

If appropriate for this study, a scanned copy of the signed consent form should be uploaded to the participant's Epic/EMR record.

Patient I.D. plate

COMBINED PARENTAL PERMISSION / << (delete if not applicable)>> RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title:

Application No.:

Sponsor/Supporter/Funded By: *<<Please choose the most appropriate header. It is required that entities providing monetary or material support be listed here. If there are multiple supporters, please list them and identify the type of support. Delete this line if not applicable>>*

Principal Investigator: *<<Include name, address, email address, and phone information>>*

<<This is a required statement for all consent forms>>

You are being asked to join a research study. Participation in this study is voluntary. Even if you decide to join now, you can change your mind later.

<<Include this statement if the study includes children. >>

If you are a parent or legal guardian of a child who may take part in this study, your permission is required for your child to participate. The assent (agreement) of your child may also be required. When we say "you" in this consent form, we mean you or your child.

<<Include this statement if cognitively impaired adults will be in the study: >>

The person being asked to be in this research study may not be able to give consent to be in this study. You are therefore being asked to give permission for this person to be in the study as his/her decision maker.

<<ONLY include this statement if this is a Single IRB study where JHM IRB is the IRB of record >>

This study is a multi-site study, meaning it will take place at several different locations. Because this is a multi-site study, this informed consent form includes two parts. The first part of this document includes information that applies to all study sites. The second part of the consent form includes information specific to the study site where you are being asked to enroll.

1. Research Summary (Key Information):

<<This section is required to be completed. Include the following statement:>>

The information in this section is intended to be an introduction to the study only. Complete details of the study are listed in the sections below. If you are considering participation in the study, the entire document should be discussed with you before you make your final decision. You can ask questions about the study now and at any time in the future.

- *Please provide a concise and focused presentation of key information that is most likely to help potential participants understand why they might or might not want to participate in the study.*
- *This section should include a summary of the purpose of the study, duration of participation, major requirements of the study and any potential benefits. This section should also contain any significant risks of participating in the study and a statement as to whether there will be any costs associated with participation. The information presented in this section may be discussed in greater detail later in the consent form.*
- *This summary of key information should be limited to one to three paragraphs, and the total length should not exceed one page.*
- *Please see the guidance on the IRB website for further information and examples.*

2. Why is this research being done?

<<Start with an introductory sentence describing the primary purpose of the research as stated in the protocol: >>

This research is being done to....

<<State what the study is designed to discover or establish. If this is a treatment study, describe how it differs from standard clinical care. >>

Are there any investigational drugs/devices/procedures?

<<Broadly identify any drugs/devices/procedures that are investigational. >>

<<If you are using a drug or device that is not FDA-approved for marketing (but which is being used in the study under an IND or IDE), state that the drug, combination of drugs, device, etc. are investigational and include the following: >>

The use of “X” (study drug or device name) in this research study is investigational. The word “investigational” means that “X” is not approved for marketing by the Food and Drug Administration (FDA). The FDA is allowing the use of “X” in this study.

<<If you are using a drug or device that is FDA-approved for marketing, but will not be used in this study for its FDA-approved indications (and is being used in the study under an IND or IDE), include the following: >>

“X” (drug or device name) is approved by the Food and Drug Administration (FDA) for the treatment of ___ (include disease name(s)). It is not approved for use in ___ (disease name(s)). The FDA is allowing the use of “X” in this research study.

<<If you are using a drug or device that is FDA-approved for marketing, but will not be used in this study for its FDA-approved indications (and is being used in the study without an IND or IDE, e.g. exempt determination made by the FDA or the IRB), include the following: >>

“X” (drug or device name) is approved by the Food and Drug Administration (FDA) for the treatment of ____ (include disease name(s)). It is not approved for use in ____ (disease name(s)).

<<If you are using a device that is not FDA-approved for marketing, but has been deemed non-significant risk (NSR) or IDE exempt by the FDA or the IRB, include the following: >>

The use of “X” (device name) in this research study is investigational. The word “investigational” means that “X” is not approved for marketing by the Food and Drug Administration (FDA).

<<If the FDA may approve the study drug while the research study is in process, include information on whether participants will be responsible for paying for the study drug if it is approved. >>

Who can join this study?

<<Describe the study population, but DO NOT state that the participant has been selected for the study: >>

People with _____ may join.

<<OPTIONAL:>>

How many people will be in this study?

<< If you choose to include this information, please make sure the enrollment number(s) match the enrollment number(s) listed in the application and/or protocol. Please note that if you revise your enrollment number(s) in the application and/or protocol, you will need to revise the information here.>>

<<If this is a multicenter study and you choose to add the number of participants, include the total number of participants at all sites, and the approximate number who will take part at Johns Hopkins.>>

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

- *<<Describe the procedures chronologically using lay language, short sentences, and short paragraphs.*
- *Blood draw measurements should be provided in teaspoons/tablespoons, ounces, etc.*
- *Use subheadings and bulleted items.*
- *Use tables, flow-charts and other diagrams that might be a helpful visual aid in explaining procedures, visit structure and timelines.*
- *Distinguish which procedures are part of the study and which are standard clinical treatments.*
- *Clarify any change in participant’s care as s/he shifts from standard clinical care to the study intervention.*
- *Define and explain all medical and scientific terms in ordinary language.*
- *Specify the assignment to study groups, length of time for participation in each procedure, the total length of time for participation, frequency of procedures, location of procedures, etc.*
- *For research involving randomization, specify the randomization procedure. For two groups use “flipping a coin.” If your research includes more than two groups use “like drawing numbers from a hat.”*
- *For double-blind studies, include a statement that the blind can be broken in case of an emergency. Example: “In the case of an emergency, the study doctor can quickly find out which drug or intervention you are assigned to receive.”*

- *For research involving the use of placebo, clearly define the term placebo. Use language like “A placebo is an inactive substance that looks like the study drug, but contains no active drug” >>*

<<If your study involves the collection of biospecimens that will be destroyed immediately upon completion of the testing (e.g. pregnancy testing), please include the following after describing the testing. You will need to select Option A in section 4 below.>>:

The biospecimens (such as blood or urine) you provide for this research study will be processed and then immediately discarded. Your samples will be used as part of this research study only and will not be used or distributed for future research.

<<See separate Biospecimen Testing Guidance for language to include about specific tests used in this study.>>

<<If your study involves communicable disease testing in Maryland (e.g. HIV, Hepatitis B and/or C), include the following>>

Communicable diseases:

The law requires us to report positive tests to the health department. This reporting will include information that identifies you (for example name, date of birth, home address, phone number, etc.) as required by Maryland law. The health department may use this information to contact you for further follow up and/or to help conduct health surveillance activities aimed at preventing or controlling diseases.

<<If your study involves photographs or video/audio recordings, please include the following >>

Photographs/Video recordings:

As part of this research, we are requesting your permission to create and use *[description of images and recordings] (e.g., photographs, video recordings, audio recordings)* to help answer the research question. Any *[insert description of images and recordings]* will not be used for advertising or non-study related purposes.

You should know that:

- You may request that the *(identify type of imaging/recording)* be stopped at any time.
- If you agree to allow the *(identify type of imaging and/or recording)* and then change your mind, you may ask us to destroy that imaging/recording. If the imaging/recording has had all identifiers removed, we may not be able to do this.

<<Include the bullet below if the information is relevant for the study>>

- We will only use these *(identify type of imaging and/or recording)* for the purposes of this research.

<<Include the bullet below if the information is relevant for the study>>

- The audio recording will be transcribed by an outside company that has agreed to keep all data confidential.

<<If participants have the choice as to whether to allow the photographs or video/audio recordings and still take part in the study, please include the following>>

Please indicate your decision below by checking the appropriate statement:

YES I agree to allow the Principal Investigator and Johns Hopkins study team members to make and use photographs/video recordings/audio recordings of me (or the participant I represent) for the purpose of this study.

NO I do not agree to allow the Principal Investigator and Johns Hopkins study team members to make and use photographs/video recordings/audio recordings of me (or the participant I represent) for the purpose of this study.

Participant Signature
(or Parent/Legally Authorized Representative Signature, if applicable)

Date

MRI

<<If the research involves research MRI, please refer to the JHM IRB website for the preferred standard language describing MRI procedures and risks. >>

Incidental Findings

<<If the research involves an imaging procedure conducted as part of a research protocol and will produce an image of clinical quality, the following incidental findings language should be included. If the image will be read by a centralized reading center, please verify the language aligns with the reading center process. >>

As part of this research study, you will undergo an imaging procedure. A qualified professional will review your research imaging. This research imaging will not include the full diagnostic information that you would get if your primary doctor referred you for imaging.

There is a possibility that while reviewing your imaging we may see an unexpected abnormality. This is called an “incidental finding.”

We will let you know if we see such an incidental finding. Depending on the type of incidental finding, we may contact you by mail, email, or phone. In the case of a potential serious emergency, someone may go to your home.

A qualified person (usually a member of the research team) will talk to you if there is an incidental finding. You do not have an option to decline information about an incidental finding from an imaging procedure.

If you want, we will give information about this incidental finding to your primary doctor or we will refer you to an appropriate doctor for further evaluation.

What could happen if there is an incidental finding?

- An incidental finding may cause you to feel anxious.
- Since a report of the incidental finding will be part of your medical record, it will be available to those accessing your medical record for your clinical care and may affect your current or future life or health insurance coverage. This risk will vary depending on the type of insurance plan involved.

The costs for any care that may come from the incidental finding, such as the need to see a doctor to diagnose or treat an incidental finding, will not be paid for by this research study. These costs would be your or your insurance company’s responsibility.

Will research test results be shared with you?

<<If this study involves testing that may generate clinically relevant results, include one of these statements :>>

This study involves research tests that may produce information that could be useful for your clinical care. We will share this information with you. *<< Please be specific about the results you plan to share. Indicate under what conditions these results will be disclosed. >>*

OR

This study involves research tests that we do not expect will be useful for your clinical care. We will not share these results with you.

OR

It is uncertain if the research tests will produce results that would be relevant for your clinical care, so we will not share these results with you.

How long will you be in the study?

You will be in this study for *<<Insert the expected duration (days, weeks or months) of participants' participation. >>*.

<<For the section below, include one of the two options, depending on whether your study will collect data only, or both biospecimens and data:>>

4. *<<Option A: Studies without biospecimens and Studies where all biospecimens are immediately destroyed after use >>* **What happens to data that are collected in the study?**

If you join this study, your data will be used to answer the research question and publish the findings of this study. You will not own your research data. If researchers use your data to create a new product or idea, including those that may have commercial value, you will not benefit financially from those efforts.

<<Include the following paragraphs if the study does not have a commercial sponsor>>

Johns Hopkins researchers and their collaborators may use the data collected in this study for future research purposes and may share some of the data with others.

Sharing data is part of research and may increase what we can learn from this study. Often, data sharing is required as a condition of funding or for publishing study results. It also is needed to allow other researchers to validate study findings and to come up with new ideas. Your data may be shared with researchers at Johns Hopkins and other institutions, for-profit companies, sponsors, government agencies, and other research partners. Your data may also be put in government or other databases/repositories.

Because science constantly advances, we do not yet know what future use of research data may include. This future research may be unrelated to the current study and may include outside collaborators.

We (Johns Hopkins) will do our best to protect and maintain your data in a safe way. One of the ways we protect data is by limiting the uses of the information and the type of information that is shared, especially your personal information. This may occur through data sharing agreements and review by oversight groups within Johns Hopkins.

If data are used or shared with types of information that may be likely to identify you, such as your name, address or medical record number, further institutional review and approval would be required. In these cases, Johns Hopkins will review whether additional consent from you is required.

Generally, if your data are used/shared without any personal identifiers or with information that is less likely to identify you (such as the date of a procedure), further review and approval is not needed.

<<Insert the following paragraph if the study has a commercial sponsor. >>

By signing this consent form, you allow the Sponsor to use study data for commercial purposes, and to use and share data from this study in the future. Johns Hopkins may also use and share study data for patient care, academic uses and publication, and when required by law. Johns Hopkins and the Sponsor will take precautions to remove any information that could identify you (like your name or medical record number) before sharing.

<<Insert the following for ALL research studies>>

Data sharing could change over time, and may continue after the study ends.

The use and sharing of your data is required for participation in this research study. If you are not comfortable with the use and sharing of your data in future research without further consent, you should not participate in this study.

4. *<<Option B: Studies with biospecimens >>* What happens to data and biospecimens that are collected in the study?

If you join this study, your data and biospecimens will be used to answer the research question and your data will be used to publish the findings of this study. Biospecimens may include any of the following: blood, tissue, saliva, urine, bone marrow, cells, etc. Most biospecimens contain DNA, which is the genetic code for each person.

You will not own the data and/or biospecimens collected from you as part of this research study. If researchers use them to create a new product or idea, including those that may have commercial value, you will not benefit financially from those efforts.

<<Insert these paragraphs if genetic testing is being done in this study>>

This study involves genetic testing on samples that you provide. The Genetic Information Nondiscrimination Act (GINA) is a federal law that helps reduce the risk of discrimination by health insurers or employers based on your genetic information. GINA does not protect you from discrimination if you apply for other types of insurance (such as life, disability or long-term care). GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

Genetic information is unique to you and your family. Even without your name or other personal identifiers, it may be possible to identify you or other members of your family with your genetic information.

Johns Hopkins follows procedures so that people who work with your DNA information for research cannot discover it belongs to you, unless you have given consent. However, new techniques will likely make it easier to link your genetic data to you in the future, so we cannot promise that your genetic information will never be linked to you.

<<Include the following paragraphs if the study does not have a commercial sponsor>>

Johns Hopkins researchers and their collaborators may use the data/biospecimens collected in this study for future research purposes and may share some of the data/biospecimens with others.

<<If future research will or may use biospecimens for any of the following, include this section>>

Future research may include:

- Genetic research: Study of human DNA to find out what genes and environmental factors contribute to diseases. Each cell contains your complete DNA.
- Gene sequencing: Gene sequencing of your DNA provides researchers with the code to your genetic material
- Cell line creation: Cell lines can be grown in the laboratory. This allows researchers to have an unlimited supply of your cells in the future without asking for more samples from you.

<<Insert these paragraphs related to future research testing if genetic research may be included as part of future research and this language is not already included above>>

The Genetic Information Nondiscrimination Act (GINA) is a federal law that helps reduce the risk of discrimination by health insurers or employers based on your genetic information. GINA does not protect you from discrimination if you apply for other types of insurance (such as life, disability or long-term care). GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

Genetic information is unique to you and your family. Even without your name or other personal identifiers, it may be possible to identify you or other members of your family with your genetic information.

Johns Hopkins follows procedures so that people who work with your DNA information for research cannot discover it belongs to you, unless you have given consent. However, new techniques will likely make it easier to link your genetic data to you in the future, so we cannot promise that your genetic information will never be linked to you.

Because science constantly advances, we do not yet know what future use of research data or biospecimens may include. This future research may be unrelated to the current study and may include outside collaborators.

Sharing data and/or biospecimens is part of research and may increase what we can learn from this study. Often, data/biospecimen sharing is required as a condition of funding or for publishing study results. It also is needed to allow other researchers to validate study findings and to come up with new ideas. Your data and/or biospecimens may be shared with researchers at Johns Hopkins and other institutions, for-profit companies, sponsors, government agencies, and other research partners. Your data and/or biospecimens may also be put in government or other databases/repositories.

We (Johns Hopkins) will do our best to protect and maintain your data/biospecimens in a safe way. One of the ways we protect data/biospecimens is by limiting the uses of the information and the type of information that is shared, especially your personal information. This may occur through data/specimen sharing agreements and review by oversight groups within Johns Hopkins.

If data/biospecimens are used or shared with types of information that may be likely to identify you such as your name, address or medical record number, further institutional review and approval would be required. In these cases, Johns Hopkins will review whether additional consent from you is required. Generally, if your data/biospecimens are used/shared without any personal identifiers or with information that is less likely to identify you (such as the date of a procedure), further review and approval is not needed.

<<Insert the following paragraph if the study has a commercial sponsor>>

By signing this consent form, you allow the Sponsor to use study data/biospecimens for commercial purposes, and to use and share data/biospecimens from this study in the future. Johns Hopkins may also use and share study data for patient care, academic uses and publication, and when required by law. Johns Hopkins and the Sponsor will take precautions to remove any information that could identify you (like your name or medical record number) before sharing.

<<Insert the following for ALL research studies>>

Data/biospecimen sharing could change over time, and may continue after the study ends.

The use and sharing of your data and biospecimens is required for participation in this research study. If you are not comfortable with the use and sharing of your data/biospecimens in future research without further consent, you should not participate in this study.

<<Include this section if you will be submitting genomic data to an NIH designated repository>>

Genomic Data Sharing

Genomic studies, including genome-wide association studies (GWAS), examine genetic differences in the entire human genome (the complete set of human genes) and the association between these genetic differences and health conditions.

As part of this study, we will collect information about your health and your individual genes. This information will be sent to a National Institutes of Health (NIH) designated data repository that includes genomic and other data from studies funded by the NIH.

The aim of collecting this information is to look for genetic connections that may:

- Increase the likelihood of getting a certain disease (such as asthma, cancer, diabetes, heart disease or mental illness) or a condition (such as high blood pressure or obesity);
- Affect the progress of a certain disease or condition;
- Affect treatments (medicines, etc.) that work for certain diseases in some people, but not in others.

We or our collaborators will remove direct personal identifiers (such as your name or date of birth) and instead code your information before sending it to the repository. The NIH will never receive this code or the personal identifiers we have removed.

The repository is a controlled-access repository. This means that your individual de-identified data is only available to researchers who apply to the NIH. The NIH will review data requests for scientific merit and for methods to protect data and methods to ensure data will be used for the approved purpose. We will not always know what types of health-related research will be done with the data that are sent to the repository. Information from Johns Hopkins participants that is sent to the repository will only be shared with researchers at other not-for-profit organizations (for example, other academic institutions).

Genomic summary results (GSR) data for non-sensitive studies may be made available by NIH without controlled-access. GSR data does not include information about you as an individual, but consists of statistical information calculated using your data combined with data from other people.

What are the risks to your privacy?

There may be risks to your privacy and the privacy of your relatives from storing your information in the repository. Although the NIH takes measures to protect privacy, we do not know how likely it is that your identity could become re-connected with your genetic and health information.

If your genetic information were re-identified, personal information about you, your health and your risk of disease could become known to others. This could present unknown risks. Current federal law will help protect you from genetic discrimination in health insurance and employment.

Are there benefits to sharing your genetic information?

There is no direct benefit to you from placing your genetic information in the repository. Allowing researchers to study your genetic information may lead to a better understanding of how genes affect health. This may help other people in the future.

5. What are the risks or discomforts of the study?

- *<<Identify each intervention with a subheading and then describe any reasonable risks, discomforts, inconveniences.*
- *Each medication/drug/device used must be listed. Within subheadings, consider the use of bulleted items.*
- *In a treatment study, describe the risks associated with joining the study as compared with the risks associated with continuing standard clinical care.*
- *If this is a placebo-controlled study, include the risk that the participant's disease/condition may not be treated and that the participant's condition may worsen.*
- *If the study includes a washout period, describe the possible risks of discontinuing medications.*
- *List risks in order of relative probability (e.g., "likely," "less likely" or "unlikely," and "rare but serious"). Always include risk of death where this risk exists. To the extent that probability can be quantified by percentages, please include when available.*
- *All drugs that are mandated (i.e., no substitutions permitted) by the protocol, even those that are standard of care, must be included in the procedures section, and the risks that are listed on their package inserts should be described in this section. If applicable, include a list of contraindicated medications.*
- *In addition to physiological risks/discomforts, describe psychological, emotional, financial, social, and legal risks that might result. For example, address the risk for the loss of confidentiality of sensitive information. >>*

Radiation

<<If the research involves radiation exposure, please include the standard risk statement language in the imaging/radiation section of the eIRB Application. >>

Blood Draw

<<If the research involves blood draws, include the following: >>

Taking blood may cause discomfort, bleeding, or bruising where the needle enters the body. In rare cases, it may result in fainting. There is a small risk of infection.

Interviews or questionnaires

<<If the research involves interviews or questionnaires, include the following: >>

You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

Identifiable private information

<<If the research involves identifiable private health information, include the following: >>

There is the risk that information about you may become known to people outside this study.

Unknown risk

<<If the research involves an intervention or the risk profile of any research procedures are not well known, end with the statement: >>

There may be side effects and discomforts that are not yet known.

6. Are there risks related to pregnancy?

- *<<Insert this heading and section if applicable.*
- *Describe foreseeable risks to an embryo/fetus.*
- *Describe any required pregnancy testing and actions that may be taken if the participant or a participant's partner becomes pregnant.*
- *Describe any required contraceptive measures.*
- *If the research involves pregnant females or females capable of becoming pregnant, and the risk profile of the research procedures on an embryo or fetus are not well known, end with the statement: >>*

It is unknown whether this research may hurt an embryo or fetus.

7. Are there benefits to being in the study?

<<State the direct benefits, or the possibility of direct benefits, that are likely for research participants.>>

<<If there are no direct benefits to individual participants, state: >>

There is no direct benefit to you from being in this study.

<<If there is a potential for direct benefits to individual participants, state: >>

You may or may not benefit from being in this study.

<<Describe the generalizable or societal benefits and use a sentence such as: >>

If you take part in this study, you may help others in the future.

<<Do NOT include financial rewards for participation in the study as a benefit. Any payment to participants should be included in the "Will you be paid if you join this study" section. Results of tests given to participants and free medical care are not considered benefits. If results will be provided this should be explained in "What will happen if you join this study?" >>

8. What are your options if you do not want to be in the study?

- *<<Describe any alternatives that should be considered before deciding whether or not to be in the study. If applicable, explain why these procedures are being withheld. If there are no alternatives, state that an alternative is to not take part in the study.*
- *In a treatment study, describe the option of continuing with standard clinical care and whether clinical care could include the study intervention proposed.*
- *If the prospective participants are suffering from a terminal illness, and there are no alternative treatments available, you should say so, but you might include some palliative care language.*
- *If the prospective participants have a chronic, progressive disorder for which no treatment has been demonstrated to be safe and effective, say that as well.*
- *Avoid suggesting that participation in the research is the only way to obtain medical care and attention.*
- *If other treatments are available to the participant, include the following: >>*

You do not have to join this study. Other options include *<<describe options, including routine care or dietary or lifestyle options, as applicable. Include a statement informing participants that alternatives should be discussed in detail with their doctor or other health care professionals >>*

<<End with the statement: >>

If you do not join, your care at Johns Hopkins will not be affected.

<<If participants are employees/students at Hopkins: >>

If you do not join, your employment/education at Johns Hopkins will not be affected.

9. Will it cost you anything to be in this study?

<<Healthy Volunteer Studies: If billing will not be required, then state "No" as the answer to this question and do not include the text below.

Studies only enrolling at international sites: Do not include the text below. Provide whatever cost information is applicable to your study. >>

You will receive a separate Insurance and Research Participant Financial Responsibility Information Sheet (Sheet). This Sheet will give you the following information:

- The procedures, tests, drugs or devices that are part of this research and that will be paid for by the study (no cost to you).
- The procedures, tests, drugs or devices that will be billed to you and/or your health insurer. If you have health insurance, you will be responsible for any co-pays or deductibles not covered by your insurance.

10. Will you be paid if you join this study?

- *<<State whether the participant will be paid or offered other types of rewards (e.g., coupons, gift cards). If not, state: No.*
- *List rates of payment or other financial rewards (transportation, babysitting, etc.).*
- *List method and timing of payment, and provisions for partial payment if a participant leaves early.*

- *If participants will be paid, include the following statement: >>*

You may be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total payments from Johns Hopkins exceed \$600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

11. Can you leave the study early?

<<If appropriate to the study, add some or all of the following statements: >>

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.
- *<<If participants are Hopkins employees/students: >>* Leaving this study early will not affect your employment/education.

If you leave the study early, Johns Hopkins may use or share your health information that it has already collected if the information is needed for this study or any follow-up activities.

<<If gradual withdrawal will be required for safety considerations, explain this and any unique procedure(s) required for timely and safe withdrawal. >>

12. Why might we take you out of the study early?

<<Insert this heading and section if applicable. >>

<<If appropriate to the study, add some or all of the following statements: >>

You may be taken out of the study if:

- Staying in the study would be harmful.
- You need treatment not allowed in the study.
- You fail to follow instructions.
- You become pregnant.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

13. How will your privacy be maintained and how will the confidentiality of your data be protected?

<<If sponsor would like to add further information in this section, you may do so and the JHM IRB will decide if the language is acceptable. >>

HIPAA Authorization for Disclosure of Protected Health Information

What information is being collected, used, or shared?

To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Johns Hopkins Medicine and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from

your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?

The people who may request, receive, or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Johns Hopkins, for example if needed for your clinical care or study oversight. To improve coordination of your research and clinical care, some information about the study you join will be included in your electronic medical record.

By signing this form, you give permission to the research team to share your information with others outside of Johns Hopkins. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team.

We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?

You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?

Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?

You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

How will your information be protected?

<<If the research involves the collection of identifiable information, please include the specific steps you will take to minimize the risk of breach of confidentiality (e.g. include details of where the data will be stored and analyzed, and who will have access to the data).>>

14. Will the study require any of your other health care providers to share your health information with the researchers of this study?

<<Insert this heading and section if applicable. >>

As a part of this study, the researchers may ask to see your health care records from your other health care providers. *<<Optional: >>*You will be asked to give us a list of other health care providers that you use.

15. What is a Certificate of Confidentiality?

<<Insert this heading and section if applicable. >>

<<For NIH-funded studies based in the U.S. >>

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.

<<For NIH-funded international studies that will collect identifiable data>>

This study is protected by a Certificate of Confidentiality that helps keep your information private when stored in the U.S.

16. What does a conflict of interest mean to you as a participant in this study?

<<Insert this heading and wording if applicable. >> A researcher has a financial or other interest in this study.

<<For studies that also have an institutional conflict: >> A researcher and Johns Hopkins University have a financial or other interest in this study.

In some situations, the results of this study may lead to a financial gain for the researcher and/or Johns Hopkins University. This financial interest has been reviewed in keeping with Johns Hopkins' policies. It has been approved with certain conditions, which are intended to guard against bias in how the study is conducted, how the results are analyzed, and how participants are protected.

If you have any questions about this financial interest, please talk to *<<name and telephone number of non-financially interested designee. >>* This person is a member of the study team, but does not have a financial interest related to the study. You may also call the Office of Policy Coordination 410-361-8667 for more information. The Office of Policy Coordination reviews financial interests of researchers and/or Johns Hopkins.

17. What treatment costs will be paid if you are injured in this study?

<<Insert this heading and choose the appropriate section for your consent form: >>

<<Insert the following language for all applicable studies except commercially sponsored studies with an IND/IDE held by the commercial sponsor: >>

Johns Hopkins does not have a program to pay you if you are hurt or have other bad results from being in the study. *<<OR for studies sponsored by the federal government: >>* Johns Hopkins and the federal government do not have programs to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

By signing this form, you will not give up any rights you have to seek compensation for injury.

OR

<<Insert the following language for commercially sponsored studies with an IND/IDE held by the commercial sponsor: >>

Johns Hopkins does not have a program to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The study sponsor, *<<insert study sponsor name>>*, has agreed to pay the usual and standard costs of treatment or hospital care you receive as a direct result of a study-related injury that are not covered by a health insurer (provided the costs are not the result of care required to treat your underlying disease or condition).

Any costs that are not covered by the study sponsor or a health insurer will be billed to you.

By signing this form, you will not give up any rights you have to seek compensation for injury.

18. What other things should you know about this research study?

<<Always include this statement>>

During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.

<<Include these statements if this study is a clinical trial and will be registered at clinicaltrials.gov: >>

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. If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

<<Include this statement for a blinded study or a study where medical information will not be available to participants until the study is completed: >>

During this study, you will not have access to certain medical information and test results collected for study purposes. If an emergency occurs while you are in the study, medical information needed for your treatment can be made available to your study doctor and other physicians who treat you. When the study is completed, all the information in your medical record will be available to you.

What is the Institutional Review Board (IRB) and how does it protect you?

This study has been reviewed by an Institutional Review Board (IRB), a group of people that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study. You may contact the IRB at 410-502-2092 or jhmeirb@jhmi.edu.

<<Include this statement if this is a single IRB study: >>

For this multi-site study, Johns Hopkins has agreed to serve as the single IRB (sIRB) providing oversight for all sites. You may contact the Johns Hopkins IRB at 410-502-2092 or jhmeirb@jhmi.edu with your questions or concerns.

What should you do if you have questions about the study, or are injured or ill as a result of being in this study?

Call the principal investigator, <<insert PI name>> at <<insert telephone number>>. If you wish, you may contact the principal investigator by letter. The address is on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-502-2092.

<<Include this section if the research is more than minimal risk. A 24 hour number must be included if the research is more than minimal risk to ensure participants have access to a physician for an urgent medical problem>>.

If you have an urgent medical problem or think you are injured or ill because of this study, call 911 or go to your local emergency department. You should also call <<Insert the name of the Principal Investigator, or if the Principal Investigator is not a medical doctor, include designated physician>> at <<insert telephone number>> during regular office hours and at <<insert phone or pager number available 24 hours >> after hours and on weekends. If this doctor is not available, the operator will page the “on call physician.”

<<If you insert a pager number, include the following instructions:

After the tone, enter the phone number where you can be called, press the # key, and hang up.

<<If this study may include participants at another Johns Hopkins site include the following language for each site: >>

If you are taking part at <<Site Name, i.e.: Johns Hopkins All Children’s Hospital, Howard County General Hospital, Sibley Memorial Hospital, Suburban Hospital>> and have questions or you have a medical problem related to your taking part in this study, call <<insert PI name>> at <<insert telephone number>> during regular office hours and at <<insert phone or pager number available 24 hours >> after hours and on weekends. If this doctor is not available, the operator will page the “on call physician.”

<<If you insert a pager number, include the following instructions: >>

After the tone, enter the phone number where you can be called, press the # key, and hang up.

19. Assent Statement

<<Insert this statement if the study includes children, except when (a) the child is incapable of understanding the explanation: or, (b) the study intervention offers the prospect of direct benefit to the child that is only available through research. >>

This research study has been explained to my child in my presence in language my child can understand. He/she has been encouraged to ask questions about the study now and at any time in the future.

<< Include the following recommended section if applicable>>

20. Optional Study Components:

- *<<We recommend (but do not require) any optional study components be added to this section of the consent.*
- *Optional study components could include but are not limited to optional pharmacokinetic/ pharmacodynamic/pharmacogenomic sub-studies for which a separate consent form is not being submitted.*

- *If you choose to use this section, please include all details (procedures, risks, and signature lines) about any optional sub-studies that participants will be invited to take part in.*
- *If you choose not to use this section, these optional components could be placed in Section 3 “What will happen if you join this study”, or as per preference by sponsor.*

This part of the consent form is about optional component(s) of the study that you can choose to take part in or not. You can still take part in the main study even if you say “no” to this/these optional component(s).

Future Contact

<<If participants will be asked to allow future contact by the current research team, the yes/no option must include the full signature of the participant. If you include yes/no options, you must track the yes and no responses. >>

We would like your permission for our research team to contact you in the future. Please note that your decision below does not prevent other researchers at Johns Hopkins from contacting you about other research.

Please sign and date your choice below:

YES _____
Signature of Participant

Date

NO _____
Signature of Participant

Date

21. What does your signature on this consent form mean?

Your signature on this form means that you have reviewed the information in this form, you have had a chance to ask questions, and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant (Print Name) Date/Time

Signature of Person Obtaining Consent (Print Name) Date/Time

<<If a physician is required to take part in the consent process and will conduct the entire consent process, then the physician should sign above as the person obtaining consent. If the physician will only discuss the risks, benefits, and alternatives, the physician must complete the second signature page and the non-physician consent designee discussing the remainder of the consent should sign above. >>

<<Add any of the following that are applicable for this study and delete any that do not apply>>

Signature of Legally Authorized Representative (LAR) (Print Name) Date/Time
FOR ADULTS NOT CAPABLE of GIVING CONSENT

Relationship of LAR to Participant Date/Time
(Indicate why the LAR is authorized to act as a surrogate health care decision-maker under state or applicable local law)

Signature of Parent/Legal Guardian/Court-Appointed Representative (Print Name) Date/Time
FOR CHILD PARTICIPANT

Do not use this form for consenting research participants unless the Johns Hopkins Medicine Logo appears here.

Date:
Principal Investigator:
Application No.:

Description of relationship to child research participant (for example: parent, legal guardian, court-appointed representative)

Signature of Parent #2 (Print Name) Date/Time
(Required if DHHS 45 CFR 46.406 or 46.407/FDA 21 CFR 50.53 or 50.54 study)

Signature of Child Participant (optional unless IRB required) (Print Name) Date/Time

Signature of Interpreter/Witness to Consent Procedures (Print Name) Date/Time
(Required for studies enrolling non-English speakers using the short form process or otherwise as determined required by the IRB)

I have received the separate Insurance and Research Participant Financial Responsibility Information Sheet.

Signature of Participant, LAR or Parent/Guardian (Print Name) Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

Do not use this form for consenting research participants unless the Johns Hopkins Medicine Logo appears here.

Date:
Principal Investigator:
Application No.:

<<If a physician is required to take part in the consent process and will not be conducting the entire consent process, then this signature page must be completed and attached to the consent form. >>

DOCUMENTATION OF PHYSICIAN/MID-LEVEL PROVIDER CONSENT PROCESS

My signature below indicates that I have discussed the risks, benefits, and alternatives, answered any questions, and believe the participant is able to make an informed choice to join the study.

Signature of Physician/Mid-Level Provider (Print Name) Date/Time

Signature of Participant (Print Name) Date/Time

<<Add any of the following that are applicable for this study and delete any that do not apply>>

Signature of Legally Authorized Representative (LAR) (Print Name) Date/Time
FOR ADULTS NOT CAPABLE of GIVING CONSENT

Relationship of LAR to Participant (Indicate why the LAR is authorized to act as a surrogate health care decision-maker under state or applicable local law) Date/Time

Signature of Parent/Legal Guardian/Court-Appointed Representative (Print Name) Date/Time
FOR CHILD PARTICIPANT

Do not use this form for consenting research participants unless the Johns Hopkins Medicine Logo appears here.

Date:
Principal Investigator:
Application No.:

Description of relationship to child research participant (for example: parent, legal guardian, court-appointed representative) Date/Time

Signature of Parent #2 (Print Name) Date/Time
(Required if DHHS 45 CFR 46.406 or 46.407/FDA 21 CFR 50.53 or 50.54 study)

Signature of Child Participant (optional unless IRB required) (Print Name) Date/Time

Signature of Interpreter/Witness to Consent Procedures (Print Name) Date/Time
(Required for studies enrolling non-English speakers using the short form process or otherwise as determined required by the IRB)

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).