Official Title: Use of a Non-Invasive Brainstem Neuromodulation Device to Improve Neurovascular Status in Parkinson's Disease
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Department of Radiology

USING TIME VARYING NON-INVASIVE NEUROMODULATION TO IMPROVE NEUROVASCULAR STATUS IN PARKINSON'S DISEASE

Informed Consent Form to Participate in Research

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SUMMARY

You are invited to participate in a research study. The purpose of this research is to understand how a non-invasive neuromodulation investigational device affects people between the ages of 21-85 years old diagnosed with Parkinson's disease. Your participation in this research will involve 3 in-person visits, 3 virtual visits and up to 4 phone calls, and will last 17 weeks. Your participation in this research will involve the following:

- Daily at-home use of a neuromodulation investigational device for 12 weeks
- Three (3) magnetic resonance imaging (MRI) scans which will last approximately 1 hour
- Two (2) transcranial sonograms which will last approximately 1 hour. Pulse wave velocity may be collected at the time of the transcranial sonograms.

All research studies involve some risks. Risks and side effects related to the investigational device may include drowsiness, dizziness, or nausea. The MRI machine does not use radiation and is considered safe. Some people may experience discomfort in the scanner if they are uncomfortable in tight places. You may not benefit directly from this study, but it is hoped that your participation will help others with Parkinson's disease in the future. It is possible that you may experience fewer symptoms associated with Parkinson's disease.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. Your other choice is to not participate. You will not lose any services, benefits, or rights that you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Dr. Chris Whitlow. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study, contact Dr. Whitlow at [redacted].

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted].

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have Parkinson's disease. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to understand how an investigational, non-invasive neuromodulation device affects people with Parkinson's disease. A non-invasive device is one that stays outside of the body, as compared to an implanted device. Neuromodulation means that the device stimulates activity in the brain. Importantly, the U.S. Food and Drug Administration (FDA) has determined that the device is a nonsignificant risk device, which means that does not have the potential for serious risks.

The study device is an investigational device. This means it has not been cleared or approved by the FDA. Devices that do not have clearance or approval by the FDA cannot be sold or prescribed by your physician.

In this study, we will be comparing two different stimulation patterns generated by the device. You will not know which stimulation pattern you receive. Whether either of the stimulation patterns will lead to improvement in Parkinson's symptoms is unknown, and that is why we are conducting this study.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

There will be up to 20 participants in the study.

WHAT IS INVOLVED IN THE STUDY?

You will be randomized into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. You will have an equal chance of being placed in one of two groups which differ in neurostimulation patterns.

Neither you nor the investigator will know which study device treatment pattern you are receiving. This is done so that a fair evaluation of results can be made.

Participants in both treatment groups may or may not feel pressure as well as cooling and/or warming temperatures in their ear canals. Participants in both treatment groups may also hear sounds associated with study device treatments. While some participants will be more aware of these sensations than others, all can be expected in both treatment conditions.

In general, knowledge regarding treatment conditions may make it difficult to gather clean clinical trial results. This is true if the knowledge is held by the study doctor, study staff, caregivers or the participant themselves. Therefore, it is important not to discuss your treatment experience and to not ask questions about how the device works. However, you should feel free to ask as many questions as you have about how to use the device and/or what the study will be like. All study participants will receive a summary of the study results and information regarding their stimulation pattern by mail after completion of the study.

Please initial below:
I understand that knowledge regarding treatment conditions may corrupt the study results.

_____ Initials

If you take part in this study, you will have the following tests and procedures:

MRI scan

You will be placed inside an MRI scanner, a large device that will take pictures of your brain using magnetic fields. The scans will be obtained while you lie on your back. The study requires that you remain in the machine while the pictures are taken, and that you remain as still as possible unless asked to move. The duration of the MRI session will be approximately 1 hour. No needles or injections are used and there is also no discomfort or physical pain. Prior to having the MRI scans, you will be asked questions about your medical history. This will include whether you 1) have metal clips or fragments in your eyes, brain or spinal cord, 2) have a pacemaker, artificial heart valve, ear implant or spinal cord stimulator, 3) have had prior surgery for an aneurysm (bulging of a large blood vessel due to weakness of its wall) in your body or head, and 4) might be pregnant (if female).

Neuromodulation Device

The study device consists of a headset, which looks like a music headset, and a base station that powers the headset. The headset has metallic earpieces that fit into the ear canals. When activated the study device will deliver a prescribed stimulation pattern for approximately 20 minutes. It has been found that the stimulation provided by the study Device can create small changes in the blood flow to the brain and the aim of the study is to observe and document those changes using during the MRI. It is unlikely that you will be aware of any difference in your heart rate or blood flow characteristics.

You will also use this study device at home, twice daily, at least one hour apart. Each study treatment is approximately 20 minutes. You will use the study device for 12 weeks.

Hypercapnia Challenge

You will be asked to wear a mask that will be attached to a machine called a RespirAct. This device is designed to maintain your oxygen (O_2) levels while increasing your carbon dioxide (CO_2) level slightly. The result of the increased CO_2 is that the blood vessels in your brain will dilate allowing us to better understand how blood flow through your brain. Possible side effects include dizziness or temporary shortness of breath.

While you may feel short of breath (similar to how you may feel after exercise), you will not be deprived of oxygen at any point during the test. If you have reported symptoms related to difficulty breathing, you may be excluded from this portion of the scan. The hypercapnia challenge is approximately 8 minutes.

Transcranial Doppler Sonography

Following your MRI, you will receive a transcranial Doppler ultrasound on your head. This is a non-invasive, painless ultrasound technique that uses high-frequency sound waves to measure the rate and direction of blood flow inside vessels. Pulse wave velocity may be collected at this time. This is the velocity at which the blood pressure pulse propagates through the circulatory system. A technologist will use a small device called a transducer that will help provide data about blood flow. One or more transducers will be placed directly on your skin, with a small amount of gel facilitating the ultrasound. The gel can be easily washed off after the scan. You will be awake and lying on a bed during the scan. The ultrasound will be approximately one hour.

Study Phone Calls

During the study, you will participate in interim phone calls the day after you are trained how to use the study device. This call will be to ensure you have successfully used the study device at home. A phone call will occur during week 3, week 6, and week 9. During these calls, a study member will ask about any adverse events, any changes to medications, and to confirm that you have not experienced issues in using the study device.

Ear Exam

An ear exam may be performed to screen for earwax buildup that may affect the efficacy of the study device. A tool called an otoscope will be used to look at the outer ear canal and eardrum. This exam will take approximately five minutes.

If any ear abnormalities are noted during the ear exam (this can include pain, infection, damage/injury, or excessive earwax), it will be your responsibility to resolve it before continuing in the study. If you choose not to resolve any ear issues, including earwax removal, you will be excluded.

Assessments

The following assessments will be administered throughout the study. These assessments may be conducted in-person or remotely.

- Medical and medication history
- Non-Motor Symptom Scale
- Movement Disorder Society-Unified Parkinson's Disease Rating Scale**
- Timed Up and Go Test
- Montreal Cognitive Assessment
- Geriatric Depression Scale
- Parkinson's Anxiety Scale
- Epworth Sleepiness Scale
- Functional Assessment of Chronic Illness Therapy – Fatigue

** Please note that a portion of the Movement Disorder Society-Unified Parkinson's Disease Rating Scale may be video recorded for review.

As part of this research study, you will be videotaped. This is being done to ensure accuracy of the assessment in the case that the motor examination portion requires review. You understand that you may request the filming or recording be stopped at any time during the course of the research study. You can also withdraw your consent to use and disclose the videotape before it is used. You should also understand that you will not be able to inspect, review, or approve the videotapes (including articles containing such) before they are used in this study.

Please choose one of the following regarding the use and disclosure of the videotape used in this research study:

_____ I would like the videotapes of me to be destroyed once their use in this study is finished.

____ The videotapes of me can be kept for use in future studies provided they are kept secure and any future study will be reviewed by an IRB. I understand that I will not be able to inspect, review or approve their future use.

We can send copies of your test results to your personal physician. Even if you do not wish to have any of your medical information sent to your physician, you can still participate in this research study.

Do you request that we send important medical findings from your study tests/exams to your personal physician?

[ ] Yes [ ] No _____ Initials

Study Schedule

Screening *(may initiate visit in clinic and complete visit remotely)*	▪ Review and sign consent form ▪ Review inclusion/exclusion criteria ▪ Review medical and medication history ▪ Non-Motor Symptom Scale ▪ Movement Disorder Society -Unified Parkinson's Disease Rating Scale ▪ Montreal Cognitive Assessment ▪ Geriatric Depression Scale ▪ Parkinson's Anxiety Scale ▪ Epworth Sleepiness Scale ▪ Functional Assessment of Chronic Illness Therapy – Fatigue ▪ MRI safety screening ▪ Ear exam (may be performed)
Week 0 *Baseline clinic visit*	▪ Try on unpowered study device ▪ MRI scan with hypercapnia challenge ▪ Transcranial Doppler ultrasound with hypercapnia challenge. Pulse wave velocity may be collected at this time. ▪ MDS-UPDRS part III only (this assessment may be videotaped) ▪ Timed Up and Go Test ▪ Study Device training at site ▪ Ear exam ▪ Urine Pregnancy test (if appropriate) ▪ Medication review
1 day after device training *Phone call*	▪ Check in call to confirm successful first at-home study treatment
Week 3 *Phone call*	▪ Review medications and any medical problems since last contact
Week 6 *Phone call*	▪ Review medications and any medical problems since last contact

Week 9 *Phone call*	▪ Review medications and any medical problems since last contact
Post-treatment *remote visit*	▪ Non-Motor Symptom Scale ▪ Movement Disorder Society -Unified Parkinson's Disease Rating Scale ▪ Montreal Cognitive Assessment ▪ Geriatric Depression Scale ▪ Parkinson's Anxiety Scale ▪ Epworth Sleepiness Scale ▪ Functional Assessment of Chronic Illness Therapy – Fatigue ▪ MRI safety screening ▪ Device usability questionnaire ▪ Medication review
Week 12 *Post-treatment clinic visit*	▪ Study Device collection ▪ MRI scan with hypercapnia challenge ▪ Transcranial Doppler ultrasound with hypercapnia challenge. Pulse wave velocity may be collected at this time. ▪ MDS-UPDRS part III only (this assessment may be videotaped) ▪ Timed Up and Go Test ▪ Ear exam ▪ Urine Pregnancy test (if appropriate) ▪ Medication review
Week 17 *Follow up remote visit*	▪ Non-Motor Symptom Scale ▪ Movement Disorder Society -Unified Parkinson's Disease Rating Scale ▪ Montreal Cognitive Assessment ▪ Geriatric Depression Scale ▪ Parkinson's Anxiety Scale ▪ Epworth Sleepiness Scale ▪ Functional Assessment of Chronic Illness Therapy – Fatigue ▪ MRI safety screening ▪ Medication review
Week 17 *Follow up clinic visit*	▪ MRI scan with hypercapnia challenge ▪ MDS-UPDRS part III only (this assessment may be videotaped) ▪ Timed Up and Go Test ▪ Ear exam (if needed)

How Long Will I Be in the Study?

You will be in the study for 17 weeks. You can stop participating at any time. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff, perform a final clinic visit, and return the study device.

What Are the Risks of the Study?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks and certain short-term side effects related to the study device include:

More likely:

- Drowsiness
- Dizziness (whirling or spinning sensation; may also be called "giddiness" or vertigo)
- Treatment site discomfort (skin itching, skin irritation felt within the ear canal or around the ear area or pressure felt within ear canal)

Less likely:

- Nausea
- Vomiting
- Tinnitus (a ringing in the ear)
- Headache

There may be some unknown risks. If you experience side effects, you should contact the study doctor, who will gather additional information about what you experienced, when and for how long.

The ear exam may cause temporary discomfort (pressure) or irritation in the ear canal.

The transcranial ultrasound and collection of pulse wave velocity have no harmful side effects and does not use radiation (such as x-rays).

The hypercapnia CO_2 challenge may cause dizziness or temporary shortness of breath.

The MRI machine does not use radiation (such as x-rays) and is considered safe. Some people may experience discomfort in the scanner if they are uncomfortable in tight places (known as claustrophobia). No serious biological effects have been reported from MRI scans. If you experience fear of the confined space while in the scanner, you can stop the test.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other side effects that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

As part of this study, you will be asked questions about depression and anxiety. If we learn that you or someone else is in danger of harm, the study team is required to report that information to the proper authorities.

There may be a risk of device malfunction should the device not be used per the instructions in the Quick Reference Guide, or if it is plugged into a non-approved power source. If you travel outside of the country, please alert the study staff at least 3 weeks in advance so that an adapter for the country you are traveling to, can be provided. You should not use your own travel adapter.

Regardless of which treatment pattern you are assigned as part of this study, your Parkinson's symptoms may not improve or may get worse.

BIRTH CONTROL RESTRICTIONS

The study device has not been tested by pregnant women. Therefore, it is unknown whether use of the study device could involve risks to either a pregnant woman or the unborn child. It is known that use of the device can cause temporary side effects like nausea and dizziness, which can also be symptoms of pregnancy. Therefore, if you are pregnant, planning to become pregnant, you cannot participate in this study.

Females:
In order to reduce the risk of pregnancy, if you are a woman of child-bearing potential who might engage in heterosexual intercourse during the study, you should use an effective method of birth control. Acceptable methods of birth control are, as follows:

- Abstinence
- Oral Hormonal Contraception
- Patch Contraception
- Hormonal Ring
- Intrauterine Device (IUD)
- Contraceptive Implantation
- Contraceptive Shot
- Barrier Method, including:
- Male Condom
- Female Condom
- Diaphragm
- Cervical Cap with spermicide
- Contraceptive Sponge
- Spermicide

The study doctor or study staff will discuss this with you.

If you become pregnant while you are participating in this study, stop using the device and tell your study doctor or study staff immediately. The device will be collected by the study staff, and your participation in this study will be ended.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will benefit other people in the future. It is possible that you may experience fewer and/or less severe symptoms associated with Parkinson's disease.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have.

Treatment for Parkinson's may include medication (such as Levodopa) and deep brain stimulation (DBS). Benefits for medication may include reduced tremors and reduced stiffness/rigidity. Risks may include nausea, hypotension, or arrhythmias. DBS benefits may include a decrease in motor symptoms and decrease medication needs in some people. Risks may include hemorrhage, infection, or headache.

WHAT ARE THE COSTS?

All study costs, including any procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility. The neuromodulation investigational device is provided by the Device sponsor. Neither you nor your insurance company will be billed for the investigational device. All study devices must be returned to Wake Forest University at the completion of the study treatment period. If study devices are not returned, you will be provided with a pre-paid shipping box that can be used to return the study Device.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

If you choose to participate in this study, you agree that your de-identified clinical data may be shared with The Michael J. Fox Foundation for Parkinson's Research (the study funder). This data may be kept for storage at a central repository either hosted by The Michael J. Fox Foundation, its collaborators, or consultants and will be kept indefinitely. In order to advance scientific discoveries, your de-identified data will be made publicly available (with no personal identifying information) for the intended use of research in Parkinson's disease as well as other biomedical research studies that may not be related to Parkinson's disease.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed

unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

WILL YOU BE PAID FOR PARTICIPATING?

You will be paid a total of $300 for completing all study visits. You will be paid to cover travel expenses related to the in-person clinic visits.

Payment Schedule	
Week 0 *Baseline visit*	$75
Week 12 *Post-treatment clinic visit*	$100
Week 17 *Follow up clinic visit*	$125

To receive payment, you must provide your social security number, name and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not let them know what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study but you will not be paid.

The findings from this research may result in the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the Michael J. Fox Foundation. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [redacted].

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Dr. Chris Whitlow at [redacted].

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:**

1) Name
2) Date of birth
3) Phone number
4) Medical history
5) Medical images

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study may be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS), the Device sponsor, Michael J. Fox Foundation and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups, it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for an indeterminate period of time. This authorization does not expire, and any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completed.

You can tell Dr. Chris Whitlow that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Dr. Christopher T. Whitlow
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form, you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

A description of this clinical trial 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.

Procedures and other medical reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. Reasons for this may include because it is in your best medical interest or you had an unexpected reaction. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

This study may enroll students from the Wake Forest University Medical Center campus. In addition to your rights as a research participant noted in the previous section, as a student, you are under no obligation to participate in this study. You may refuse to participate or withdraw from the study at any time and for any reason without affecting your grades, performance evaluations, or assignments. You will not be pressured into participating in this research study by any statements or implied statements that your grades, performance evaluations or assignments will be affected by your willingness to enroll in the study. Your medical records/information will not be used by the faculty, administration, or study staff to make decisions regarding the status of your medical benefits. If you have questions regarding your enrollment in the study and your status as a medical student, please contact the Office of Student Services for additional information.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Chris Whitlow at [redacted].

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate, Issis Pumarol, at [redacted].

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm