Northwestern University Institutional Review Board (IRB)

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IRB Reliance and Education Lead
What is an IRB?

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

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

As part of that mission, the IRB:

- Establishes policies and procedures
- Monitors regulatory and institutional compliance
- Conducts independent review of research
- Manages the NU Federal wide Assurance (FWA)
The structure of the NU IRB
Northwestern University
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
Functional Framework

Compliance

Education and Training

Ethics

Reliance

Biomedical (Chicago)

Social and Behavioral (Evanston)

5 IRB Panels

1 IRB Panel

Northwestern | RESEARCH
Why do we need IRB?
Timeline of Events

- 1953: First U.S. Federal Policy for Protection of Human Subjects
- 1947: Nuremberg Code
- 1946: Nuremberg Doctors' Trial
- 1944-1945: Nazi Medical War Crimes
- 1947: American Psychological Association
- 1948: UN adopted Universal Declaration of Human Rights
- 1963: Jewish Chronic Disease Hospital Study
- 1963-1966: Willowbrook Study
- 1964: Declaration of Helsinki
- 1979: The Belmont Report
- 1980: Publication of FDA Regulations
- 1981: HHS & FDA Revise Regulations
- 1982: CIOMS Guidelines
- 1991: Publication of the Common Rule
- 1995: Establishment of The National Bioethics Advisory Commission
- 1999: The Death of Jesse Gelsinger
- 2000: OHRP
- 2004: SACHRP

- Tuskegee Syphilis Study
- Willowbrook Hepatitis Study
- Stanford Prison Study
- University of Minnesota Psychosis Study
But really--why do we need IRB in this day and age?

• Difficult to be objective about one’s own work

• People underestimate the risks involved in areas they are very familiar.
  – E.g., procedures, CT scans, adding supplements, surveys on sensitive issues, confidentiality risks, etc.

• People overestimate the benefit of things that are important to them.
Day-to-day IRB
Does the Project Require IRB Approval?

From IRB perspective, a project is either:

- Non-human subjects research, which does not require IRB oversight
- OR
- Human subjects research that meets Exempt, Expedited, or Full Board review criteria

Human Subject Research Determination Form
Questions to Ask

1. Is it Research?

2. Are Human Subjects Involved?

If YES to both, it is Human Subjects Research, and the IRB needs to review.
1. Is it Research?

• 45 CFR 46.102 (d)

A systematic investigation designed to develop or contribute to generalizable knowledge.

  – Contributes to a theoretical framework
  – Results expected to be generalizable
  – Results are intended to be replicated in other settings
2. Are Human Subjects Involved?

• 45 CFR 46.102 (f)

A **living** individual **about whom** an investigator obtains

- Data through **intervention or interaction** with the individual
- **Identifiable private information**
Identifiable Private Information

• Observation or recording is not expected
• The individual can reasonably expect information will not be made public
• The identity of the participant may readily be ascertained or associated with the 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

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. (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)
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.
Northwestern IRB Submission Process

1. PI Submits New Application
2. IRB Analyst Pre-Review
3. Assigned to Reviewer or Panel
4. Approval Criteria Met?
5. Modification Required for Formal Review
6. Changes Requested
7. Post Approval Modifications
   - Continuing Review
   - Reportable new information
# 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) |
Speaking “IRB”
What the IRB is looking for:

Criteria for approval 45 CFR 46.111:

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. Data collection is monitored to ensure **participant safety**.
6. **Privacy and confidentiality** of participants is protected.
7. Additional safeguards are included for **vulnerable populations**.
What the IRB is looking for:

Additional considerations:

1. The researcher has adequate training and experience and there is not a conflict of interest.

2. The research methodology is reasonable and will accomplish the purpose of the study.

3. Participants are fully debriefed if deception used.
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

https://irb.northwestern.edu/single-irb
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?