Informed Consent Form

Cortical Electrophysiology of Response Inhibition in Parkinson's Disease

IRB Approval Date: January 30, 2025

NCT06234995

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 40 people who are being studied at Emory.

Why is this study being done?

This study is being done to answer the question: how does brain activity (brain waves) change when people try to start and stop movements, and how does having Parkinson's disease or deep brain stimulation affect that ability. You are being asked to be in this research study because you have Parkinson's disease and plan to undergo deep brain stimulation surgery.

Do you have to be in the study?

It is your choice to join this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you choose, take time to learn about the study.

What do you have to do if you choose to join this study?

If you qualify and choose to join the study, you will participate for 18 months (4 study visits). The researchers will ask you to do the following: perform a computer response task while recording brain wave activity (in the clinic and in the operating room). All of these procedures will be paid for by the study.

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question. This study is not intended to benefit you directly.

What are the risks or discomforts you should know about before deciding?

The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious. Risks for this study include:

- loss of privacy
- breach of confidentiality

You can find a full list of expected risks, their frequency and severity in the section titled "What are the possible risks and discomforts?"

Alternatives to Joining This Study

Since this is not a treatment study, the alternative is not to participate.

Costs
There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities.

There is more information in the "Costs" section further below.

What Should You Do Next?
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions such as how much time you will have to spend on the study, any words you do not understand and more details about study procedures. Make sure you understand which parts of the study are research and which are standard care that you would have even if you did not join the study. Take time to think about this and talk about it with your family and friends.

Emory University
Consent to be a Research Subject / HIPAA Authorization

Title: Cortical electrophysiology of response inhibition in Parkinson's disease (PATIENT)

IRB #: STUDY00007291

Principal Investigator: Svjetlana Miocinovic, MD, PhD

Study Supporter: National Institutes of Health (NIH)

Introduction
You are being asked to be in a medical research study. This form tells you what you need to think about before you choose if you want to join the study. **It is your choice. If you choose to join, you can change your mind later and leave the study.** Your choice will not cause you to lose any medical benefits. If you choose not to join this study, your doctor will still treat you.

Before you decide:
- Read this form or have it read to you
- Listen to the study doctor or study staff explain the study to you
- Ask questions about anything that is not clear

You will get a copy of this form. Take your time to think about joining the study. You may wish to discuss it with family or friends. Do not sign this form if you still have questions or something does not make sense to you. By signing this form, you will not give up any legal rights.

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials.

What is the purpose of this study?
We want to learn more about the cortex and basal ganglia, which are brain structures involved in Parkinson's disease (PD). We want to study how changes in brain activity are different between people with and without PD while they are starting and stopping movements. We also want to better understand how brain activity changes with treatment (medications or deep brain stimulation (DBS)).

What will you be asked to do?
The study consists of 3 phases (before, during and after DBS surgery):

- Phase 1 is one research visit before DBS surgery to record an EEG (brain waves) while you perform a computer test to measure response times, off and on levodopa.
- Phase 2 of the study occurs during the DBS surgery - it involves doing about 15 extra minutes of brain activity recordings with temporary research recording electrodes placed through the same skull entry hole as the DBS electrode.
- Phase 3 is two EEG visits about 6-12 months after the surgery, where you will do the same computer tests at different DBS settings.

In-clinic visits (Phase 1 and 3):
1.The study doctor will check your medical records to gather information about your medical history, movement disorder history and treatments, including medications, DBS settings (if applicable), and information from clinical rating scales and clinical neurocognitive testing.

2. We will ask you to hold your PD medications for 12 hours on the day you come for the study (same as for clinical evaluations).

3. For the EEG recording session, a cap (similar to a swim cap) will be placed on your head and electrodes attached. Some gel will be placed in your hair/on your head so that the electrodes can get a good connection to detect any electrical charges that come from brain activity. This gel can be easily removed with hair washing. You will not have any hair shaved. We also may place a few flat electrodes on the skin over other parts of your body (such as arms or face) to record changes in muscle activity and eye movements. If you have DBS device with sensing capabilities, we may record and download brain activity data from the device.

4. During the EEG study session you will be seated in a chair. You will be asked to rest quietly with your eyes open and to perform a computer task with button presses. EEG recording will be done off and on PD medication. If you have DBS, recordings will be done off medications and with stimulation settings different from your clinically optimized setting.

5. Video-recorded clinical PD exam will be done for the study. You will not be able to participate in the study if you do not wish to be videotaped, as capturing your motor symptoms is essential to the study.

Each EEG visit will last about 3 hours.

Intraoperative recording (Phase 2):
1. During the DBS surgery you will have brain recordings to help your surgeons find the best target for the DBS implant. You will also have neurological exams to help the doctors know which brain cells are being tested and if the DBS electrode is in an appropriate position. This procedure is the same whether you participate in this research study or not.

In addition to these routine procedures, the surgeon will temporarily place two thin electrodes on the surface of the brain to record brain activity. These electrodes are placed through the same skull opening used to place the DBS electrode into the brain and will be removed at the end of surgery. We will also attach small sensors to your skin to measure your movements and muscle signals. We may also attach skin electrodes to your scalp to measure brain activity. This will only be done if you participate in the study. You may still be in the study even if you do not want these additional electrodes placed on the brain surface (you can choose at the bottom of this form).

2. During the surgery you will be asked to perform a computer task that involves looking at the screen and pressing buttons. You do not have to do any tasks that you do not want to, and you can change your mind anytime, even during the surgery. This part of the procedure is only required for the study and is not necessary for correct placement of the DBS electrode. This part of the procedure will not affect the positioning of the DBS electrode. If you are not awake during surgery, you will not be asked to perform the research task.

3. During the surgery, the doctors will apply test stimulation to your brain. This is done for the routine DBS surgery to test the placement of the electrode. Additional stimulation with the DBS electrode will be done for the study.

4. When you finish the study, your surgery will be completed in the same way as all DBS surgeries. After the surgery, you will spend at least one night in the hospital, and you will have an MRI the following day to check the DBS electrode position. This is the same whether you participate in this study or not.

The time required for the surgery portion of the research study will be about 15 minutes (in addition to time needed for routine procedures).

Who owns your study data and samples?
If you join this study, you will be donating your data. You will not be paid if your data is used to make a new product. If you leave the study, the data that was already collected may be still be used for this study.

What are the possible risks and discomforts?
There are no known risks of EEG brain wave recordings. The gel in the hair can be sticky and can affect appearance but can be easily removed with shampooing. There is a risk of boredom during the EEG session. We will minimize this risk by offering frequent breaks. Downloading data from sensing DBS device (if you have one) will reduce battery longevity by 1 day for every 1 hour of downloading.

There may be discomfort associated with being off medication and/or DBS, as PD symptoms may worsen (for instance, rigidity, tremor, or dystonia). If you become too uncomfortable, you can request to skip the off-treatment portion of the study visit or stop the study visit entirely.

The risk of standard DBS surgery includes bleeding, stroke, infection and seizure. Your doctors will discuss these risks with you. If you participate in this study, there are some extra possible risks or discomforts. During your surgery, you will need to be still and follow instructions given to you by the study staff. This may be uncomfortable because of your position on the operating table. You may stop research tasks at any time if you are too uncomfortable. Placement of cortical electrodes may cause damage or bleeding on the surface of the brain, but this is extremely unlikely. Placement of temporary electrodes and prolonging surgery by 20 minutes (to place research electrodes and perform the task) may increase the risk of infection, but this is also unlikely.

There is a risk of accidental release of personal health information that is collected for the research. To minimize this risk, all information will be kept on password-protected computers and in a locked cabinet accessible only to the researchers.
Researchers may learn something new during the study that may affect your choice to be in the study. If this happens, they will tell you about it. Then you can choose if you want to stay in this study. You may be asked to sign a new form if you choose to stay in the study.

Will you benefit from the study?
There will be no direct benefit to you from participating in this study. However, this study will help researchers learn more about changes that occur in Parkinson's disease. It is hoped that this information will help in the treatment of future patients with deep brain stimulation.

Will you be paid for your time and effort?
You will get a $50 gift card for each completed EEG study visit, for your time and effort. If you do not finish the study, we will compensate you for the visits you have completed. You will get $150 total, if you complete all study visits. You will not be compensated for the intraoperative portion of the study.

If you would have difficulty participating in a research visit due to travel requirements (for example, if you have difficulty traveling in the medication off state), you will be provided a hotel room for one night (or be reimbursed for one night hotel stay up to $250) and provided a meal allowance for yourself and a caregiver ($25 per person) for each research visit that includes a hotel stay. If you are traveling more than 50 miles to and from the research site specifically for research purposes (meaning your research visit is not combined with a routine clinical appointment), you will additionally be compensated for mileage (via check or gift card; using standard government mileage rates).

You may be asked to fill out a tax form with your Social Security or Taxpayer Identification Number depending on the amount and method of payment. If your payment will be sent to your house in the mail and could be seen by others in your household you can choose not to be compensated. You can decline payment if you are concerned about confidentiality, or you can talk to the study team if there are other ways to be compensated.

What are your other options?

You do not have to enter this study. The care you are receiving from your regular doctors will be unaffected.

How will your private information be protected?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

We will store all the data that you provide using a code. We need this code so that we can keep track of your data over time. This code will not include information that can identify you (identifiers). Specifically, it will not include your name, initials, date of birth, or medical record number. We will keep a file that links this code to your identifiers in a secure location separate from the data.

We will not allow your name and any other fact that might point to you to appear when we present or publish the results of this study.

Your data may be useful for other research being done by investigators at Emory or elsewhere. We may share the data, linked by the study code, with other researchers at Emory, or with researchers at other institutions that maintain at least the same level of data security that we maintain at Emory. We will not share the link between the study code and your identity.

We may also place data in public databases accessible to researchers who agree to maintain data confidentiality, if we remove the study code and make sure the data are anonymized to a level that we believe that it is highly unlikely that anyone could identify you. Despite these measures, we cannot guarantee anonymity of your personal data.

We will use your data only for research. We will not sell them. However, the results of this research might someday lead to the development of products that could be sold by a company. You will not receive money from the sale of any such product.

Returning Results to Participants
In general, we will not give you any individual results from the study. If we find something of medical importance to you, we will inform you, although we expect that this will be a rare occurrence (for example, if we find DBS settings that may offer better therapeutic benefit than your clinical settings, we will inform you and your neurologist).

Medical Record
If you have been an Emory patient before, then you already have an Emory medical record. If you have never been an Emory patient, you do not have one. An Emory medical record will be made for you if an Emory Atlanta provider or facility gives you any services or procedures for this study. Copies of the consent form/HIPAA authorization that you sign will be put in any Emory medical record you have now or any time during the study. The results of the study tests (brain wave recordings and exams during research visits) will be used only for research purposes and will not be placed in your medical record.

In Case of Injury
If you get ill or injured from this research, contact the person listed in the contact section of this form. Emory will help you get immediate medical care. However, Emory, the Federal Government (including but not limited to the National Institutes of Health as applicable) do not have programs to pay for this medical care or compensate you if you are hurt from being in this study.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

You do not give up any legal rights you may have by being in this study, including any right to pursue a claim through the legal system.

Costs
There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities. If the study procedures result in any medical complications that would not fall under “injury” as discussed above, the cost of treatment for those complications may be charged to you or your insurance.

Withdrawal from the Study
You have the right to leave a study at any time without penalty.

The researchers also have the right to take you out of the study without your consent for any reason. They may do this if they believe it is in your best interest or if you do not agree to changes that may be made in the study.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. As part of this study, we will be requesting health care entities who are covered by the Health Insurance Portability and Accountability Act and regulations (HIPAA) to provide us with health information that identifies you (“individually identifiable health information”

or "IIHI"). Because the health care entities are covered by HIPAA, we must have your authorization to obtain your IIHI from them. However, the researchers who get your IIHI from the health care entities are not covered by HIPAA. Once they receive your IIHI from the health care entities, they will put it in a separate research record that is not a part of your medical record. IIHI placed in the separate research record is not be covered by HIPAA.

Purpose of this Authorization:
By signing this form, you give us permission to get your IIHI from health care entities and to use and share your IIHI as described in this document. You do not have to sign this form. If you do not sign this form, then you may not participate in the research study.

No Provision of Treatment
There is no research-related treatment involved in this study. You may receive any non-research related treatment whether or not you sign this form.

IIHI that Will be Used/Disclosed:

The IIHI that we will use or share for the research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your IIHI Will be Used/Disclosed:
We will use and share your IIHI for the conduct and oversight of the research study. Once we have your IIHI we will keep it in a separate research record that will be used for the conduct of the study. If you leave the study, we may use your IIHI to determine your vital status or contact information.

Use and Disclosure of Your IIHI That is Required by Law:
We will use and disclose your IIHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults.

People Who will Use/Disclose Your IIHI:
The following people and groups will use and disclose your IIHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your IIHI to conduct the study.
- Emory may use and disclose your IIHI to run normal business operations.
- The Principal Investigator and research staff will share your IIHI with other people and groups to help conduct the study or to provide oversight for the study. This includes sharing your IIHI with people and groups at other sites who are helping conduct the study.
- The following people and groups will use your IIHI to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration. These include the Emory IRB, the Emory

University and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including: Office for Human Research Protections.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your IIHI may be shared with that new institution and their oversight offices.

Expiration of Your Authorization
Your IIHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your IIHI. If you want to do this, you must contact the study team at:

Dr. Svjetlana Miocinovic
Emory Brain Health Center
[redacted]

At that point, the researchers would not collect any more of your IIHI. But they may use or disclose the information you already gave them as described in this Authorization. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. HIPAA does not apply to research that does not include treatment that is billed to insurers or government benefit programs. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them. The researchers and people and companies working with them are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.

To maintain the integrity of this research study, you generally will not have access to your IIHI related to this research until the study is complete. When the study ends, and at your request, you generally will only have access to your IIHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. You will not have a right of access to IIHI kept in a separate research record used only for research purposes. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your IIHI. Information without identifiers is not subject to HIPAA and may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

Contact the study coordinator [redacted] or study doctor Svjetlana Miocinovic at [redacted]:

- if you have any questions about this study or your part in it,
- if you have questions, or concerns about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have complaints about the research or an issue you rather discuss with someone outside the research team.

You may also let the IRB know about your experience as a research participant through our Research Participant Survey at **https://tinyurl.com/ycewgkke.**

Consent and Authorization

Please initial below if you opt to participate in and authorize use and disclosure of your PHI in the optional studies described above.

YES	NO	
_____	_____	Using cortical electrodes to study surface brain activity during surgery.

TO BE FILLED OUT BY SUBJECT ONLY

Print your name, **sign**, and **date** below if you choose to be in this research study. You will not give up any of your legal rights by signing this form. We will give you a copy of the signed form to keep.

_____

Name of Subject

_____ _____

Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____

Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**