Cornell University
Office of
Research Integrity and Assurance

Human Research Participant Protection Program

Institutional Review Board (IRB)

Policy 1: Determining whether a Research Activity Needs IRB Review and Approval

1. Subject

All research activities that involve the collection of information through intervention, interaction with, or observation of individuals, or the collection or use of private information about individuals, must be evaluated to determine whether they constitute human participant research, and the type of review required before the research activities can begin. This policy provides guidelines for making this determination and outlines the appropriate review requirements.

2. Scope

All Cornell IRB Policies & Procedures apply to all human participant research projects conducted by faculty, staff, or students affiliated with any Cornell program or campus (e.g., Ithaca, Tech, Geneva) other than the Weill Cornell Medicine campuses, or by anyone conducting research in which the participation of Cornell University meets the definition of "engagement" as indicated by the Office of Human Research Protections (OHRP).

3. Policy Statements

- The researcher is responsible for ensuring full and continuing compliance with all University and IRB policies in the conduct of their research.
- A researcher may consult with the IRB Administrative staff in the Office of Research Integrity and Assurance (ORIA)—henceforth called "Staff"—or use the Decision Tree, to make a self- determination as to whether the proposed research activity does or does not constitute human participant research.
- If a researcher determines that their activity does not involve human participant research, they may initiate the project without seeking approval from the Staff.
- If the research activity **does** constitute human participant research, the researcher must submit a completed application through the Research Administration Support System (RASS) for review. Investigator self-experimentation is considered to be research with human participants (see Addendum). Research activities may not commence until the researcher receives a written letter of IRB ("Board") approval or a notice of exemption from Board review from the Staff.

4. Procedures

All IRB protocol applications must be submitted through the RASS-IRB system (rass.cornell.edu/irb). For detailed policy and procedure requirements for each review type, consult IRB policies 2 and 3.

The Principal Investigator (PI) should consult the Decision Tree entitled "Does Your Project Require an Application to the Cornell IRB Office"? or consult with the Staff to determine whether the research activity does or does not constitute human participant research.

4.1 For research activities that **do not** constitute Human Participant Research

- Researchers are not required to complete Human Participant Research Training (see this webpage for more information about IRB training requirements).
- For each change that is proposed or occurs during the execution of the research, the PI should re-consult the IRB Decision Tree or contact the Staff to determine whether that change affects the classification of the project as "not human participant research."

4.2. For research activities that **do** constitute Human Participant Research

- If the research activity involves human participant research, the PI must complete and submit a protocol application along with all relevant study materials in the RASS-IRB system. Visit the IRB website and read IRB Policies 2 and/or 3 for more detailed submission requirements.
- No research activities may begin until the PI receives a written notice of Board approval or written notice of exemption for the protocol from the Staff.
- A copy of the approval/exemption notice and all submission documents will be archived by the Staff until five years after the termination of the research activity. In addition, the PI should maintain these documents for the longest of these periods: three years after the research activity has concluded and all publication and/or reports have been accepted; the period of time specified by any funders or sponsors of the research; or the period of time required by University Policy 4.21, Research Data Retention.
- All personnel named on a human participant research protocol must complete human participant research ethics training *before* the Board can approve the protocol (or Staff can issue an exemption determination). Consult the IRB training web page for more details.

4.3. For Human Participant Research that is eligible for Exemption from Board Review

- Upon a review of the application and study materials, and confirmation of completion of Human Participant Research training requirements, if the Staff determines that a human participant research project is eligible for exemption from Board review, the Staff will issue a formal notice of exemption to the PI.

- For certain changes that are proposed or occur during the execution of the research activity, the PI must submit an amendment request via RASS-IRB to determine if the change affects the eligibility of the research activity to continue to be exempt from Board review and approval.
- Consult IRB Policy 2: Determining Research Eligible for Exemption from IRB Review, for requirements and procedures for review and continuing approval of requests for exemption.

4.4 For research activities that require Board Review and Approval

- For research activities that are determined to require Board review and approval, the Staff will review applications and instruments for completeness and consistency, and will also confirm completion of Human Participant Research training requirements.
- For research activities that qualify for expedited review, the Staff will then assign a Board member to review and approve the protocol via the Expedited Review Process.
- For research activities that do not qualify for expedited review, the staff will place the protocol on the Board's agenda for Convened Committee (also called Full Board) Review.
- Consult Policy 3: Expedited and Full Committee Review Procedures for requirements and procedures for review and continuing approval of IRB protocols.

4.5 For non-exempt, collaborative human participant research projects that involve investigators from multiple institutions

- Review and approval from a Single IRB (sIRB) might be appropriate, or required by a funder. In those cases, an IRB Reliance Agreement—sometimes called an Authorization Agreement—will need to be executed. Requests for Reliance Agreements should be submitted through RASS-IRB.

5. Regulations and Guidance Applicable to Human Participant Research Determination

5.1. Federal Regulations

- Cornell has filed a Federal Wide 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 when engaging in human participant research funded by the Public Health Service (PHS). 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.
- Requirement for IRB review and approval of human participant research before its initiation: 45 (Code of Federal Regulations (CFR)) 46.108(b)
- Definitions of human participant research: 45 CFR 46.102.

5.2. Ethical Codes

- The Nuremberg Code (1948)
- The Belmont Report (1974)
- Declaration of Helsinki (last revised in 2000)

Approved: April 2007; Updated Revised: May 2008, February 2012, October 2013, January 2024

Addendum

INVESTIGATOR SELF-EXPERIMENTATION

Federal regulations are silent on the matter of researchers who want to participate in their own studies. However, the regulations do not distinguish between self-experimentation and research on people who are recruited for a specific project. As part of its commitment to the protection of the rights and welfare of individuals participating in research, Cornell's Human Research Protection Program requires investigators who wish to act as participants in their own studies to submit for review and approval following standard procedures outline in the IRB policies.

Though investigator self-experimentation may not raise the conventional ethical concerns outlined in the Belmont Report, all human research projects should undergo ethical review to assure the safety of people involved and the integrity of the research at the university. While researchers may be aware of the risks of self- experimentation, they may also be more willing to accept risks that are ill-advised. Application for review with the IRB office allows a neutral third party to raise concerns and/or propose measures to promote the welfare of researchers.