

Introduction to the IRB: Requirements and Resources

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Objectives

- Briefly discuss:
 - When IRB review is required
 - Who can do research at Northwestern
 - Collaborating with other institutions
 - Research in the classroom
 - Getting started with an application
 - Where to find IRB resources

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 is conducted in accordance with all federal, institutional, and ethical guidelines.

When do I need to worry about the IRB?

- Whenever conducting research, the first step is to figure out if the project falls under the oversight of the IRB
- Remember that the IRB can only review prospectively, so this consideration needs to happen prior to any research activities
 - Research that should have been covered by the IRB that is conducted without oversight will create problems down the line

When is IRB Review needed?

- **Research** - a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
- **Human participant** - a living individual about whom a researcher conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.

So is this human research (according the federal definition)?

- Complete the Human Research Determination Form (HRP-503):
<https://irb.northwestern.edu/resources-guidance/protocol-templates-forms/>
 - If yes, move on to completing a full application
 - If no, you can submit the form to us for an official determination letter (or self-determine)
 - If unsure, submit to the completed form to use for review

Who can do Research at Northwestern ?

- Anyone can do research at Northwestern
- Only some researchers can serve as the Primary Investigator (PI)
- This has to do with Northwestern faculty appointment status, not experience or other qualifications
 - <https://research.northwestern.edu/researcher-resources/pi-eligibility-for-irb-protocols,-iacuc-protocols,-and-sponsored-research-proposalsawards.html>

Who can do Research at Northwestern ?

- For those who cannot automatically serve as the PI, some can request to serve in that role on a case-by-case basis
 - <https://irb.northwestern.edu/submitting-to-the-irb/initial-studies/principal-investigator-eligibility-and-permissions.html>
- For other roles, they will need to work with an eligible PI

Collaborating across Institutions

- When working with researchers at other institutions it is important to figure out the IRB review for each institution
 - If your project is federally funded one institution needs to review the whole project, which working with our Reliance department (<https://irb.northwestern.edu/reliance/>)
 - If not federally funded, a reliance agreement may or may not make sense, if not each institution will review separately

Research in the classroom

- Additional considerations when working with your students
 - No person with grading authority can know which of their students chose to participate or not participate in research until after final grades have been submitted
 - This means extra credit is usually off the table
 - We will want to know how you are ensuring that students do not feel any pressure to participate in the study
 - Extra language to include in the consent when students are participants: <https://irb.northwestern.edu/resources-guidance/consent-templates-hipaa-requirements/biomedical-social-behavioral-consent-templates/>

Research in the classroom

- Additional considerations when working with your students
 - FERPA: <https://irb.northwestern.edu/resources-guidance/checklists-worksheets/docs/ferpa-compliance-general-3311.docx>
 - Student data (grades, assignments, etc.) cannot be accessed for research purposes without student permission or a FERPA exception.
 - Note that a FERPA exception is issued by the Registrar, the IRB will still require a discussion of why a waiver of consent (issued by the IRB) is required.

Getting Started

- Figure out who will serve as the PI, if special permission is needed, get that ball rolling
 - <https://irb.northwestern.edu/submitting-to-the-irb/initial-studies/principal-investigator-eligibility-and-permissions.html>
- Set up an eIRB+ account
 - <https://irb.northwestern.edu/submitting-to-the-irb/eirb/>
- Complete your CITI training
 - <https://irb.northwestern.edu/compliance-education/human-research-protections-training/>

Getting Started

- The online application is brief, most of the work will be in the supporting documents you upload, so start on your protocol
 - <https://irb.northwestern.edu/resources-guidance/protocol-templates-forms/>
 - For most language research that will be HRP-583

Getting Started

- Next you will complete your other supporting documents
 - Consent forms: <https://irb.northwestern.edu/resources-guidance/consent-templates-hipaa-requirements/biomedical-social-behavioral-consent-templates/>
 - Recruitment materials: <https://irb.northwestern.edu/resources-guidance/recruitment-materials-guidelines.html>
 - The IRB needs to review all participant-facing materials, so all surveys, instructions, stimuli, prompts, interview guides, etc. also need to be provided for review in their final form

Getting Started

- Finally, you will complete the online form and upload all the supporting materials to the appropriate sections:

<https://irb.northwestern.edu/submitting-to-the-irb/initial-studies/filling-out-the-eirb+-application.html>

- The PI will submit the application to the IRB, which will start the IRB Review process

Key IRB Resources

- Getting started: <https://irb.northwestern.edu/submitting-to-the-irb/getting-started/>
- Protocol Templates: <https://irb.northwestern.edu/resources-guidance/protocol-templates-forms/>
- Consent Templates: <https://irb.northwestern.edu/resources-guidance/consent-templates-hipaa-requirements/biomedical-social-behavioral-consent-templates/>
- Recruitment Requirements: <https://irb.northwestern.edu/resources-guidance/recruitment-materials-guidelines.html>

Key IRB Resources

- PI Eligibility: <https://irb.northwestern.edu/submitting-to-the-irb/initial-studies/principal-investigator-eligibility-and-permissions.html>
- CITI Training: <https://irb.northwestern.edu/compliance-education/human-research-protections-training/>
- eIRB+ Information and Technical Support: <https://irb.northwestern.edu/submitting-to-the-irb/eirb/>
- Reliance: <https://irb.northwestern.edu/reliance/>
- FERPA Requirements: <https://irb.northwestern.edu/resources-guidance/checklists-worksheets/docs/ferpa-compliance-general-3311.docx>

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Zoom Office Hours

Wednesdays 2:30-3:30

To get on the schedule for the upcoming
week, please email

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IRB Website: www.irb.northwestern.edu

Questions?

