

Cornell University
Office of Research Integrity and Assurance
Human Research Participant Protection Program

SOP 1: DETERMINING WHETHER A RESEARCH ACTIVITY NEEDS IRB REVIEW
OR EXEMPTION FROM IRB REVIEW

1. Subject of Policy & Procedure

All research activities that involve (1) the collection of information through intervention, interaction with, or observation of individuals or (2) the collection or use of private information about individuals must be evaluated to determine if the project (a) does not constitute human participant research, (b) constitutes human participant research but eligible for exemption from IRB review, or (c) must be submitted to the Institutional Review Board for Human Participants (IRB) for review and approval.

This policy assists a faculty member, student, employee or other individual in making a decision that a research activity involves human participants and if the activity must be submitted to the IRB for their review and approval or if ORIA can exempt the research activity from IRB review.

2. Scope of Policy & Procedure

This Policy & Procedure applies to all on-going and future human participant research projects being conducted by Cornell's faculty, students, and staff or on property maintained by Cornell.

3. Terms and Definitions

Employees (faculty and staff) and students should consult the IRB Glossary at <http://www.irb.cornell.edu/glossary/>.

4. See Also

Affected researchers and employees should also consult the Decision Tree entitled "Is your activity covered under the Human Research Protection Program?" See <http://www.irb.cornell.edu/documents/IRB%20Decision%20Tree.pdf>.

5. Regulations and Guidance Applicable to Human Participant Research Determination

5.1. Federal Regulations

5.1.1. Cornell has filed a Federalwide Assurance (FWA) with the Office for Human Research Protections (OHRP) of the U.S. Department of Health & Human Services guaranteeing its application of the federal policy for the protection of human participants in 45 CFR 46 and its Subparts A, B, C, and D, when engaging in human participant research. By institutional policy, the same standards apply to all human participant research, regardless of funding support. Cornell's appointment of an appropriately constituted IRB is included in the FWA.

5.1.2. Requirement for IRB review and approval of human participant research before its initiation: 45 CFR 46.108(b)

5.1.3. Definitions of human participant research: 45 CFR 46.101-103.

5.2. Ethical Codes

5.2.1. The Nuremberg Code (1948)

5.2.2. The Belmont Report (1974)

5.2.3. Declaration of Helsinki (last revised in 2000)

6. Process for Human Participant Research Determination

6.1. Research Activities that **do not** Constitute Human Participant Research

Responsibilities of the Protocol Principal Investigator

The Protocol Principal Investigator (Protocol PI) should consult the IRB Review Decision Tree entitled “Is your activity covered under the Human Research Protection Program?” (IRB Decision Tree) to make the initial determination as to whether his or her research activity constitutes human participant research. In addition, the Protocol PI may consult the Office of Research Integrity and Assurance (ORIA) for additional assistance in determining when a research activity constitutes human participant research.

If, in using the Decision Tree, the Protocol PI determines that the research activity does *not* involve human participant research, the Protocol PI may initiate the project. The Protocol PI and the members of his or her research staff for the project are not required (a) to provide any materials to ORIA or the IRB for their review and/or approval or (b) to participate in the Education Training Program on the Use of Human Participants in Research.

For each change that is proposed or occurs during the execution of the research activity, the Protocol PI may need to re-consult the IRB Decision Tree to determine whether that change affects the need for review and approval by the IRB or a determination by ORIA of exemption from IRB review.

Responsibilities of ORIA

If ORIA determines that the research activity does not constitute human participant research, ORIA will notify the Protocol PI by email or memorandum that the research activity does not involve human participant research and, thus, does not require IRB review and approval or an exemption from IRB review. The Protocol PI is required to maintain this notification for a period of five years after the research activity has concluded and all publication and/or reports have been accepted. *See* SOP ___: Document Management.

6.2. Research Activities that **do** Constitute Human Participant Research

Responsibility of the Protocol Principal Investigator

If the Protocol PI, in using the Decision Tree, or ORIA determines that the research activity

does involve human participant research, the Protocol PI will complete and submit to ORIA for processing an Exemption Form or the appropriate Initial Approval Request form (Social and Behavioral Studies; Clinical and Medical Studies; or Research as Class Instruction and Training Programs), and other materials required for review. *See* SOP 2: Requirements for Submission of Research Protocols for a Determination by ORIA of Exemption from IRB Review.

6.2.1. Research Activities that are Eligible for Exemption from IRB Review

Responsibility of ORIA

If ORIA determines that the research project is human participant research but eligible for Exemption from IRB review (*See* SOP 3: Determining Research Eligible for Exemption from IRB Review), ORIA will issue a formal notice of exemption covering the duration of the project to the Protocol PI.

For each change that is proposed or occurs during the execution of the research activity, the Protocol PI may need to consult with ORIA to determine if the change affects the eligibility of the research activity to continue to be exempt from IRB review and approval.

A copy of this notice and all submission documents will be archived by ORIA until five years after the termination of the research activity. In addition, the Protocol PI should maintain these documents for a period of five years after the research activity has concluded and all publication and/or reports have been accepted. *See* SOP ____: Document Management.

6.2.2. Research Activities that require IRB Review and Approval

Responsibility of ORIA

For research activities that are determined to require IRB review and approval, ORIA shall review all research protocol application materials for (a) *completion* and (b) *the need for the Protocol PI, all co-investigators, and key personnel to complete training in the use of human participants in research*. After it has been determined that the research protocol application is complete, it will be submitted to the IRB for their review and approval via the Expedited Review Process or the Convened Committee Review Process. *See* SOP 3: Initial and Continuing Review by the IRB: Requirements for Submission of Applications, Approval Criteria, and Expedited and Convened Committee Review Procedures.

Responsibility of the Protocol Principal Investigator

When the research activity involves human participant research requiring review and approval by the IRB, the Protocol PI, all co-investigators, and all key personnel must complete the on-line tutorial regarding human participant research (<http://www.osp.cornell.edu/HSCCompliance/index.html>) *before* the IRB can approve the research protocol. Proof of completion of this training is electronically generated and maintained by ORIA.