PURDUE
UNIVERSITY

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Researcher Responsibilities

Reason for Guideline

This guideline serves to inform researchers of their responsibilities related to the conduct of human subjects research.

Definitions

None

Guidelines

The Human Research Protection Program (HRPP) has developed the following guidelines to inform researchers conducting human subjects research (both exempt and non-exempt) of their related responsibilities.

Education

Researchers are responsible for taking training on the conduct of human subjects research prior to engaging in the human subjects research activities. These requirements are outlined in VPR Policy I.1.2 Education Policy for Conducting Human Subjects Research. The principal investigator is responsible for overseeing the training of all research team members including key personnel, non-key personnel and research personnel who work with identifiable, private information. The principal investigator must maintain records of training for these research personnel and make such records available for inspection at the request of the HRPP or the Institutional Review Board (IRB).

Ethical Principles

Researchers are responsible for conducting research in accordance with the ethical principles outlined in the Belmont Report. These principals are the fundamental ethical principles upon which human subject protections are based and they are as follows:

- **Respect for Persons**. Ethical research honors the autonomy of individuals to make an informed choice about participation in research and provides suitable protection for vulnerable persons.
- **Beneficence**. Ethical research has scientific or scholarly value in which the potential benefits outweigh the risks which are justified and minimized.
- **Justice**. Ethical research is designed and conducted so that the burdens and benefits are fairly distributed regardless of age, race, gender, ethnicity, etc.

Conduct of Research

Researchers are responsible for ensuring the research is conducted according to the IRB approved protocol. Principal Investigators are also responsible for the actions of all co-investigators and research team members.

Conduct of Student Research

Faculty advisors supervising student research serve as the Principal Investigator (PI). They are responsible for the research study, which also means being responsible for any non-compliances committed by the student researchers. Graduate and Undergraduate students may not serve as PI. The faculty advisors (PIs) are responsible for ensuring that students are adequately prepared to conduct human subject research as well as the IRB application process. This includes not only completing the required CITI educational training, but also writing the IRB application. Faculty are responsible for reading each student IRB application prior to submission. If a meeting is requested by either the IRB staff or the student researcher to discuss revisions or other matters pertaining to the application, the faculty advisor must attend with the student. IRB staff will not meet with a student without the faculty advisor for at least the initial meeting; subsequent meetings are at the discretion of the IRB staff member. Issues that arise which cannot be resolved will be referred to the appropriate Chair, who will then meet with the faculty member.

Subject Enrollment

Researchers may not initiate recruitment activities, including screening, or enrollment of subjects prior to obtaining formal approval from the IRB. These activities may also not occur after the expiration IRB approval. A subject is "enrolled" in the research once they have signed an informed consent document or, if signed consent has been waived, when a person has otherwise been identified as a research subject. Researchers are responsible for not enrolling more than the number of subjects approved by the IRB. The number of subjects may be increased only if the IRB approves an amendment to increase the study enrollment.

Informed Consent

Researchers are responsible for obtaining and documenting informed consent with the consent/assent form(s) approved by the IRB unless waived by the IRB for the specific project. Additionally, researchers must provide a copy of the signed informed consent form to subjects for their records. The original consent forms should be maintained in a secured location for three (3) years after closure of the protocol.

Revisions, Amendments and Changes

If revisions or changes to any aspect of the protocol are desired, researchers must submit a Revision Request to the IRB. Such changes pertain to research team members, research design, procedures, number of subjects, subject population, and changes to consent documents, study instruments or recruitment materials. IRB approval must be obtained before implementing any changes unless the change is to remove an immediate hazard to subjects in which case the IRB should be immediately informed following the change.

Continuing Review

Research protocols are approved for less than or equal to 365 days. The expiration date appears on the IRB approval notice. Prior to the expiration date of the protocol, researchers are required to submit a completed Continuing Review Form with any required supplementary materials. It is the researcher's responsibility to submit the Continuing Review Form and any supplementary materials in a timely manner to ensure a lapse in IRB approval does not occur. Once the protocol's approval expires, researchers must cease all research activities related to the protocol until the protocol is once again in approved status. Even if the research protocol has been completed, the completed Continuing Review Form must be submitted to the IRB.

Reporting

Researchers must report unanticipated problems and adverse events to the IRB. If the problem/adverse event is serious, or the problem/event is expected but occurs with unexpected severity or frequency, or the problem/event is unanticipated it must be reported to the IRB within 48 hours of learning of the event and a written report submitted within five (5) business days. All other problems/events can be reported at the time the Continuing Review. Additionally, researchers must report all noncompliance including deviations to the IRB immediately upon learning of the event.

Record Retention

Researchers must retain research records for at least three (3) years after the closure of the IRB approved protocol. All research records regulated by HIPAA regulations must be kept for at least six (6) years after closure of the protocol. Such HIPAA related records include research authorizations, waivers of authorization, etc.

Conflict of Interest

Researchers must disclose to the Human Research Protection Program any conflicts of interest of research team members. Conflicts of interest include conflicts as defined by Purdue University's Policy as well as any conflicts related to the conduct of the study (e.g., a faculty member wishing to recruit their own students to participate in their research study).

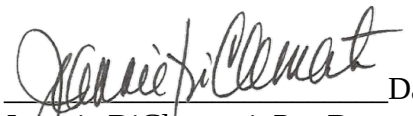
Applicable Regulations and Guidelines

45 CFR 46
21 CFR 50
21 CFR 56

Related Documents

VPR Policy I.1.2 Education Policy for Conducting Human Subjects Research VPR Policy C-39 Conflict of Interest
IRB Standard Operating Procedures

Internal Approval Signatures



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