Jefferson - Office of Human Research (OHR)

OHR Policy and Form Revisions

Subject: Revised IRB Policies and Forms – May 22, 2020

In an effort to keep the research community informed of new and revised Office of Human Research (OHR) policies and forms, 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 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 (OHR)

POLICIES

Policy Number	Title	Version Date
GA 101	**The Authority and Purpose of the Institutional Review Boards**	**5/22/2020**
Changes: Update to COI review process.		

Policy Number	Title	Version Date
GA 102	**Activities Requiring IRB Approval**	**5/22/2020**
Changes: Addition of OHR-36, which is used to determine if an activity is quality improvement or human research.		

Policy Number	Title	Version Date
GA 105	**Use of a Single IRB in Multi-Site Research Studies**	**5/22/2020**
Changes: This policy has been completely revised and defines the procedure for use of single IRB (sIRB) oversight in multi-site research studies.		

Policy Number	Title	Version Date
GA 106	**Conflicts of Interest**	**5/22/2020**
Changes: This policy has been completely revised and defines the procedure for managing conflicts of interest (COI) for individuals involved with human subjects research.		

Policy Number	Title	Version Date
GA 107	**Management of OHR Administrative Personnel**	**NA**
Changes: This policy has been deleted.		

Policy Number	Title	Version Date
GA 112	**Emergent Use of a Drug, Biologic, or Medical Device**	**5/22/2020**
Changes: This policy has undergone a periodic revision and defines the procedure for emergent use of a test article (drug, biologic, or device).		

Policy Number	Title	Version Date
GA 115	**Management of Research Concerns**	**5/22/2020**
Changes: This policy has been completely revised and describes how OHR handles concerns or complaints about a clinical research study.		

Policy Number	Title	Version Date
GA 122	**Conflicts of Interests Disclosure for IRB Members**	**NA**
Changes: This policy is being deleted and the relevant content added to GA 106.		

Policy Number	Title	Version Date
GA 124	**Good Clinical Practice for Investigators**	**5/22/2020**
Changes: This policy has undergone a periodic revision and provides guidance to investigators and key personnel on Good Clinical Practice (GCP) for human subjects research.		

Policy Number	Title	Version Date
GA 125	**Investigator Responsibility and Delegation of Responsibility**	**5/22/2020**
Changes: This policy has undergone a periodic revision and defines the responsibilities of the principal investigator and the delegation of authority to members of the study team.		

Policy Number	Title	Version Date
GA 128	**Designation of the Institutional Official Responsible for the Human Research Protection Program**	**5/22/2020**
Changes: This policy has undergone a periodic revision and designates the Senior Compliance Officer as the Institutional Official (IO) with overall responsibility for the Human Research Protection Program (HRPP).		

Policy Number	Title	Version Date
GA 133	**Human Research Training**	**5/22/2020**
Changes: Clarification that those doing biomedical research must take the biomedical and GCP courses. Those doing socio-behavioral research must take either the socio-behavioral course or both the biomedical and GCP courses. Clarification that IRB Members are included in this policy.		

Policy Number	Title	Version Date
OP 203	**IRB Consultants**	**5/22/2020**
Changes: This policy has been completely revised and describes the procedure for utilizing consultants to assist in IRB review of research.		

Policy Number	Title	Version Date
OP 205	**IRB Member Responsibilities**	**5/22/2020**
Changes: This policy has been completely revised and defines the responsibilities of IRB members.		

Policy Number	Title	Version Date
RR 401	**Initial Review - Criteria for IRB Review and Approval**	**5/22/2020**
Changes: Information on single IRBs has been removed and is now addressed in GA 105.		

Policy Number	Title	Version Date
RR 402	**Continuing Review by Convened IRB**	**5/22/2020**
Changes: This policy has undergone a periodic revision and describes the process for the continuing review of research by convened IRB.		

Policy Number	Title	Version Date
RR 403	**Review of Exempt Studies**	**5/22/2020**

Changes: This policy has undergone a periodic revision and defines the requirements for classifying a study as exempt from IRB review.

Policy Number	Title	Version Date
RR 404	**Expedited Review of New and Continuing Research**	**5/22/2020**
Changes: This policy has undergone a periodic revision and defines the expedited review procedure for new studies and continuing reviews.		

Policy Number	Title	Version Date
RR 407	**Suspension or Termination of Human Subjects Research**	**5/22/2020**
Changes: This policy has been completely revised and defines the process for suspending or terminating previously approved research.		

Policy Number	Title	Version Date
RR 408	**Review of Amendments**	**5/22/2020**
Changes: This policy has undergone a periodic revision and defines the review procedure for amendments to previously approved research.		

Policy Number	Title	Version Date
RR 411	**Payment of Subjects for Participation**	**NA**
Changes: This policy is being deleted and the relevant content has been added to RR 412.		

Policy Number	Title	Version Date
RR 412	**Recruiting Methods, Enrollment Incentives, and Subject Payment**	**5/22/2020**
Changes: This policy has been completely revised and defines the criteria the IRB will use to asses subject recruitment, enrollment incentives, and subject payment.		

Policy Number	Title	Version Date
RR 413	**Review of Research Involving Investigational Drugs and Devices**	**5/22/2020**
Changes: This policy has been completely revised and defines the IRB submission and review criteria for human subjects research involving drugs and devices.		

Policy Number	Title	Version Date

SC 504	**Populations Requiring Special Consideration (Women, Prisoners, Children)**	**5/22/2020**
Changes: Policies SC 505 and SC 506 have been combined into this policy which defines investigator and Institutional Review Board (IRB) requirements for populations requiring special consideration.		

Policy Number	Title	Version Date
SC 505	**Prisoners as Human Subjects in Research**	**NA**
Changes: This policy is being deleted and the relevant content has been added to SC 504.		

Policy Number	Title	Version Date
SC 506	**Enrollment of Children and Neonates in Research**	**NA**
Changes: This policy is being deleted and the relevant content has been added to SC 504.		

Policy Number	Title	Version Date
SC 508	**Pennsylvania Reporting Requirements**	**5/22/2020**
Changes: This policy has been completely revised and provides guidance on Pennsylvania state laws related to human subjects research.		

Policy Number	Title	Version Date
SC 509	**International Research**	**5/22/2020**
Changes: This policy has been completely revised and establishes guidelines to ensure that research fully or partially outside the United States is conducted in a compliant and ethical manner.		

Policy Number	Title	Version Date
G 608	**Sociobehavioral Research**	**5/22/2020**
Changes: This policy has undergone a periodic revision and provides guidance for issues specific to sociobehavioral research.		

Policy Number	Title	Version Date
G 612	**Respecting the Privacy of Research Subjects and Potential Research Subjects**	**NA**
Changes: This policy is being deleted and the relevant content has been added to IC 701.		

Policy Number	Title	Version Date
G 615	**IRB Fees**	**5/22/2020**
Changes: This policy has undergone a periodic revision and provides guidance regarding IRB fees.		

Policy Number	Title	Version Date
G 619	**Radioactive Materials**	**5/22/2020**
Changes: This policy has undergone a periodic revision and provides guidance for approval and use of radioactive materials.		

Policy Number	Title	Version Date
G 620	**Department of Defense (DoD) Requirements for the Conduct of Human Subjects Research**	**5/22/2020**
Changes: This policy has undergone a periodic revision and describes the requirements for IRB review and investigator responsibilities when conducting human subjects research sponsored of or funded by the DoD.		

Policy Number	Title	Version Date
G 621	**Safeguarding and Protection of Children in Research Studies**	**5/22/2020**
Changes: This is a new policy that compiles the various policies, guidelines, codes, and assurances that contribute to the protection and safeguarding of children involved in research.		

Policy Number	Title	Version Date
IC 701	**Informed Consent and HIPAA Authorization: General Requirements**	**5/22/2020**
Changes: The subject privacy information from G 612 has been added. Clarification that the MCARE consent signature requirements apply to all Jefferson studies regardless of location.		

Policy Number	Title	Version Date
IC 704	**Child Assent and Parental Permission for Participation in Research**	**5/22/2020**
Changes: This policy has undergone a periodic revision and defines the procedures to ensure that effective assent and consent are obtained when children are participating in research.		

Policy Number	Title	Version Date
IC 705	**Informed Consent – Non-English Speaking Subjects and Translations**	**5/22/2020**
Changes: Clarification that after a subject consents using the short form process, the IRB will determine the requirements for providing an English translation of the study information (e.g., no further translation or a translation of a study summary or the full English consent).		

Policy Number	Title	Version Date
IC 707	**Surrogate Consent**	**5/22/2020**
Changes: Clarification that, in general, surrogate consent is used with adults with a temporary condition that impairs decision making capacity.		

Policy Number	Title	Version Date
IC 708	**Research in Emergency Settings (Prospective Review)**	**5/22/2020**
Changes: This policy has undergone a periodic revision and describes the exception from informed consent requirements for emergency research and the requirement for prospective review.		

FORMS

Form Number	Title	Version Date
OHR-1	**Proposal Transmittal and Approval Form**	**5/22/2020**
Changes: Reference to University Policy 107.03, Attachment 2 for more detailed information on conflicts of interest.		

Form Number	Title	Version Date
OHR-8	**Informed Consent**	**5/22/2020**
Changes: Clarification that the MCARE consent signature requirements apply to all Jefferson studies regardless of location.		

Form Number	Title	Version Date
OHR-8B	**Surrogate Consent**	**5/22/2020**
Changes: Clarification about surrogate consent. Clarification that the MCARE consent signature requirements apply to all Jefferson studies regardless of location. Administrative changes.		

Form Number	Title	Version Date
OHR-8D	**Addendum to Consent Form**	**5/22/2020**
Changes: Clarification that the MCARE consent signature requirements apply to all Jefferson studies regardless of location.		

Form Number	Title	Version Date
OHR-37	**Checklist for International Research**	**5/22/2020**
Changes: A new form for studies involving international research that must be included with your IRB submission to certify that the research adheres to OHR Policy SC 509, International Research.		

Form Number	Title	Version Date
OHR-38	**Subcontractor Checklist: Safeguarding and Protecting Children**	**5/22/2020**
Changes: A new form to use as a checklist for subcontractors to indicate that appropriate criteria are met for safeguarding and protecting children.		