### REMOVE ALL THE INSTRUCTIONS IN BLUE BEFORE SUBMITTING

### REMOVE ALL GREY HIGHLIGHTING BEFORE SUBMITTING

#### RESEARCH CONSENT FORM AND HIPAA AUTHORIZATION

**Protocol Title:**

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

**Principal Investigator:** *[please provide 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.

**CONCISE SUMMARY:**

Key information must be provided at the beginning of the informed consent document. Consider the following:

* The prospective research participant or legally authorized representative must be provided with information “that a reasonable person would want to have in order to make an informed decision,” as well as an opportunity to discuss such information.
* The informed consent must begin with a ‘concise and focused presentation of the key information most likely to assist in comprehension of why one may or may not want to participate in the study.
* The focused and concise summary should include:
  + Statement that the project is research and that participation is voluntary
  + Summary of purpose, duration, procedures, key risks, discomforts, and benefits
  + Other key information as appropriate, such as summary of cost and payment information or alternatives to participation in the research (especially for treatment studies)
  + Rather than a list of isolated facts, the goal is to help process the information given to make it easier for a subject or legally authorized representative to make an informed decision
* The information here does not need to be repeated within the body of the informed consent.

(Examples of focused and concise summaries are on the UMB HRPO website)

*Include required components of informed consent elements below which have not been included in the above concise summary.*

**PURPOSE OF STUDY**

* Explain the purpose of the research project.
* If an investigational drug or device is being used and an IND/IDE has been obtained, please describe and state that the FDA is allowing the use of this in the study
* Please state if a placebo is being used.
* Explain how/why the potential participant qualifies for the study and inform him/her why he/she is being asked to participate in the study.

*Do not include inclusion/exclusion criteria in 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 participants 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 participant will undergo if he/she agrees to join the study.
* Explain how treatment groups will be assigned.
* 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 actual time commitment involved in participation.
* State the expected duration of participant’s participation.
* Clearly state the amount of blood to be drawn at each visit and the total amount to be drawn over the course of the study (in household measures, i.e. teaspoons).
* Clarify what will be done to the participant solely for research purposes and/or what is experimental in the project (including a detailed description of the investigational agent or device, if applicable).
* If the study procedures are long and complex and include several steps, bulleted format, and short paragraphs. It is recommended that a flow chart be included in the consent form to enhance the participant’s ability to understand the procedures.
* If clinically relevant research results may be uncovered, the consent document must include whether or not the participant will be told of these results, and under what conditions.

[For clinical trials describe the chances of being assigned to any one group. 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.

# **For studies involving the collection of identifiable private information or identifiable biospecimens, participants 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, even if identifiers are removed, will not be distributed for future research studies

Also include the following:

* Whether the research 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 participant’s request?
  + Will the research results be conveyed to the participant and/or health care provider?
  + Will the participants be contacted after the completion of the original research?
  + 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.

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

If you take part in this research, 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 participant that are related only to the research in clear simple terms.
* 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.
* Along with physical risks, be sure to consider social, psychological, legal, 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 participant which are currently unforeseeable unless the risk profile of all research-related interventions is well known and the research involves no investigational drugs or devices. If there are unforeseeable risks, please include the following statement:

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

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

*“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.”*

If applicable -

* Include pregnancy and/or male and female fertility risks to the adult.[If the research involves pregnant women or women 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 research may hurt your baby or your pregnancy in ways that are unknown.

[For research that involves risks to an embryo or fetus] The procedures involved in this research may harm a pregnancy or unborn child in the following ways: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. You should not become pregnant or father a baby while on this research study.

Include any risks to a nursing infant if applicable.

# **POTENTIAL BENEFITS**

* If the participant 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 participant 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.”* State the potential personal or societal benefits of participation.

*Do not overstate direct benefits to participants when it is not realistic to expect benefits. If applicable, state possible general benefits for science or other patients with similar diseases, or for the population at large (if applicable). However, do not state such benefits it the person who will be consenting is a surrogate for the research subject, and should not be considering those benefits.*

**For research 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 healthcare, payment, or other consideration for participation in a research study is not considered a benefit.*

**ALTERNATIVES TO PARTICIPATION**

* Explain realistic alternatives to participation; specifically, state what treatment is available or recommended if participant declines to participate, include for example, approved standard of care, other research studies, palliative care, or no treatment.
* [For clinical trials] The important risks and possible benefits of these alternatives are listed below: [Describe the important risks and potential benefits of the alternative procedures and courses of treatment.]
* If the research 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, your healthcare at University of Maryland, Baltimore will not be affected.”*

# **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 coded, what measures investigators will use to ensure the information is maintained in a confidential manner, whether or not the participant’s name or other identifier will be used***,*** and how 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 (i.e. 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 permitted by law.
* Inform participants that study records will be considered confidential, and (if appropriate), that the participant’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 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 this organization. [Add to this list other organizations that may have access to the subject’s records such as the Food and Drug Administration, when the research if FDA-regulated, the Department of Health and Human Services, when the research is conducted or funded by DHHS, the sponsor, contract research organization, sponsor’s agent and other collaborating institutions.]
* [For clinical trials, include] The monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical records for verification of the research procedures and date. By signing this document you are authorizing this access.
* If HIV/Hepatitis/TB testing will be done, please 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)

State the following in this section –

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

# **RIGHT TO WITHDRAW**

State the following in this section –

* “Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at anytime. Refusal to take part or 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 medical injury related to the research, please contact the investigator Insert Name at Insert Phone Number. "
* Please state either that there are no adverse consequences (physical, social, economic, legal, or psychological) of a participant's decision to withdraw from the research, or state the consequences of a participant's decision to withdraw from the research. If the latter applies to this study, then please also state the procedures for orderly termination of participation by the participant. State that a written withdrawal is requested/required and to whom it should be sent.

[Include the following paragraph for clinical trials:]

* 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 research 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 must not access for purposes related to the study the subject’s medical record or other confidential records requiring the subject’s consent. 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 please add the following –

* “You will be told of any significant new findings which develop during the study which may affect your willingness to participate in the study.”
* If the study includes students, staff or faculty, a statement must be included to state “If you are an employee or student, 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 research?

The person in charge of the research study or the sponsor can remove you from the research 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 research staff, if the person in charge decides that the research study is no longer in your best interest.]The sponsor can also end the research study early. The study doctor will tell you about this and you will have the chance to ask questions if this were to happen.

# **COSTS TO PARTICIPANTS**

**General Instructions**

* Study participants shall not have undisclosed financial risks due to their participation in the research study. You must provide an explanation of the expected party responsible to pay for these procedures. Specifically, state who will pay or whether the participant will be responsible for payment.
* Select the statements below that are applicable to the study.
* Delete the statements that do not apply.
* Words and phrases highlighted in [yellow] mean you must choose the applicable word or phrase. Once selected, remove the brackets and the yellow highlights.
* If applicable, the statements you choose should be consistent with the related budget and other documents between UMB-CCT, UMB-SPA, University of Maryland Medical Center, and the Sponsor.
* You must clearly state whether the participants will be responsible for the cost of drugs, devices, or treatments that are provided or conducted solely for the purpose of the study.

**Statement 1:**

There will be no fee to enroll in the study. However, you or your insurance will be billed for costs of medical care that you would have needed or received if you were not in the study.

**Statement 2:**

There may be expenses associated with your participation in the study such as co-insurance, deductibles, co-pays, travel expenses, lodging, meals, fuel, parking fees, etc.

**Statement 3:**

In this study, there may be tests and procedures you will have that are standard of care (SOC) to treat your condition or disease. SOC tests and procedures would be done whether or not you take part in the study. These SOC tests and procedures will be billed to you or your insurance.

**Statement 4:**

The following tests and procedures that are routine costs for research studies will also be billed to you or your insurance:

* [Provide list of test and procedures that will be billed to the participant or insurance.]

**Statement 5:**

Include the following statement if the study involves a treatment intervention.

The sponsor of the study will provide the study [drug][device]. You or your insurance [will][will not] be charged for the [drug][device].

**Statement 6:**

You or your insurance may be billed for [administering the study drug][implanting and removing the study device.]

**Statement 7:**

Include the following statement if there is a procedure that the participant would have or go through only because they are participating in the study.

If you have a procedure only because you are participating in the study, the sponsor of the study will pay for it.

# **PAYMENT TO PARTICIPANTS**

**General Instructions**

* Select the statements below that are applicable to the study.
* Delete the statements that do not apply.
* Include any applicable statements to outline remuneration amount or other compensation, and payment method (e.g. check, gift certificate, transportation).
* Describe whether participants will receive any payment or incentives for their participation. Include all payments or gift items:
* Reimbursement for meals
* Reimbursement for parking
* Monetary compensation, including gift cards
* Items such as movie tickets, toys, etc.
* In general, all payments to participants should be prorated for partial participation:
* Indicate how payment will be prorated.
* Researchers should not make the condition to pay participants a large lump sum at the end only if they complete the entire study.
* Describe how and when the participant will receive payments and incentives (e.g., gift items; after each study visit or some other milestone).

**Statement 1:**

If the study offers payment to participant, replace the statement below with a description of the payment offered following the instructions above.

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

**Statement 2:**

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)).

**Statement 3:**

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**

**Any language proposed by the sponsor contrary to the following concepts must be deleted.**

* The Sponsor/Funder/Other Entity should not require the healthcare provider to submit claims to the subject’s health insurance, government programs like Medicare and Medicaid, or any other person or entity for costs to treat a study-related injury prior to submitting an invoice to the sponsor.
* The Sponsor/Funder/Other Entity should not require a healthcare provider to bill the subject or the subject’s insurance first, and then reimburse the subject or the subject’s insurance for costs to treat a study-related injury.

**Instructions – subject injury part 3**

* Select between Statement 1 and Statement 2 below for the one applicable to your study.
* The statements you choose should be consistent with any applicable agreements negotiated between UMB-CCT, UMB-SPA, University of Maryland Medical Center, and the Sponsor.
* Words and phrases highlighted in [yellow] mean you must choose the applicable word or phrase. Once the right statement is selected, remove the brackets and the yellow highlights.

**Statement 1:**

Include the following statement if the sponsor has agreed to pay for the cost of study-related injuries to a participant.

The sponsor has agreed to pay for the cost of your medical care for injuries caused by the sponsor’s [drug][device] or the proper performance of a study procedure.

The cost of medical care for injuries not caused by the sponsor’s [drug][device] or a study procedure may be your responsibility, depending on the cause of the injury. In such cases, you, your insurance, or another party may be responsible for the costs of medical care.

For example, the sponsor will not pay for:

* the cost of medical care caused by the natural progression of your disease.
* expenses that are caused by the negligence of a healthcare provider.
* not following study instructions.

UMB and/or its affiliated healthcare facilities or healthcare providers will not provide any financial compensation or reimbursement to you for the cost of medical care or other expenses arising from an injury.

**Statement 2:**

Include the following statement if the Sponsor has not agreed to pay for the cost of injuries to a participant.

UMB and/or its affiliated healthcare facilities or healthcare providers will not provide any financial compensation or reimbursement to you for the cost of medical care or other expenses arising from an injury.

In such cases, you or your insurance may be billed for the costs of medical care.

## 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 participants 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 participant. 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

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.

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

Please incorporate all signature lines (below) which are applicable to your study and delete all others.

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

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| --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Participant’s Signature  Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Parent/Guardian  *(When applicable)*  Relationship:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Investigator or Designee Obtaining Consent Signature  Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of Parent/Guardian #2  (*When applicable,* *as required by CFRs-requirements for permission by parents’ assent*)  Relationship:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |
|  | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Witness\*  Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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\*Witness is optional unless IRB required, participant is illiterate, or unable to sign. It is prudent to include a witness line, however, in your consent form because you will not know who your future participants will be and you may find that you will need a witness.

###### **Health Insurance Portability and Accountability Act (HIPAA)**

###### **AUTHORIZATION TO OBTAIN, USE AND DISCLOSE**

**PROTECTED HEALTH INFORMATION FOR RESEARCH**

**Name of Study Participant:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**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/your child. If you/your child 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.*
* *Research tests [INCLUDE ALL ITEMS THAT APPLY]*

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

**People and Organizations Who Will Use or Share This Information:**

* Dr. *< PI name >* and his/her research team.
* 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 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 [INCLUDE ALL ITEMS THAT APPLY]*

**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. He/she will stop collecting health information about you/your child. This researcher might not allow you/your child to continue in this study. He/she 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/your child 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/your child 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/your child’s 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/your child have the right to a copy of your/your child’s health information created during this research study. You may have to wait until the study ends. Ask this research how to get a copy of this information from him/her.

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

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name (printed) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

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