Northwestern University
Institutional Review Board
(IRB)

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Manager, social and Behavioral IRB
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

- >15,000+ 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
- Lurie Children’s Hospital
- Shirley Ryan Ability Lab
- Other affiliates
- Research Privacy Board
Why do we need IRB?
Timeline of Events

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

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

Source: NIH Office of Extramural Research-Training Modules
It is required by federal regulation but even without that it is a moral responsibility. We need IRB because:

- No one can be objective about their own work
- People underestimate the risks involved with areas they are very familiar
- People overestimate the benefit of things that are important to them.

More importantly, society trusts researchers to do the right thing.

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 intended to develop or contribute to generalizable knowledge.

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.
Factors that inform the IRB review:

- Codes of Ethics
- Standards of practice
- NU HSPP
- CFR, FDA, FERPA, HIPAA, MHDDCA
- International Country Codes
- Academic / Professional Values
- Framework for ethical decision making
- Moral Virtue
- Ethical decision making
- Cultural values, norms and other local considerations
- Legal / Regulatory Standards
IRB Ethical Responsibilities

Belmont Report (1979): 3 Ethical Principles

1. Respect for Persons
2. Beneficence
3. Justice
## IRB Review Categories

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

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
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

CHICAGO:

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QUESTIONS?