January 22, 2019

Subject: Revised IRB Forms and Policies including Common Rule – January 21, 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.

The 2018 Common Rule will be effective as of Monday, January 21, 2019. The most important changes to the Common Rule that affect the Jefferson research community are as follows:

- **Modified/New Exempt Categories** – There are modifications, as well as additions, to the exempt categories list. The OHR-18 (Application for Exemption from IRB Review) has been adjusted to reflect these changes.
    - The new exemption category of "benign behavioral interventions" has been added.
    - The exemption category for retrospective data collection has been expanded to include prospective data collection.
    - It is important to note that studies submitted on or after 1/21/19 that previously would have met expedited review criteria may now be exempt. Please carefully review the OHR-18 to determine which type of review your study meets and submit the appropriate documents. If there are any questions about this, please contact OHR before initial submission.
- **Consent Posting on Public Website**: For studies conducted or supported by a Federal department or agency, one IRB-approved consent form must be posted on https://ClinicalTrials.gov after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject. For instructions on how to post on ClinicalTrials.gov, please reach out to Melissa.McCarey@Jefferson.edu.

Call OHR with any questions about these changes.

In addition to the Common Rule changes, the OHR has made additional changes based on suggestions from the research community. The following summary of modifications are as follows and the complete list of changes appears in table below:

- **First Steps – Intro to an IRB Submission** – A new guidance document is now available to help guide you through a new IRB submission. The form is helpful if you are new to the IRB submission process, and also is a good refresher if it's been awhile since your last submission. If you are planning an IRB submission, please review this form. If you still have questions, please contact OHR.
- **Continuing Review Determination in OHR-9** – The Current Study Status section has been broken down into 3 segments: FDA Regulation, Continuing Review Determination, and Study Status. Please carefully review and complete appropriate sections, as they assist the IRB in determining whether further continuing review will be required. Reach out to OHR with any questions on how to complete these Parts.

- **Optional Assent Section in OHR-8 –** The child assent has been combined with the main consent form. A separate "Optional Assent" signature section has been added after the Main Consent's signature page. If your study involves enrolling minors, this section may be used. This section can also be used for adults with impaired decision-making capacity. This form is NOT for Surrogate Consent which is generally used for adults with a temporary inability to consent (use the OHR-8B). If your study does not involve assent, the entire Optional Assent Section should be deleted. Due to this change, the OHR-8C has been deactivated.

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 Common Rule will affect your study/submission, please contact Kyle.Conner@Jefferson.edu.

Thank you,

The Office of Human Research

Forms

Form Number	Title	Version Date
NA	**First Steps – Intro to an IRB Submission**	1/21/2019
Changes: A new guidance document is now available to help guide you through a new IRB submission. The form is helpful if you are new to the IRB submission process, and also is a good refresher if it's been awhile since your last submission. If you are planning an IRB submission, please review this form. If you still have questions, please contact OHR.		
OHR-1	**Proposal Transmittal and Approval Form**	1/21/2019
Changes: A reminder has been added to page 1 on posting an IRB-approved consent to clinicaltrials.gov. Also, if your study involves Digital Technology or is an Investigator-Initiated Trial involving multiple research sites, a checklist has been added with contact information prior IRB submission.		
OHR-2	**Summary of Interventional Human Subjects Research**	1/21/2019
Changes: Administrative Changes. A question on non-English speaking participants expanded.		
OHR-2B	**Summary of Non-Interventional Human Subjects Research**	1/21/2019
Changes: Administrative Changes. A question on non-English speaking participants expanded		

OHR-3	Request for Waiver of Subject Authorization to Collect Protected Health Information	1/21/2019
Changes: An option for a waiver of written authorization based off of a distinct cultural group or community has been added.		

OHR-8	Informed Consent	1/21/2019
Changes: Administrative Changes. The Optional Assent Section has been added after the Main consent signature page for studies enrolling minors.		

OHR-9	Continuing or Final Review of Research Protocols Involving Human Subjects	12/19/2018
Changes: Administrative Changes. The status section has been modified for clarity. Please note that this version was released and effective on 12/19/2018.		

OHR-12	Amendment to Research Protocol	1/21/2019
Changes: Administrative Changes. Number 1 has been expanded for studies with no expiration date.		

OHR-18	Application for Exemption from IRB Review	1/21/2019
Changes: Administrative Changes. Modifications and additions to the exempt categories have been made, per Common Rule.		

OHR-34	Research Not Requiring IRB Review: A Checklist	1/21/2019
Changes: Administrative Changes.		

Policies

Policy Number	Title	Version Date

GA 101	The Authority and Purpose of the Institutional Review Boards	1/21/2019
Changes: Tribal law applies where applicable.		

GA 102	Activities Requiring IRB Approval	1/21/2019
Changes: Clarified definitions pertaining to human subject research. Clinical trials are now specifically defined. Definition of human subjects Includes “information or biospecimens” obtained from through intervention and intervention and interaction OR “identifiable private information or identifiable biospecimens.”		

GA 120	Reporting and Reviewing Unanticipated Problems Involving Risks to Subjects or Others	1/21/2019
Changes: Clarified reporting of external events for multi-center studies.		

RR 401	Initial Review - Criteria for IRB Review and Approval	1/21/2019

Changes: Pregnant women removed from vulnerable populations; Reliance arrangement with non-institutional IRB must be documented.	

RR 403	Review of Exempt Studies	1/21/2019
Changes: New exemptions added; including exemptions for secondary research on identifiable private information and identifiable biospecimens under various circumstances; various regulatory requirements, such as limited IRB review, may apply.		

RR 404	Expedited Review of New and Continuing Research	1/21/2019
Changes: Clarified an IRB may use the expedited review procedure to review research that meets the criteria for limited IRB review.		

RR 415	Undergraduate Research	1/21/2019
Changes: New Policy developed to differentiate between undergraduate student educational research projects and undergraduate student academic research projects and describe how undergraduate student academic research projects will be overseen and regulated.		

IC 701	Informed Consent and HIPAA Authorization: General Requirements	1/21/2019
Changes: Some clinical trials must post consent form online.		

IC 704	Child Assent and Parental Permission for Participation in Research	1/21/2019
Changes: Clarified the Assent process.		

IC 706	Waiver and Alteration of Informed Consent and HIPAA Authorization	1/21/2019
Changes: Clarified the requirements for the waiver and alteration of informed consent.		