March 21, 2018 revision to February 20, 2018 Announcement

Subject: Revised IRB Forms and Policies – Consent – March 21, 2018

This announcement is being updated to clarify which aspects of the policy are now effective: The changes to the consent forms will begin immediately, but as described in this announcement. The change in investigator responsibility due to the PA Supreme Court ruling will begin once the modified consent form has been approved by the IRB. Subjects who have already been enrolled do not have to be re-consented due to these changes unless otherwise specified by the IRB. The consent forms for ongoing studies do not have to be immediately revised. However, at the time of continuing review, if enrollment is still open, you must submit a revised consent form with the appropriate investigator signature line. The new, revised OHR-8 template must be used for new studies.

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

A Pennsylvania Supreme Court decision (Shinal vs. Tom, M.D. – 2017) has initiated changes to our consent form and process. The Court ruled that a physician must personally discuss the procedures, risks, benefits, and alternatives with the patient for certain procedures. Although this case was the result of clinical treatment, we are applying the decision to research.

In order to comply with this decision, and to ensure that the subject is properly informed about the study, an additional line of guidance must be added to the signature page of consent forms. The following describes how you will determine what this line of guidance will be. The associated IRB policy and forms have been modified to assist you with this change.

The Pennsylvania Medical Care Availability and Reduction of Error Fund (Mcare) law specifies the procedures for which consent must be obtained. The following list of procedures is based on Pennsylvania's Mcare law as applicable to research and appears in OHR Policy IC 701:

1. Administration of anesthesia
2. Performance of surgical procedures
3. Administration of chemotherapy and radiation
4. Administration of blood and/or human source products
5. Insertion of a surgical device or appliance
6. Performance of any HIV-related testing

7. Administration of experimental medication, use of an experimental device, use of an approved medication or device in an experimental manner, or removal of bone, fluids or tissue for use in research or in the manufacture of a product. (This would not include leftover tissues from clinical procedures.)

8. Invasive procedures, such as halo placement, central venous catheterization, pulmonary artery catheterization. (Routine needle sticks, such as peripheral intravenous catheter placement, vaccination, and venipuncture are not considered invasive in the context of this policy.)

Using the list above as a reference, you must select one of the following guidance options to appear in the consent form above the investigator signature line.

1. Include the following text for studies involving any Mcare procedures. Note: The investigator performing this role must be a physician.

The **physician investigator's** signature certifies that s/he **personally** provided the study participant with a description of the study, study procedures, risks, benefits and alternatives to participation.

2. Include the following text for studies that receive FULL IRB review but do not include any Mcare procedures. Note: The investigator performing this role does not have to be a physician.

The **investigator's** signature certifies that s/he **personally** provided the study participant with a description of the study, study procedures, risks, benefits and alternatives to participation.

3. Include the following text for all other studies. Note: In this case, the informed consent discussion may be conducted by the PI, a Co-I or other properly trained key personnel designated by the PI. When key personnel conduct the consent discussion, an investigator should be available (e.g. by phone) to clarify information or answer questions as necessary.

The investigator's signature certifies that the study participant has been provided with a description of the study, study procedures, risks, benefits and alternatives to participation.

OHR Policy IC 701, Informed Consent and HIPAA Authorization: General Requirements, has been revised to reflect these changes.

To assist you in implementing this change for your study, the following forms have been revised:

OHR-8, Informed Consent Form template: The new, revised OHR-8 template must be used for new studies. The correct investigator signature line options have been added to this template. Using the Mcare list of procedures as a reference, you will choose the correct investigator signature line to appear in the consent form for your study.

Please note that the content and format of the OHR-8 have been fully revised to comply with upcoming requirements for simplified consent forms. The consent form will begin with a table summarizing the elements of consent. The elements of consent which involve more detail (e.g. procedures, risks, injury, HIPAA) are addressed in separate sections following the summary table. The goal of this format is to provide a more user friendly summary of the study to the subject and to the person obtaining consent.

OHR-2 and OHR-2B, Summaries of Research: These forms are submitted to the IRB for new studies. A section has been added to each of these forms which will prompt you to determine which investigator signature line should be added to the consent form. These sections will also act as a reference for IRB reviewers to ensure that the correct option is selected.

OHR-9, Continuing Review Form: The consent forms for ongoing studies do not have to be immediately revised. However, at the time of continuing review, if enrollment is still open, you must submit a revised consent form with the appropriate investigator signature line. To facilitate this addition, a section has been added to this form which will prompt you to determine which investigator signature line should be added to the consent form.

As part of each consent process after all signatures have been obtained, always take a minute to make sure that all printed names, signatures, and dates have been properly completed on the consent form signature page.

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.

Thank you,

The Office of Human Research

Forms

Form Number	Title	Version Date
OHR-2	Summary of Interventional Human Subjects Research	2/20/2018

Changes: A section has been added which will prompt you to determine which investigator signature line should be added to the consent form.

OHR-2B	**Summary of Non-Interventional Human Subjects Research**	**2/20/2018**
Changes: A section has been added which will prompt you to determine which investigator signature line should be added to the consent form.		

OHR-8 Guidelines	**Informed Consent**	**2/20/2018**
Changes: Informed consent must begin with a concise and focused presentation of the key information. Informed consent must be organized and facilitate comprehension. New required elements of consent and new investigator signature requirements have been added.		

OHR-9	**Continuing or Final Review of Research Protocols Involving Human Subjects**	**2/20/2018**
Changes: A section has been added which will prompt you to determine which investigator signature line should be added to the consent form.		

Policies

Policy Number	Title	Version Date

IC 701	**Informed Consent and HIPAA Authorization: General Requirements**	**2/20/2018**
Changes: Informed consent must begin with a concise and focused presentation of the key information. Informed consent must be organized and facilitate comprehension. New required elements of consent and new investigator signature requirements have been added.		

If you have any questions or comments about these changes, if you requested changes you do not see or if you have any new suggestions, please contact patrick.herbison@jefferson.edu .