

# Using the IRB Website as a Research Tool

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# INSTITUTIONAL REVIEW BOARD (IRB) OFFICE

Search this site



About

Submitting to the IRB

Resources & Guidance

Compliance & Education

Reliance

For Participants

## Submitting to the IRB

HOME > SUBMITTING TO THE IRB

eIRB+

Getting Started

Initial Studies

Modifications

Continuing Review & Closure

Reportable New Information (RNI)

Types of Reviews

# Submitting to the IRB



EIRB+

EIRB+



GETTING STARTED

GETTING STARTED



# eIRB+

- eIRB+ is Northwestern University's electronic submission and review system for human research.
- [eIRB+ Support Form](#)
- Off-Campus Access: VPN and Multi-Factor Authentication Methods and Assistance
- [eIRB+ Access Permissions](#)
  - The Principal Investigator (PI) is automatically granted access to create and edit study applications, receive all communications from the IRB, and submit initial applications and clarification requests.
  - Study Team Members are automatically granted read-only access to the study. In order to obtain permission to create and edit applications or obtain PI Proxy, they must also be added to the Guest List with the appropriate permissions.

# Getting Started

- Is my project human research?
  - [Human Research Determination Form \(HRP-503\)](#)
- Biomedical vs. Social-Behavioral Research
  - The category you submit to should be based on the procedures involved in the research project, not your NU department affiliation.
- Definitions: checklists, SOPs, worksheets
- [Researcher Resource Library](#)

# Initial Studies

- [Principal Investigator Responsibilities, Eligibility, and Permissions](#)
- Filling out the Application
  - Provides assistance for technical aspects of IRB process, such as navigating eIRB+ and what should be uploaded before submitting initial study

- Following the Application



- Post-submission Process
  - Non-Committee vs. Committee Review

# Modifications

Guidance on a variety of types of modifications:

- [Personnel Changes](#): Adding study personnel and guidance on study access and submission rights.
- [Changing the PI](#): Transfer of responsibilities and eligibility
  - Important to change PI before departure from NU
- Study Document Changes submitted in a modification: protocol updates, changes to recruitment material, consent updates, investigational product updates
- Funding Changes: upload grants and link CERES ID
- Changes to exempt research
  - Do the changes to the study affect the exempt determination?

# Continuing Review And Closure

- Continuing Reviews allow the IRB to monitor the progress of the study and ensures that the study continues to meet the requirements for approval.
- The Principal Investigator is responsible for submitting the Continuing Review information no sooner than 60 days but no later than 30 days before the study's current expiration date to ensure adequate time for the IRB to process the Continuing Review.
- When a non-exempt human research study is complete, including those without an expiration date, the PI must promptly submit a continuing review in the Northwestern eIRB+ system to close the study. Refer to the IRB Office's [Guidance on Study Closure](#) to determine when a study is ready to be closed. [The steps on how to close a study are outlined on the Continuing Review & Closure Page.](#)





# INSTITUTIONAL REVIEW BOARD (IRB) OFFICE

Search this site



About

Submitting to the IRB

Resources & Guidance

Compliance & Education

Reliance

For Participants

## Resources & Guidance

HOME > RESOURCES & GUIDANCE

Protocol Templates & Forms

Consent Templates & HIPAA Requirements

Study Support Resources

Recruitment Materials & Guidelines

Policies & Guidance

Checklists & Worksheets

SOPs

# Resources & Guidance

Throughout the lifecycle of a research study, many regulations, policies, and standard operating procedures apply – from the initial submission, through continuing reviews and modifications, and finally to study closure. Our resources can provide navigation for the research community, as well as for IRB analysts and reviewers.

- It is important to always download these resources directly from the IRB website, instead of saving a personal copy or re-using from a previous study, to ensure you have current information since our resources may be updated at any time.

## Definitions

### Protocol Templates & Forms

Protocol templates and forms are ready-to-use documents that will guide you through the process of writing protocols and other supporting documents for your studies. It is important to use the correct template or form to ensure pertinent information is included. Use of our templates is required for most studies.

human subjects research, you may use the human research determination form.

# Protocol Templates & Forms

- Is your study human research?
  - Human Research Determination Form (HRP-503)
- Which protocol template should you use?
  - Biomedical Research Templates
  - Social and Behavioral Research Templates
- [Additional Reviews](#): COI, Radiation Safety, SRC
- Other supporting documents
  - Registry Best Practices (HRP-1103)
  - Emergency Use of Investigational Product (HRP-1203)
  - Compassionate Use Request for Investigational Device (HRP-1201)
  - Incident Assessment Tool (IAT) (HRP-1207)

# Consent Templates & HIPAA Requirements

- Biomedical, Social Behavioral, and Additional Consent Templates
- Consent and Waiver of Consent
  - Types of consent, applicable situations, and conditions for approval
  - Webpage includes links to applicable checklists
- [Suggested Consent Language](#)
  - Provides template language for common risks, study design (randomization), and conflict of interest

# Study Support Resources and Templates

- Screening, enrollment, and withdrawal logs
- Participant eligibility checklists
- Drug or device accountability logs
- Documentation of Consent Process Form to documents the consent process for individual participants in real-time.
- Research Record/Study File
  - All Northwestern PIs must keep and maintain records documenting uninterrupted valid human subject training for all members of the research team. PIs may use the [Social Behavioral Research DOA / Biomedical Research DOA](#) to track study team training, in addition to keeping copies of certificates of completion.

# Recruitment Materials and Guidelines

- This page summarizes the "dos and don'ts" of research recruitment at NU.
- Required elements of materials:
  - Study number, PI's name, eligibility criteria, etc.
- Elements that are not allowed
- Not all Recruitment Materials require IRB Review, per the FDA

# Checklists and Worksheets

## Checklists

- Checklists are documents that IRB members, Designated Reviewers, and Compliance Analysts are required to complete as they review the research study.

## Worksheets

- Guidance materials used by the IRB in initial reviews, continuing reviews, and modification reviews, to enhance compliance with federal, state, and local requirements.

Study teams are encouraged to review checklists and worksheets as they develop their studies to anticipate criteria for approval.

# Policies and Guidance

- [Investigator Manual](#)
  - PI responsibilities including responding to PAM requests in a timely manner and closing the study promptly
- Data Policies: GDPR, FERPA, Public Use Data, Reporting Data Incidents, Research Using Mental Health Data
- FDA Policies: Investigational Devices, Mobile Medical Apps
- Submission Guidance: Engagement Determinations, Quality Improvement Projects, Study Closures, Research Participant Payments

# Standard Operations Procedures (SOPs)

- [SOPs](#), or standard operating procedures, are documents that outline the relevant policy and the IRB Office practices in accordance with Human Research Protections (HRP).
- If you have questions about the IRB Office policies and practices, reviewing our SOPs is helpful through the approval process and during post-approval monitoring





# INSTITUTIONAL REVIEW BOARD (IRB) OFFICE

Search this site



About

Submitting to the IRB

Resources & Guidance

Compliance & Education

Reliance

For Participants

## Compliance & Education

HOME > COMPLIANCE & EDUCATION

Post-Approval Monitoring

Directed Reviews (For-Cause Audits)

Corrective and Preventive Action (CAPA) Plans

FDA Site Inspections

Human Research Protections Training

Education

# Compliance & Education

The goals of the Compliance and Education unit within the Northwestern University IRB Office are to enhance the caliber of research performed by Northwestern University investigators and those investigators relying on the Northwestern University IRB for review. We strive to increase the effectiveness of the university's Human Research Protection Program (HRPP) through program oversight, education, and outreach. We accomplish these by ensuring research at Northwestern complies with the federal regulations, state laws, and institutional policies that govern human research.

The IRB's compliance and education program aims to ensure that educational resources and guidance materials are available to all research staff; that researchers and their teams have the study support tools and resources needed to perform compliant research; and to assess human research projects to ensure the participants' rights and welfare are fully protected.

In these subpages you will find additional information and links to various policies, guidance documents, and information that pertains to post approval activities.

# Post-Approval Monitoring

- Types of monitoring activities
  - Self-assessments and IRB Compliance conducted reviews
  - Study status assessments for studies without an expiration date
  - Routine corrective and preventative action (CAPA) plan assessments
  - Recruitment materials and processes review
- Overview of the review process
  - PAM self-assessment
  - In-person visit or virtual review
  - CAPA plan assessment
  - Preparing for a monitoring assessment
  - Closeout and follow-up actions

# Directed Reviews (For-Cause Audits)

- Preparing for a directed review visit
- Closeout and follow-up actions
- Differentiating required corrective actions vs. recommended corrective actions

# Corrective and Preventive Action (CAPA) Plans

- Step 1: Take immediate corrective actions
- Step 2: Conduct a root cause analysis
- Step 3: Prepare the CAPA plan
- Step 4: Document the CAPA plan

# FDA Site Inspections

- FDA inspections can be:
  - Announced or unannounced
  - Routine or for-cause
  - On studies that are open or closed
  - Study-specific or investigator-specific
  - Of a single study or multiple studies
- Preparing for an FDA site inspection
- What happens after an FDA site inspection
- Notifying the IRB of an FDA site inspection
- Information investigators must provide to the IRB after an FDA inspection

# Human Research Protections Training

- Northwestern University requires all individuals involved in the conduct of [human research](#) to complete Human Research Protections Training and refresh their training every 3 years.
- IRB approval will be withheld if these training requirements are not met.

# Education

- *Navigating Human Research & Regulatory Review MyHR Learn course*
- IRB Brown Bags
- [Special Event Training Request](#)



# INSTITUTIONAL REVIEW BOARD (IRB) OFFICE

Search this site



About

Submitting to the IRB

Resources & Guidance

Compliance & Education

Reliance

For Participants

## Reliance

HOME > RELIANCE

Single IRB Planning

Northwestern Serving as the IRB of Record

Northwestern Relying on an External IRB

SMART IRB & IREx

Northwestern Affiliates & Chicagoland Partners

Research at Northwestern Qatar

# Reliance

In order to maintain regulatory compliance, and to help facilitate human research initiatives, the Reliance Unit provides resources and support for researchers engaging in reliance activities with External collaborators. Engaging in reliance minimizes the need for duplicative IRB review while protecting the rights and welfare of human research participants. The resources and information found on the associated webpages provide a complete overview of the reliance process, from beginning to end. If you need additional information or have questions, please contact us at [irbreliance@northwestern.edu](mailto:irbreliance@northwestern.edu).

## Virtual Office Hours

Do you have reliance, single IRB, or multi-site research questions? The Reliance Team hosts open office hours every Tuesday. You are invited to join the Zoom waiting room and be admitted one-by-one for 10-15 minutes time slots in the order you joined Zoom. [Register here!](#) (Updated for 2024)

- If your question exceeds 10-15 minutes, or if we ran out of time during office hours, email [irbreliance@northwestern.edu](mailto:irbreliance@northwestern.edu) and request to setup a meeting so we can support you.



# Reliance

- **Single IRB Planning**
  - Federally funded research involving multiple institutions
- **Northwestern Serving as the IRB of Record**
  - NU is IRB of Record/Lead IRB
- **Northwestern Relying on an External IRB**
  - NU is ceding IRB review to another entity
- **SMART IRB & IREx**
  - Information about using these reliance platforms
- **Northwestern Affiliates & Chicagoland Partners**
  - Information about NMHC, Shirley Ryan, Lurie, and other NU partners
- **Research at Northwestern Qatar**
  - Information about IRB review of human subjects research conducted at Northwestern Qatar



# INSTITUTIONAL REVIEW BOARD (IRB) OFFICE

Search this site



About

Submitting to the IRB

Resources & Guidance

Compliance & Education

Reliance

For Participants

## For Participants

HOME > FOR PARTICIPANTS

Find a Research Study

Participant Resources

Participant Rights

Participant FAQs

# For Participants

Northwestern University is committed to protecting the rights, safety, and welfare of people who volunteer for research. Research volunteers contribute valuable information through their participation in studies that can answer important questions and help improve lives. Volunteers are also known as "subjects" or "participants." These webpages have basic information about research and about the rights of research participants.



FIND A RESEARCH STUDY

FIND A RESEARCH STUDY



PARTICIPANT RESOURCES

PARTICIPANT RESOURCES



# INSTITUTIONAL REVIEW BOARD (IRB) OFFICE

Search this site



About

Submitting to the IRB

Resources & Guidance

Compliance & Education

Reliance

For Participants

About

HOME > ABOUT

Contact Us

IRB Information

IRB Fees

News

Events

For Panel Members

Fostering Accessibility and Inclusion in Research (FAIR)

IRB Metrics

## Welcome to the Northwestern University IRB Office

Our mission is to protect the rights and welfare of human research participants. We are governed by [45 Code of Federal Regulations Part 46 \(45 CFR 46\), Protection of Human Subjects](#) that dictate the scope and purpose of Institutional Review Board (IRB) activities, and follow [ethical principles](#) for the conduct of human research.

The protection of research participants at Northwestern University is a shared responsibility, with the institution, researchers, IRB committees, and the IRB Office working together toward this common goal.

The IRB Office is primarily responsible for developing and directing the University's Human Participant Protection Program (HRPP), which also involves other offices at Northwestern University. The HRPP's mission is to be a model program of excellence in protecting the rights and welfare of human participants involved in research.



# INSTITUTIONAL REVIEW BOARD (IRB) OFFICE

Search this site 

About

Submitting to the IRB

Resources & Guidance

Compliance & Education

Reliance

For Participants

## About

HOME > ABOUT > FOSTERING ACCESSIBILITY AND INCLUSIVITY IN RESEARCH (FAIR)

Contact Us

IRB Information

IRB Fees

News

Events

For Panel Members

Fostering Accessibility and Inclusion in Research (FAIR)

Community-Engaged Research

Language Inclusion

Selection of Participants

Gender-Affirming Language

DEI Initiatives

# Fostering Accessibility and Inclusivity in Research (FAIR)



[Please complete our FAIR community survey here!](#)

# Questions

- General Questions or Concerns : [irb@northwestern.edu](mailto:irb@northwestern.edu)
- Biomedical Research Questions: [irb@northwestern.edu](mailto:irb@northwestern.edu)
- Social and Behavioral Research Questions: [sbsirb@northwestern.edu](mailto:sbsirb@northwestern.edu)
- Compliance Questions or Concerns: [irbcompliance@northwestern.edu](mailto:irbcompliance@northwestern.edu)
- Reliance Questions: [irbreliance@northwestern.edu](mailto:irbreliance@northwestern.edu)
- Training and Education Questions: [irbtraining@northwestern.edu](mailto:irbtraining@northwestern.edu)
- eIRB+ Technical Questions: [eIRB+ Support Form](#)