# **SITE SPECIFIC CONSENT INFORMATION**

**Site Name**:

**Study Title**:

JHM IRB Application Number:

**Site Principal Investigator**:

**Site Principal Investigator Contact Information:**

**Emergency Contact:**

**Other Study Contact(s):**

**Introduction:**

This study is being done at multiple sites. This part of the consent form includes information about your site and is specific to participation at your site only. Before making your decision, both the site-specific information and general study information will be reviewed with you. You will have the opportunity to discuss any questions, including questions about this portion of the consent document, with your site’s study team.

**Site-Specific Study Procedures & Associated Risks:**

*<<Brief description of any differences in study procedures/risks. This section is only needed if certain procedures described in the main consent document will not occur at the site or if additional procedures will occur at the site that are not described in the main consent document. >>*

**Costs to Study Participants:**

*<<Brief description of costs to participants. Only include if different than costs as described in the main consent document. >>*

**Payment for Study Participation:**

*<<Brief description of payments. Only include if different than the payment/method of payment as described in the main consent document. >>*

**Compensation for Research-Related Injury:**

*<<Please add any locally-required language for research-related injury and contact information outlining who subjects should call in the event of any research-related injuries. Only include if this is applicable>>*

**Site IRB Contact Information:**

*<< If your site wishes to include local IRB contact information, please include this here. If this is not required, please delete this section. >>*

**Additional information about your local site:**

*<<Please insert any additional required language for your site, as applicable for this study. Examples may include*

* *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*
* *Locally required HIPAA authorization language: The following language has already been approved by the JHM IRB. Please consider whether this language may be used at your site.* 
  + - *If this language is acceptable, it may remain in this section.*
    - *If this language is not acceptable, and locally-approved HIPAA authorization language is required, please delete the language and replace it with your own language. Please note, generally any project that requires the collection and potential sharing of protected health information will require a HIPAA authorization so this language should not simply be removed without adding your site’s alternative language or confirming a separate authorization will be obtained.*
    - *Alternatively, if your site requires use of a separate HIPAA authorization, please delete this section and include the following sentence. [insert site name] requires that you sign a separate authorization form related to the use of your protected health information for this research study. This is required for participation in this study. >>*

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

**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 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 [*insert site name*], for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of [*insert site name*]. 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.

**Signature Lines:**

*<< If your site wishes to include site-specific signature lines, please include them here. If your site does not have site-specific signature requirements, the JHM signature lines will be added in this section. >>*