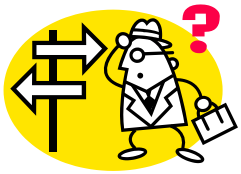
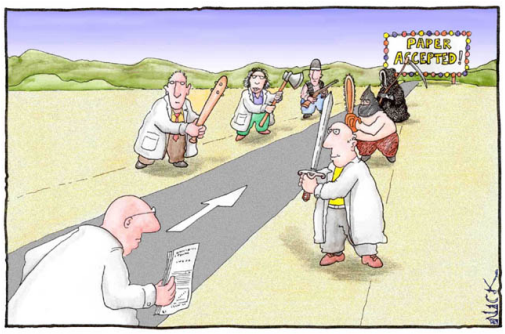
Demystifying the Human Subjects Process



- ***Who, what, where, when and why?***
- ***Determining appropriate level of review***
- ***Completing IRB forms – what they want to know & why***



Most scientists regarded the new streamlined ~~peer review~~ IRB process as 'quite an improvement.'

Who, what, where, when?

The University of Washington requires that all research undertaken by faculty, students or staff involving human subjects must be reviewed and approved PRIOR to contacting potential subjects or beginning secondary data analysis

Who, what, where, when?

But Why?

The Belmont Report, 1979

Issued by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

In response to the National Research Act of 1974

Basic Ethical Principles established by the Common Rule (45 CFR 46)

- **Respect for Persons**
  - Individuals as autonomous agents (can agree or decline)
  - Protection for those with diminished autonomy
- **Beneficence**
  - Maximize possible benefits and minimize possible harm
- **Justice**
  - Who receives the benefits of research and who bears its burdens?

Applying the Ethical Principles

Respect for persons	Beneficence	Justice
Informed Consent	**Risks/Benefits**	**Enrollment**
• Obtain & document • Voluntary participation (no coercion) • Protect privacy	•Lowest risk •Risks reasonable in relation to benefits •Maintain confidentiality	•Select participants equitably •Avoid exploitation of vulnerable populations

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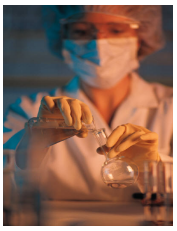
Why research requires review

- Imagine you are a medical researcher involved in clinical trials of a new drug for strokes



Subjects as autonomous agents?

Maximize benefits & minimize risks?

Who receives benefits & burdens?

Why research requires review

- Imagine you are an education researcher involved in a study on teaching reading

Subjects as autonomous agents?

Maximize benefits, minimize risks?

Who receives benefits & burdens?

Some definitions

The University of Washington requires that all research undertaken by faculty, students or staff involving human subjects must be reviewed and approved PRIOR to contacting potential subjects or beginning secondary data analysis

What is "Research?"

Systematic investigation that is intended to increase the body of *generalizable knowledge*

NOTE: Class projects and program evaluations generally do not fall into this category.

What Research Involves Human Subjects?

Research involving data that are *about persons* who are *living**, when data are *identifiable* or *obtained through interactions or interventions*.

Examples

- Opinions, thoughts, memories, video records
- School or health records
- Immigration status
- Results of experiments or other interventions

Examples of research that does *not* require human subjects review:

- Examination of public documents
- Asking persons for factual information about institutions
  - School size, number of teachers, textbooks used
  - Interviews asking factual questions about district policies
- De-identified data
  - (e.g., school records or survey data with no names, school IDs, or other identifiers)

Who is "the IRB?"

- Different committees for biomedical (3) and socio-behavioral (3) research, plus 1 combined
- Each committee includes
  - Researchers (from across UW system)
  - Community members
  - HSD Staff

What is an IRB review?

An Institutional Review Board (IRB) evaluates whether proposed research will be conducted following the "Common Rule" guidelines for ethical conduct:

- Respect for persons → informed consent
- Benificence → risk vs benefits
- Justice → equitable participation & benefits

REMEMBER:

All of the information you provide in your Human Subjects application enables the IRB to decide whether your research follows the Federal regulations for conduct of research on human subjects.

Potential Risk/Benefit Analysis

- Potential benefit (to individual or society) depends on the scholarly integrity of the research
- Faculty signature assures scholarship (BUT the IRB reads for this, too!)
- Potential risks can be of various types
  - Physical
  - Emotional
  - Economic
  - Professional

Some Risk Assessment Factors

- "Vulnerable populations" (e.g., children)
- Power issues that might result in coercion
  - How are subjects approached & recruited?
  - Can subjects really decline?
- Risks associated with breach of confidentiality
  - Identifiable data (*de facto* nature of video)
  - Stigma of participating in the study?
- Risks from study procedures

3 Types of Review

- Full Review (committee)
- Minimal Risk Review (staff)
- "Exempt" (*fits specific categories, is not subject to annual review)* - staff

Relevant Exempt Categories

- Educational research conducted in established educational settings
- Survey/interview/observational research, **unless** subjects 1) can be identified and disclosure would put at risk, or 2) **are minors**
- Secondary use of existing data

Minimal Risk/Full Review

- Determined by the risk potential risk to subjects
- Minimal risk = no more risk than encountered in typical daily life
- If more (or if complex) then full review

APPLICATION TIP #1: C & C

- Clarity (jargon free)
  - Do NOT cut and paste from your proposal
- Completeness
  - Leave no question un-answered!!
  - Attach everything a subject will see (all consent forms, recruitment flyers, surveys, screenshots, etc.), plus recruitment scripts, debriefing scripts, etc.

The IRB needs to understand what you are planning to do and why FORM

TIP #2: Consent forms and process important

- "Consent" or "Assent?"
- Informed about the activities of highest risk (e.g., the most sensitive survey items)
- Informed in understandable language
- Consent/assent must be freely given
- Consent/assent can be withdrawn at any point
- **Use the templates on HSD web site**

Help with the Process

- HSD website (and staff)
  - CITI web-based training
  - All current forms and policies
  - **SOP for research on students**
- Faculty Advisor (signs for students)
- Louise Clauss (screens COE applications and obtains other signatures)
- Susan Nolen (COE rep to IRB)