Northwestern University
Institutional Review Board (IRB)

Marcella Oliver
IRB Education Specialist
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
- Training and Education
- Compliance
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

- Tuskegee Syphilis Study
- Willowbrook Hepatitis Study
- Stanford Prison Study
- University of Minnesota Psychosis Study

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
- Legal / Regulatory Standards
- Ethical decision making
- Moral philosophy Framework for ethical decision making Moral Virtue

Belmont
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
# 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
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
5. Post Approval
   - Modifications
   - Continuing Review
   - Reportable new information
Pop Quiz!

Which study meets the definition of research with human subjects?

a) A physician plans to conduct a study of comments posted on a blog for patients with diabetes.

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

c) A grad student 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 students with the proposed outcome consisting of a report of recommendations for the department.
Correct Answer: b

a) A physician plans to conduct a study of comments posted on a blog for patients with diabetes. (Publicly available info)

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

c) A grad student proposes asking the director of a local free clinic about the number of patients in the last two years with newly diagnosed HIV/AIDS. (No human subjects—no identifiers collected)

d) A university designs an in-house study to improve the mentoring of students with the proposed outcome consisting of a report of recommendations for the department. (Not generalizable knowledge)
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
- Training queries/issues: irbtraining@northwestern.edu
- Social and Behavioral IRB: 847-467-1723
QUESTIONS?