November 1, 2018

Subject: Revised IRB Forms and Policies including Burden-Reducing Provisions - November 1, 2018

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.

The revised Common Rule will become effective January 21, 2019 but several burden-reducing provisions are being implemented now. The burden-reducing provisions are designed to streamline certain aspects of the IRB review and approval process. The IRB policies and forms have been revised so that you can benefit from these time saving measures.

The 3 burden-reducing provisions are:

1. The definition of "research" has been revised to include new categories of activities that are not considered research. Please see the revised OHR-34 form for the new, complete list of the activities that are not considered research.

2. Certain categories of research will no longer require continuing annual review by the IRB.

   If the study is NOT FDA-Regulated, and meets any of the following criteria below, the IRB may determine that continuing review is not required:

a. Research eligible for expedited review

b. If the research has progressed to the point that remaining activities involve only one or both of:

   - Data analysis, including analysis of identifiable private information or identifiable biospecimens, and/or;

   - Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

Note that the IRB will make these determinations at the time of initial approval and continuing review. Therefore, continuing reviews **must still be submitted** for ongoing studies in order for the IRB to make this determination. You will be notified of the IRB's decision in the approval letter. Even if the IRB determines that continuing review is no longer required, you must continue to submit all study changes, including amendments, personnel changes, serious adverse events, unanticipated problems, and final reports to the IRB. Please note that most studies that require initial review by the full IRB will require continuing review.

3. The requirement that IRBs review grant applications or other funding proposals related to the research has been eliminated. This is not applicable to current OHR processes.

In addition to the 3 burden-reducing provisions, the OHR has made additional changes based on suggestions from the research community. The complete list of changes appears below.

Note: If you have already filled out the previous version of a form for a submission, you do not have to start over with the new form indicated below. But if you just started filling out the previous version, please start over with the new form indicated below.

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 about how the new burden –reducing provisions will affect your study/submission, please contact Kyle.Conner@Jefferson.edu.

Thank you,

The Office of Human Research

Forms

Form Number	Title	Version Date
N/A	**Overview of IRB Submissions for New Studies**	**11/1/2018**
Changes: Administrative Changes.		

N/A	**New IRB Submission Checklist**	**11/1/2018**
Changes: Administrative Changes.		

OHR-1	**Proposal Transmittal and Approval Form**	**11/1/2018**
Changes: Administrative Changes.		

OHR-2	**Summary of Interventional Human Subjects Research**	**11/1/2018**
Changes: Options have been provided to help you clarify which 'Mcare' investigator signature line should be added to the consent form. Administrative Changes.		

OHR-2B	Summary of Non-Interventional Human Subjects Research	11/1/2018
Changes: Options have been provided to help you clarify which 'Mcare' investigator signature line should be added to the consent form. Administrative Changes.		

OHR-3	Request for Waiver of Subject Authorization to Collect Protected Health Information	11/1/2018
Changes: Administrative Changes.		

OHR-4	Record / Chart Review / Computer Database Research Study	11/1/2018
Changes: The section on PRC Approval and a question on funding have been deleted due to redundancies on the OHR-1. Administrative Changes.		

OHR-8/8A	Informed Consent	11/1/2018
Changes: The OHR-8A has been merged with the OHR-8. The OHR-8A is no longer in use. The OHR-8 has been modified to make it easier to use for studies that do not require a lengthy consent form (e.g. blood draw studies). In addition, examples have been provided throughout the body of the OHR-8 for studies only involving blood draws or simple sample collection. The Contacts table has been expanded to include additional locations. Administrative Changes.		

OHR-8B	Surrogate Consent	11/1/2018
Changes: This form has been fully revised to make it easier to use. The instructions for completing a Surrogate Consent from the last page has been reformatted as an introductory paragraph. A section has been added to help you clarify which 'Mcare' investigator signature line should be added to the consent form. Administrative Changes.		

OHR-8H	Verbal Consent for Use/Disclosure of PHI	11/1/2018
Changes: Standard consent template language has been added for consistency with the main consent template (OHR-8).		

OHR-9	Continuing or Final Review of Research Protocols Involving Human Subjects	11/1/2018
Changes: A prompt has been added as a reminder for HUD studies to be treated as a research studies when completing the OHR-9. The Current Study Status section has been moved towards the beginning of the OHR-9 for ease in determining the study's eligibility for no further continuing review. Language has been clarified on reporting requirements for SAEs/UAPs. The OHR Policy has been updated as well. A question has been added in Part D to submit applicable safety reports as part of the submission. Options have been provided to help you clarify which 'Mcare' investigator signature line should be added to the consent form. Administrative Changes.		

OHR-12	Amendment to Research Protocol	11/1/2018
Changes: The number of subjects enrolled to date question has been expanded to incorporate each subject's status in the study. Another option has been included under the Re-Consent Determination section for those consent amendments that would typically require a re-consent but no subjects have been enrolled. Administrative Changes.		

OHR-12B	Adding Study Personnel	11/1/2018
Changes: Administrative Changes.		

OHR-12C	Removing Study Personnel	11/1/2018
Changes: Administrative Changes.		

OHR-15/16	Human Biological Specimen, Tissue and/or Genetic Research	11/1/2018
Changes: The OHR-16 has been merged with the OHR-15. The OHR-16 is no longer in use. The section on PRC Approval and a question on funding have been deleted due to redundancies on the OHR-1.		

OHR-18	Application for Exemption from IRB Review	11/1/2018
Changes: A table has replaced the questions in Section 3 and expanded to Pregnant women, Human fetuses and/or Neonates and Children. Administrative Changes.		

OHR-25	Device Worksheet	11/1/2018
Changes: The format of the document has been modified for ease of completion. Starting at Section 1, the appropriate selection for the protocol will determine which following section will need to be completed.		

OHR-33	IRB-Approved Protocols and External Funding: Does the IRB Protocol Cover the Work Proposed in the Grant Application?	11/1/2018
Changes: Administrative Changes.		

OHR-34	Research Not Requiring IRB Review: A Checklist	11/1/2018
Changes: Due to the revised definition of "research," the additional categories of activities that are not considered research have been included in the OHR-34. Administrative Changes.		

POLICIES

Number	Title	Version
GA 101	**The Authority and Purpose of the Institutional Review Boards**	**11/1/2018**
Changes: Clarified IRB authority, policy and procedures.		

Number	Title	Version
GA 102	**Activities Requiring IRB Approval**	**11/1/2018**
Changes: Clarified the activities that require IRB review.		

Number	Title	Version
GA 103	**Maintenance of Policies, Procedures, and Internal Forms**	**11/1/2018**
Changes: Clarified minor changes can be made without OHR, Director approval.		

Number	Title	Version
GA 113	**IRB Reporting of Findings and Actions to Investigators**	**11/1/2018**
Changes: Clarified procedures for reporting IRB findings.		

Number	Title	Version
GA 120	**Reporting and Reviewing Unanticipated Problems Involving Risks to Subjects or Others**	**11/1/2018**
Changes: The table showing the SAE and UAP reporting timeframes has been modified to clarify what events need to be reported.		

Number	Title	Version
GA 127	**Subject Screening and Enrollment**	**11/1/2018**
Changes: Clarified process for screening subjects using the electronic medical record.		

Number	Title	Version
GA 133	**Human Research Training**	**11/1/2018**
Changes: Clarified human research training requirements for Investigators and key personnel.		

Number	Title	Version
QA 302	**Quality Assurance/Quality Control, IRBs**	**11/1/2018**
Changes: Administrative changes.		

Number	Title	Version
RR 402	**Continuing Review By Convened IRB (i.e., "Full Review")**	**11/1/2018**
Changes: Simplified policy and added information describing when IRB may determine that continuing review is not required.		

Number	Title	Version
RR 404	**Expedited Review of New and Continuing Research**	**11/1/2018**
Changes: Revised requirements for expedited review for continuing research.		

Number	Title	Version
RR 408	**Review of Amendments**	**11/1/2018**
Changes: Clarified reporting requirements for modifying a protocol to eliminate immediate hazards.		

Number	Title	Version
IC 701	**Informed Consent and HIPAA Authorization: General Requirements**	**11/1/2018**
Changes: Added the allowance for electronic signatures.		

Number	Title	Version
IC 702	**Documentation, Waiver and Alteration of Informed Consent**	**11/1/2018**
Changes: Administrative changes.		

Number	Title	Version
IC 703	**Parental Permission for a Child to Participate in a Research Protocol**	**11/1/2018**
Changes: This policy has been deleted and combined with policy IC 704.		

Number	Title	Version
IC 704	**Child Assent and Parental Permission for Participation in Research**	**11/1/2018**
Changes: Policy IC 703 has been combined with policy IC 704.		

Number	Title	Version
IC 706	**Waiver and Alteration of Informed Consent and HIPAA Authorization**	**11/1/2018**

Changes: Administrative changes.

Number	Title	Version
IC 707	**Surrogate Consent**	**11/1/2018**
Changes: Clarified the procedure for obtaining surrogate consent.		

Other minor formatting/administrative changes have been made to other policies.