PURDUE
UNIVERSITY

HRPP GUIDELINE 207
Issuing Office: Office of Research Administration
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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

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.

1. **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).
2. **Ethical Principles**. Researchers are responsible for conducting research in accordance with the ethical principals outlined in the Belmont Report. These principals are the fundamental ethical principals upon which human subject protections are based and they are as follows:
    a. **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.
    b. **Beneficence**. Ethical research has scientific or scholarly value in which the potential benefits outweigh the risks which are justified and minimized.
    c. **Justice**. Ethical research is designed and conducted so that the burdens and benefits are fairly distributed regardless of age, race, gender, ethnicity, etc.
3. **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.

4. **Subject Enrollment.** Researchers may not initiate recruitment activities, including screening, or enroll subjects prior to the date of IRB approval or after the expiration date of IRB approval. A subject is considered enrolled in research when they have signed an informed consent document or, if signed consent has been waived, when a subject has consented to participate in the research activities regardless of whether or not that person withdraws from the study. Researchers are responsible for enrolling only the number of subjects that were indicated and approved in the protocol. Researchers should submit a revision to the protocol requesting an increase in the number of subjects to be enrolled and receive IRB approval prior to enrolling beyond the originally approved number.
5. **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.
6. **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, 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.
7. **Continuing Review.** Research protocols are approved for a specific period of time and end at the end of the day on the expiration date as noted on the approval form. 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.**
8. **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 5 business days. All other problems/events can be reported at the time the Continuing Review Form is

submitted. Additionally, researchers must report all noncompliance including deviations to the IRB immediately upon learning of the event.

9. **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.
10. **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
SOP 409 Unanticipated Problems and Adverse Event Reporting
SOP 411 Noncompliance
SOP 301 Exemption Determination
SOP 302 Initial Review
SOP 304 Continuing Review
SOP 305 Revision Requests
SOP 320 Informed Consent Requirements
SOP 306 Protocol Closure

Approval

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