September 1, 2016

Subject: Revised IRB Forms – September 1, 2016

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

General Changes:

Many of the changes made to the forms below are administrative in nature and fall into the following categories:

1. Some forms have had a version date and number added to them to help you version your documents. A separate announcement will be sent out with more information.
2. Updating the number of hardcopies needed (or not needed) for an IRB submission.
3. Department/group names and contact information have been updated (e.g. DHSP changed to OHR, CRMO changed to CTO, etc.).

Number	Title	Version
NA	**Overview of IRB Submissions for New Studies**	9/1/16
Changes: Administrative changes. Note: This form is a table that shows which forms are needed for new IRB submissions.		

Number	Title	Version
NA	**New IRB Submission Checklist**	9/1/16
Changes: Administrative changes. Note: This form is a checklist that should be included with new IRB submissions. It is to help you organize the forms needed for your submission.		

Number	Title	Version
NA	**IDX Custom Report Request Form**	9/1/16
Changes: Administrative changes including clarification of instructions for submitting the form.		

Number	Title	Version

OHR-1	**Proposal Transmittal and Approval Form**	9/1/16
Changes: Administrative changes. Clarification of requirements for all cancer related research.		

Number	Title	Version
OHR-2	**Summary of Interventional Human Subjects Research**	9/1/16
Changes: Administrative changes.		

Number	Title	Version
OHR-2B	**Summary of Non-Interventional Human Subjects Research**	9/1/16
Changes: Administrative changes.		

Number	Title	Version
OHR-4	**Record / Chart Review / Computer Database Research Study**	9/1/16
Changes: Administrative changes.		

Number	Title	Version
OHR-8	**Informed Consent Document for Human Subjects Research**	9/1/16
Changes: Administrative changes.		

Number	Title	Version
OHR-8B	**Surrogate Consent for a Research Protocol**	9/1/16
Changes: Administrative changes. Clarification that when a patient's power of attorney consents for the patient, that a copy of the power of attorney documentation should be retained in the study file. Also, the requirement for the subject to initial and date each page of the consent form was eliminated previously (see April 10, 2015 IRB Announcement). The announcement extends to any individual signing for the subject (e.g. surrogate). The requirement for the surrogate to initial and date each page of the consent form has been removed from the instructions in the OHR-8B.		

Number	Title	Version
OHR-8C	**Child's Assent to Participate in a Clinical Trial**	9/1/16
Changes: Administrative changes.		

Number	Title	Version
OHR-9	**Continuing or Final Review of Research Protocols Involving Human Subjects**	9/1/16
Changes: Administrative changes. A question was added to gather information on how well the subjects are tolerating study treatment. Also, please note that you have the ability to run a report of all the serious adverse events (SAEs) or unanticipated problems (UAPs) for a given study. This can be done in the eSAEy and eazUP systems. We hope that these reports will be helpful when submitting continuing reviews and at other times when a list of this nature is called for. Please see the May 31, 2016 IRB		

Announcement for more information.

Number	Title	Version
OHR-12	**Amendment to Research Protocol**	**9/1/16**
Changes: Administrative changes.		

Number	Title	Version
OHR-12B	**Adding Study Personnel**	**9/1/16**
Changes: Administrative changes. Clarification of the signatures required for this form.		

Number	Title	Version
OHR-12C	**Removing Study Personnel**	**9/1/16**
Changes: Administrative changes.		

Number	Title	Version
OHR-15	**Request for Human Biological Specimens for Research**	**9/1/16**
Changes: Administrative changes.		

Number	Title	Version
OHR-34	**Research Not Requiring IRB Review: A Checklist**	**9/1/16**
Changes: Administrative changes. Clarification of categories and the addition of 1 category: Research that does not involve collection of private information about living individuals.		

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