**Part 2 of 2: STUDY SITE INFORMATION**

|  |  |
| --- | --- |
| Site Name: | [insert name of organization] |
| Site Principal Investigator: | [insert name/credentials of responsible PI at organization] |
| Site Principal Investigator Contact: | [insert 10-digit phone for PI] |
| Site Study Coordinator *(if applicable)*: | [insert name/credentials of alternate point of contact for the study] |
| Site Study Coordinator Contact *(if applicable)*: | [insert 10-digit phone for alternate point of contact for the study] |

***This part of the consent form includes information about the site that is asking you to participate in this study and is specific to participation at your site only. Before making your decision, both the site-specific information and the general study information should be reviewed with you. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.***

**Site specific procedures and risks:**

*<<Please add any site-specific procedures and the risks of these procedures. Only include this section if the site will be conducting procedures that are not being done at all sites, and therefore are not already described in the Part 1 consent form.. Only include if this is applicable>>*

**Payments for your time spent taking part in this study or expenses:**

*<<Brief description of payments to participants. Only include if this is applicable.>>*

**Costs to you if you take part in this study:**

*<<Brief description of costs to participants. Only include if this is applicable, or simply state “There is no cost to you for taking part in this study.”.>>*

**Payment in case you are injured because of this research study:**

*<<Please add any locally-required language for research-related injury. Only include if this is applicable>>*

**Who to call for any questions or in case you are injured:**

*<<Please add any locally-required contact information outlining who participants should call in the event of any research-related injuries.* ***In addition, the following paragraph MUST REMAIN in this section when Vanderbilt University Medical Center IRB is the IRB of Record.*** *Only include this section if applicable>>*

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the Vanderbilt University Medical Center Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

**Additional information about your local site:**

*<<Please insert any additional required language for your site, as applicable for this study. Examples may include, but are not limited to:*

* *Local language regarding state law requirements for reporting of communicable diseases.*
* *Locally required language for any specific research procedures, e.g. commercialization of cell lines.*
* *Local conflict of interest disclosures.>>*

**Confidentiality:**

*<<Insert a description of how records and data/specimens will be stored and maintained and who will have access. Describe any study specific issues that may increase the risk of breach of confidentiality.>>*

*<<If the study receives any funding from the NIH, insert this* ***or your locally required*** *Certificate of Confidentiality language.>>*

This study may have some support from the National Institutes of Health (NIH). If so, 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, future research, or insurance purposes. Disclosures that you make yourself are also not protected.

**Authorization to Use/Disclose Protected Health Information**

*<<Please add any locally-required HIPAA Language. Only include if this is applicable:*

* *If your site requires separate HIPAA pages, delete this section and include your pages following this form.*
* *If your site does not have locally-required HIPAA language, the VUMC IRB, as the IRB of Record will provide language upon request.>>*

*<<If your site requires specific signature lines, please replace the Vanderbilt IRB standard signature lines below with your site-specific signature lines. These should include all signatures required by your site for the study.>>*

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

# STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

**I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.**

Date Signature of patient/volunteer

Consent obtained by:

Date Signature

Printed Name and Title

Time: \_\_\_\_\_\_\_\_\_\_\_\_\_\_