**General Information and Instructions for Preparing the JHM IRB Combined Informed Consent/Authorization Document**

**Instructions:**

* Many sections of the informed consent template document include brief instructions to provide a general overview of information required in the section. **Please delete all *instructions* before submitting your consent form to the JHM IRB for review.**

**Document Formatting:**

***Section Headings*:**

* 14 point font [Times New Roman is preferred font]
* Section headings marked ***Insert if applicable*** may be omitted if they do not apply to your study.

***Text:***

* 12 point font [Times New Roman is preferred font]
* Suggestions/hints for the text to be written under each heading are included and instructions are ***in blue***.
* Please delete all ***instructions*** before submitting this form.
* For new consent forms, remove “track changes” or inserted comments from the consent document before it is uploaded into the eIRB Application for IRB review. Consent forms being revised in a change in research should have tracked changes.

**Required Paragraphs**:

* The HIPAA Privacy Authorization developed by the General Counsel must be included in all consent forms.
* The required institutional boilerplate language is provided under “**What other things should you know about this research study?**”

**Writing Tips:**

* The information in the consent form must be consistent with what is described in the application and supporting documents.
* Individuals taking part in the study should be referred to as participants, not patients.
* Investigational drugs and interventions should not be referred to as “treatment”.
* The use of the second person (e.g., “You will receive…”) is generally preferred.
* The use of the first person (e.g., “I understand that…”) is generally not preferred.

**Reading Level and Spell Checking**:

* Investigators are expected to write consent forms in plain language at a level appropriate for the target population. The preferred reading level is 8th grade. For guidance on using plain language, visit <http://www.plainlanguage.gov/>
* The completed version of the informed consent document should be spell checked and proofread before being submitted.

**Contact Information for PI or Other Study Team Members**:

* Make sure that the contact information inserted into the consent form is current and accurate.

**Signature Lines**:

* The signature page of the informed consent document must include applicable signature lines for your study.
* Include time and date of signature.
* **Delete signature lines that are not required for your study**.

**Approved Consent Forms:** Only the approved consent form with the JHM IRB Logo may be used to consent participants for research studies.

**Questions?**

* Please visit the JHM IRB website and go to the “Guidelines and Policies” section for further information on various topics that may affect/are related to informed consent.
* Please call the JHM IRB office (410-955-3008) if you have any questions