported by the National Institute of Health (NIH) National Institute on Drug Abuse (NIDA).

Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

What is research?

Doctors and investigators are committed to your care and safety. There are important differences between research and clinical (non-research) treatment plans:

- The goal of research is to learn new things in order to help groups of people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.
- The goal of clinical care is to help you get better or to improve your quality of life. Doctors can make changes to your clinical care plan as needed.

Research and clinical care are often combined. One purpose of this informed consent document is to provide you clear information about the specific research activities of this study.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you have been implanted with intracranial (inside the skull) electrodes in order to map the brain areas that are involved in electrical (epileptic) seizures and that are involved in normal brain functions, for purposes of planning your epilepsy treatment, and because you are at least 18 years old.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

Normal brain functions can be mapped by passing low levels of electrical current through intracranial electrodes, in order to determine which parts of the brain are involved in particular functions, such as movement, sensation (sight, hearing, touch and other sensation), memory and thinking. Standard clinical (non-research) testing often includes this type of intracranial electrical stimulation mapping, depending on the individual person's epilepsy and brain function.

The ways in which low levels of electrical current are applied through intracranial electrodes appear to be safe (not injurious to the brain) for planning treatment, based on studies completed a number of years ago and on continuing observations of intracranial electrical stimulation mapping for planning treatment. This electrical stimulation mapping does not cause pain and the person cannot feel the stimulation.

We think that intracranial electrical stimulation mapping may be able to locate other brain functions, in addition to those that are currently used for clinical treatment planning, by testing brain tasks that have not been standardly used. If we can improve these brain function maps, we may be able to improve the safety of epilepsy surgery in the future, or to find locations in the brain that could be useful in planning other treatments for epilepsy or other conditions that affect those functions.

How long will the research last?

The research will occur only at the end of your intracranial monitoring session. It will occur after your seizures have been recorded and after you have completed clinical (non-research) electrical stimulation mapping. At this time in the hospital admission, the person is waiting for the electrodes to be removed in the operating room. If you choose to participate in this research, electrical stimulation mapping will be performed while you are waiting for the electrodes to be removed. The research participation will not delay removal of the electrodes and will not prolong your stay in the hospital.
Your participation will occur in four 60-minute blocks per day (2 sessions in the morning and 2 sessions in the afternoon), with 15 minutes rest between blocks, with no more than 4 hours of testing per day.

What will I need to do to participate?

You will be asked to perform brief tasks, such as reading aloud and recalling what you read, or selecting responses on a computer monitor. During these tasks, the intracranial electrodes will receive low levels

of electrical current; you will not feel this current. This electrical stimulation also will occur at times when you are not being asked to perform any task.

You will not need to make any special scheduling arrangements, because you will be in the hospital room, where the study will be performed.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way that being in this study could be bad for me?

There is a possibility that seizures might occur during the time of stimulation. Sometimes a seizure during stimulation might be a seizure that would occur even if you were not receiving the stimulation (a "spontaneous" seizure), and sometimes a seizure during stimulation might be a seizure that was brought on by the stimulation (an "induced" seizure). We often cannot determine whether a seizure was spontaneous or was induced by stimulation, but in either case we will stop the stimulation immediately if you have a seizure that causes loss of consciousness or other problems. We will treat the seizure as we would treat any epileptic seizure.

More detailed information about the risks of this study can be found under ***"What are the risks of this study? Is there any way being in this study could be bad for me? (Detailed Risks)" and in the "What happens to the information collected for the research?" section.***

Will being in this study help me in any way?

We do not expect any direct benefits to you for participating in this study. It is unlikely that we would find new information that would immediately change the epilepsy surgery treatment planning for you, but if such information was found it would be communicated directly to you and your doctors. Your participation may yield information to improve brain stimulation diagnosis and treatment in the future, including for people with epilepsy.

What happens if I do not want to be in this research?

There are no known alternatives, other than deciding not to participate in this research study. If you decide not to participate in this research, you will continue to receive your standard epilepsy care.

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?

We expect about 30 participants will be in this research study.

What happens if I say "*Yes, I want to be in this research*"?

You will continue to stay in the same hospital room as earlier during this admission. The researchers will suggest times for the research. You can adjust the times and take breaks from the testing, to eat, use the bathroom, to rest or other reasons.

During the testing, you will be sitting in a chair, with a computer monitor in front of you. You will be asked to focus on the task that is presented on the computer monitor or that is given to you in other ways by the researcher.

Each task will be explained to you. You will then be asked to perform the task to the best of your ability.

The tasks may be easy or difficult. These tasks are not designed to evaluate abilities, so your performance on the tasks will not be used to rate your abilities.

The tasks are designed not to be embarrassing or upsetting. If you find some of the tasks boring or in some other way unpleasant, you can choose not to continue those tasks by informing the researcher.

While you are performing tasks or simply resting, the intracranial electrodes will receive low levels of electrical current. You will not feel this current.

The researchers will be watching the electroencephalogram (EEG) recording during the stimulation. They will stop the stimulation if you have a seizure.

What happens if I say "Yes", but I change my mind later?

If you take part in this research study, and want to leave, you should tell us. Your choice not to be in this study will not negatively affect your right to any present or future medical care. You may choose not to participate or to leave the study at any time without penalty or loss of benefits.

We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

If you stop being in the research, information about you that has already been collected may not be removed from the study database.

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

Can I be removed from the research?

It's possible that we will have to ask you to leave the study before you finish it. If you appear to be having problems during the study, we will remove you from the study, even if the electrical stimulation did not appear to be the cause. We will also help arrange other care for you, if needed.

What are the risks of being in this study? Is there any way being in this study could be bad for me? (Detailed Risks)

Privacy & confidentiality risks: There is some risk of a data breach involving the information we have about you. We comply with the University of Minnesota's security standards to secure your information and minimize risks, but there is always a possibility of a data breach.

You may have audio and video recordings taken of you for this study. It is possible that you or your voice may be recognizable and your identity may be known.

Assessment risks: There is a possibility that you may feel fatigue, embarrassment, frustration, or other challenges while in the study. You will be encouraged to take breaks and if you do not want to complete an activity in the study please let someone on the study time know. When doing the questionnaires you and may skip questions or assessments completely.

There may be risks that are unknown.

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any costs to you.

What happens to the information collected for the research, including my health information?

We try to limit the use and sharing of your information, including research study records, any medical records and any other information about you, to people who have a need for this information. But we cannot promise complete confidentiality.

Overview

If you participate in this study, your information, including your health information, will be used and shared for purposes of conducting this research. As described later in this Consent Form, your information may also be used and shared for publishing and presenting the research results, future research, and any optional elements of the research you agree to in this Consent Form and authorization, which may include creating audio and video recordings of you. If you sign and date this Consent Form and authorization, you are giving us permission to use and share your health information for these purposes, and if we are using your medical records, you are giving permission to any health care providers who are treating you to share your medical records with us.

What health information will be made available?

Health information about you to be used and shared for the research includes those items checked by the research team below:

☒ Your medical records, which may include records from hospital and clinic visits, emergency room visits, immunizations, medical history and physical exams, medications, images and imaging reports, progress notes, psychological tests, EEG/EKG (electrocardiogram)/ECHO (echocardiogram) reports, lab and pathology reports, dental records and/or financial records. These records may be used and shared for as long as this research continues.

☒ Information collected as part of this research study, including research procedures, research visits, and any optional elements of the research you agree to, all as described in this Consent Form and authorization. This information might not be part of your medical record, and may include things like responses to surveys and questionnaires, and information collected during research visits described in this Consent Form and authorization.

What about more sensitive health information?

Some health information is so sensitive that it requires your specific permission. If this research study requires any of this sensitive information, the boxes below will be marked and you will be asked to initial

to permit this information to be made available to the research team to use and share as described in this Consent Form and authorization.

☐ My drug & alcohol abuse, diagnosis & treatment records _____ (initial)
☐ My HIV (human immunodeficiency virus)/AIDS (acquired immunodeficiency syndrome) testing records _____ (initial)
☐ My genetic testing records _____ (initial)
☐ My mental health diagnosis/treatment records ____ (initial)
☐ My sickle cell anemia records _____ (initial)

Who will access and use my health information?
If you agree to participate in this study, your information will be shared with:

- The study doctor and study staff may share your information with representatives of the University of Minnesota and M Health. These people may use your information to provide oversight and administrative support for the research, conduct evaluations and reviews, and perform other activities related to the conduct of the research;
- The University of Minnesota and representatives of this institution and its affiliates, including those that have responsibilities for monitoring or ensuring compliance, such as the Quality Assurance Program of the Human Research Protection Program;
- Others at the University of Minnesota and M Health/Fairview who provide support for the research or who oversee research (such as the Institutional Review Board or IRB which is the committee that provides ethical and regulatory oversight of research at the University, systems administrators and other technical and/or administrative support personnel, compliance and audit professionals (Such as the Quality Assurance Program of the Human Research Protection Program (HRPP)) , individuals involved in processing any compensation you may receive for your participation, and others);
- The research sponsor(s), any affiliates, partners or agents of the sponsor(s) involved in the research, organizations funding the research, and any affiliates, partners or agents of the funding organization(s) involved in the research;
- Organizations who provide accreditation and oversight for research and the research team, and others authorized by law to review the quality and safety of the research (such as United States (U.S.) government agencies like the U.S. Food and Drug Administration, the Office of Human Research Protections, the Office of Research Integrity, or government agencies in other countries);
- Organizations that process any payments that may be made to you for participating in this study, and any other individuals or organizations specifically identified in this Consent Form;
- Greenphire ClinCard.

Additional sharing of your information for mandatory reporting
If we learn about any of the following, we may be required or permitted by law or policy to report this information to authorities:

- Current or ongoing child or vulnerable adult abuse or neglect;
- Communicable, infectious or other diseases required to be reported under Minnesota's Reportable Disease Rule;
- Certain wounds or conditions required to be reported under other state or federal law; or
- Excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy.

How will my information be used in publications and presentations?
We may publish the results of this research in scientific, medical, academic or other journals or reports, or present the results at conferences. Information that makes it easy to identify you (such as your name and contact information, social security number [SSN] and medical records number) will not be part of any publication or presentation. If you have an extremely unique or rare condition that is not shared by many others, it is possible that some people may be able to determine your identity even without these identifiers.

What will be done with my data when this study is over?
Your data may be used for any future research after this study is complete.

Do I have to sign and date this Consent Form and authorization and give my permission to make my information, including my health information, available for use and sharing?
No, you do not have to sign and date this Consent Form and authorization. But if you do not sign and date, you will not be able to participate in this research study. Treatment available outside of the study, payment for such treatment, enrollment in health insurance plans and eligibility for benefits will not be impacted by your decision about signing and dating this Consent Form and authorization.

Does my permission for making my health information available for use and sharing ever expire?
No, there is no expiration date.

May I cancel my permission for making my health information available for use and sharing?
Yes. You may cancel your permission at any time by writing to the researcher at the address on the first page of this Consent Form and authorization. If you cancel your permission, you will no longer be in the research study. You may also want to ask someone on the research team in canceling will affect any research related medical treatment. If you cancel your permission, any health information about you that was already used and shared may continue to be used and shared for the research study and any optional elements of the study to which you agree in this Consent Form and authorization.

What happens to my health information after it is shared with others?
When we share your information with others as described in this Consent Form and authorization, privacy laws may no longer protect your information and there may be further sharing of your information.

Will I be able to look at my records?
It is possible that the research team may not allow you to see the information collected for this study. However, you may access any information placed in your medical records after the study is complete.

A description of this clinical trial will be available at 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.

Will I receive research test results?
Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the investigator will contact you to let you know what they have found.

Certificate of Confidentiality
To help protect your privacy, the National Institutes of Health has granted a Certificate of Confidentiality. The researchers can use this Certificate legally to refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena (an order issued by a governmental agency to provide testimony or be present). The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. It is unclear if the Certificate will work in foreign countries.

The Certificate does not prevent a researcher from reporting information learned in research when required by other state or federal laws, such as mandatory reports to local health authorities for abuse or neglect of children/vulnerable adults, or information to the Food and Drug Administration (FDA) when required in an FDA audit. However, the Certificate limits the researcher from disclosing such information in follow up civil, criminal, legislative or administrative legal proceedings if the information was created or compiled for purposes of the research.

You also should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

Will anyone besides the research team be at my consent meeting?

You may be asked by the research team for your permission for an auditor to observe your consent meeting. Observing the consent meeting is one way that the University of Minnesota makes sure that your rights as a research participant are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the research team. The auditor will not document any personal (for example, name, date of birth) or confidential information about you. The auditor will not observe your consent meeting without your permission ahead of time.

Whom to Contact About This Study

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00060558.

To share feedback privately with the University of Minnesota Human Research Protection Program (HRPP) about your research experience, call the Research Participants' Advocate Line at 612-625-1650 or go to https://research.umn.edu/units/hrpp/research-participants/questions-concerns . You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

The University of Minnesota HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous. If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the University of Minnesota HRPP.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the research team or the HRPP. See the telephone number on the first page of this form for research team contact information and "Whom to Contact About This Study" of this form for HRPP contact information.

What happens if I am injured while participating in this research?

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research related injury let the study doctor know right away.

Will I be compensated for my participation?

If you agree to take part in this research study, we will pay you $20 per hour, up to $300 for the time that you spend on the computer tasks, questionnaires, and stimulation and mapping procedures during your hospital stay. You will be paid with a prepaid debit card.

Payment will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card. We will give you a debit card and each time you receive a payment for participation in this study, the money will be added to the card after each completed visit.

You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 3 months). We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. You will also receive letters

with additional information on how you can use this card and who to call if you have any questions. Be sure to read these letters, including the cardholder agreement, for details about fees.

The debit card system is administered by an outside company. The company, Greenphire, and MasterCard, will be given your name and address and social security number. They will use this information only as part of the payment system. Your information will not be used for any other purposes and will not be given or sold to any other company. Greenphire and MasterCard will not receive any information about your health status or the study in which you are participating.

Payment you receive as compensation for participation in research is considered taxable income. If payment to an individual equals or exceeds $600 in any one calendar year, the University of Minnesota is required to report this information to the Internal Revenue Service (IRS). Research payments to study participants that equal or exceed $600 during any calendar year will result in a FORM 1099 (Miscellaneous Income) being issued to you and a copy sent to the IRS.

Optional Element:

The following research activity is optional, meaning that you do not have to agree to it in order to participate in the research study. Please indicate your willingness to participate in this optional activity by placing your initial next to the activity.

Yes, I agree	**No, I disagree**	
_____	_____	The investigator may record audio or video of me to aid with data analysis. The investigator will not share these recordings with anyone outside of the immediate research team.

SIGNATURES:

Your signature documents your permission to take part in this research. You will be provided a copy of this signed and dated document.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent