The Use & Abuse of IRBs: Assessment of Student Learning

My Objectives

- Provide you a basic understanding of what the IRB is about.
- Provide an ethical argument based on the IRB regulations for why “informed consent” is not an “absolute”.
- Give you some tools to help educate your IRBs about their proper roles and scope of authority.

What is the purpose of the IRB?

- The purpose is not to harass investigators.
- The purpose is not to rewrite your research.
- The purpose is not to prevent research from happening.
- The purpose is not to provide permission to publish research findings.
- The purpose is not to validate the importance of your “research.”
- The purpose is to protect human subjects.

Why do IRBs exist?

Abuse of the researcher privilege:
Tuskegee Syphilis Study
Milgram Experiment
etc...

The power of the IRB

Only committee on campus whose decisions (to not approve) cannot be appealed or overruled.

"Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.”
— 45CFR46.112

This gives IRBs an inordinate amount of power...
... which should be used judiciously and wisely!
The Use & Abuse of IRBs

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1. IRBs should exercise the least amount of oversight power in review of research as is consistent with the protection of human subjects in that research and is consistent with the federal regulations.

2. IRBs should facilitate the research they review as much as possible. Research is good…and IRBs support research.

3. IRBs are supposed to be collegial ethical “peer review” committees…although they have largely become regulatory compliance and oversight bodies.

Curt’s general rules for IRB’s

Two general kinds of IRBs:

- **Biomedical**
  - Typically see high risk/high benefit research
  - Requires judgment

- **Social Science**
  - Typically see low risk/low benefit research

Perspective

Beneficence: Risk & Benefit

**Risks—to subjects:**
- Magnitude of Harm
- Probability of Harm

**Benefits—to subjects:**
- Magnitude of Benefit
- Probability of Benefit

“…risk/benefit assessments are concerned with the probabilities and magnitudes of possible harm and anticipated benefits.” —The Belmont Report

Scientific review?

What is the IRB’s responsibility with regard to the scientific validity of the study?

The regulations are silent on this matter. However, the IRB must determine that…

“Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.” —45CFR46.111(a)(2)

Generally, as risks increase, so does the scrutiny of the scientific merits.

See [http://www.hhs.gov/ohrp/archive/irb/irb_chapter4.htm](http://www.hhs.gov/ohrp/archive/irb/irb_chapter4.htm)

Social benefit?

In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research.

“The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.” —45CFR46.111(a)(2)

Table of Harms

Relative to what benefit?
The Use & Abuse of IRBs

What activities do IRBs evaluate?

(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research.

—45CFR46101(a)

Is it “research”?

“... the term "research" designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.”

—The Belmont Report

Is it “research”?

Definition:

(d) Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

—45CFR46.102(d)

See http://www.hhs.gov/ohrp/archive/irb/irb_chapter4.htm#f3

“Publication”...

Is it “research”?

Are these research?

CAPP Test
Applying rubrics to random samples of student work
Surveys of student engagement
Student evaluations of teaching
An investigation by the student newspaper of student cheating on campus
Cross-Institutional Assessment

Is it a human subject?

Definition:

Human subject means 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.

—45CFR46102(f)

Private Information: reasonable expectation that information will not be made public.

Private Information: must be individually identifiable.

Is it a human subject?

Review of anonymous transcripts
Reading identified student papers
Genetic analyses of anonymous tissue samples
Analysis of video tapes pulled from security cameras in the campus center
Reading anonymous student papers
Minimal Risk

**Definition:**
"Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."
— 45CFR46.102(i)

Confidentiality is not a "research" risk or a risk that rises above minimal.

Respect for Persons

Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection.

...To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others.
— The Belmont Report

Waiver of informed consent

(1) The research involves no more than minimal risk to the subjects;
(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
(3) The research could not practicably be carried out without the waiver or alteration; and
(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
— 45CFR46.116(d)

Balancing...

Respecting Persons vs. Benefits of Research

...when risks are minimal

Respecting persons (informed consent) is not an absolute obligation.

Exemption Categories

1. Educational Practices

"Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods."
— 45CFR46.101(b)(1)

Exemption Categories

2. Surveys, Interviews, Tests...

"Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

(ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation."
— 45CFR46.101(b)(2)
Important caveat regarding children:

“Exemptions at §46.101(b)(1) and (b)(3) through (b)(6) are applicable to this subpart. The exemption at §46.101(b)(2) regarding educational tests is also applicable to this subpart. However, the exemption at §46.101(b)(3) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.” —45CFR46.401(b)

Exemption Categories

4. Existing Stuff….

“Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.” —45CFR46.101(b)(4)

Exemption Categories

Exemptions Summary:

- Educational Practices
- Individually Identified Test Data, Surveys, Interviews — if not harmful data is disclosed
- Anonymous Test Data, Surveys, Interviews
- Publicly Available Information

Who decides what is exempt?

- The regulations are silent on this matter.
- The institution is responsible for assuring that research is compliant.
- It follows that the IRB should make this determination based on an adequate understanding of the research in question.
- This is a matter of policy.

See http://answers.hhs.gov/ohrp/categories/1564

Exemption Categories

In general, from the IRB’s perspective, most of these kinds of projects are either exempt or outside the scope of the authority of the IRB.

IRB Review does not add any protection to the students whose work is evaluated.

Written informed consent does not add any protection to students whose work is evaluated.

Blanket notification to students would be sufficient, with an opt out.

Who sets IRB policy?

Again, the regulations are silent.

My recommendation:

- The IRB should not set its own policy...
- Left to their own devices, IRBs tend toward mission creep.
- Policy should be set by the institution (faculty & administration) in consultation with the IRB.
The institution’s role

* Sets IRB policy
* Cannot overturn IRB denial of approval
* Can deny permission to an IRB approved protocol

Resources

The Belmont Report:
http://www.hhs.gov/ohrp/belmontArchive.html

OHRP:
http://www.hhs.gov/ohrp/index.html

45CFR Part46 - The Code of Federal Regulations:
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

OHRP Decision Charts:
http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html

Thank You!

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