

October 28, 2020

Subject: Revised IRB Forms and Policies - October 28, 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.

Note: Please remember to always access the most current forms and policies on the [Office of Human Research](#) website. When opening documents, if prompted for user name and password, click cancel and the document should open.

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.

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 Johanna.Yates@Jefferson.edu or Patrick.Herbison@Jefferson.edu. If you have any questions about filling out OHR forms or your submission, please contact Kyle.Conner@Jefferson.edu.

Thank you,

The Office of Human Research

Forms

Form Number	Title	Version Date
OHR-9	Continuing or Final Review of Research Protocols Involving Human Subjects	9/14/2020
Changes: A question in Section F has been added to remind researchers to submit any relevant multi-center reports to the IRB.		
OHR-18	Application for Exemption from IRB Review	9/4/2020
Changes: Clarification has been added to Category 5.		
OHR-34	Research Not Requiring IRB Review: A Checklist	9/4/2020
Changes: Two categories have been added for research not requiring IRB review.		

Policies

Number	Title	Version
--------	-------	---------

GA 102	Activities Requiring IRB Approval	9/4/2020
Changes: A description of how active studies are tracked was added.		

Number	Title	Version
OP 202	Recruiting, Appointing and Performance Evaluation of IRB Members, Chairs, and Vice Chairs	10/28/2020
Changes: The IRB Member Evaluation Form is not used and was removed. The evaluations are documented in a running document.		

Number	Title	Version
RR 401	Initial Review - Criteria for IRB Review and Approval	9/16/2020
Changes: A description of the process for ensuring diversity in enrollment was added.		

Number	Title	Version
RR 403	Review of Exempt Studies	9/4/2020
Changes: Clarification of the following aspects of exempt determinations: Review, tracking, which categories limited IRB review applies to (2, 3, 7, 8), Jefferson does not intend to conduct category 7 or 8 studies. Jefferson also does not intend to implement broad consent as defined in 45 CFR 46.		

Number	Title	Version
RR 404	Expedited Review of New and Continuing Research	9/14/2020
Changes: Clarification of no further continuing review (NFCR) studies including the steps when continuing review is required for a NFCR study. The reviewer should document the reasons on the RQ-1 reviewer questionnaire and the approval letter will indicate that the study has been approved for a defined period and include the expiration date.		
A description of how studies are tracked was added.		

Number	Title	Version
RR 407	Suspension or Termination of Human Subjects Research	9/14/2020
Changes: Definitions of suspension and termination of IRB approval added. Clarification of reporting requirements for suspensions and terminations.		

Number	Title	Version
GA 620	Department of Defense (DoD) Requirements for the Conduct of Human Subjects Research	9/9/2020
Changes: Changes made reflecting Jefferson's intention not to conduct research that will recruit military volunteers. Addition of 2 elements of consent for DoD studies.		

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