PURDUE
UNIVERSITY

Determination of Human Subjects Research

HRPP GUIDELINE 202
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Guideline Summary

All Purdue University faculty, students, and staff involved in activities that fall under the federal definitions of human subjects research are required to comply with federal and state laws as well as University policies and procedures for the protection of human research subjects.

Reason for Guideline

This guideline serves to clarify types of activities that are determined to be research in order to assist investigators in the Institutional Review Board (IRB) process at Purdue University.

Definitions

For an activity to be **research**, it must fall under the Department for Health and Human Services definition:

> [a] systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Research also includes activities that fall under "clinical investigation" as defined by the Food and Drug Administration (FDA). Under FDA regulations, activities are research when they include:

- Use of a drug other than the use of a FDA approved drug in the course of medical practice (21 CFR 312.3(b))
- Use of a medical device other than the use of a FDA approved medical device in the course of medical practice (Food, Drug and Cosmetic Act 530(g)(3)(a)(i))
- Gathering data that will be submitted to or held for inspection by FDA in support of a FDA marketing permit for a food, certain dietary supplements, an infant formula, a food or color additive, a drug, biologic or medical device for human use, or an electronic product. (21 CFR 50.1(a) or 56.101(a))

Research reviewed by the IRB must include **human subjects**. A human subject (or human participant) is defined as:

> A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. (45 CFR 46.102(f))

The definition continues:

> Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. (45 CFR 46.102(f))
>
> Interaction includes communication or interpersonal contact between investigator and subject. (45 CFR 46.102(f))
>
> Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). (45 CFR 46.102(f))
>
> Use of human tissue/specimens for research purposes is considered human subjects research under certain circumstances. Please see the publication *Research Involving Private Information or Biological Specimens* issued by National Institutes of Health Office of Extramural Research June 6, 2005 http://grants.nih.gov/grants/policy/hs/index.htm.

The FDA's definition is similar defining "human subject" as an individual who is or becomes a participant in research, either as a recipient of a test article or as a control. A subject may be either a healthy person or a patient. (21 CFR 56.102(e))

Guidelines

The Human Research Protection Program has developed the following guidelines to assist researchers in determining which activities qualify as human subjects research and are therefore subject to IRB review.

1. In order for an activity to be research it must meet the definition of research as stated above as well as include a human subject as defined above.
2. Human research activities must be reviewed by the IRB irrespective of funding.
3. If after reading the research definitions there is still a question as to whether or not the activity is considered research, consider the following:
    a. Will the activity be disseminated via thesis, conference or meeting, submission to or publication in a journal, or an internet posting?

b. Will the activity be listed as a scholarly or scientific activity on your vita?

If you answered "yes" to either of these questions, your activity should be reviewed as research by the IRB. Please note, should you decide that your activity is not research and does not require IRB review and approval for the conduct of the activity, you cannot later publish the data or otherwise distribute the results.

Examples of research activities

- Formal investigations/experiments
- Pilot or feasibility projects
- Exploratory studies
- Student independent studies, directed projects, theses, or dissertations
- Some demonstration activities
- Some service programs
- Oral histories designed to compare/contrast, draw conclusions, inform policy, or generalize findings or oral histories done with the intent to be archived for future research
- Anonymous surveys

Examples of non-research activities:

- Classroom activities that teach research methodologies or simulate research activities
- Activities conducted to improve the quality of teaching in a particular classroom or of a particular program, not meant to contribute to generalizable knowledge
- Activities required for quality assessment (QA) or quality improvement (QI) not meant to contribute to generalizable knowledge
- Searches of existing literature
- Interviews of individuals where the questions focus on things not people (e.g. questions about policies or business procedures)
- Oral histories which are NOT intended to draw conclusions, inform policy or generalize findings and for which the sole purpose is to create a historical record of specific personal events and experiences and provide a venue for people to tell their stories

Applicable Regulations and Guidelines

45 CFR 46

21 CFR 50

21 CFR 56

Food, Drug and Cosmetic Act

Research Involving Private Information or Biological Specimens

http://grants.nih.gov/grants/policy/hs/index.htm

Related Documents

Approval

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