Online Ethics Center
FOR ENGINEERING AND SCIENCE

The Least You Need to Know About Rules Governing Human Subjects Research

Author(s)

Kenneth D. Pimple

Year

2008

Description

A handout that can be adapted for use an any institution that provides a short outline of major rules and guidelines governing the use of human subjects in research.

Body

1) Research involving human subjects is regulated in the United States by the Federal Government. The regulations were imposed primarily in response to a variety of abuses by researchers and are intended to protect human subjects.

The history of human subjects research and regulation is long, but the single most important document for researchers in the United States is *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. You can find it at http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm. It's short and you should read it.

The Belmont Report identifies three fundamental moral principles that are particularly relevant to human subjects research.

A. **Respect for persons.** This principle requires researchers to (a) honor their subjects' right to make their own decisions – their autonomy – and (b) to protect potential subjects who have a diminished ability to make important decisions.

B. **Beneficence.** Beneficence requires researchers to avoid harming human subjects, and that studies should maximize possible benefits and minimize possible harms to individual subjects as well as society at large.

C. **Justice.** The principle of justice means that the risks and benefits should be spread equitably across society. It is unfair, for example, if the burden of research is carried by poor people when everyone, rich and poor, can benefit from the results.

2) All human subjects research is overseen by the IUB Human Subject Office and must be reviewed by the IUB Institutional Review Board (IRB).

A. What counts as human subjects research?

i. A **human subject** is any individual about whom a researcher obtains data through intervention or interaction or identifiable private information. "Intervention and interaction" can take the form of talking to an individual, studying existing data on an individual, observing an individual, communicating with an individual via the Internet, and obtaining data about an individual via a number of other kinds of interactions.

ii. **Research** is defined by the Department of Health and Human Services as "a systematic investigation, including research development testing and evaluation, designed to develop or contribute to generalizable knowledge" (45 CFR 46).

-

If you begin a project with the intention of publishing the results, it is almost always regarded as "research" under this definition. "Publication" is here construed broadly and includes, e.g., oral presentation at a professional conference.

B. **What is a review?** Research projects are reviewed at one of three levels, depending mostly on the level of potential risk to the human subjects. The categories are:

i. **Exempt** – You might think that if a study is "exempt," it wouldn't need to be reviewed. Don't blame the IRB for stupid terminology; blame the Federal Government. Think of "exempt review" as "exempt from continuing review." Exempt studies require less oversight, do not require an informed consent document, can be approved relatively quickly, and do not require continuing review. Most qualitative research qualifies as exempt, but some does not. Note that the IRB, not the researcher, determines whether a study is exempt. The paperwork for exempt review is less burdensome than for expedited or full review, but you still have to do the paperwork.

ii. **Expedited** – Expedited studies are reviewed frequently by a subset of IRB members and require more paperwork than exempt research but less than studies that require full review. Requires continuing review (typically annually).

iii. **Full** – Studies requiring full review (as determined by the IRB) are reviewed monthly by the full board. Requires continuing review (typically annually).

Needless to say, if you don't follow the rules, you can get in trouble. For example, if you don't follow the rules for your dissertation research, you might not get a degree. But you should also realize that failure to follow the regulations can have bad results for many other people. In the

last few years, more than a dozen universities have had ***all*** of their human subjects research suspended by the Federal Government due to violations by a few researchers. You wouldn't want to be the cause of that, would you?

3) You cannot start gathering data until you have received approval from the IRB. No exceptions. This means you have to budget enough time for an IRB review.

4) The IRB review process is primarily intended to protect human subjects, but an unintended consequence is that it forces researchers to think carefully about the moral and logistical dimensions of their research ***before*** they start collecting data. Reviewers often provide helpful advice on improving research.

5) The IUB IRB can be reached at <<Enter your own instituiton's IRB URL>>

The people at the IUB IRB are friendly and helpful. They want to make the review process as painless as possible. Don't hesitate to ask them for advice.

6) A good way to learn ***more*** than the least you need to know is to read "Protection of Human Subjects in Research" or "Protection of Human Subjects in Non-Biomedical Research,"

Notes

Also available at the TeachRCR.us site.

Rights

Use of Materials on the OEC

Resource Type

Instructor Materials

Parent Collection

Ken Pimple Collection

Topics

Human Subjects Research

Discipline(s)

Research Ethics