### REMOVE ALL THE INSTRUCTIONS IN BLUE BEFORE SUBMITTING

### REMOVE ALL GREY HIGHLIGHTING BEFORE SUBMITTING

#### RESEARCH CONSENT FORM AND HIPAA AUTHORIZATION

**Protocol Title:** [Enter full study title]

**Study No.:** [Include the UMB protocol number only]

**Principal Investigator:** [Name, degrees, phone number]

**Sponsor:** [Delete if not applicable]

Add a statement here to indicate that if they are consenting for someone else - a child or someone unable to provide consent themselves - then the word “you” means that person. (e.g. *Throughout this document, “You” always refers to the person taking part in the study.*)

|  |
| --- |
| **CONCISE SUMMARY:**Key information must be provided at the beginning of the informed consent document. Consider the following:* UMB requires that all informed consent documents begin with a focused and concise description of the key information of the research study. This information must be written using lay language and simple terms.
* The concise summary section must provide the prospective study subject or legally authorized representative with information “that a reasonable person would want to have in order to make an informed decision.” The researchers must also provide them with an opportunity to discuss this information and the time to decide whether they may or may not want to participate in the study.
* This concise summary should include:
	+ Statement that the study is research and that participation is voluntary
	+ Purpose of the Research (1-2 Sentences)
	+ Procedures and Duration (4-8 Sentences)
	+ Key Risks and Benefits (6-8 sentences); and
	+ Other key information as appropriate, such as a summary of cost and payment information or alternatives to participation in the study (especially for clinical trials)
* The information here does not need to be repeated within the body of the informed consent.

Examples of Informed Consent Concise Summaries are posted on the [UMB HRPO website](https://www.umaryland.edu/hrp/for-researchers/consent-form-templates/). |

Revise the sections below to address additional informed consent requirements. Do not change or replace the headings for each section.

**PURPOSE OF STUDY**

* Explain the purpose of the research study.
* Include a clear description of the research test product (i.e., survey, drug, or device), if applicable.
* If an investigational drug or device is being used and an IND/IDE has been obtained, identify which drug or device is investigational and state that the FDA is allowing the use of the drug or device in the study.
* State if a placebo is being used.
* Explain how/why the potential subject qualifies for the study and inform them why they are being asked to participate in the study.
* Do not include inclusion/exclusion criteria in the consent form unless the criteria are directly relevant to the subject's decision-making (e.g., safety issues, excluded medications, changes in behavior such as alcohol use).
* State the number of subjects at this site and, in total, if this is a multi-center study.

**PROCEDURES**

* Briefly explain in lay terms the study design, as well as the procedures the subject will undergo if they agree to join the study. Describe each procedure in separate paragraphs or bullet points.
* Describe each procedure in separate paragraphs or bullet points.
* **Group Assignments:** When dividing subjects into multiple groups, explain how they will be assigned to each group. Describe the roles and procedures for each group, as applicable.
* **Use of Placebo:** State if a placebo is being used and explain its use in readily understandable terms.
* **Group Randomization:** If randomization will determine treatment assignment, explain it in readily understandable terms. It is suggested that randomization means that treatment will be determined by chance, like drawing a card, drawing a number, or flipping a coin.
	+ **For example:** *“The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have an \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* [equal/one in three/etc.] *chance of being given each treatment.”*
	+ For double-blinded studies, add**:** “*Neither you nor the study doctor will know which treatment you are getting.”*
	+ For single-blinded studies, add**:** *“You will not be told which treatment you are getting; however, your study doctor will know.”*
* Specify the number of required hospital visits, clinic visits, inpatient or outpatient, and actual time commitment involved in participation for each visit.
* State the expected total duration of the subject’s participation.
* Clearly state the amount of blood researchers will collect at each visit and the total amount to be drawn over the course of the study (in household measures, i.e., teaspoons).
* Distinguish which procedures are part of the subject’s standard clinical care, what will be done to the subject solely for research purposes, and/or what is experimental in the project.
	+ Standard of Care procedures should refer to activities scheduled as part of the subject’s standard care, regardless of the subject's participation in this research study.
	+ Solely for Research procedures should include any procedures that would be done only for the purpose of the study. These activities include those considered part of the subject’s standard of care when they are performed more frequently or for longer periods than what would take place if the subject was not part of the research study.
* Study procedures that are long, complex, or include several steps should use bulleted format and short paragraphs to aid comprehension.
* The use of tables, images, or a flow chart may be included in the consent form to enhance the subject’s ability to understand the procedures.
* If clinically relevant research results may be uncovered, the consent document must include whether or not the subject will be told of these results and under what conditions.
* **Drug Interactions**: When applicable, include a statement regarding the possible interactions between the study drug(s) and other medications, dietary supplements, or alternative medicines.
* **Biospecimen Collection**: Describe the types of specimens to be collected and the tests/analyses to be done on the data and samples.

# **For studies involving the collection of identifiable private information or identifiable biospecimens, subjects should be informed of the following:**

* + A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and then could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or legally authorized representative.

 ***OR***

A statement that the subject’s information or biospecimens collected as part of the research study, even if identifiers are removed, will not be distributed for future research studies

* + Whether the study will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).
	+ Will the specimens be used to generate a cell line for genetic testing?
	+ Will the specimens be stored without any identifiers (de-identified), and if so, will they be linked specimens or unlinked specimens? If linked, will the specimens and all links to clinical data be destroyed or removed from the bank upon the subject’s request?
	+ Will the study results be conveyed to the subject and/or healthcare provider?
	+ Will the subjects be contacted after the completion of the original study?
	+ Will the subject’s biospecimens (even if identifiers are removed) be used for commercial profit, and whether or not the subjects will or will not share in this profit.
	+ For research with biospecimens, specify whether the study might include whole genome sequencing or genome-wide association studies (GWAS) and whether GWAS data will be put into federal or other databases (e.g., dbGaP).

## What are my responsibilities if I take part in this RESEARCH STUDY?

If you take part in this study, you will be responsible to:

For all clinical trials, describe any responsibilities of the subject. Delete this section if the research is not a clinical trial.

# **POTENTIAL RISKS/DISCOMFORTS:**

* Describe any foreseeable risks or discomforts to the subject that are related only to their participation in the study.
* Risks should be described in clear and simple terms that would be understood by the targeted study population.
* Risks should be stated by the severity and likelihood, or they should be compared with natural risks that are understood by most patients. Use categories such as likely, less likely, unlikely, and/or rare.
* Simplify percentages whenever possible. For example, say 25 out of 100 patients instead of 25%
* **Washout Period:** For clinical trials, describe the risk associated with a washout period when applicable
* **Use of Devices**: the description must describe the risks associated with the use of the device itself and the long-term risks, such as the risks of removal, consequences of removal, and device maintenance. Also, describe any risks due to possible malfunction and its consequences.
* Along with physical risks, be sure to indicate when present social risks (e.g., social rejection if the diagnosis is disclosed), psychological risks (e.g., discomfort answering specific survey questions), legal risks (e.g., mandatory reporting of certain activities to legal authorities), and economic risks.
* All consent forms should list the risk of the potential for the loss/breach of confidentiality.
* There may be risks to the subject which are currently unforeseeable unless the risk profile of all study-related interventions is well known and the study involves no investigational drugs or devices. If there are unforeseeable risks, state:

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

* In addition, state how all risks will be minimized. For example, state, if applicable:

*“Risk of loss of confidentiality will be minimized by storing data in a secure location such as a locked office and locked cabinet.”* or *“Electronic data will be password-protected.”*

**When applicable, include risks associated with pregnancy or breast-feeding:**

* Include pregnancy and fertility risks for all genders.
* If the study involves individuals who are pregnant or of child-bearing potential and involves an investigational product or procedures whose risk profile in pregnancy is not well known, add:

“*If you are or become pregnant, this study may hurt your baby or your pregnancy in ways that are unknown.”*

* For a study that involves risks to an embryo or fetus, add:

“The procedures involved in this study may harm a pregnancy or unborn child in the following ways [specify]. You should not become pregnant or father a baby while participating in this study.”

* Include any risks to a nursing infant.
* If conducting GWAS, address the risks associated with identification through genetic information. Example text: “*Even without your name or other identifiers, your genetic information is unique to you. There is a potential risk that someone will identify you from your genetic information or learn something about you by looking at your genetic information. This risk may increase in the future as technologies advance and as more researchers study your genetic information. These risks may also affect members of your family. You should discuss your participation in this study with your family and ask the study doctor about any questions or concerns you may have.*”

# **POTENTIAL BENEFITS**

* Explain the expected potential benefits to the participant, if any, and their likelihood. Do not overstate direct benefits to subjects when it is not realistic to expect benefits.
* If the subject will not benefit from participation, clearly state:

*“*You will not benefit directly from your participation in this study*.”*

* If there is the potential for the subject to receive benefit state:

*“*You may or may not benefit by taking part in this study. There is no guarantee that you will receive direct benefit from your participation in this study.*”*

* If applicable, state possible general benefits for science in terms of the knowledge to be gained, or other patients with similar diseases, or for the population at large (if applicable). However, do not state such benefits if the person who will be consenting is a surrogate for the study subject and should not be considering those benefits.
* **For research studies involving children, the following statement in the parental consent must be included:**

*“*You need to decide if your child’s participation in this research study is in your child’s best interest.*”*

* Receiving standard healthcare, payment, or other considerations for participation in a research study is not considered a benefit.

# **ALTERNATIVES TO PARTICIPATION**

* Summarize realistic alternatives to participation. Specifically, state what treatment is available or recommended if the subject declines to participate in the study. Include, for example, approved standard of care, other research studies, palliative care, or no treatment.
* Example text: “*You do not have to take part in this study. Your other choices include* [specify]. *Please talk to your doctor about your choices before deciding if you will take part in this study.*”
* If the study does not involve a treatment intervention, state:

“This is not a treatment study. Your alternative is to not take part. If you choose not to take part in the study, your decision not to participate should not affect your healthcare.”

# **COSTS TO SUBJECTS**

**General Instructions**

* Study subjects shall not have undisclosed additional costs from participating in the research study.
* Include the Required Statement below.
* Modify the statement in the highlighted section to align with the study.
* You must not deviate from this unless approved by \_\_\_\_\_\_\_\_\_\_\_and the approval is provided to the IRB. The IRB will reject any submission which contains statements that deviate from the required language without approval.

**REQUIRED STATEMENT:**

There will be no fee to enroll in the study. However, in accordance with applicable law and policy, you or your insurance may be billed for the costs of medical care that are required by the study. You or your insurance will also be 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.

* Include the following statement if the study involves a treatment intervention (be sure to delete the inapplicable language).

The sponsor of the study will provide the study [drug][device]. You or your insurance [will][will not] be billed for the study [drug][device], but you or your insurance may be billed for the cost of getting the study [drug][device] ready and [giving it to you][implanting it].

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 – CHOOSE ONE OF THE FOLLOWING OPTIONS:**

**OPTION 1 (if the study offers no payment to the subject):**

You will not be paid for taking part in this study.

**OPTION 2 (if the study offers payment to the subject):**

**Describe Payments:**

1. Describe whether subjects will receive any payment or incentives. Include all payments or gift items:
	* Monetary compensation, including gift cards
	* Reimbursement for meals, parking, etc.
	* Items such as movie tickets, toys, etc.
2. Include payment method (e.g., check, gift card, transportation, etc.).
3. In general, all payments to subjects should be prorated for partial participation:
	* Indicate how payment will be prorated.
4. Researchers should not condition a large lump sum at the end of the study only if subjects complete the entire study.
5. Describe how and when subjects will receive payments and incentives (e.g. after each study visit or some other milestone)
6. Include the paragraph below:

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

**Instructions – subject injury part 1**

~Do not edit the text below~

**If you have an injury, promptly seek medical care from any healthcare provider. If you have an emergency, call 911 or go to the nearest emergency room. 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.

**Instructions – subject injury part 2**

* If the Sponsor will not pay for any costs in the event of study-related injury, then use Statement 1.
* If the Sponsor will pay for at least some of the costs in the event of study-related injury, then use Statement 2. The Sponsor may request to use its own statement; deny this request stating that this is UMB’s approved language, and any deviation to either Statement 1 or Statement 2 will require additional review by legal counsel.

**Statement 1:**

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.

**Statement 2:**

If you are injured as a result of being in this study, the sponsor has agreed to pay for the cost of your medical care for injuries caused by the sponsor’s study [drug][device] or the proper performance of a study procedure. However, the sponsor will not pay for:

* the cost of medical care caused by the natural progression of your disease
* costs that are caused by the negligence of a healthcare provider
* costs resulting from you not following study instructions

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.

# **CONFIDENTIALITY AND ACCESS TO RECORDS**

* Explain whether or not the study will involve confidential information. If it does, briefly indicate who will have access to the information, whether or not it will be de-identified or coded, what measures investigators will use to ensure the information is maintained in a confidential manner, whether or not the subject’s name or other identifier will be used***,*** and how confidential information (including audio and video tapes) will be stored and destroyed at the end of the study.
* If information requiring a Confidentiality Certificate is to be involved (e.g., illegal criminal behavior, drug use, physical abuse, sexually sensitive material, and HIV status), state the protections afforded by the Certificate. In the absence of a Certificate, state that the confidentiality of data will be maintained to the fullest extent required by law.
* Inform subjects that study records will be considered confidential and (if appropriate) that the subject’s name will not be used in reports or publications.
* Depending upon study sponsorship, include a statement that study records can be reviewed by federal agencies, private sponsor, and the IRB.

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.

* Add to this list other organizations that may have access to the subject’s records, such as the Food and Drug Administration (when the study is FDA-regulated), the Department of Health and Human Services (when the study is conducted or funded by DHHS), the sponsor, contract research organization, sponsor’s agent, and other collaborating institutions.
* For clinical studies, include:

“The monitors, auditors, the IRB, and the Food and Drug Administration 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.”

* If HIV/Hepatitis/TB testing will be done, add a statement that a positive result will be reported, as required under State law. **Note: There are many other reportable conditions. To see a list, go to:** [**http://phpa.dhmh.maryland.gov/SitePages/what-to-report.aspx**](http://phpa.dhmh.maryland.gov/SitePages/what-to-report.aspx)**.**

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.

* For FDA-regulated non-Phase I controlled trials add:

“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 the results. You can search this website at any time.”

* For studies involving genetic testing:

“Genetic Testing: It is against federal law (Genetic Information Nondiscrimination Act, or GINA) for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law, however, does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.”

# **RIGHT TO WITHDRAW**

Your participation in this study is voluntary. You do not have to take part in this study. You are free to withdraw your consent at any time. 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 at **Insert Name at Insert Phone Number**.

* State either that there are no adverse consequences (e.g., physical, social, economic, legal, or psychological) of a subject's decision to withdraw from the study or state the consequences of a subject's decision to withdraw from the study. If the latter applies to this study, then also state the procedures for orderly withdrawal by the subject. **State that a written withdrawal is requested/required and to whom it should be sent.**
* For clinical studies, include:
* *“If you withdraw from this study, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care.”* **Note: The consent document cannot give the subject the option of having data removed.**
* *“If you agree, this data will be handled the same as study data.* **Note: If a subject withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the investigator may not access the subject’s medical record or other confidential records requiring the subject’s consent for purposes related to the study. However, an investigator may review study data related to the subject collected prior to the subject’s withdrawal from the study and may consult public records, such as those establishing survival status.**
* If applicable, include:

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

* If the study includes UMB students, staff, or faculty, include:

“If you are an employee or student at the University of Maryland, Baltimore (UMB), your employment status or academic standing at UMB will not be affected by your participation or non-participation in this 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 [add additional reasons why the subject may be withdrawn, if appropriate. For example, failure to follow instructions of the study team if the person in charge decides that the study is no longer in your best interest.]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

**Instructions**

* Do not edit or delete the text in this section.
* The University Statement must be included in the informed consent document regardless of the study risk.

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.

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

External groups relying on UMB for their IRB reviews may include their institution statements here.

**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.

Incorporate all signature lines (below) applicable to your study and delete all others.

**NOTE**: The subject and person obtaining consent signature lines are required for all research studies.

The signature of a second parent or guardian may be requested by the IRB as required by the regulations governing research involving children.

The Witness signature is optional unless the research subject is illiterate, unable to sign the consent document, or otherwise required by the IRB. Including a witness line in your consent form is prudent because you will not know who your future participants will be and may find that you will need a witness.

**Research Participant**

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

Subject’s Signature Date Printed Name

**Parent/ Guardian/Legally Authorized Representative (LAR)**Sign your name below, if you give permission for the person named above to take part in this study.

Signature of Parent/Guardian/LAR Date Printed Name

Relationship:

Signature of Parent/Guardian #2 (When applicable) Date Printed Name

Relationship:

**Investigator or Designee Obtaining Consent**

Signature of Investigator or Designee Date Printed Name

**Witness**

Witness Signature Date Printed Name

######  **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:** *<Title>*

**UMB IRB Approval Number:** *<IRB number>*

Researcher’s Name: *<PI name>*

Researcher’s Contact Information:

 *<Department / Institution name>*

***University of Maryland School of Medicine (UMSOM)***

 *<Street Address>, <Room number>*

 *<Phone number>*

**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:

Delete any bulleted items below that do not apply. Replace *[Specify others if applicable] with* any additional information that may be obtained from participants that is not listed below.

* Billing and payment information and the medical information required to justify it
* Information that relates to your health or medical condition from your medical records
* Information obtained from the study procedures outlined in this Authorization, including:
	+ Laboratory results obtained on specimens collected from you (blood, urine, or tissue)
	+ Results of physical exams and other tests or procedures
	+ Any other medical information we learn from you about your health history
	+ Interviews, questionnaires, or surveys
* *[Specify others if applicable]*

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:

Delete any bulleted items below that do not apply. Replace *[Specify others if applicable]* withany additional people and organizations not listed below.

* Dr. *< PI name >* and the study team
* Other researchers and centers that are part of this study, including people who oversee research at those institutions
* People or groups hired to provide services related to this research (i.e., service providers, laboratories, etc.)
* The sponsor of the study or its agents, such as data repositories or contract research organizations
* Organization(s) that will coordinate health care billing or compliance such as offices within UMSOM; the University of Maryland, Baltimore (UMB); University of Maryland Faculty Physicians, Inc. (FPI) and the faculty practices of the UMB; University of Maryland Medical System (UMMS) and the Veterans Affairs Maryland Health Care System (VAMHCS)
* Your health insurer to pay for covered treatments outlined in the Cost to Subject section of Research Consent form
* [Specify others if applicable]

**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)
	+ Veteran Affairs Maryland Health Care System (VAMHCS)

 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, UMMS, or VAMHCS 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, UMMS, or VAMHCS.
* 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

Signature of Parent/Guardian/LAR Date Printed Name
*(When applicable)*

Relationship to Subject:

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.