University of Southern California
Department of Neurological Surgery
1200 N State Street, Suite 3300
Los Angeles, CA 90033

Informed Consent to take part in a Human Research Study

Protocol Title: Evaluation of neurocognitive changes in Parkinson's disease patients with deep brain stimulation
Principal Investigator: Darrin Lee, MD, PhD
Department: Neurological Surgery
24-Hour Telephone Number**:** 800-872-2273

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

You have been asked to participate as a subject in a medical experiment. Before you decide whether you want to participate in the experimental procedure, you have a right to the following information:

CALIFORNIA LAW REQUIRES THAT YOU MUST BE INFORMED ABOUT:

1. The nature and purpose of the study.
2. The procedures in the study and any drug or device to be used.
3. Discomforts and risks reasonably to be expected from the study.
4. Benefits reasonably to be expected from the study.
5. Alternative procedures, drugs, or devices that might be helpful and their risks and benefits.
6. Availability of medical treatment should complications occur.
7. The opportunity to ask questions about the study or the procedure.
8. The ability to withdraw from the study at any time and discontinue participation without affecting your future care at this institution.
9. Be given a copy of the signed and dated written consent form for the study.
10. The opportunity to consent freely to the study without the use of coercion.

I have carefully read the information contained above and I understand fully my rights as a potential subject in this study.

Date: _____ Time: _____

Signature: _____
(Research Participant)

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KEY INFORMATION

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A person who takes part in a research study is called a "research participant." The use of "you" in this consent form refers to you as the research participant. The study Investigator will be called the "study doctor" throughout this consent form.

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

Why am I being invited to take part in a research study?

We are inviting Parkinson's disease patients with deep brain stimulation electrodes in the subthalamic nucleus to take part in this research study.

What should I know about being in 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 may discuss whether to participate with family, friends and/or your doctor.
- You can ask any questions before making a decision.

Why is this research being done?

We are trying to understand the mechanisms underlying the effectiveness of deep brain stimulation (DBS) in patients with Parkinson's disease (PD). Currently we know that DBS is beneficial for improving the motor symptoms of PD. However, some studies also suggest that DBS may help to improve other cognitive functions such as memory, decision-making, and impulsivity. The aim of this study is to confirm if DBS in PD patients affects these other brain processes and, if so, to understand how these improvements take place. Such an understanding may help us to better determine how the brain is wired, which could form the basis for future treatments in the future.

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How long will I take part in this research?

We expect that as a minimal time commitment you will take part in this research for at least one day, with your research sessions lasting approximately two hours.

Depending on our research findings or expansion of the study, we may ask you to take part in additional research sessions in the future.

You will be asked to come into the clinic for at least one study visit in order to complete a series of neuropsychological tests.

More detailed information about the study procedures can be found under the *"What can I expect if I take part in this research*?" section.

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

This study is comprised of a series of neuropsychological test (e.g. being asked to list a series of numbers or adding numbers together quickly). These test are analogous to playing a game and are not expected to pose significant risks. Some risks include psychological stress from the test. Other risks include brief worsening of Parkinson's disease symptoms while the stimulation parameters are being changed.

More detailed information about the risks of this study can be found under the *"What are the risks and possible discomforts?"* section.

Will being in this study help me in any way?

There are no direct benefits to you from your taking part in this research

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

Participation in research is completely voluntary. You do not have to take part in this study and continue with your regular care.

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To follow, please find more detailed information about this study than already provided above.

About this consent form

Please read this form carefully. It provides important information about participating in research. You have the right to take time in making decisions about participating in this research. If you have any questions about the research or any portion of this form, you can ask us at any time. If you agree to participate in this research you will be asked to sign this form. A copy of the signed form will be provided to you for your records.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at Dr. Darrin Lee: Darrin.Lee@med.usc.edu.
This research has been reviewed by the USC Institutional Review Board (IRB). If you wish to speak with someone from the IRB, you may contact the IRB at (323) 442-0114, by email at irb@usc.edu, or by mail at the following address:

USC Institutional Review Board (IRB)
1640 Marengo St., Suite 700
Los Angeles, CA 90033

The IRB is available between the hours of 8:00 AM and 4:00 PM, Monday to Friday. Contact the IRB for any of the following:

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

Participation is voluntary

You are invited to take part in this research because you have Parkinson's disease and have been treated with deep brain stimulation as part of your regular care. It is your choice whether or not to participate. If you chose to participate, you may change your mind and leave the study at any time. Refusal to participate or stopping your participation will involve no penalty or loss of benefits to which you are otherwise entitled.

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How many people will take part in this research?

About 30 people will take part in this research. This study aims to investigate the effects of different deep brain stimulation settings on cognitive functions such as memory, decision-making, and impulsivity. This could help us learn which settings are best for Parkinson's patients and better understand how beep brain stimulation works.

What can I expect if I take part in this research?

As part of your treatment for Parkinson's disease, you had a deep brain stimulator inserted. Different stimulation settings can affect your thought process in different ways and we will be testing you on a series of neuropsychological tests while changing these settings. These tests are specifically designed to evaluate your cognitive function and are used for research purposes only.

As a participant, you will take four different tests with your deep brain stimulation on the normal setting and then will repeat the same four tests with your deep brain stimulation setting changed to low frequency, high frequency, and off. During these different stimulation settings, you may notice temporary worsening of your Parkinson's disease symptoms. In total, you will take these the tests four times and the session will last approximately three hours. These tests include the following:

Random Number Generation Test (5 minutes)

You will be asked to say a sequence of 100 numbers (each number ranging from one to nine) as randomly as possible, every second.

Verbal Fluency (5 minutes)

You will be asked to list as many words in a specific category as you can in one minute.

Color-Word Interference Test (10 minutes)

You will be presented with a page containing a series of colored words and asked to say the color or name of the words as quickly as you can without making mistakes.

Quotient Task (20 minutes)

This test, called Pearson Quotient task, is similar to a video game. You will face a computer screen, wearing a head band and will need to press the computer space bar when instructed.

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What are my responsibilities?
As a participant, you are responsible for showing up for your scheduled research session on time and completing the tasks to the best of your ability.

What are the risks and possible discomforts?
This study involves neuropsychological testing, and you may experience tiredness, fatigue, boredom or frustrations. There is the possibility of experiencing discomfort during the testing period. If this occurs, you will have the option to stop testing at any point in time.

Turning off or lowering the frequency of your deep brain stimulation settings for the purposes of this study may involve temporary worsening of your Parkinson's disease symptoms. There is a risk of breach of confidentiality, although specific protocols are in place to prevent any such occurrence.

Possible side effects of stimulations include discomfort, numbness or tingling sensations, muscle tightness of the face or arm, speech problems, balance problems, lightheadedness, vision problems such as double vision, and/or unwanted mood changes, such as anger and depression.

What happens if I get hurt during the Study?
If you think you have been hurt by taking part in this study, tell the study doctor immediately. If you require treatment because you were injured from participating in this study, treatment will be provided. You or your health plan/insurance will be billed for the cost of this treatment.

There are no plans to offer any type of payment for injury. However, by signing this form you have not given up any of your legal rights.

Are there any benefits from being in this research study?
There are no direct benefits to you from your taking part in this research.

What happens if I say yes, but I change my mind later?
You can leave the research at any time. Your decisions will not be held against you.

If you withdraw from the study, you will no longer be able to participate in the study. No new information or samples will be collected about you or from you by the study team. Your withdrawal has no effect on the lawfulness of the data processing that occurred prior to your withdrawal.

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Can I still get medical care at USC if I choose not to participate in this research*?*

Yes, you may still get medical care at USC if you choose not to participate in this study. Your decision will not change the care you receive now or in the future. Taking part in this research is your choice. If you decide to take part in this study, you may leave/stop the study at any time. There will be no penalty to you and your medical care will not be affected. If you would like to stop participating in this research you should let us know. We will make sure that you stop the study safely.

It is possible that the investigator may ask you to stop the study before it is finished. If this happens we will tell you why and arrange for other care for you if needed.

Will I be compensated for participating in this research?

You will not be compensated for your participation in this research.

What will I have to pay for if I participate in this research?

There is no cost to you for taking part in this study.

If I take part in this research, how will my privacy be protected? What happens to the information you collect?

We will keep your records for this study confidential as far as permitted by law. However, if we are required to do so by law, we will disclose confidential information about you. Efforts will be made to limit the use and disclosure of your Personal Information, including research study and medical records, to people who are required to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the USC IRB and other representatives of collaborating organizations or institutions.

Data from this study will be kept on password-protected devices with encryption. Only members of the study team will have access to this data. Data will be kept for at least two years following completion of this study in case required for follow-up studies.

If identifiers are removed from your identifiable private information that are collected during this research, that information could be used for future research studies or distributed to another investigator for future research studies without your consent.

Federal law provides additional protections of your medical records and related health information. These are described in the HIPAA Authorization document. You will be

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asked to sign a separate HIPAA Authorization for Research form authorizing the access, use, creation, and disclosure of your health information.

Can I be removed from the research without my approval?

The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal include that you no longer meet the criteria for inclusion in the study, either due to a change in your clinical condition or a change in the inclusion/exclusion criteria. We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

If you are having a medical emergency, while you are participating on the study, call 911 or go to an emergency room right away. You should let emergency personnel or providers know that you are taking part in this study.

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STATEMENT OF CONSENT

I have read (or someone has read to me) the information provided above. I have been given a chance to ask questions. All my questions have been answered. By signing this form, I am agreeing to take part in this study.

Name of Research Participant	Signature	Date Signed (and Time*)

Person Obtaining Consent

I have personally explained the research to the participant and/or the participant's legally authorized representative using non-technical language. I have answered all the participant's questions. I believe that he/she understands the information described in this informed consent and freely consents to participate.

Name of Person Obtaining Informed Consent	Signature	Date Signed (and Time*)

A Witness is Required When:

(1) the participant cannot see, read, write, or physically sign the consent form, or
(2) the Short Form method is used to obtain consent.
In these situations, the witness must sign and date the consent form.
If no witness is needed, leave this signature line blank.

Name of Witness	Signature	Date Signed

** If a study procedure is done on the same day the informed consent is signed, the time and date are required. No study procedures may be done before the participant has signed the informed consent.*