Subject: Revised IRB Forms and Policies - January 20, 2020

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.

Cooperative Single IRB submissions to Jefferson IRB - In general, any institution located in the United States that is engaged in cooperative (involving more than one institution), federally funded research, must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. Please see Policy RR 401 and the forms indicated below for more information about this new requirement.

Short Forms - All short form consents were modified for consistency with the revised Common Rule. Most users will be able to enter their site specific study information into the fields that have been inserted into these documents. There are now 20 languages available (see below). All short forms have been consolidated onto the main OHR forms page and the separate Abington short form page has been deactivated. Please note that short forms are generally used when a non-English speaking subject must be consented and there is not enough time to get a full translated consent. Short forms must be approved by the IRB. Please see OHR policy IC 705 for more information on the short form consent process. Please note that for less complex studies that do not require a long consent form, the regular OHR-8 should be used and the parts that are not applicable removed.

Policy GA 109 - The process for removing study personnel on a study has been clarified: If a PI, Co-I or key personnel leaves the study, this must be documented by the study team (e.g. entering a stop date in JeffTrial, or for studies not in JeffTrial, submitting an OHR-12C to the IRB).

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 policies, if you requested changes you do not see, or if you have any new suggestions, please contact Johanna.Yates@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	**New IRB Submissions Checklist**	**1/20/20**

Changes: A checkbox was added indicating that for cooperative single IRB submissions, the approval from the Federal department or agency supporting or conducting the research or lead institution is required.

OHR-1	**Proposal Transmittal and Approval Form**	**12/5/19 (Administrative), 1/3/20 (Administrative), 1/20/20**
Changes: A question was added indicating that for cooperative single IRB submissions, the approval from the Federal department or agency supporting or conducting the research or lead institution is required. There are now 2 options if your study requires Nursing Department approval. One for Jefferson Health New Jersey and one for other locations.		

OHR-2	**Summary of Interventional Human Subjects Research**	**1/20/20**
Changes: A question was added asking for additional information if your study is part of a cooperative single IRB submissions.		

OHR-8H	**Verbal Consent with Optional Use of Disclosure of PHI**	**1/20/20**
Changes: A change clarifying that generally the subject does not sign a verbal consent form.		

OHR-8S	**Short Form Consent**	**11/4/19**
Changes: All short form consents were modified for consistency with the revised Common Rule. Most users will be able to enter their site specific study information into the fields that have been inserted into these documents. There are now 20 languages available including: Albanian, Arabic, Bengali, Brazilian Portuguese, Cambodian, Farsi, French, Greek, Gujarati, Haitian Creole, Hindi, Indonesian, Italian, Korean, Polish, Russian, Simple Chinese, Spanish, Traditional Chinese, and Vietnamese.		

OHR-9	**Continuing or Final Review of Research Protocols Involving Human Subjects**	**1/20/20**
Changes: Revision to Enrollment and Risk Data section indicating not to include deaths on the line for completed subjects.		

POLICIES

Policy Number	Title	Version Date
GA 103	**Maintenance of Policies, Procedures, and Internal Forms**	**1/20/20**

Changes: Clarification that, as appropriate, policy and form announcements are sent to the research community and are also available on the OHR website.

GA 109	**Roles and Responsibilities of Study Personnel and Department Chairs**	**1/20/20**
Changes: The process for removing study personnel has been clarified: If a PI, Co-I or key personnel leaves the study, this must be documented by the study team (e.g. entering a stop date in JeffTrial, or for studies not in JeffTrial, submitting an OHR-12C to the IRB).		

GA 114	**Reporting of Unanticipated Problems, Terminations, Suspensions and Non-Compliance**	**1/20/20**
Changes: This policy was retired. OHR Policy QA 301will reference TJU policy 110.15, Institutional Review Board Review of Noncompliance Issues, which is the official policy for OHR's non-compliance requirements. Unanticipated problems, terminations, and suspensions are covered in other OHR policies.		

GA 129	**Protection of Privacy Interests of Research Subjects and Confidentiality of Subject Data**	**1/20/20**
Changes: The content of the IRB issued HIPAA waiver letter has been clarified.		

GA 132	**Thomas Jefferson University Human Research Protection Program**	**1/20/20**
Changes: Several aspects of the Human Research Protection Program have been clarified.		

QA 301	**Quality Assurance/Quality Improvement Program**	**1/20/20**
Changes: This policy has been updated and merged with QA 302 to clarify and consolidate the requirements for the quality assurance and improvement program.		

QA 302	**Quality Assurance/Quality Control Programs, IRBs**	**1/20/20**
Changes: This policy has been incorporated into QA 301 and retired.		

RR 401	**Initial Review – Criteria for IRB Review and Approval**	**1/20/20**
Changes: In general, any institution located in the United States that is engaged in cooperative (involving more than one institution), federally funded research, must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. Please see the policy for more information about this new requirement.		

SC 503	**Review and Approval of a Humanitarian Device Exemption**	**1/20/20**
Changes: Humanitarian Use Devices (HUDs) are devices that are intended to benefit patients by treating or diagnosing a disease or condition that affects a relatively small number of individuals. This threshold has been changed in the regulations (21 CFR 814.102) and in this policy from not more than 4000 to not more than 8000 individuals in the United States per		

year.