

September 21, 2016

Subject: Revised OHR Policy and Procedures Manual – September 21, 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

Policies

General Changes:

Some of the changes made to the policies are administrative. For example:

1. Title changes (e.g. from Vice President for Research to Associate Provost for Research Support Services).
2. A note has been added to page 1 indicating that approval signatures are on file. The individual signature lines for each policy have been removed.

Number	Title	Version
GA 103	Maintenance of Policies, Procedures, and Internal Forms	9/21/2016
Changes: Administrative changes.		

Number	Title	Version
GA 109	Roles and Responsibilities of Study Personnel and Department Chairs	9/21/2016
Changes: Policies referenced have been corrected.		

Number	Title	Version
GA 110	Signatory Authority	9/21/2016
Changes: Administrative changes.		

Number	Title	Version
GA 113	IRB Reporting Findings and Actions to Investigators	9/21/2016
Changes: To assure timely review, a study that is initially not approved may be reviewed by a different IRB Board. In this case, the original reviewer(s) will be invited to provide comments as consultants.		

Number	Title	Version
GA 114	Reporting of Unanticipated Problems, Terminations, Suspensions and Non-compliance	9/21/2016

Changes: Administrative changes.

Number	Title	Version
GA 125	Investigator Responsibility and Delegation of Responsibility	9/21/2016

Changes: Policies referenced have been corrected.

Number	Title	Version
GA 126	Sponsor Agreements	9/21/2016

Changes: Administrative changes.

Number	Title	Version
GA 133	Training for Investigators	9/21/2016

Changes: For non-Jefferson personnel, OHR has the option of accepting certification of training that is comparable to that which is described in this policy.

Number	Title	Version
OP 202	Recruiting, Appointing and Performance Evaluation of IRB Members, Chairs, and Vice Chairs	9/21/2016

Changes: Clarification of IRB Member evaluation. Administrative changes.

Number	Title	Version
OP 205	Duties of IRB Members	9/21/2016

Changes: Administrative changes.

Number	Title	Version
OP 206	IRB Meeting Administration	9/21/2016

Changes: Clarification that the 2 IRB voting options are 'Approved' and 'Not Approved'. The determination is made according to the 'Guidance for IRB Voting Criteria' which is located on the OHR website under 'IRB Reference Documents'. When approved, any requested changes will be reviewed by designated IRB personnel. When not approved, the proposal must be revised, re-submitted in full, and reviewed by a convened IRB. To assure timely review, a study that is initially not approved may be reviewed by a different IRB Board. In this case, the original reviewer(s) will be invited to provide comments as consultants.

Number	Title	Version
QA 302	Quality Assurance/Quality Control Program, IRBs	9/21/2016

Changes: Community outreach activities will be audited as part of the Office of Human Research (OHR) Quality Assurance/Quality Improvement Program. Administrative changes.

Number	Title	Version
QA 303	Audits by Regulatory Agencies	9/21/2016
Changes: Administrative changes.		

Number	Title	Version
RR 402	Continuing Review and Amendments	9/21/2016
Changes: Clarification: For studies that received full and expedited review, a final report (OHR-9) must be submitted to the IRB once the study is completed. Administrative changes.		

Number	Title	Version
RR 403	Review of Exempt Studies	9/21/2016
Changes: Clarification: For exempt studies, the IRB must be notified (e.g. memo, email) once the study is completed.		

Number	Title	Version
RR 404	Expedited Review of New and Continuing Research	9/21/2016
Changes: Clarification: For an expedited review, the reviewer will make the recommendation to approved or not approve as described in Policy OP 206. Recommended changes may be reviewed using the expedited procedure unless: <ol style="list-style-type: none"> 1. The reviewer determines that the proposal does not meet the criteria for expedited review and should be reviewed by a convened Board. 2. In the opinion of the reviewer, the proposal should be disapproved as the term is used at 45 CRF 46.110(b). In this case the proposal must be revised, re-submitted in full, and reviewed by a convened Board. 		

Number	Title	Version
RR 408	Review of Amendments	9/21/2016
Changes: Administrative changes.		

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