Approved June 4, 2010

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

SOP 17: PROTOCOL PRINCIPAL INVESTIGATOR'S ROLES AND RESPONSIBILITIES

1. Subject of Policy & Procedure

This Standard Operating Procedure describes the general qualifications, roles, and responsibilities of a Principal Investigator conducting a research project with human participants. The *IRB Guidebook* from the Office of Human Research Protections (OHRP) defines Principal Investigator as "the scientist or scholar with primary responsibility for the design and conduct of a research project."

2. Scope of Policy & Procedure

This Policy & Procedure applies to all on-going and future human participant research projects conducted by Cornell faculty, staff, or students or by anyone conducting a research activity supported by Cornell or where Cornell is considered to be engaged in the research.

3. Terms and Definitions

All parties to whom this policy applies (*e.g.,* faculty, students, staff, IRB members) should consult the IRB Glossary at http://www.irb.cornell.edu/glossary/.

4. See Also

Affected researchers and employees should also consult:

1. Cornell University Federal Wide Assurance Registration: http://www.irb.cornell.edu/regulations/fwa.htm

2. Cornell SOPs, at http://www.irb.cornell.edu/policy

5. Regulations Applicable to the Protocol PI's Role and Responsibilities

5.1. 45 CFR 46, HHS, Protection of Human Subjects
5.2. 21 CFR 50, FDA, Protection of Human Subjects

6. Qualifications to be a Principal Investigator on a Protocol Submitted to the Cornell IRB

6.1. Principal Investigator: The Cornell IRB allows only one individual to be identified in the protocol as the Principal Investigator (Protocol PI). The Protocol PI is the "go to" person for any compliance issues. All other investigators on the protocol are considered co-investigators or key personnel.

To qualify as a PI on a protocol submitted to the Cornell IRB, an individual must be directly affiliated with Cornell, as follows:

- A current member of the Cornell faculty and/or staff
- A current student (undergraduate, graduate, postdoctoral fellow) enrolled at Cornell

6.2. Co-Investigator, Key Personnel: Individuals who are not affiliated with Cornell, per 6.1 above, may be listed as a co-investigator or personnel on a protocol submitted to the Cornell IRB. Therefore, a non-Cornell individual who seeks to propose human participant research in which Cornell is engaged, must first designate a Cornell-affiliated person to serve as the Principal Investigator on the protocol.

7. Protocol PI's Responsibilities for Study Design

7.1. The Protocol PI must develop a research protocol that is sufficiently detailed to enable the IRB to assess the risks and benefits of the study.

7.2. The research plan should account for the relevant ethical standards (*e.g.,* Belmont Report, Declaration of Helsinki).

Respect: Human research must be conducted with an awareness of the dignity and freedom of every person.

Beneficence: The Protocol PI is obligated to minimize harms to human research participants and should strive to maximize benefits, when appropriate. This principle requires that the risks of research are reasonable in light of the expected benefits, the study design is sound, and the investigators are competent to conduct the study and protect the participants' welfare.

Protecting Vulnerable Participant Populations: Both the federal government and the Cornell IRB recognize that certain populations, such as prisoners, pregnant women, and children, may be particularly vulnerable to undue influence or coercion with respect to their consent to participate. A Protocol PI who plans to recruit participants from a vulnerable population should consult the relevant SOP carefully in planning the design, recruitment, and execution of the study.

7.3. The Protocol PI should consult SOP 15: International Human Research when designing a research protocol to be conducted outside the United States.

8. Protocol PI's Responsibilities for Management of Study Personnel

8.1. The Protocol PI should ensure that all study personnel are adequately trained in conducting human participant research by taking Cornell's Human Participant Online Training, at http://www.irb.cornell.edu/training/, as well as any additional training that is necessary for the safe and effective conduct of the research and/or as required by the IRB upon its review of the protocol.

8.2. The Protocol PI should ensure that all study personnel execute the study in keeping with the:

(a) Approved protocol issued by the IRB, including any conditions of approval,

(b) Signed agreement with the study sponsor, and
(c) Policies of the Cornell IRB (see www.irb.cornell.edu/policy)

9. Protocol PI's Responsibilities for Study Execution

In signing an application for IRB review, the Protocol PI certifies the accuracy of its contents to the best of his or her knowledge. Therefore, the PI must ensure that all procedures to be followed in the study are described accurately and completely in the study protocol submitted to the IRB for review.

In conducting a research study, the Protocol PI is responsible for the following:

9.1. Not initiating the research until he or she has received written IRB approval for the research protocol.

9.2. Ensuring that all resources and facilities necessary to protect the health and welfare of human participants are in place before the research begins.

9.3. Retaining ultimate responsibility for conduct of the project, including obtaining informed consent from participants. Duties may be delegated only to those appropriately trained study personnel who are approved by the IRB to conduct those procedures on the specific protocol.

9.4. Conducting the study according to (a) the most current IRB-approved protocol, including any IRB conditions for approval, (b) federal regulations, and (c) the IRB's SOPs. The Protocol PI must provide information about the study to the IRB, when requested. The Protocol PI must cease conduct of the study if the IRB suspends or terminates the protocol. *See* SOP 6: Suspensions and Terminations of IRB Approval of Research Protocols (www.irb.cornell.edu/policy).

9.5. Remaining current on the literature related to the study, in order to accurately monitor the safety and wellbeing of participants and assess risks and benefits to the participants at every stage of the study.

9.6. Recruiting participants in a fair and equitable manner, weighing the risks and benefits of participation and providing special protections, as necessary, to participants who are members of vulnerable populations.

9.7. Using only participants from whom valid informed consent has been obtained, in accordance with SOP 10: Informed Consent Options, Processes, and Documentation (www.irb.cornell.edu/policy). The Protocol PI will ensure that the most current, IRB-approved consent form/process is used.

9.8. Ensuring that medical care for research-related injuries, or counseling for emotional or psychological distress, is available and clearly defined, along with appropriate contact information, in the informed consent document.

9.9. Maintaining complete records of protocol application documents, the IRB-approved protocol, and other documents relating to participant recruitment, informed consent, data collection instruments, personnel credentials and safety, as well as the conduct of the study, including unanticipated events.

10. Protocol PI's Reporting Responsibilities

The Protocol PI is responsible for making the following reports in conducting the research study:

10.1. Submitting to the IRB all protocol modifications and amendments, in accordance with SOP 3, Section 11 (www.irb.cornell.edu/policy). As noted in SOP 3, a Protocol PI must submit an amendment for all modifications or changes to the research protocol and may not implement an amendment to a previously approved protocol unless and until the IRB reviews and approves it, except where necessary to eliminate apparent immediate hazards to human participants. In cases where the above exception is required, the PI must provide a written explanation to the IRB about the rationale for the implementation of the change.

10.2. Submitting an application for Continuing Review, at the intervals determined by the IRB, but not less than once per year, in accordance with SOP 3.

10.3. Reporting unanticipated or adverse events involving risks to participants, in accordance with SOP 4 and SOP 7 (www.irb.cornell.edu/policy).

10.4. Submitting a Final Closure Report Form at the conclusion of the study, in accordance with SOP 8 (www.irb.cornell.edu/policy).

10.5. Reporting to the IRB any Conflict of Interest involving the Protocol PI or any key personnel at the time of project initiation and at anytime during the conduct of research.