

December, 2014

Subject: Revised IRB Policies and Forms – Dec 2014

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 [Division of Human Subjects Protection page](#) of the OHR website.

Thank you

The Office of Human Research

Policies

Number	Title	Version
GA 102	Activities Requiring IRB Review	12/17/2014
Changes: Update to the regulatory references for this policy.		

Number	Title	Version
GA 122	Conflicts of Interests Disclosure for IRB Members	12/17/2014
Changes: Limit of financial interests reduced from \$10,000 to \$5,000.		

Number	Title	Version
OP 206	IRB Meeting Administration	12/17/2014
Changes: Clarification of requirements for IRB meeting minutes.		

Number	Title	Version
QA 301	Quality Assurance/Quality Improvement Program	12/17/2014
Changes: Revisions to make policy consistent with current procedure.		

Number	Title	Version
RR 403	Review of Exempt Studies	12/17/2014
Changes: Clarification of documentation procedures for IRB reviewers.		

Number	Title	Version
SC 508	Differences in State and Federal Law and Reporting Requirements Affecting the Protection of Privacy Interests of Research Subjects	12/17/2014
Changes: Formatting and grammatical changes to list of reportable information.		

Forms

Number	Title	Version
OHR-2	Summary of Interventional Human Subjects Research	12/17/14
Changes: Modification of table for collecting information about drug or device (Part C).		

Number	Title	Version
OHR-2B	Summary of Non-Interventional Human Subjects Research	08/2014
Changes: Change title of form. Change to data confidentiality and security section. Clarification of when OHR-27 is required for studies including pregnant women (Part B).		

Number	Title	Version
OHR-4	Record / Chart Review / Computer Database Research Study	12/17/14
Changes: OHR-1 is required for all new IRB submissions. COI and signature requirements removed from this form.		

Number	Title	Version
OHR-8	Informed Consent Document for Human Subjects Research	12/17/14
Changes: Formatting changes to make all headers/footers the same throughout the document.		

Number	Title	Version
OHR-8A	Informed Consent - Blood Draw	12/17/14
Changes: Formatting changes to make all headers/footers the same throughout the document.		

Number	Title	Version
OHR-8S	"Short" Informed Consent Document for Human Subjects Research	12/17/14
Changes: Lines for printed name of participant and witness added to form.		

Number	Title	Version
OHR-9	Continuing or Final Review of Research Protocols Involving Human Subjects	10/2014
Changes: Reminder to <u>not</u> include patient identifiers (name, DOB, MR#, etc.) on documents submitted/uploaded to the IRB. Clarification of information required for studies that do not involve interaction with subjects. Determination of full or expedited review added (for IRB use only).		

Number	Title	Version
OHR-12	Amendment to Research Protocol	12/17/14
Changes: Clarification of instructions and documents to be included with submission.		

Number	Title	Version
OHR-15	Request for Human Biological Specimens for Research	12/17/14
Changes: OHR-1 is required for all new IRB submissions. COI and signature requirements removed from this form.		

Number	Title	Version
OHR-16	Tissue and Genetic Research	12/17/14
Changes: OHR-1 is required for all new IRB submissions. COI and signature requirements removed from this form.		

Number	Title	Version
OHR-18	Application For Exemption from IRB Review	12/17/14
Changes: OHR-1 is required for all new IRB submissions. COI and signature requirements removed from this form.		

Additional

IRB and ORA Q&A for Investigators & Sponsors
This new document has been added to the right side of the IRB web page. The document provides answers to questions that investigators and sponsors frequently ask about IRB and ORA timelines and procedures.

If you have any questions or comments about these changes, please contact patrick.herbison@jefferson.edu .