Northwestern University Institutional Review Board (IRB)

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IRB Role in Research

The sole mission of the IRB is the protection of humans who participate in research…..

It is not to annoy researchers.
The structure of the NU IRB
NU IRB Facts

- >10,000 Submissions a Year
- 6 IRB Review Boards (2 Campuses)
- Avg. 655 Studies Reviewed at Panel each Year
- 60% Biomedical and 40% Social Behavioral
Three administrative areas:

- IRB
- Human Research
- Compliance
- Training and Education
Northwestern IRB Affiliated Partners

- Northwestern Medicine (NMFF, NMPG, NMH)
- Rehabilitation Institute of Chicago
- Lurie Children’s Hospital
- Research Privacy Board
Why do we need IRB?
Timeline of Events

- Willowbrook Hepatitis Study
- Humphrey “Tea Room Trade” study
- Stanford Prison Study
But really--why do we need IRB in this day and age?

• No one can be objective about their own work – history bears this out but it is true.
• People underestimate the risks involved with areas they are very familiar (procedures, CT scans, adding supplements, surveys on sensitive issues, etc.)
• People overestimate the benefit of things that are important to them.
The IRB evaluation of the conduct of research involves:

- **Academic / Professional Values**
- **Ethical decision making**
- **Legal / Regulatory Standards**

- Codes of Ethics
- Standards of practice
- NU HSPP 5.0

- Moral philosophy
- Framework for ethical decision making
- Moral Virtue

- CFR, FDA, FERPA, HIPAA, MHDDCA, etc.
IRB Ethical Responsibilities

Belmont Report (1979): 3 Ethical Principles

1. Respect for Persons
2. Beneficence
3. Justice
Trust is the highest honor and obligation in research
Day-to-day IRB
When Does the IRB Get Involved?

When it is Human Research.

It’s Research when there is a systematic investigation.

It’s Human Research when there are:

• Living individual(s) about whom information is collected through intervention or interaction; or
• Identifiable Private Information

When it is a systematic investigation that involves living people or their identifiable information about whom the information collected is intended to develop or contribute to generalizable knowledge the IRB needs to see it.

Other resources: Human Research Determination Form (HRP-503)

HRP-310 WORKSHEET Human Research Determination
111 Regulatory Criteria

- Participant Selection
- Vulnerable Populations
- Voluntary Consent
- Benefits
- Risks
- Research Design
Speaking “IRB”
What the IRB is looking for:

1. **Risks** to participants are **minimized**.
2. Risks are **reasonable** in relation to anticipated benefits.
3. Selection of participants is **equitable**.
4. **Informed consent** is sought from each participant and is appropriately documented.
5. The researcher has **adequate training** and experience and there is not a conflict of interest.
6. **Privacy and confidentiality** of participants is protected.
7. Additional safeguards are included for **vulnerable populations**.
8. **Data collection** is monitored to ensure participant safety.
9. The **research methodology** is **reasonable** and will accomplish the purpose of the study.
10. Participants are fully **debriefed** if deception used.
Special considerations: International Research:

- Observation, privacy, and boundaries in the field
- Cultural sensitivity in recruitment, consent and data collection.
- Data management plan to protect confidentiality.
- Researching illegal activity
- When there are two IRBs involved

Special considerations with Internet Research:

- Private v public forum
- Is it just text or is it a ‘person’?
- Who owns the information on the Internet?
NU IRB Submission Process

1. PI Submits New Application
2. IRB Coordinator Pre-Review
3. Assigned to Reviewer or Panel
4. Approval Criteria Met?
   - Modification Required for Formal Review
   - Changes Requested
   - Post Approval Modifications
   - Continuing Review
   - Reportable new information
Quick Quiz: Which study meets the definition of research with human participants?

A. A researcher plans to conduct a linguistic study of comments posted on a local public blog.

B. A developmental psychologist proposes videotaping interactions between groups of toddlers and their caregivers to determine which intervention methods most effectively manage aggression.

C. A researcher proposes asking the director of a local free clinic about the number of patients in the last two years with newly diagnosed HIV/AIDS.

D. A university designs an in-house study to improve the mentoring of women students in engineering with the proposed outcome consisting of a report of recommendations for the department.
Which are the ethical pros and cons of:

Recruitment of participants using:

1. Paper flyers or posters posted on bulletin boards
2. Email solicitation
3. Craigslist
4. Facebook
General Contact Information

For additional information on IRB submission templates, regulatory guidance, upcoming education/training opportunities, and staff contacts, please visit our website:

https://eirbplus.northwestern.edu

- Main number (BioMedical): 312-503-9338
- General IRB queries: irb@northwestern.edu
- eIRB assistance/queries: eirb@northwestern.edu
- Compliance queries/issues: irbcompliance@northwestern.edu
- Social and Behavioral IRB: 847-467-1723