

Beginning the IRB Application Process

What is IRB and does my project need IRB approval?

The Institutional Review Board (IRB) of Northwestern University is a multi-disciplinary committee that reviews research involving human subjects in order to ensure that the rights and welfare of human subjects are protected. Federal law and NU policy mandates that all social/behavioral research involving human subjects must receive IRB approval prior to the start of the research. If your proposed research involves collecting data from human subjects (e.g., interviews, surveys), you will need to follow the steps listed below to obtain IRB approval for your project.

Step 1: Familiarize yourself with the NU Human Subjects Protection Policy

The Human Subjects Protection Policy contains federal, state, local, and institutional policy, thus it is important for you to be familiar with the requirements. The IRB web site includes numerous resources and links for necessary information:

<http://www.research.northwestern.edu/oprs/irb/social-behavioral/>.

Step 2 Complete Online Training in Human Subjects Research

Northwestern University requires that all investigators, faculty and students, complete the required Human Subjects Protection Training for Social/Behavioral Research prior to initiation of research involving human subjects. The training is done online at www.citiprogram.org. The training program is set up as a series of modules that you can complete individually. You must complete all required training modules, but the training need not be done in a single session. Remember to select Northwestern University as your institution when registering.

Step 3: Identify your Principal Investigator and make sure he/she has completed the IRB training.

IRB requires research projects to have a Principal Investigator (PI). Only NU Faculty Members may be designated as a Principal Investigator. Generally, student investigators choose their faculty advisor to serve as PI, but sometimes a faculty member with similar research interests is a more appropriate choice.

Please remember that all PI must complete the Citiprogram human subject training, if they haven't already done so. One of the most significant keys to success is choosing a PI to provide support, guidance, communication, and oversight of your research project. As PI, the faculty member must approve and submit your IRB application. It is imperative to meet/consult with the PI to review and discuss your research project throughout the process. Most members of the NU faculty have knowledge of this process and will be instrumental in the development and implementation of your research. Further, they can provide guidance as you develop your proposal, application, and consent documents.

Step 4) Develop your Research Proposal/Protocol:

You must have a fully developed research plan to apply for IRB review. When you and your Faculty Advisor/PI complete and submit your online application (see step 6 below), you will need to upload a copy of your research protocol/proposal. The key elements for a research proposal/protocol for a social/behavioral project can be found at the following link:

<http://www.research.northwestern.edu/oprs/irb/forms/documents/KEYELEMENTSOFA SOCIALSCIENCERESEARCHPROPOSA7-28-03.doc>

Step 5: Determine the type of IRB Review for which you should apply:

Different types of research projects/protocols are subject to different types of IRB review. These include:

Exempt Research

Expedited IRB review

Convened (full) IRB review

When your faculty advisor/PI completes the online application, he or she will need to apply for the appropriate type of review and category that applies to your project within the review type. Read the types of IRB review and consider your research procedures. The following flow charts will assist you to determine the appropriate review type and category:

<http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm>.

Step 6: Submit your eIRB application:

Your faculty advisor/PI will submit your IRB application using the eIRB Internet based system. Refer to the following link for information, tutorials, FAQs, and procedural assistance:

<http://www.research.northwestern.edu/oprs/irb/eirb/>

After your application has been submitted, it will automatically be sent to your faculty advisor/PI's department for review and approval by the department's designated IRB Coordinator. Once the department's IRB Coordinator determines that the application is complete and give approval, your application is then sent to the IRB panel for review and approval. If no changes are needed, then your application is approved. If changes are required, then your application is sent to your faculty advisor/PI for revision and resubmission.