Cover Page

Document: Informed Consent Form: ICF Part 2

Official Title of Study: Subcortical-cortical network dynamics of anesthesia and consciousness (Noted at top of following document)

NCT04502550

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Local Context Information Sheet about participation in a research study titled: Subcortical-cortical network dynamics of anesthesia and consciousness

To be conducted at
The University of Texas Southwestern Medical Center

Part 2

Who is conducting the study? The lead Principal Investigator (PI) for this multi-site study is Dr. Nader Pouratian, MD, PhD, Department of Neurological Surgery at UT Southwestern Medical Center. Dr. Nader Pouratian, a neurosurgeon at UT Southwestern Medical Center is the local researcher conducting the study at the UT Southwestern Medical Center.

This information sheet will describe any information that you need to know that is specific to UT Southwestern Medical Center. You will also be given the Part 1 informed consent document that will describe the purpose of the study and what will be done. You should talk to the researchers about this study if you have any questions.

Your doctor is a research investigator in this study. He is interested in both your medical care and the conduct of this research study. At any time, you may discuss your care with another doctor who is not part of this research study. You do not have to take part in any research study offered by your doctor.

Site-specific Procedures and Risks

All procedures outlined in the Part 1 general consent form under "DBS Implantation Study Procedures" will take place at the UT Southwestern Medical Center site.

Procedures outlined under "DBS Pulse Generator Implantation or replacement Study Procedures" differ in that there will be no blood draw at UT Southwestern Medical Center, and all participants will receive deep brain stimulation at therapeutic frequencies during propofol administration.

The risks associated with participation are the same as the risks explained in the Part 1 general consent form.

Compensation

You will be issued a UT Southwestern Greenphire ClinCard (amount of $50), which can be used as a credit or debit card. Compensation will be credited to the card after completion of the consent. 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.

Costs – Will taking part in this study cost anything?

You or your health insurance company will be responsible for the cost of treatments and procedures that would be done whether or not you took part in this study, such as deep brain stimulation surgery. It is important to understand that some insurance companies may not cover these costs because you are in a research study. If this happens you might have unexpected expenses from being in this study, such as the costs associated with treating side effects. If your insurance company does not cover these treatments or procedures, you will be required to pay for them. Ask the researchers if you have any questions about what it will cost you to take part in this study (for example bills, fees, or other costs related to the research).

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The sponsor will provide the study drug/device free of charge during this study. The sponsor will also pay for the cost of additional time in the operating room.

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.

Neither the University of Texas Southwestern Medical Center, its affiliates, or the University of California, Los Angeles have a program to pay you if you are hurt or have other bad results from being in the study. 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.

Additional information about your local site:

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. Medical information collected during this study and the results of any test or procedure that may affect your medical care may be included in your medical record. The information included in your medical record will be available to health care providers 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 whose 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:

- Information obtained from your medical record
- Information related to your medical history and treatments prior to the study
- Information that is created or collected during your participation in the study including medical / treatment history and relevant imaging
- Demographic information like your age, race, ethnicity, gender, type of work you do, the years of education you have completed, contact information, and home address

We will get this information by asking you, asking your doctor, and/or by looking at your chart at the University of Texas Southwestern Medical Center.

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 Health General Medical Sciences, 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 following collaborators at other institutions that are involved with the study: University of California, Los Angeles
- 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 UTSW 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 Research offices at: the University of Texas Southwestern Medical Center
- 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.

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 University of Texas Southwestern Medical Center and the University of California, Los Angeles for review or testing. 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 the UT Southwestern study team (please refer to address below in the “Contact Information” section). 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:

Primary contact:
Emily Koenig, Research Assistant can be reached at (214)645-5465, or emily.koenig@utsouthwestern.edu.

Mailing Address:
Dr. Nader Pouratian
UT Southwestern Medical Center
Dept. of Neurological Surgery
Dr. Nader Pouratian, MC 8855
5323 Harry Hines Blvd.
Dallas TX 75390-8855

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.

This form is yours to keep.

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 Part 1 and Part 2 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 the Part 1 and Part 2 signed consent document, information about this study, and the results of any test or procedure that may affect your medical care, may be included in your medical record. Information in your medical record will be available to health care providers 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

Blind or Illiterate Signature Section *At the time of consent, also complete this section if consent is obtained from an individual who is unable to read and/or write but can otherwise communicate and/or comprehend English (e.g., blind, physically unable to write, etc.)*

Declaration of witness:

By signing below, I confirm I was present for the entire consent process. The method used for communication (e.g., verbal, written, etc.) with the subject was: _____.

The specific means (e.g., verbal, written, etc.) by which the subject communicated agreement to participate was: _____.

Printed Name of Witness	Signature of Witness	Date	Time AM PM