Northwestern University
Institutional Review Board (IRB)

Marcella Oliver
IRB Reliance and Education Lead
What is an IRB?

An Institutional Review Board (IRB) is a committee established to review and approve research involving humans.

The purpose of the IRB is to ensure that all human research be conducted in accordance with all federal, institutional, and ethical guidelines.

The sole mission of the IRB is the protection of humans who participate in research.
The structure of the NU IRB
NU IRB Facts

- >14,000 Submissions a Year
- 6 IRB Review Boards (2 Campuses)
- 70% Biomedical and 30% Social Behavioral
Three administrative areas:

- IRB
- Human Research
- Training and Education
- Compliance
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

- 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.
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
The IRB evaluation of the conduct of research involves:

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

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<th>Review Type</th>
<th>Description</th>
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| **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. The research **methodology is reasonable** and will accomplish the purpose of the study.
2. **Risks** to participants are **minimized** and 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. Participants are fully **debriefed if deception used**.
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
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
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 (Bio-medical): 312-503-9338
- General IRB Questions: irb@northwestern.edu
- Social and Behavioral Questions: sbsirb@northwestern.edu
- Reliance Agreements: irbreliance@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
Contact Information

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QUESTIONS?