## Title of research study: ***[insert title of research study here with protocol number, if applicable]***

## Investigator: ***[insert name of principal investigator]***

## Sponsor/Funding Source or Support: ***[insert name of entity.]***

## Financial Interest Disclosure: [Include if there is a financial interest to disclose. Otherwise, delete.] The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study:

**[Include if the investigator is also the participant’s treating physician. Otherwise, delete.]** Your doctor, who is also responsible for this research study, **[or,** If your doctor is also the person responsible for this research study, please note that s/he**…]** is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

## Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

## Why am I being invited to take part in a research study?

We invite you to take part in a research study because \_\_\_\_\_\_\_\_\_\_\_\_\_. [Fill in the circumstance or condition that makes subjects eligible for the research.]

## What should I know about a research study?

1. Someone will explain this research study to you.
2. Whether or not you take part is up to you.
3. You can choose not to take part.
4. You can agree to take part and later change your mind.
5. Your decision will not be held against you.
6. You can ask all the questions you want before you decide.

## Why is this research being done?

[Tell the subject the purpose of the research. Explain the background of the research problem. Explain any potential benefits to others.]

## How long will the research last and what will I need to do?

We expect that you will be in this research study \_\_\_\_\_\_\_\_ [for hours/days/months/weeks/years, until a certain event].

You will be asked to \_\_\_\_\_\_\_\_\_ [include a high level summary of the procedures that will be done. For example: You will be given an investigational drug and asked to come for 3 study visits. You will give a total of 3 blood samples and fill out questionnaires asking about how you feel.]

More detailed information about the study procedures can be found under ***“What happens if I say yes, I want to be part of this research?”***

## Is there any way being in this study could be bad for me?

[This beginning section of the consent form should identify the most important risks, e.g., emotional distress resulting from a series of questions in a social-behavioral research project or similar to the information that a physician might deliver in the clinical context in telling a patient how sick, e.g., the chemotherapy drugs will make them, but with a particular emphasis on how those risks are changed by participating in the study]

More detailed information about the risks of this study can be found under ***“Is there any way being in this study could be bad for me? (Detailed Risks)”***

## Will being in this study help me in any way?

[This beginning section of the consent form should identify one or more likely benefits resulting from participation in the study; in doing so, you should not overemphasize the benefits. If you need to discuss benefits in additional detail, add an additional section later in the consent document]

[Include if there are benefits to participation. Otherwise delete.] We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. [First describe any direct benefits to the subject, then any benefits to others. If benefits from participation may not continue after the research has ended, describe them here. Monetary reimbursement for participation is not a benefit.]

[Include for a study with no benefits to the participant. Otherwise delete.] There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. [Describe any benefits to others. Monetary reimbursement for participation is not a benefit.]

## ***[Include for research involving prisoners]*** Taking part in this research study will not improve your housing or correctional program assignments. Taking part in this research study will not improve your chance of parole or release.

## What happens if I do not want to be part of this research?

Participation in research is completely voluntary. You can decide to participate or not to participate.

[Include if there are alternatives other than participating.] Instead of being in this research study, your choices may include: [List alternative procedures. For student subject pools, describe alternatives for course credit. For clinical trials, describe the options that you would normally offer the patient. If applicable, include supportive care as an option.]

[Include if there are no alternatives to participating.] Your alternative to participating in this research study is to not participate.

## Detailed Information: The following is more detailed information about this study in addition to the information listed above.

## Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at [Insert contact information for the research team]

This research has been reviewed and approved by an Institutional Review Board (“IRB”). You may talk to them at (301) 560-2912 or MHRI-ORIHelpDesk@medstar.net if:

1. Your questions, concerns, or complaints are not being answered by the research team.
2. You cannot reach the research team.
3. You want to talk to someone besides the research team.
4. You have questions about your rights as a research participant.
5. You want to get information or provide input about this research.

## How many people will be studied?

We expect about \_\_\_\_\_ people here will be in this research study out of \_\_\_\_\_ people in the entire study nationally [or internationally].

## What happens if I say yes, I want to be in this research?

[Tell the subject what to expect using lay language and simple terms. Whenever appropriate, include the following items:]

* A description of the procedures that will be performed, including a detailed timeline. If practical, prepare a timeline chart or schematic to accompany descriptions of procedures and tests for research that require more than 1 or 2 steps/visits
* The drugs or biologics that will be given to the subject
* All devices that will be used
* All hospitalizations, outpatient visits, and telephone or written follow-up correspondence
* The length and duration of visits and procedures
* If blood will be drawn, indicate the amount [in English units] and frequency
* With whom the subject will interact
* Where the research will be done
* When the research will be done
* List experimental procedures and therapies and identify them as such
* How often procedures will be performed
* What is being performed as part of the research study
* What is being performed as part of standard care
* What procedures are part of regular medical care that will be done even if the subject does not take part in the research
* 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
* When applicable, indicate that the subject will be contacted for future research

[Include for a clinical trial that involves randomization. Otherwise delete.] 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 research add] Neither you nor the study doctor will know which treatment you are getting. [For single blinded research add] You will not be told which treatment you are getting, however your study doctor will know.

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

[Delete this section if the research is not a clinical trial.]

If you take part in this research, you will be responsible for: [Describe any responsibilities of the subject.]

## What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you.

[Include if there are potential adverse consequences to withdrawing from the research. Otherwise delete] If you decide to leave the research, [Describe the adverse consequences.] If you decide to leave the research, contact the investigator so that the investigator can [Describe the procedures for orderly termination by the subject, if any.]

[Include for FDA-regulated research. Otherwise delete.] If you stop being in the research, 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.]***

***[For research that is not FDA-regulated, describe what will happen to data collected up until the point of withdrawal. Describe whether subjects will be asked to explain the extent of their withdrawal and whether they will be asked for permission to collect data through interaction or collection of private identifiable information. For example, a subject may wish to withdraw from the experimental procedure because of unacceptable side effects, but may agree to undergo follow-up procedures and data collection.]***

## Is there any way being in this study could be bad for me? (Detailed Risks)

[Delete this section if there are no risks or discomforts.]

[The risks of procedures may be presented in a table form.]

[Describe each of the following risks, if appropriate. If known, describe the probability and magnitude of the risk.]

* [Physical risks
* Psychological risks
* Privacy risks
* Legal risks
* Social risks
* Economic risks]

[Include for research that involves procedures whose risk profile is not well known, including all research involving an investigational product. Otherwise delete.] In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death.

[Include for research that involves pregnant women or women of child-bearing potential and procedures that involve risks to an embryo or fetus or whose risk profile in pregnancy is not well known. Otherwise delete.] The procedures in this research are known to hurt a pregnancy or fetus in the following ways: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. [Omit the previous sentence if there are no known risks.] The research may also hurt a pregnancy or fetus in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death. [Omit the previous two sentences for research whose risk profile in pregnancy is well known.] You should not be or become pregnant [include as applicable “***or father a baby”]*** while on this research study.

***[***Include for research that ***may result in additional costs to the subjects. Otherwise delete.]*** Taking part in this research study may lead to added costs to you. [Describe what these costs are.]

[Include for a clinical trial. Otherwise delete.] You and your insurance company will be charged for the health care services that you would ordinarily have to pay for. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. The research team will confirm coverage by your insurance before any research procedures are conducted. Any expense associates with this study that is not paid by your insurance may be billed to you. Your study doctor (or their designee) will let you know what (if any) expenses you may be responsible for in advance of study procedures so that you may decide if you would like to continue or decline participation.

[Include for Veterans Administration (VA) research. Otherwise delete.] You will not be required to pay for care received as a subject, except that some veterans are required to pay co-payments for medical care and services provided by the Veterans Administration (“VA”). These co-payment requirements will continue to apply to VA-provided medical care and services that are not part of this study.

## What happens to the information collected for the research?

Efforts will be made to limit the use and 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 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.]

[Describe any limitations on confidentiality based on possible legal issues. For example, if the research team is likely to uncover abuse, neglect, or reportable diseases, explain that this information may have to be disclosed to appropriate authorities.]

***[If data or specimens will be retained after the study for future research, explain where the data or specimens will be stored, who will have access to the data or specimens, and how long the date or specimens will be retained.]***

***[If identifiable private information or identifiable specimens will be collected during the research, add one of the following statements:***

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

**OR**

Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.

[Include for research where the sponsor may pay for medical expenses of the subject.] If the sponsor pays any of your medical expenses, we may be required to give the sponsor your name, date of birth, and Medicare ID or social security number.

[Include for a clinical trial. Otherwise delete.] The sponsor, monitors, auditors, the IRB, and/or the Food and Drug Administration will be granted direct access to your medical records to conduct and/or oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential in any publication.

[Include for FDA-regulated controlled drug and device trials (except Phase I drug trials) and FDA-regulated pediatric post-market surveillance trials of devices. Otherwise delete.] 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.

[Include if a HIPAA authorization is required. Otherwise delete.] Federal law provides additional protections of your medical records and related health information. These are described in an attached document.

[Include for research involving prisoners. Otherwise delete.] If you are a prisoner, your medical records may also be given to officials and agencies within the criminal justice system when necessary and permitted by law.

## HIPAA Authorization

**[Include if HIPAA Authorization is required. Otherwise, delete this section.]**

**[If included, do not alter any of the following text, except as indicated.]** We are committed to respecting your privacy and to keeping your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information including the health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. The health information we may collect from you and use for this research includes: **[Below includes a list of data elements that may be necessary for the research. Modify the list below to reflect only the health information that is necessary to address the research question. Remove or modify elements below as needed.]**

* Information in your medical records necessary for this research
* Results of physical examinations
* Medical history
* Lab tests, or certain health information indicating or relating to a particular condition as well as diaries and questionnaires
* Records about study medication or drugs
* Records about study devices
* Billing information
* HIV testing results
* Substance abuse information: **[Specify.]**
* Mental health information: **[Specify.]**
* Genetic health information: **[Specify.]**

**[If the research includes mental health information, add the following statements. Otherwise, delete.]**

You have the right to inspect and copy the mental health and developmental disabilities records that will be collected as part of this study.

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of MedStar Health and its clinical partners (or affiliates): the MedStar Health Research Institute Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or MedStar Health policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator’s office].

The following entities may receive your health information:

**[Delete any of the following paragraphs that do not apply.]**

* Authorized members of the MedStar Health workforce, who may need to see your information, such as administrative staff members from the MedStar Health Research Institute, Office for Research Integrity and members of the Institutional Review Board.
* Laboratories and other individuals and organizations that may need to see your health information in connection with this study.
* Other MedStar Health research centers and MedStar Health contractors who are also working on the study.
* Study monitors and auditors who make sure that the study is being done properly,
* [Insert name of company sponsoring the study.] \_\_, who is sponsoring the study, and that company’s contractors and partners.
* Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).
* Others: **[Specify by name or category any other individuals or organizations who may access, receive, or use the personal health information in connection with this research study.]** The following individuals or organizations may also access, receive, or use your personal health information: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those people may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

 This research authorization will remain in effect until the end of the study unless you revoke consent for participation in this study. If you revoke consent MedStar Health may not gather new information about you, or use or disclose your personal health information collected in this study for any purpose other than the research study described in this consent unless MedStar Health obtains permission to do so from you.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

**[Insert all of this information.]**

PI’s Name:

Institution:

Department:

Address:

**[Describe the exceptions to the right to revoke authorization.]**

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study if you do not allow this. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

## Can I be removed from the research without my consent?

[Delete this section if not applicable.]

[Include for research where this is a possibility. Otherwise delete.] 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 [describe reasons why the subject may be withdrawn, if appropriate.]

[Include for research where this is a possibility. Otherwise delete.] We will tell you about any new information that may affect your health, welfare, or choice to stay in the research study.

## What else do I need to know?

[Include for sponsored research. Otherwise delete.] This research is being funded by [Insert name of sponsor].

[Include for commercially funded research involving more than minimal risk. This section must be consistent with the final clinical trials agreement. If not commercially funded delete.] If you need medical care because of taking part in this research study, contact the investigator and medical care will be made available.

If you feel that you are having a medical emergency, you should go to the emergency room right away.

If you experience injury or illness resulting from participation in this research the sponsor will pay for reasonable and necessary expenses associated with the diagnosis, hospitalization, and /or treatment of any injury or illness resulting from the research.

The sponsor shall not be responsible for any expense resulting from injury or illness due to:

 (1) neglect, recklessness or willful misconduct of the research team;

(2) failure of the research team to follow the study protocol or written instructions, recommendations, guidance from the sponsor;

(3) Pre-existing conditions or underlying illness;

(4) Early withdrawal from the study or

(5) if you fail to comply with the protocol or information in the informed consent. .

MedStar Health has no program to pay for medical care for a research-related injury. [Describe any compensation available for research related injury.]

[Include for Federally Funded or unfunded research involving more than minimal risk. Otherwise delete.] If you need medical care because of taking part in this research study, contact the investigator and medical care will be made available. Generally, this care will be billed to you, your insurance, or other third party.

If you feel that you are having a medical emergency, you should go to the emergency room right away.

MedStar Health has no program to pay for medical care for a research-related injury. [Describe any compensation available for research related injury.]

[Include for Veterans Administration (VA) research. Otherwise delete.] If you are injured or made sick from taking part in this research study, medical care will be provided. In general this medical care will be provided in VA medical facilities. This care will be provided at no cost to you. Contact the investigator for more information.

[Include if subjects will be paid. Otherwise delete.] If you agree to take part in this research study, we will pay you \_\_\_\_\_\_\_\_ [indicate amount] for your time and effort. [Indicate if the amount is pro-rated for research visit completion.]

[Include for Department of Defense (DOD) research that targets military personnel where subjects will be paid. Otherwise delete.] Military personnel should check with their supervisor before accepting payment for participation in this research.

[Include for research involving prisoners where there may be a need for follow-up examination or care after the end of participation. Otherwise delete.] If you are released from jail before you finish this research study, you should take steps to get insurance or Medicaid coverage. Regular medical visits and standard treatment will be billed to you or your health insurance. You may continue to participate in the research study after your release from prison. If you move out of the area, we will help you make arrangements to be seen by a physician.

[Include for a clinical trial.] Instead of being in this research study, your choices may include: [include alternatives.] The important risks and possible benefits of these alternatives include: [Describe the important risks and potential benefits of the alternative procedures and courses of treatment.]

***[Include when applicable.]*** Your information and samples (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans ***[or replace with plans when using identifiable information/samples]*** to tell you, or to pay you, or to give any compensation to you or your family.

***[When applicable, include whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and for research involving biospecimens,]*** Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers ***will/will not*** contact you to let you know what they have found. If the researchers return genetic test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional genetic counseling. You may have to pay for those additional services yourself.

[There are three signature pages attached to this template consent. Use the signature page or pages appropriate for your study. The IRB recommends that you make separate consent documents for each signature page to be used.]

[Omit the signature page if there is no written documentation of consent required.]

**Signature Block for Capable Adult**

|  |
| --- |
| Your signature documents your permission to take part in this research. |
|  |  |  |
| Signature of subject |  | Date |
|  |  |
| Printed name of subject |
|  |  |  |
| Signature of person obtaining consent |  | Date |
| Printed name of person obtaining consent |  |  |

***[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects.]***

|  |
| --- |
| My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject. |
|  |  |  |
| Signature of witness to consent process |  | Date |
|  |  |
| Printed name of person witnessing consent process |

**Signature Block for Adult Unable to Consent**

|  |
| --- |
| Your signature documents your permission for the named subject to take part in this research. |
|  |
| Printed name of subject |  |  |
|  |  |  |
| Signature of legally authorized representative |  | Date |
|  |  |
| Printed name of legally authorized representative |
|  |  |  |
| Signature of person obtaining consent |  | Date |
| Printed name of person obtaining consent |  |  |

***[Add the following block if you will document assent of the subject.]***

|  |  |
| --- | --- |
| Assent | * Obtained
* Not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.
 |

 ***[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects.]***

|  |
| --- |
| My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject. |
|  |  |  |
| Signature of witness to consent process |  | Date |
|  |  |
| Printed name of person witnessing consent process |

**Signature Block for Children**

|  |
| --- |
| Your signature documents your permission for the named child to take part in this research. |
|  |  |
| Printed name of child |
|  |  |  |
| Signature of parent or individual legally authorized to consent to the child’s general medical care |  | Date |
|  | * Parent
* Individual legally authorized to consent to the child’s general medical care (See note below)
 |
| Printed name of parent or individual legally authorized to consent to the child’s general medical care |
| **Note:** Investigators must ensure that individuals who are not parents can demonstrate their legal authority to consent to the child’s general medical care. Contact legal counsel if any questions arise. |
|  |  |  |
| Signature of second parent |  | Date |
|  |  |
| Printed name of second parent |
| If signature of second parent not obtained, indicate why: (select one) |
| * The IRB determined that the permission of one parent is sufficient. ***[Delete if the IRB did not make this determination]***
* Second parent is deceased
* Second parent is unknown
 | * Second parent is incompetent
* Second parent is not reasonably available
* Only one parent has legal responsibility for the care and custody of the child
 |

***[Add the following block if you will document assent of children]***

|  |  |
| --- | --- |
| Assent | * Obtained
* Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.
 |

 ***[Add the following block to all consents]***

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of person obtaining consent and assent |  | Date |
| Printed name of person obtaining consent |  |  |

 ***[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects.]***

|  |
| --- |
| My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject. |
|  |  |  |
| Signature of witness to consent process |  | Date |
|  |  |
| Printed name of person witnessing consent process |