April 12, 2019

Please note: This will be the last OHR announcement sent out to the Listserv distribution lists. All IRB announcements will only be sent to people who have joined the MyJeffHub community. To join this community, please contact Julia Center at Julia.Center@Jefferson.edu.

Subject: Revised IRB Forms and Policies including Modified Subject Injury Language – April 12, 2019

In an effort to keep the research community informed of new and revised Office of Human Research (OHR) forms and policies, we are providing a summary of recent changes.

For consistency between studies and convenience for study coordinators, the OHR-8 template has been modified in the following sections:

- **Research-Related Injury and Costs** – Depending on what your study entails, select the correct option in each section. Make sure that the language chosen in the table matches the language chosen in the body of the consent. Please note that the option you select may not be the finalized language. You must always ensure that the language matches the contract and budget. Reach out to your assigned budget and contract specialists with any questions.
- **Privacy and Confidentiality: HIPAA Authorization** – New HIPAA language has been added to the OHR-8 consent template. The new HIPAA language has also been used to create a standalone HIPAA authorization document. The standalone document can be used when requested (e.g. a CIRB submission). This standalone HIPAA authorization template replaces all previous HIPAA authorizations used for research.
- **MCARE Investigator Signature Requirement** – Previously it was communicated that this requirement only applied to studies being done in Pennsylvania. However, this is now applicable regardless of where the study is being conducted.
- **Optional Assent Section** – The Assent section of the consent template has been clarified. The Assent section should be completed for all subjects under the age of 17, and/or individuals with impaired decision-making capacity.

Note: Please remember to always access the most current forms and policies on the Office of Human Research website. Note: When opening documents, if prompted for user name and password, click cancel and the document should open. If you have any questions or comments about these forms/policies, if you requested changes you do not see, or if you have any new suggestions, please contact Johanna.Yates@Jefferson.edu or Jacquie.Wright@Jefferson.edu. If you have any questions on your submission, please contact Kyle.Conner@Jefferson.edu.

Thank you,

The Office of Human Research

Forms

Form Number	Title	Version Date
NA	**Authorization to Use or Disclose Health Information for Research**	**4/12/2019**
Changes: This HIPAA Authorization may be used as a standalone document in cases where it is not appropriate to include the HIPAA language in the consent form, i.e., submission to CIRB.		

OHR-2	**Summary of Interventional Human Subjects Research**	**4/12/2019**
Changes: A question has been added on medical coverage related to a research-related injury.		

OHR-8	**Informed Consent**	**4/12/2019**
Changes: The Research-Related Injury, Costs, and Privacy and Confidentiality: HIPAA Authorization sections have been modified for consistency and ease of completion. Previously it was communicated that the MCARE investigator signature requirement only applied to studies being done in Pennsylvania. However, this is now applicable regardless of where the study is being conducted. The Assent section of the consent template has been clarified. The Assent section should be completed for all subjects under the age of 17, and/or individuals with impaired decision-making capacity. The Contacts section has been modified. Please know you can add other contact information/phone numbers if needed.		

OHR-15A	**Prospective Collection of Human Biological Specimens**	**NA**
Changes: This document is no longer in use.		

NA	**Local Context Questionnaire for Site Relying on Jefferson IRB**	**3/18/2019**
Changes: This is a new questionnaire that must be completed for multicenter studies where Jefferson is the reviewing IRB. This needs to be completed by the relying site, and provided to the Jefferson IRB as part of the initial IRB submission. This may also be emailed separately to Crystal.Lijadu@Jefferson.edu.		

NA	**TJU SMART IRB Acknowledgement Template**	**3/18/2019**
Changes: The SMART IRB platform is used to initiate single IRB review of a study. This new SMART Letter is an acknowledgement in ceding IRB review and may only be used for institutions that are SMART IRB participating members. This should be completed by the Jefferson research team, signed off by the local site, and emailed directly to Crystal.Lijadu@Jefferson.edu. For questions on SMART IRB, please contact Crystal.Lijadu@Jefferson.edu.		

Policies

Policy Number	Title	Version Date
QA 303	**Inspections by the FDA and Other Regulatory Agencies**	**4/12/2019**
Changes: This policy has been clarified to state that IRBs at all Jefferson entities must notify Jefferson Center City IRB when they have been notified of an inspection		

G 611	FDA Inspections of Clinical Investigators	4/12/2019
Changes: This policy has been deleted and the information incorporated into QA 303		

IC 701	Informed Consent and HIPAA Authorization: General Requirements	4/12/2019
Changes: Clarified that if a study is collecting PHI, HIPAA authorization language must be in the consent form or a separate document unless the IRB approves a waiver. Also, MCARE is now applicable regardless of where the study is being conducted.		

IC 704	Child Assent and Parental Permission for Participation in Research	4/12/2019
Changes: The policy statement has been clarified to state that all children age 7 – 17 should be given the opportunity to assent. The Assent section should be completed for all subjects under the age of 17, and/or individuals with impaired decision-making capacity.		

IC 709	Treatment and Cost of Research Related Injury	4/12/2019
Changes: This new policy describes what treatment and compensation will be provided to research subjects as a result of a research-related injury		

In addition, a number of administrative changes were made to other forms and policies.