UNIVERSITY of MARYLAND BALTIMORE

RESEARCH CONSENT FORM AND HIPAA AUTHORIZATION

Protocol Title: Neural and Immune Correlates of Painful Chemotherapy-Induced Neuropathy, Feasibility and Preliminary Efficacy of a Motor Cortex Non-Invasive Brain Stimulation Intervention

Study No.: HP-00115652

Principal Investigator: Timothy J. Meeker, PhD

Sponsor: National Institute on Minority Health and Health Disparities

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CONCISE SUMMARY:

Your participation in this research study is voluntary. The purpose of this study is to see if a type of brain stimulation called transcranial direct current stimulation (tDCS) can relieve the pain caused by certain types of chemotherapy. This study also hopes to identify what parts of the brain and immune system play a role in this condition. There will be up to five sessions over 10 weeks.

- The first session takes 4 hours. It involves sensory testing and filling out questionnaires. This session will include a paid lunch.
- The second session takes 2 hours. One hour will be in a magnetic resonance imaging (MRI) machine to image your brain. Additionally, you have the option to participate in a second MRI session lasting an hour.
- There will then be ten treatments over a two-week period for which you will be randomly assigned to receive either the real treatment or a 'sham' treatment. You will be trained to use the brain stimulation device. The treatments will take place in your home and will be remotely supervised by study staff. Each treatment will take 20 minutes.
- After completing the treatments, there will be another MRI session with 60 minutes spent in the MRI machine.
- Finally, there will be a final 3-hour sensory testing session six weeks after completing the treatments. You can opt for completing this session via a 15-minute phone interview.

Each session will include a blood draw of about 25 milliliters (five teaspoons). Patients may experience pain relief associated with tDCS. There is a slight risk of infection with blood draws. Use of the brain stimulating device can cause mild itching or skin irritation and redness. While every effort is made to protect your private health information, there is still a risk of disclosure. There is no cost to participate in this study. You will be paid $50 per hour. If you complete the entire study, you can earn up to $800.

PURPOSE OF STUDY

Previous studies have shown that this type of stimulation known as transcranial direct current stimulation (tDCS) can increase activity in the areas of the brain that control pain. There are differences in pain sensitivity and the areas of the brain between non-Hispanic Black (NHB) and non-Hispanic White (NHW) individuals, which may influence the effectiveness of treatments. This research aims to:

1. Test if tDCS is a helpful treatment for pain caused by certain types of chemotherapy.

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2. Investigate how pain caused by certain types of chemotherapy treatments affects brain function in NHB and NHW patients.
3. Examine the role of inflammation in pain caused by certain types of chemotherapy and its connection to pain severity and brain function.

You are being asked to participate in this study because you have a painful disorder called chemotherapy-induced peripheral neuropathy (CIPN). This can occur when cancer patients are treated with certain anti-cancer medications. You will be one of about 68 patients with painful CIPN to take part in this study. An additional 48 pain-free participants will also take part in this study.

PROCEDURES

The first session will take 4 hours. Lunch will be provided for you. After you sign the consent form you will complete questionnaires about your health, experiences with discrimination, and feelings about pain. Then we will measure your responses to various types of painful and nonpainful stimuli through a set of standardized tests. You will receive standard instructions on how to complete the test. At the end of this session, a technician will draw about 25 milliliters (five teaspoons) of blood. This blood sample will allow us to measure immune components, vitamins, and other substances.

Types of stimuli include the following:

- Mechanical Threshold: Fibers of various strength on your leg one at a time. You will be asked if you feel the fiber when it is applied. Your threshold to touch will be established when you can accurately and consistently identify a particular stimulus.
- Mechanical Pain Threshold: Weighted probes will be applied to your leg. You might find the weighted probes painful, but they won't injure you and the pain will be tolerable. Our goal is to find the lightest weight that produces a painful experience. You will be asked to rate your pain level for the weighted probes. When you report that the sensation of pain was felt, then the next lower weight is applied until no pain is reported. The probe weight is then increased again until a painful sensation is reported. This continues for a total of three changes from painful to non-painful stimuli.
- Suprathreshold Mechanical Pain Rating: Various weighted probes above your pain threshold will be applied to your leg one at a time. You will be asked to rate the intensity of pain on a 0-100 numerical scale.
- Thermal Detection and Pain Thresholds: A temperature probe will be placed against your leg. The temperature of the probe will slowly increase. You will click a button as soon as you feel any change in temperature. This will be repeated 3 times to establish your thermal detection threshold.
- Thermal Pain Threshold: Using the same temperature probe, the temperature of the probe will increase slowly. This time, you will click the button as soon as you feel pain. Our goal is to find the lowest temperature that produces a painful experience. You will be asked to rate your pain level. This will be repeated 4 times.
- Suprathreshold Heat Pain Rating: Using the same temperature probe, the temperature will increase slowly to a level above your pain threshold. There will be several different temperatures. You will be asked to rate the intensity of pain on a 0-100 numerical scale for each stimulus.

During each in-person study session, you will be asked to provide a urine sample for drug testing and, if you are a female of reproductive age, for a pregnancy test. The drug test will show if you have used any of the following:

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- marijuana,
- cocaine,
- heroin,
- opium,
- morphine,
- amphetamine,
- methamphetamine,
- ecstasy,
- phencyclidine (PCP or angel dust),
- Vicodin (hydrocodone),
- Oxycontin (oxycondone),
- Lorcet (hydrocodone),
- Lortab (hydrocodone),
- Percocet (oxycodone),
- Percodan (oxycodone), and
- Dilaudid (hydromorphone).

All results will be kept confidential, including any positive tests. However, you may not be able to take part in the study depending on the medications you are prescribed.

The second study session will be an MRI session at University of Maryland Baltimore's Center for Translational Research in Imaging. The session will take 2 hours. It starts with you completing a set of questionnaires about how you feel that day. Then you will be placed in the MRI machine. While you are in the MRI machine you will experience various types of painful and nonpainful stimuli like during the first session. You will spend about one hour in the MRI machine. At the end of the session, a technician will draw about 25 milliliters (five teaspoons) of blood. The brain scans from this study will be reviewed by a radiologist who works for University of Maryland Medical Center. You or your physician will be informed if any medically relevant information is found.

There will be an additional MRI session lasting about one hour. At the end of the session, a technician will draw about 25 milliliters (five teaspoons) of blood. This session is optional.

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There will then be ten treatments over a two-week period for which you will be randomly assigned to receive either the real treatment or a 'sham' treatment. You will have an equal chance of being given either intervention and no one will know which treatment you will receive. The brain stimulating device connects to the scalp through two sponges attached to a custom headgear. These sponges allow the device to deliver 2 milliamps of electricity through the head. You will be trained on the proper placement of the headgear and how to use the brain stimulation device. The treatments will take place in your home and will be remotely supervised by study staff. The remote, at-home intervention sessions will be conducted over Zoom. You will receive a meeting link via email. Once the Zoom meeting begins, you will complete a screening questionnaire by interview. Next, you will set up the headgear by opening a new set of sponge-electrodes, dampening them with sterile single-use saline solution, and attaching them to the headgear. Then you will put on the headgear in front of the camera. A trained study team member will visually inspect the placement. When placement has been confirmed, you will activate the tDCS device by entering your code in front of the camera to allow the study team member to verify the correct entry. You will be observed for the entire twenty-minute session. When the device is finished, you will complete three additional brief questionnaires.

Within a week of the last treatment, you will participate in an additional MRI session. You will complete a set of questionnaires. While you are in the MRI machine you will experience different mechanical and thermal stimuli some of which will be painful. You will spend 60 minutes in the MRI machine. At the end of the session, a technician will draw about 25 milliliters (five teaspoons) of blood.

Six weeks after the last treatment you will participate in a final 3-hour sensory session. You will complete questionnaires about your health and feelings about pain. We will measure your responses to painful and nonpainful mechanical and heat stimulation. At the end of the session, a technician will draw about 25 milliliters (five teaspoons) of blood. You can opt for completing this session, without the blood draw, via a 15-minute phone interview. During this phone interview you will be asked to respond to questions from two questionnaires.

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It is expected that your entire study participation will last up to 10 weeks. You may enquire about the results of this study after you have completed the study. It may take a couple of years after your last date of participation for any study results to be available. The study results will be posted, when available, on the study website at ClinicalTrials.gov. However, neither you nor your doctor will be notified of the results of any testing described in this protocol, aside from the MRI scans.

At each in-person session 25 milliliters (five teaspoons) of blood will be drawn by a part-time lab technician. If you participate in all 5 in-person sessions in the study, the total amount of blood drawn during your participation in the study will be 125 milliliters (8 and 1/3 tablespoons). If you only participate in the non-optional sessions in this study, the total amount of blood drawn will be 75 milliliters (5 tablespoons). Your blood samples will only be identified by an anonymous study code. If you withdraw from the study, you can choose to have your blood samples destroyed. These samples will be stored at Morgan State University and will be retained for 10 years.

Your biomedical specimens and information that are collected for this study may be used for future studies. These future studies may include whole genome sequencing unless you specifically opt out of this testing.

Your biomedical data and samples will have all identifiable information removed from them and replaced with an anonymous study code.

All procedures performed as part of this study are for research purposes only and therefore are not part of any clinical care.

You may continue to use any pain medications prescribed by your doctors, however any changes in dose will lead to withdrawal from the study.

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH STUDY?

If you take part in this study, you will be responsible for showing up on time to appointments and participating in remote intervention study sessions.

POTENTIAL RISKS/DISCOMFORTS:

Risk of breach of confidentiality: It is possible your private health information may be accidentally revealed to unauthorized persons. We will take all necessary steps to ensure that this does not happen. You will be assigned a study code. All records related to your involvement in this research study will be stored in a locked file cabinet in a locked room. Your identity on these records will be indicated by a study number rather than by your name and any other identifying information.

Information obtained from questionnaires will not be disclosed to anyone not involved in the study, except as required by law or regulation. Blood samples will be identified with your study code.

Risk of questionnaires: It is possible that some questions may upset you or that you will become tired from answering questions. You may choose not to answer any question that upsets you or you may quit the study if you choose. If you become upset and feel that you need psychological counseling, study staff will help you to get that counseling. If you become tired during any part of the study session, you can take a break. Please remember you may choose to quit part of the study at any time for any reason.

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Risk of thermal testing: During some sessions, we will ask you to endure a well-controlled test of medium to strong pain. If you want to stop this portion of the experiment at any time, we will stop testing. If you want to reschedule another session, the examiner will allow you to do so, and we will compensate you for your time. The examiner will remind you that you can choose to end the experiment at any time.

Risk of mechanical testing: Mechanical stimulation may be painful. Additionally, the examiner will ask you to rate your pain as the examiner applies these probes. Each test will last 3 to 7 minutes. You can stop at any point for a brief rest or stop completely for the day. The place where the temperature probe was placed may be red for a few minutes after the test. This is a natural response and will fade within several minutes.

Fatigue: To minimize fatigue during sensory testing, you will be offered breaks during the study procedures.

Risk of tDCS: You may feel mild discomfort and tingling during the tDCS intervention. We will lessen this discomfort by using the correct saline to wet the sponges which you will be provided with. We will also provide you with training and make sure that you have new sponges for each session. You will be trained by the study staff in the use of the tDCS intervention.

Risks of MRI: Some people cannot receive an MRI scan because they have metal or a device containing metal (a pacemaker, for example) in their body. An MRI technician will screen you to see if you are able to receive an MRI scan. Some people find the confining experience (claustrophobia) of the MRI machine unpleasant. The examiner will stop the experiment and remove you from the MRI machine at any time if you request it.

Risk of blood draw: During the blood draw you may feel pain when the needle is in place. Rarely, mild pain may last for a day. About half of the time, you may have bruising after the blood draw, though this should be mild. Rarely, bleeding may require you to change the bandage. There is a very rare risk of infection from drawing blood.

There may be risks in this study which are not known yet.

POTENTIAL BENEFITS

For patients with painful CIPN non-invasive brain stimulation may provide temporary pain relief. There is no guarantee that you will receive direct benefit from your participation in this study. Otherwise, you will not benefit directly from your participation in this study. It is possible this study could benefit future patients with your condition. It could also help us understand how CIPN affects the brain and immune system.

ALTERNATIVES TO PARTICIPATION

You do not have to take part in this study. Your other choices include continuing your usual treatment. Please talk to your doctor about your choices before deciding if you will take part in this study.

COSTS TO SUBJECTS

You will not have any expenses related directly to your involvement in this study. There will be no fee to enroll in the study. However, you or your insurance will be billed, in accordance with applicable law and policy, for the costs of medical care that are required by the study. You or your insurance will also be

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billed for costs of medical care, including tests and procedures, that you would have needed or received if you were not in the study. These costs may include co-insurance, deductibles, and co-pays. You may also incur additional ancillary costs such as travel, lodging, parking, meals, etc.

The sponsor of the study will provide the study intervention device. You or your insurance will not be billed for the study intervention device.

Talk to your insurance plan and make sure that you understand what your insurance pays for and what it doesn't pay for if you take part in this research study. Also, find out if you need approval from your plan before your plan will agree to pay for any costs of this research study.

PAYMENT TO SUBJECTS

Participants will be compensated $50 per hour for each in-person session. Partial hours will be prorated by rounding up in 15-minute increments. The questionnaire/sensory testing session will last up to 4 hours with participants potentially earning $200. The first MRI session will last up to 2 hours with participants potentially earning $100. The second MRI session, which is optional, can take up to 1 hour to complete with participants potentially earning $50. Patients with CIPN who complete the two-week remote intervention sessions will be paid $250. The last MRI session will last up to 2 hours with participants potentially earning $100. The final study session will occur six weeks after the intervention is complete and will last up to 2 hours. Participants may earn up to $100 for this session. However, you can opt for completing this final session via a 15-minute phone interview. You will not be compensated if you opt to complete this follow-up by phone. Parking and meals during sessions longer than 4-hour sessions will be provided free of charge. Transportation will be provided free of charge for those participants who choose this option. All payments related to participation, including meals and transportation will be made electronically after each session through Uplift Alliance.

You may need to report payments you receive for participating in the study as taxable income, which could affect your eligibility to receive certain government benefits (e.g., from the Maryland Supplemental Nutrition Assistance Program (SNAP) and the Maryland Temporary Cash Assistance program (TCA). If you owe a debt to the State of Maryland or the federal government (e.g., child support, taxes), the amount you receive may be reduced.

STUDY-RELATED INJURY

If you have an injury, promptly seek medical care from any healthcare provider. <u>If you have an emergency, call 911 or go to the nearest emergency room</u>. You should tell the healthcare provider that you have participated in a research study.

If you believe the injury is related to the study, notify the study doctor. UMB, if requested, will assist you to get medical care or referrals.

If you are injured as a result of being in this study, you or your insurance will be responsible for paying your medical expenses. Neither the hospital nor UMB has agreed to pay for the cost of medical care or other costs arising from an injury. However, you do not give up any of your legal rights by being in this study, and you may choose to pursue legal action if you are injured by being in the study.

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CONFIDENTIALITY AND ACCESS TO RECORDS

Individual participant information will be treated as confidential. Individual participant information will be kept in a locked file drawer in a locked lab or office space, or password protected computer. In all practically possible cases data will be de-identified and coded by study and participant code. Study data will be retained for at least six years after the study is completed.

Your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Efforts will be made to limit disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of the University of Maryland, Baltimore (UMB), or the study site. Additional organizations that may inspect your information include the Food and Drug Administration (FDA), the Department of Health and Human Services and the Morgan State University IRB.

The study monitors, auditors, the IRBs and the FDA will be granted direct access to your medical records for verification of the study procedures and date. By signing this document, you are authorizing this access.

The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted, and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information will work to keep your personal information confidential. Your personal information will not be given out unless required by law.

A description of this clinical 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 results. You can search this website at any time.

RIGHT TO WITHDRAW

Your participation in this study is voluntary. You do not have to take part in this study.

If you are an employee or student at Morgan State University (MSU) or the University of Maryland, Baltimore (UMB), your employment status or academic standing at MSU or UMB will not be affected by your participation or nonparticipation in this study. You are free to withdraw your consent at any time. If you decide to withdraw from the study you may choose to have your blood samples destroyed. Your refusal to take part or your decision to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to stop taking part, or if you have questions, concerns, or complaints, or if you need to report a study-related injury, please contact the investigator

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at timothy.meeker@morgan.edu (Timothy J Meeker). To withdraw from this study please contact the study coordinator or the investigators by email.

If you withdraw from this study, the already collected data may not be removed from the study database.

You will be told of any significant new findings that develop during the study, which may affect your willingness to participate in the study.

CAN I BE REMOVED FROM THE STUDY?

The person in charge of the study or the sponsor can remove you from the study without your approval. Possible reasons for removal include missing three or more scheduled sessions or failing to maintain eligibility for the study. The sponsor can also end the study early. The study doctor will tell you about this, and you will have the chance to ask questions if this happens.

UNIVERSITY STATEMENT FOR MORGAN STATE UNIVERSITY

The Morgan State University (MSU) is committed to providing subjects in its research studies all rights due to them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in this study. This study has been reviewed and approved by an Institutional Review Board (IRB). The IRB is a group of scientists, physicians, experts, and community representatives. The IRB's membership includes persons who are not affiliated with MSU and persons who do not conduct research studies.

If you have questions, concerns, complaints, or believe you have been harmed through participation in this study as a result of researcher negligence, you can contact members of the IRB or the Office of Research Compliance (ORC) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research study subject. The contact information for the IRB and the ORC is:

Morgan State University
Institutional Review Board
Office of Research Compliance
1700 E. Coldspring Lane
Baltimore, MD 21251
irb.research@morgan.edu
research.compliance@morgan.edu

UNIVERSITY STATEMENT FOR UNIVERSITY OF MARYLAND, BALTIMORE

The University of Maryland, Baltimore (UMB) is committed to providing subjects in its research studies all rights due to them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in this study. This study has been reviewed and approved by an Institutional Review Board (IRB). The IRB is a group of scientists, physicians, experts, and community representatives. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research studies.

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If you have questions, concerns, complaints, or believe you have been harmed through participation in this study as a result of researcher negligence, you can contact members of the IRB or the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research study subject. The contact information for the IRB and the HRPO is:

University of Maryland, Baltimore
Institutional Review Board
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037

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CONSENT TO PARTICIPATE – SIGNATURE PAGE

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

Banked Blood Sample Agreement

1. I agree to permit my blood samples to be **banked** for use in future research to learn more about the biological mechanisms underlying persistent pain.

___Yes ___No

2. I wish to opt out of my blood samples being included in any future studies using whole genome analysis to investigate biological mechanisms underlying persistent pain or for any other reason.

___Yes ___No

RESEARCH PARTICIPANT

If you agree to participate in this study, please sign your name below.

Subject's Signature	Date	Printed Name

INVESTIGATOR OR DESIGNEE OBTAINING CONSENT

Signature of Investigator or Designee	Date	Printed Name

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HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)
AUTHORIZATION TO OBTAIN, USE, AND DISCLOSE
PROTECTED HEALTH INFORMATION FOR RESEARCH

Name of Study Subject:_____

Date of Birth: _____ **Medical Record Number: _____**

NAME OF THIS RESEARCH STUDY: *Neural and Immune Correlates of Painful Chemotherapy-Induced Neuropathy, Feasibility and Preliminary Efficacy of a Motor Cortex Non-Invasive Brain Stimulation Intervention*
UMB IRB APPROVAL NUMBER: *HP-00115652*

RESEARCHER'S NAME:

Timothy J. Meeker, PhD

RESEARCHER'S CONTACT INFORMATION:

Department of Biology,
Morgan State University,
1700 E. Cold Spring Ln., Key Hall G51
Baltimore, MD 21251
443-885-4468

This research study will use health information that identifies you. If you agree to participate, this researcher will use just the health information listed below.

THE SPECIFIC HEALTH INFORMATION TO BE USED OR SHARED:

- *Billing and payment information and the medical information required to justify it.*
- *Sensory testing*
- *Self-report medical history*
- *Blood tests including folate levels, vitamin B12 and D levels, hemoglobin A1c and inflammatory marker levels*
- *Urine drug testing*
- *Brain imaging*

Federal laws require this researcher to protect the privacy of this health information. The researcher will share it only with the people and groups described here.

PEOPLE AND ORGANIZATIONS WHO WILL USE OR SHARE THIS INFORMATION:

- Dr. Luana Colloca and Timothy Meeker and the study team including research coordinators, students of Drs. Colloca and Meeker
- The sponsor of the study or its agents, such as data repositories or contract research organizations
- Organization that will coordinate health care billing or compliance such as offices within UMSOM; the University of Maryland, Baltimore (UMB); University of Maryland Faculty



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Physicians, Inc. (FPI) and the faculty practices of the UMB; University of Maryland Medical System (UMMS).

THIS AUTHORIZATION WILL NOT EXPIRE. BUT YOU CAN REVOKE IT AT ANY TIME.

To revoke this Authorization, send a letter to this researcher stating your decision. The researcher will stop collecting health information about you. This researcher might not allow you to continue in this study. The researcher can use or share health information already gathered.

ADDITIONAL INFORMATION:

- You can refuse to sign this form. If you do not sign it, you cannot participate in this study. This will not affect the care you receive at:
    - University of Maryland Faculty Physicians, Inc. (FPI)
    - University of Maryland Medical System (UMMS)

  It will not cause any loss of benefits to which you are otherwise entitled.
- Sometimes, government agencies such as the Food and Drug Administration or the Department of Social Services request copies of health information. The law may require this researcher, the UMSOM, FPI, or UMMS to give it to them.
- This researcher will take reasonable steps to protect your health information. However, federal protection laws may not apply to people or groups outside the UMSOM, UMB, FPI, or UMMS.
- Except for certain special cases, you have the right to a copy of your health information created during this research study. You may have to wait until the study ends. Ask the researcher how to get a copy of this information from the study.

My signature indicates that I authorize the use and sharing of my protected health information for the purposes described above. I also permit my doctors and other healthcare providers to share my protected health information with this researcher for the purposes described above.

Subject's Signature	Date	Printed Name

Privacy Questions? Call the UMSOM Privacy Official (410-706-0337) with questions about your rights and protections under privacy rules.

Other Questions? Call the researcher named on this form with any other questions.

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