Northwestern University
Institutional Review Board (IRB)

Marcella Oliver
IRB Reliance and Education Lead
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
- Shirley Ryan Ability Lab
- Lurie Children’s Hospital
- Research Privacy Board
Why do we need IRB?
Timeline of Events

- **1948**
  - UN adopted Universal Declaration of Human Rights
- **1947**
  - Nuremberg Code
  - American Psychological Association
- **1946**
  - Nuremberg Doctors' Trial
- **1939-1945**
  - Nazi Medical War Crimes
- **1944-1974**
  - Cold War Human Radiation Experiments
- **1932-1972**
  - Syphilis Study at Tuskegee
- **1953**
  - First U.S. Federal Policy for Protection of Human Subjects
- **1963**
  - Jewish Chronic Disease Hospital Study
- **1966**
  - Henry Beecher's Publication
- **1963-1966**
  - Willowbrook Study
- **1974**
  - Federal Protections for Human Subjects
- **1979**
  - The Belmont Report
- **1980**
  - Publication of FDA Regulations
- **1981**
  - HHS & FDA Revise Regulations
- **1982**
  - CIOMS Guidelines
- **1991**
  - Publication of the Common Rule
- **1993-1994**
  - Advisory Committee on Human Radiation Experiments
- **1995**
  - Establishment of the National Bioethics Advisory Commission
- **1996**
  - HIPAA Privacy Rule
- **1999**
  - The Death of Jesse Gelsinger
- **2004**
  - SACHRP
- **2000**
  - OHRP

**Key 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

- **Legal / Regulatory Standards**
  - CFR, FDA, FERPA, HIPAA, MHDDCA, etc.

- **Academic / Professional Values**
  - Moral Virtue

- **Ethical decision making**
  - Belmont Framework for ethical decision making

- **Moral philosophy**
  - Moral Virtue
IRB Ethical Responsibilities

Belmont Report (1979): 3 Ethical Principles

1. Respect for Persons
2. Beneficence
3. Justice
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

- 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**.
NU IRB Submission Process

PI Submits New Application

IRB Coordinator Pre-Review

Assignment to Reviewer or Panel

Approval Criteria Met?

Modification Required for Formal Review

Changes Requested

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)
Single IRB
NIH Single IRB Policy

The National Institutes of Health (NIH) Policy on the Use of a Single Institutional Review Board of Record for Multi-Site Research establishes the expectation that all sites participating in multi-site studies involving non-exempt human subjects research funded by the National Institutes of Health (NIH) will use a single Institutional Review Board (sIRB) to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects at 45 CFR Part 46.

This policy, which is consistent with 45 CFR Part 46.114, is intended to:

• Enhance/streamline IRB review process in multi-site research
• Eliminate duplicative IRB review
  – Reduce administrative burdens/inefficiencies
  – Maintain human subject protections
  – All IRB’s to concentrate on single site protocols
NIH Single IRB Implementation Plan (Phase 1)

- Pre-Consultation
- Dedicated Webpage
- Template Letters of Support
- SOP’s
- OSR/IRB Workflow
- Independent/Commercial IRB Questionnaire
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
- Reliance Agreements: irbreliance@northwestern.edu
- Social and Behavioral IRB: 847-467-1723
Contact Information

Marcella Oliver  
IRB Reliance and Education Lead  
Northwestern University, IRB Office  
312-503-6071  
m-oliver2@northwestern.edu  
irbreliance@northwestern.edu
QUESTIONS?