Cover Page to Accompany ClinicalTrials.gov Document

Informed Consent: August 12, 2021

For Protocol:

Evaluating the Physiological and Psychological Effects of a Novel Meditation 9 Technique on Cerebral Activity Measured with fMRI and F-18 Fluorodopa (FDOPA)

Thomas Jefferson University IRB ID: 21D.632

Clinical Trial Number: NCT05103618

Jefferson Office of Human Research
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Department: Integrative Medicine and Nutritional Sciences, Radiology

Principal Investigator: Andrew B Newberg, MD

Study Title: Evaluating the Physiological and Psychological Effects of a Novel Meditation Technique on Cerebral Activity Measured with fMRI and F-18 Fluorodopa (FDOPA)

Lay Title: The Effect of Meditation in Controls and Subjects with Parkinson's Disease on brain activity measured by functional MRI with FDOPA

General Information Section

Informed Consent

You are being asked to take part in a research study. Research is different from standard medical care, and is done to learn something new.

Please read on to find out:

- The purpose of this research.
- How this research is different from standard medical care.
- The procedures and the drug(s) involved.
- The risks.
- The possible benefits.
- The alternatives to taking part in this research.

You will have the opportunity to discuss this study with the research personnel. Use this information to decide if you want to take part in this research. This process is called informed consent.

Voluntary Participation

You do not have to take part in this research. It is your choice whether or not you want to take part. If you choose not to take part or choose to stop taking part at any time, there will be no penalty or loss of benefits that you would normally get.

Purpose

The purpose of this research is to use functional magnetic resonance imaging (fMRI) and Positron Emission Tomography (PET) to measure alterations in brain and body activity from the practice of meditation over a period of time. The study will further our understanding of the physiological and psychological effects and dopaminergic function of Orgasmic Meditation (OM Meditation) in 6 couple-pairs in a control group and in 30 couple-pairs in which one member has Parkinson's disease (PD). This study will utilize F-18 Fluorodopa (FDOPA) PET imaging which utilizes an experimental radioactive tracer called FDOPA which helps us evaluate the activity in the dopamine neurons in the brain. In order to assess the brain and body function more effectively, we would like to have you undergo a small battery of diagnostic tests that include magnetic resonance imaging (MRI), and positron emission tomography (PET).
A secondary goal of this study is to determine if undergoing meditation alters body or brain physiology. Specifically, this study will examine Orgasmic Meditation (OM Meditation), which consists of a practice that utilizes female sexual stimulation by a partner who is also considered to be performing the meditation practice. We are seeking specifically to observe the effects of OM Meditation in couple-pairs over time and to particularly measure whether there is an effect on intimacy and sexual dysfunction in women with PD.

How this Research is Different from Standard Medical Care

The MRI scans conducted in this study is equivalent to the standard of care fMRI scans. Briefly describe the main experimental aspects of this study including how the study differs from standard of care and any drugs/devices that are not yet approved.

The study drug that will be used for PET imaging is called 18F Fluorodopa (FDOPA) which utilizes an experimental radioactive tracer called FDOPA that helps us evaluate the activity in the dopamine neurons in the brain. There is evidence that meditation practices alter the amount of dopamine in the brain, and we are performing this pilot sub-study in order to better evaluate this effect. Scans may be performed at the Marcus Institute of Integrative Health PET-MRI scanner. In addition, you will receive several questionnaires and initial evaluations. A secondary goal of this study is to determine if undergoing OM Meditation alters body or brain physiology.

The control group will consist of 6 couple-pairs, amounting to 12 total participants. These participants will be proficient in the practice of OM Meditation. In this case, proficiency requires that subjects are formally trained in the practice of OM meditation and have been performing this practice regularly (2-3 times per month) for at least one year. During the initial visit, female control subjects will receive an initial FDOPA PET-MRI scan and a series of surveys, while the control partner will only receive surveys. After a period of 2-3 months, control subjects will return

for a follow-up visit, during which female control subjects will receive a follow-up FDOPA PET-MRI scan and follow-up surveys, while the control partner will only receive follow-up surveys.

The active group will consist of 30 couple-pairs, amounting to 60 total participants. The female participant in each couple-pair must have a Parkinson's Disease (PD) diagnosis. During the initial visit, female subjects will receive an initial FDOPA PET-MRI scan and a series of surveys, while the partner will only receive surveys. Then, couple-pairs may receive training about the practice of OM Meditation. After training, couple-pairs will practice OM Meditation 3 to 4 times a week for 2-3 months. Participants should keep a logbook documenting their practice. After 3 months of practice, subjects will return for a follow up visit, during which female subjects will receive a follow-up FDOPA PET-MRI scan and follow-up surveys, while the partner will only receive follow-up surveys.

In the group of 30 couple-pairs of subjects in which one has PD, we will randomize them to undergo the OM practice initially (in between the two FDOPA PET-MRI scans) or into the waitlist period in which they will continue to receive standard of care for those two months and then have the repeat scan. The waitlist group will then practice OM for the next two months (but there will not be an additional FDOPA PET-MRI scan).

Number of Participants

About 80 participants will take part in this research at Jefferson to account for screen failures, attrition, and early withdrawals. The goal is to enroll 72 subjects total. There will be two groups: the control group and the PD meditation group.

For the control group, we intend to enroll up to 12 subjects (6 couple-pairs). For the PD meditation group of the OM Meditation FDOPA study, we intend to enroll up to 60 subjects (30 couple-pairs) to perform the OM Meditation practice in this study. In both groups, subjects will practice OM Mediation regularly (at least 3-4 times per week) over a period of 2 months. Female subjects in the PD group will receive one initial FDOPA PET-MRI scan and one FDOPA PET-MRI scan after 2-3 months of performing the OM Meditation practice. The duration of your participation in the study will be approximately 4 months total, which will include scheduling the two FDOPA PET-MRI scans and performing the OM Meditation practice for 2-3 months. In this study of female subjects undergoing FDOPA PET-MRI scans, will receive two scans, one initially and one after 2-3 months of performing the OM Meditation practice.

The control group will consist of 6 couple-pairs, amounting to 12 total participants. During the initial visit, both control subjects will receive an initial FDOPA PET-MRI scan and a series of surveys. Then, couple-pairs may receive training about the practice of OM Meditation. After training, couple-pairs will practice OM Meditation 3-4 times a week for 2 months. After a period of 2 -3months, control subjects will return for a follow-up visit, during which both control subjects will receive a follow-up FDOPA PET-MRI scan and follow-up surveys.

The PD Meditation group will consist of 30 couple-pairs, amounting to 60 total participants. The female participant in each couple-pair has a Parkinson's Disease (PD) diagnosis. During the initial visit, female subjects will receive an initial FDOPA PET-MRI scan and a series of surveys, while the partner will only receive surveys. Then, couple-pairs will practice OM Meditation 3-4 times a week for 2 months. Participants should keep a logbook documenting their practice. After 2 months of practice, subjects will return for a follow up visit, during which female subjects will receive a follow-up FDOPA PET-MRI scan and follow-up surveys, while the partner will only receive follow-up surveys.

In the PD Meditation group of 30 pairs of subjects in which one has PD, couples will be randomized to either the active group or the waitlist group. The active group will undergo the OM Meditation practice initially (in between the two FDOPA PET-MRI scans). The waitlist group will begin the waitlist period in which they will continue to receive standard of care for those 2 months and then have the repeat scan. The waitlist group will then practice OM Meditation for the next 2 months (but there will not be an additional FDOPA PET-MRI scan).

Duration

You will be in this research study for about 3-4 months depending on group assignment. Subjects will be randomized to either the active group or the waitlist group. Active group: subjects will begin OM Meditation practice shortly after the initial evaluation. OM Meditation practice will proceed for 2 months, after which subjects will have a follow-up evaluation. The remaining subjects will be placed in the waitlist group, where they will continue their usual care for the next 2-3 months. Waitlist subjects may begin OM Meditation after the 3-month evaluation time point although after this time point as passed, they will no longer be active study subjects and will not have their OM Meditation practice evaluated.

Procedures and Risks

It is important that you know the procedures and risks involved in this research. These will be discussed with you and are included in detail later in this form. Review the information carefully when making your decision to take part in this research.

Possible Benefits

You may not personally benefit from taking part in this research, but we hope that what we learn may be helpful to future patients or society in general.

Alternatives to Taking Part in this Research

You have other options than taking part in this study. The alternative to being in this study is to not take part.

Costs

You may have costs for participating in this study. This will be discussed in detail later in this form.

Payment

You may receive payment for participation in this study. Couple-pairs may receive $50 for completing the first set of MRI and PET scans and $50 for completing the second set of scans. You may receive an additional payment to help with your travel cost from your home address to Villanova.

You will receive payments through a debit card, called a Clincard, that you are given for this study. See the informational brochure for more information about how to use Clincard.

If you would like to decline compensation for participating in this study, please initial on the line below.

If you would like to decline compensation for this study, initial here: _____
If you would like to decline compensation for the travel costs to participate in this study, please initial on the line below.

If you would like to decline compensation for travel costs, initial here: _____

If your round trip travel is 10 miles or less, you may receive $25.
If your round trip travel is 30 miles or less, you may receive $75.
If your round trip travel is 50 miles or less, you may receive $125.
If your round trip travel is 80 miles or less, you may receive $200.
If your round trip travel is 100 miles or more, you may receive $250.

Ending Study Early

There are a number of reasons you may decide or be asked to stop the study early (for example: medical issues). You may also have to stop the study early even if you do not want to. You and the research personnel will discuss the reason if this becomes necessary. If you do leave the study early, you may be asked to complete some of the procedures described in this form. You will be asked to complete surveys and assessments prior to leaving the study.

New Information

New information may come out during this study. You will be given any new information that could change your decision to take part. You may ask to see the information collected about you, but not until the entire study is complete. You will be given any research results that could affect your health after your participation in the study is complete. You would be given the results if a separate condition may be detected while doing the test for this study.

Detailed Information Section

Drugs/Devices

The drug(s) used in this study are described below:

FDOPA is the agent that will be used to measure changes in the brain for the PET scan. The FDOPA radiopharmaceutical has been used for over 30 years in a number of research studies, primarily studying Parkinson's disease and other movement disorders. More recently, at the Children's Hospital of Philadelphia, the tracer has also been used for studying changes in the pancreas in pediatric patients with congenital hyperinsulinism. Thus, the FDOPA, as a drug, is very safe for use as a PET radiopharmaceutical.

Carbidopa is a pharmaceutical drug that is used in conjunction with FDOPA imaging. It blocks peripheral metabolism of the FDOPA which allows FDOPA to be used more readily in the brain.

If you are in this study, you will participate in the study for approximately 3 months which will include baseline and follow up FDOPA PET-MRI scans, surveys and in the active group, performing the OM Meditation practice for 2 months.

Procedures

While you are in this study, you will have different procedures, tests and/or evaluations which are described below. Please note that additional tests and procedures may be needed to check on your health condition.

We will ask you to complete some questions to make certain you are eligible to participate and are able to provide informed consent voluntarily. After the informed consent process is complete, female subjects in the PD Meditation group will undergo an initial FDOPA PET-MRI scan. While their partners will not be receiving a FDOPA PET-MRI scan. Both subjects in the control group will be receiving an initial FDOPA PET-MRI scan.

The OM Meditation consists of a practice that utilizes female sexual stimulation by a partner who is also considered to be performing the meditation practice. The partners will mutually select each other prior to arrival for the study participation. Married subjects will only be allowed to do the practice with their spouse. The meditation is a practice with 2 persons: a giver and a receiver (female). In the FDOPA study, the couple-pairs will be asked to perform the OM Meditation practice for 2 months.

The goal of the practice is to experience more connection, intimacy, vitality, and fulfillment. The practice is not performed for sexual gratification but for spiritual purposes only. The meditation practice is conducted for a duration of approximately 15 minutes.

On the day of the study, you will report to the Marcus Institute of Integrative Health at Villanova. The informed consent process will be completed with you. If there is difficulty with scheduling your time in the PET-MRI scanner, it may be necessary for you to come back on a separate day to receive the PET-MRI scan. You will be asked questions about your medical history and about the medications, you are taking. You will receive a brief evaluation to confirm that you qualify for the study. You will also be asked to complete some questions about your mood. We may ask questions to test your memory, concentration, and mood. Females who are enrolled in this study will be asked to complete additional surveys. These surveys can take up to 2 hours to complete.

Female subjects of childbearing potential will need a negative pregnancy test (blood or urine) within 48 hours before the start of the scans. The positron emission tomography (PET) scan determines which areas of your brain are functioning differently. The PET scan works by injecting into your vein a radioactive medicine called FDOPA. FDOPA is an experimental tracer that measures dopamine function. By injecting the FDOPA, we can see where in the brain and body it goes so that we can take a picture of the activity in these areas. After injection of the tracer via an intravenous catheter, you will be asked to rest quietly for approximately 90 minutes. At that point, you will be brought into the scanner room and will be asked to lie down on the PET imaging table. The remainder of the procedure involves having your head held comfortably in a special head holder as a reminder not to move your head and remain still while the scanner takes pictures of your brain and body.

The magnetic resonance imaging (MRI) scan will evaluate the structure and function of the brain, along with the connecting fibers affected by pain and is performed simultaneously with the PET scan using a special PET-MRI scanner that can do both at the same time. Before the MRI scan, we will ask you a number of questions to make sure you do not have any metal in your body that might affect the scanner. While you are lying on the imaging table for the PET scan, the MRI scan will also be performed. The MRI scans add no radiation, but do make loud banging noises for which you will be given earplugs to block the sound. The MRI, along with the PET scan, is done over about 60 minutes. Your head will be in a special head holder that enables us to take pictures of your brain and body.

You may receive training in order to help you perform the meditation. You will then be asked to undergo an fMRI scan at the end of the training program in a manner similar to the initial fMRI and will complete the informed consent process again to remind you of what to expect.

Surveys and Questionnaires

You may be asked to complete several surveys depending on different group. Psychological inventories - The Speilberger State Trait Anxiety Inventory (STAI) contains a total of 40 questions, half of which relate to the way subjects are feeling at the moment and half of which ask them to describe how they usually feel. The Profile of Moods Scale (POMS) assesses overall mood. The Beck Depression Inventory (Beck 1972) is a standard 21-item questionnaire probing cognitive and somatic symptoms of depression. These surveys will be used to evaluate changes in mood, depression symptoms and anxiety. Subjects in all couple-pairs will be asked to

complete the Marital Intimacy Questionnaire (MIQ) and the Clinical Global Impression (CGI –I) Scale to assess the effect of the meditation. Couple-pairs in the active group will be asked to keep a log of their meditation practice.

The Female Sexual Function Index (FSI). We may also administer the Clinical Global Impression (CGI –I) Scale to assess the effect of the meditation. Subjects with Parkinson's will be evaluated utilizing the UPDRS scores and Parkinson's Disease Questionnaire-39 to determine any change or improvements in PD symptoms. Female subjects will be asked to complete the Female Sexual Function Index (FSFI).

Risks

Taking part in this study involves certain risks. There may also be risks that are not known at this time. If you have any medical issues during this study, call the appropriate number in the contacts section of this form.

It is possible that during the course of the MRI or PET scan procedure, a technologist or research staff may notice a possible abnormality on your MRI or PET scan (an incidental finding of which you were previously unaware). Such a finding may make you feel anxious or depressed. The information and scans will be made available to your primary care doctor or referring physician in order to manage the finding as quickly and effectively as possible.

The PI will counsel you about the abnormality and will help refer you to your primary care physician or a specialist who can further evaluate the abnormality and help you manage it. We will work with your treating physician to ensure that the incidental findings are addressed in a timely manner.

Survey Questions Risks: Some of the questions we will ask you as part of this study might make you feel uncomfortable or embarrassed. You can refuse to answer any of the questions and you are allowed to take a break at any time during the study. You can stop your participation in this study at any time.

MRI Risk: The MRI requires an MRI scanner, which does not involve any ionizing radiation exposure. Due to the strength of the magnetic field of the MRI, there is a risk of being injured if an unsecured metal object flies into the MRI scanner. In order to minimize this risk, subjects will be asked to remove all metal objects from their person. In addition, all magnetic metal objects will be cleared from the area prior to the scan. This is the standard practice when patients undergo MRI exams. It is important when discussing the study that subjects inform the staff if they have any of the following:

- Surgically implanted electrical devices
- Pacemaker
- Surgically placed metallic clips (aneurysm clips)
- Ear implants

- Any history of metal fragments in the eye

Additionally, subjects may find it uncomfortable to lie on the MRI table during the scan or experience some claustrophobia.

FDOPA PET-MRI Scan Risks: This research study involves exposure to radiation from the FDOPA and therefore subjects will receive a radiation dose that subjects would not receive if they did not have the scans. The radiation dose obtained as the result of participating in this study is the same as standard clinical brain scans using similar tracers. Therefore, at the doses subjects will receive, it is very likely that they will see no effects at all. Additionally, subjects may find it uncomfortable to lie on the PET/MR table during the scan or experience some claustrophobia. The carbidopa which is used to as a part of the FDOPA imaging procedures by itself, which is used as a premedication, has no reported side effects. Use of FDOPA for PET imaging has been used in research for over 30 years with minimal evidence of any side effects. There have been very rare adverse effects of skin redness, facial swelling, fever, and transient rise in blood pressure.

In this study of female subject with PD undergoing FDOPA PET-MRI scans, you will receive two scans, one initially and one after 2 months of performing the OM Meditation practice if in the OM Meditation group or after 2 months of continuing usual care if in the Waitlist group.

FDOPA is a radioactive tracer that will be provided by the cyclotron facility at the University of Pennsylvania and used under an Investigational New Drug application approved by the FDA. Although technically it is an experimental radiopharmaceutical, it has been used in hundreds of studies over the past 25 years. In addition, FDOPA results in some exposure to ionizing radiation. The amount is acceptable for the research subjects who will directly benefit by receiving full clinical reads of these scans that their referring physician can utilize for determination of prognosis and treatment planning. You will be required to lie still on the imaging table for 30-60 minutes, which can be uncomfortable. The premedication with carbidopa alone is part of standard imaging protocols with FDOPA. According to the package insert, carbidopa alone has not been demonstrated to have any overt pharmacodynamic actions in the recommended doses and this is a one-time dose that is not expected to result in adverse effects. However, all patients will be monitored for any adverse effects through the FDOPA imaging procedures.

Some persons may experience some discomfort while lying flat on the table for MRI or PET scans. There may be risks that are unforeseeable currently.

You should call the study doctor as soon as possible at 215-503-3422 if, during the course of this study, you develop any side effects or symptoms.

Risks to a Pregnant Woman, Embryo, Fetus, and Nursing Child (Reproductive Risks)

Taking part in this study may involve certain risks to a pregnant woman, embryo, fetus, or nursing child. In addition to the risks described below, there may also be risks that are not known at this time.

Reproductive Risks:

If you are pregnant, plan to become pregnant or are breast feeding you cannot be in this study.

If the above statement does not apply to you and you are able to have children, you will be required to use birth control during the study and for 30 days after your last dose of the study drug OR modify according to the protocol. Appropriate methods of birth control will be discussed with you. You will have one or more pregnancy tests (blood and/or urine).

If you or your partner becomes pregnant during the study, you must tell the study personnel immediately. We will ask to follow up with you for the outcome of the pregnancy.

Costs

You may have costs for participating in this study. There will be no study related items or services billed to you or your insurance company. You may be responsible for other costs. There is no plan to pay you for lost wages, lost time from work, personal discomfort, or for injuries or problems related to your underlying medical condition(s). If you receive a bill that you think is wrong, please contact the research personnel. You will be responsible to pay for your travel to and from the study site and other out-of-pocket expenses such as parking.

There may be costs to you for taking part in the study. Some of the procedures and services performed in the study are part of the regular treatment for your condition. These would be performed even if you were not enrolled in the study. The costs for these procedures and services will be billed to your insurance. Additional items may also be billed to your insurance while you are taking part in the study. These items may include administration of the study drug, as well as procedures and services to prevent, diagnose or treat potential complications arising from your participation in the study. You will be responsible for any costs your insurance does not cover. You will be responsible for insurance co-pays and deductibles.

Research-Related Injury

There is a possibility that you could have research-related injury, which is an illness or an injury that is directly caused by the study drug(s) or a study procedure. If you have a research-related injury, we will offer you reasonable and necessary care to treat injuries directly resulting from taking part in this research. Neither Jefferson nor the study will pay for costs associated with treatment of research-related injury or illness. These costs may be billed to your insurance. In addition, you will be responsible for any deductibles and co-payments required under your health plan and for any claims ultimately denied by your health plan. There are no plans for Jefferson to pay you or give you other compensation for the injury. If you think you have been injured as a result of taking part in this research study, tell the research personnel as soon as possible. Please see the contact information in this consent form.

Disclosure of Financial Interest

This study is being supported at Thomas Jefferson University by the Marcus Foundation.

Privacy and Confidentiality: HIPAA Authorization

Information will be collected about you for this study. The information will be seen by the people involved with this research. Steps will be taken to protect your identity. But the information collected about you can never be 100% secure.

HIPAA (Health Insurance Portability and Accountability Act) – This is the law that protects your personal health information.

To do this study, we need to collect, use, and share your personal health information. This form will explain why your information is being collected, what information will be collected, and who will have access to it. By signing, you are giving us permission to use your information as described in this form.

We are committed to respecting your privacy and to keeping your personal health information confidential. Your personal health information includes the information in your health care records and information that can identify you. For example, personal information may include your name, address, phone number, social security number, and medical information. The personal health information that may be collected, used, and shared for this research includes:

- Information from your medical records
- Demographic information such as name, gender, birth date, ethnicity, medical history, and health care providers
- Physical examinations, procedures, tests, labs, your medical conditions, and medications you use
- Information collected about any research related injury
- Information about mental health, sexually transmitted diseases, HIV, AIDS, drug and alcohol use, genetic test results, and other sensitive information
- Labs, imaging results (PET/MR, MRS), questionnaires, photos, video, audio and any other information/results collected for this study.

Your personal information will be used by and shared with the following:

- Personnel at Thomas Jefferson University and its affiliates for the purpose of this research
- Institutional Review Boards (ethics committees that review research) including the Jefferson and affiliate IRB(s)
- Health insurance providers
- Research monitors hired by the sponsor-investigator to oversee the study and review health care records to ensure study-related information is correct
- Government Agencies like the Food and Drug Administration (FDA)

- Public health authorities who monitor such things as sexually transmitted diseases, HIV, AIDS, child abuse, as required by law
- Groups monitoring the safety of the study such as a data and safety monitoring committee
- Others as required by law; whenever possible we will use de-identified data

When your personal information is provided to some of the people listed, it may no longer be protected under the HIPAA privacy law. You can see your health care records at any time. However, generally you will not be able to see your study records or the study results until the study is completed. A copy of this signed form, information about this study, and the results of any study test or procedure may be included in your health records which may be seen by your insurance company and your health care providers.

This authorization does not have an expiration date. Please inform the investigator in writing if you want to end your permission to collect information/samples. Please note that anything already collected will still be used and you may not be able to continue in this study.

The information from this study may be published in scientific journals or presented at scientific meetings, but you will not be identified personally

A description of this study will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Your private information and specimens, with the identifiers removed, could be used for future research studies or distributed to other researchers for future research studies without your additional permission.

Contacts

If during your participation in this study, you are having a medical emergency, call 911 or go directly to an emergency room. You should let emergency personnel or providers know that you are taking part in this study.

For Questions About:	**Person or Office**	**Contact Information**
The Study or Research Related Injury	Main Investigator: Andrew Newberg, MD Research study manager: Nancy Wintering, LCSW Research study coordinator	Phone Number: 215-503-9070 215-503-3423 215-503-4886
If you need to contact someone other than the study personnel about a concern or your rights as a research subject	Jefferson Center City Institutional Review Board (Ethics Committee)	215-503-0203 215-503-8966 215-955-4239

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Signatures

Patient/Subject: By signing this form, you are agreeing that:

- You were given the opportunity to read this form.
- All of the information in this form was discussed with you by a physician investigator to your satisfaction.
- All your questions have been answered to your satisfaction.
- You were not pressured and you voluntarily agree to take part in this research.

_____	_____	_____
Your Name	Your **Signature**	Date
_____	_____	_____
Name of Person Obtaining/ Assisting with Consent	Signature of Person Obtaining/ Assisting with Consent	Date

The **physician investigator's** signature certifies that he/she **personally** provided the study participant with a description of the study, study procedures, risks, benefits and alternatives to participation.

_____	_____	_____
Name of Investigator	Signature of Investigator	Date
_____	_____	_____
Name of Witness	Signature of Witness	Date

(Witness required if the only language the subject speaks and understands is English, but the subject cannot read English, or if the subject is blind or cannot physically sign the consent form.)

☐ **Copy of Signed Consent Form Given to the Subject**