JHM Consent Requirements for International Research

Below is a list of information that must be included in the consent forms and waivers of documentation of consent for international research studies where:

1. JH staff/faculty are on the ground and conducting research in an international setting and therefore the JHM IRB is responsible for the review and approval of the entire research project **OR**
2. JH staff/faculty have a limited role in the research (e.g. data coordinating center, not consenting any participants), but the study is federally-funded and Johns Hopkins is the prime awardee meaning the JHM IRB is responsible for ensuring the consent complies with US regulatory requirements.

You are not required to use the JHM IRB consent form template(s) for international research studies. If you decide to use a non-JHM IRB consent form template, you must be sure that the consent(s):

1. include all required consent form elements (described below)
2. are submitted in a Word document format (no pdfs)
3. are uploaded in eIRB application Section 15.3 (Adult Consent Forms) or Section 17.9 (Parental Permission Forms), NOT uploaded in the sponsor sample consent(s) sections.

CONSENT FORM ELEMENTS

A. Required Elements of Informed Consent

It is important to include the required elements of informed consent.

Use the checklist here to make sure the **basic required** consent elements are included in your written or oral presentation of study information.

B. Additional Elements of Informed Consent

Based upon the type of research and what regulations the research is subject to, there may be **additional elements** of informed consent that are required.

The checklist here outlines **additional elements** of informed consent that you may wish to include in your written or oral presentation of study information. Note the JHM IRB may determine any optional element is required based on the nature of the study (for example if the study will involve whole genome sequencing, language explaining this should be included)

REQUIRED CONSENT FORM SECTIONS

Please Note: Each of the following sections are required to be included in your consent form. Specific examples of language are presented below, but the language is **preferred – not required**. You may use the local IRB's language in lieu of the JHM language included below provided the language addresses the required element.

A. Key Information

The revised federal rule governing human subjects research (the "Common Rule") includes the new element of "key information," which **must be presented at the beginning of the consent document**.

The Common Rule defines key information as a concise and focused presentation that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research.

Please see link here for more guidance on key information.

B. Future Use of Data and/or Biospecimens

The Revised Common Rule requires that the consent form include **one** of the following statements about research that involves the collection of identifiable private information or identifiable biospecimens:

i. A statement that identifiers might be removed from the information or biospecimens and that, after such removal, the information or specimens could be used for future research studies or distributed to another investigator for future studies without additional informed consent being obtained.

Sample text: *We may use the information or biospecimens collected through this study for future research including research with external collaborators. Generally, when sharing information or biospecimens for future research we will take precautions to remove any information that could identify you (like your name or medical record number) before sharing.*

OR

ii. A statement that the information or biospecimens, even if identifiers are removed, will not be used or distributed for future research studies. This is not common.

Sample text: *We will only use data/biospecimens collected through this study for the purposes of this study. Data/biospecimens collected in this study will not be used for any future research, even if identifiers (such as name, address, date of birth, etc.) are removed.*

C. HIPAA

If identifiable health information will be sent to the US, **either** the following international HIPAA statement should be added to the consent **or** a separate standalone form can be used.

As part of your participation in this research study, your personal information may be sent to the United States for analysis or storage. There are laws in the U.S. to protect your personal information when in that country. We may share your information with members of the study team and certain third-parties, such as contractors, government agencies, and the sponsor of the study. We will try to make sure that everyone who receives your information will keep it confidential, but we cannot guarantee that your information will not be further disclosed by those third-parties.

D. Certificate of Confidentiality (If Applicable)

For NIH-funded international studies that will collect identifiable data, the following statement must be included in the consent form:

This study is protected by a Certificate of Confidentiality that helps keep your information private when stored in the U.S.

E. Conflict of Interest (If Applicable)

If applicable, add the following language:

What does a conflict of interest mean to you as a participant in this study?
A researcher has a financial or other interest in this study.

<<For studies that also have an institutional conflict: >>

A researcher and Johns Hopkins University have a financial or other interest in this study.

In some situations, the results of this study may lead to a financial gain for the researcher and/or Johns Hopkins. This financial interest has been reviewed in keeping with Johns Hopkins' policies. It has been approved with certain conditions, which are intended to guard against bias in how the study is conducted, how the results are analyzed, and how participants are protected.

*If you have any questions about this financial interest, please talk to <<**name and telephone number of non-financially interested designee**>>. This person is a member of the study team, but does not have a financial interest related to the study. You may also call the Office of Policy Coordination (410-361-8667) for more information. The Office of Policy Coordination reviews financial interests of investigators and/or Johns Hopkins.*

F. IRB Contact Information

If a local IRB is reviewing the study, please include their contact information. If there is no local IRB, include the Hopkins IRB contact language:

This study has been reviewed by the Johns Hopkins Institutional Review Board (IRB) in the United States. An IRB is a group of people that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study. You may contact the Johns Hopkins IRB at 410-502-2092 or jhmeirb@jhmi.edu.