University of Southern California
Department of Neurological Surgery
USC Neurorestoration Center
1333 San Pablo Street, MCH B51A
Los Angeles, CA, 90033

Study Title: Evaluation of Neurocognitive Changes in Parkinson's Disease Patients with Deep Brain Stimulation

Principal Investigator: Darrin. J. Lee, MD, PhD

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)

INFORMED CONSENT FOR RESEARCH

Study Title: Evaluation of Neurocognitive Changes in Parkinson's Disease Patients with Deep Brain Stimulation

Principal Investigator: Darrin. J. Lee, MD, PhD

Department: Neurological Surgery

24-Hour Telephone Number: 1800 USC CARE

INTRODUCTION

We invite you to take part in a research study. Please take as much time as you need to read the consent form. You may want to discuss it with your family, friends, or your personal doctor. If you find any of the language difficult to understand, please ask questions. If you decide to participate, you will be asked to sign this form. A copy of the signed form will be provided to you for your records.

KEY INFORMATION

The following is a short summary of this study to help you decide whether you should participate. More detailed information is listed later in this form.

1. Being in this research study is voluntary–it is your choice.

2. You are being asked to take part in this study because you have a diagnosis of Parkinson's Disease and have a Deep Brain Stimulator (DBS) as part of your treatment plan. The purpose of this study is to determine whether changes in the stimulation settings of your deep brain stimulator will change/improve your abilities to understand, remember and pay attention. Your participation in this study will last one year. Procedures will include clinic visits for up to two hours at a time to complete multiple brain health assessments and 3 functional MRI scans (fMRIs).

3. There are risks from participating in this study. The most common risk is that your movement abilities may worsen when stimulation changes are made. Also, some people experience anxiety undergoing an MRI due to the confined space and loud banging of the MRI. There is also a risk of injury if metal is brought into the MRI, which will be pulled by the MRI magnet when close by. More detailed information about the risks of this study can be found under the "Risk and Discomfort" section.

4. The possible benefits to you for taking part in this study may include an improvement in your abilities to understand, remember and pay attention

   You may not receive any direct benefit from taking part in this study. However, your participation in this study may help us learn more about how brain stimulation using a DBS effects brain function.

5. If you decide not to participate in this research, your other choices may include not participating, continuing your current medical care for your condition and/or participate in other research studies.

DETAILED INFORMATION

PURPOSE

The purpose of this study is to determine whether changes in the stimulation settings of your deep brain stimulator will change/improve your abilities to understand, remember and pay attention. We hope to learn whether specific brain stimulation settings improve brain function. You are invited as a possible participant because you have Parkinson's Disease and have a deep brain stimulator as part of your medical treatment. About 32 participants will take part in the study.

PROCEDURES

All procedures are done solely for the research study.

If you decide to take part, this is what will happen.

You will be asked to complete 3 fMRI's during this study. The MRI will last no more than an hour, during which you will be asked to lie still and also to focus on an object during the scan. No contrast (dye) will be used for this MRI.

DBS stimulation changes. There will be two types of stimulation settings that will be used in this study. They will be referred to as randomization group 1 and group 2. You will be enrolled in both groups at different times. Only the person programming your DBS will be aware of the stimulation settings.

Visit 1
Baseline
You will be asked to complete multiple paper and computer- based tasks which will assess your brain function. Once completed your DBS stimulation settings will be changed and you will be enrolled in either randomization group 1 or 2. You will be monitored for any changes in your physical wellbeing before the visit ends. If you experience unwanted and/or worse physical symptoms, your settings will be reverted back to your baseline, and you will be excluded from the study. If you tolerate the changes your DBS will remain on these new settings.

You will be asked to undergo an fMRI at this visit.

Visit 2
Session 2
About 1 week after your first visit, you will be assessed for any physical changes in your condition. You will be asked to complete multiple paper and computer-based assessments Changes will be made to your stimulation settings. You will be enrolled in randomization group 1 or 2.

Visit 3
Session 3
About 3 months after your last visit, you will repeat the brain function tasks completed in Visits 1 and 2. You will be assessed for any physical changes in your condition. Once these tasks are completed, your DBS stimulation settings will be changed again to either randomization group 1 or 2.

Visit 4
Session 4
About 3 months after your last visit, you will repeat the brain function tasks completed in previous visits. You will be assessed for any physical changes in your condition. Once these tasks are completed, your DBS stimulation settings will be changed again to either randomization group 1 or 2

You will be asked to undergo an fMRI at this visit.

Visit 5
Session 5
About 3 months after Visit 3 your last visit will repeat the brain function tasks. You will be assessed for any physical changes in your condition. Once these tasks are completed your DBS stimulation settings will be changed again into one of the randomization groups.

You will be asked to undergo an fMRI at this visit.

Visit 6
Session 6
About 6 months after your last visit, you will repeat the brain function tasks. You will be assessed for any physical changes in your condition. Once these tasks are completed your DBS settings will be changed back to your original settings

You will be asked to undergo an fMRI at this visit.

All visits will last approximately 2 hours.

RISKS AND DISCOMFORTS

Possible risks and discomforts you could experience during this study include:

Changing the DBS settings: Your movement abilities may worsen. If this happens, we will stop the stimulation and revert you to your baseline DBS settings

fMRI Scan: Feelings of claustrophobia and anxiety may be experienced. Feeling warm during the scan may also occur. The loud banging noise during the scan may cause discomfort and you will be asked to wear ear plugs. There is also a risk of injury if metal is brought into the MRI, which will be pulled by the MRI magnet when close by.

Surveys/Questionnaires/Interviews: Some of the questions may make you feel uneasy or embarrassed. You can choose to skip or stop answering any questions you don't want to.

Breach of Confidentiality: There is a small risk that people who are not connected with this study will learn your identity or your personal information.

Unforeseen Risks: There may be other risks that are not known at this time.

BENEFITS

The potential benefits to you may include an improvement in your brain function during this study.

PRIVACY/CONFIDENTIALITY

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 may publish the information from this study in journals or present it at meetings. If we do, we will not use your name.

The University of Southern California's Institutional Review Board (IRB) may review your records.

Federal law provides additional protections of your medical records and related health information. These are described in the HIPAA Authorization document. You will be asked to sign a separate HIPAA Authorization for Research form authorizing the access, use, creation, and disclosure of your health information.

Your data will be stored on electronic devices which only research staff will have access to. Your data will not be labeled with personal identifying information, but with a research code that only the research staff can link to your personal information. Devices will be password protected and installed with security software for data protection. Your data will be kept for 5 years and may be used by the investigator for future research.

ALTERNATIVES

An alternative would be not to take part in this study and continue with your current care.

PAYMENTS / COMPENSATION

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

COST

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

INJURY

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.

NEW INFORMATION

We will tell you about any new information that may affect your health, welfare, or willingness to stay in the research.

VOLUNTARY PARTICIPATION

It is your choice whether to participate. If you choose to participate, you may change your mind and leave the study at any time. If you decide not to participate, or choose to end your participation in this study, you will not be penalized or lose any benefits that you are otherwise entitled to.

The study site may still, after your withdrawal, need to report any safety event that you may have experienced due to your participation to all entities involved in the study. Your personal information, including any identifiable information, that has already been collected up to the time of your withdrawal will be kept and used to guarantee the integrity of the study, to determine the safety effects, and to satisfy any legal or regulatory requirements.

PARTICIPANT TERMINATION

You may be removed from this study without your consent for any of the following reasons: you do not follow the study investigator's instructions, at the discretion of the study investigator, your condition gets worse, or the study investigator closes the study. If this happens, the study investigator will discuss other options with you.

CONTACT INFORMATION

If you have questions, concerns, complaints, or think the research has hurt you, talk to the study investigator, Darrin Lee, MD, PhD at 323 865 9875 or by email at joannegi@med.usc.edu

This research has been reviewed by the USC Institutional Review Board (IRB). The IRB is a research review board that reviews and monitors research studies to protect the rights and welfare of research participants. Contact the IRB if you have questions about your rights as a research participant or you have complaints about the research. You may contact the IRB at (323) 442-0114 or by email at irb@usc.edu.

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 using non-technical language. I have answered all the participant's questions. I believe that the participant understands the information described in this informed consent and freely consents to participate.

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