Northwestern University Institutional Review Board (IRB)

Kathleen E. Murphy, PhD, CIP
Manager, Social and Behavioral IRB
kemurphy@northwestern.edu
IRB Role in Human Subject Research

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

It is not to annoy researchers.

As part of that mission, the IRB:

• Establishes policies and procedures;
• Monitors regulatory and institutional compliance;
• Conducts independent review of research; and
• Manages the NU Federalwide Assurance (FWA).
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
- Research Distribution: 60% Bio/40% SB
Four administrative areas:
NU 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**
- **Tuskegee**

Source: NIH Office of Extramural Research-Training Modules
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:

- Codes of Ethics
- Standards of practice
- NU HSPP 5.0
- Academic / Professional Values
- Ethical decision making
- Moral philosophy
- Framework for ethical decision making
- Moral Virtue
- Legal / Regulatory Standards
- CFR, FDA, FERPA, HIPAA, MHDDCA, etc.

[Image of a Venn diagram with intersecting circles labeled as above.]
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 Subject’s Research.

It’s **Research** when there is:

- Systematic investigation designed to develop or contribute to generalizable knowledge

It’s **Human Subject’s Research** When…

- Living individual(s)
- Data through intervention or interaction
- Identifiable Private Information

Other Considerations

**Tool:** HHS Determination Decision Charts
# IRB Review Categories

<table>
<thead>
<tr>
<th>Review Type</th>
<th>Description</th>
</tr>
</thead>
</table>
| Exempt       | - Minimal risk  
               - Belmont Principles still apply  
               - Does not apply to FDA regulated research unless it falls under Emergency Use |
| Expedited    | - Minimal risk, identifiable, more personal information  
               - Reviewed in the office except for vulnerable populations.  
               - If expedited reviewer does not approve, the study must go to the full board. |
| Full Board   | - Minimal risk research not in exempt or expedited review categories  
               - Research that is more than minimal risk  
               - Certain research with vulnerable populations (children, pregnant women, prisoners) |
111 Regulatory Criteria

Subject Selection

Vulnerable Populations

Voluntary Consent

Benefits

Risks

Research Design
Speaking “IRB”
What the IRB is looking for:

1. **Risks** to subjects are minimized.
2. Risks are **reasonable** in relation to anticipated benefits.
3. Selection of subjects is **equitable**.
4. **Informed consent** is sought from each subject 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 subjects is protected.
7. Additional safeguards are included for **vulnerable populations**.
8. **Data** collection is monitored to ensure subject safety.
9. The **research methodology** is **reasonable** and will accomplish the purpose of the study.
10. Subjects are fully **debriefed** if deception used.
Special considerations for 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

- PI Submits New Application
- IRB Coordinator Pre-Review
- Assigned to Reviewer or Panel
- 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 subjects?

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. 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](http://www.irb.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
QUESTIONS?