MedStar Health Research Institute

Note: This document contains only the language requirements for informed consent when MedStar is relying on an External IRB. It is not a complete Informed Consent Form (ICF) template.

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## 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.

**COMPENSATION FOR INJURY:**

This language must be submitted by the site and included in the consent form for review by the SIRB if appropriate to the research under review.

* The site will verify the language during the institutionally required pre-review process.

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 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.]

## 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.

**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 |