
Navigating the IRB

Department of Surgery Research Conference Toolkit Lecture

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First...



Disclaimer:

The recommendations and advice associated with this presentation are my own. I am not a member of the IRB. Although I am a member of the Northwestern University IRB Advisory Committee, the content of this presentation is not intended to represent the Northwestern IRB or any other IRB.

Today's Targets

Overview of pre-IRB application startup needs

Overview of the NU IRB application

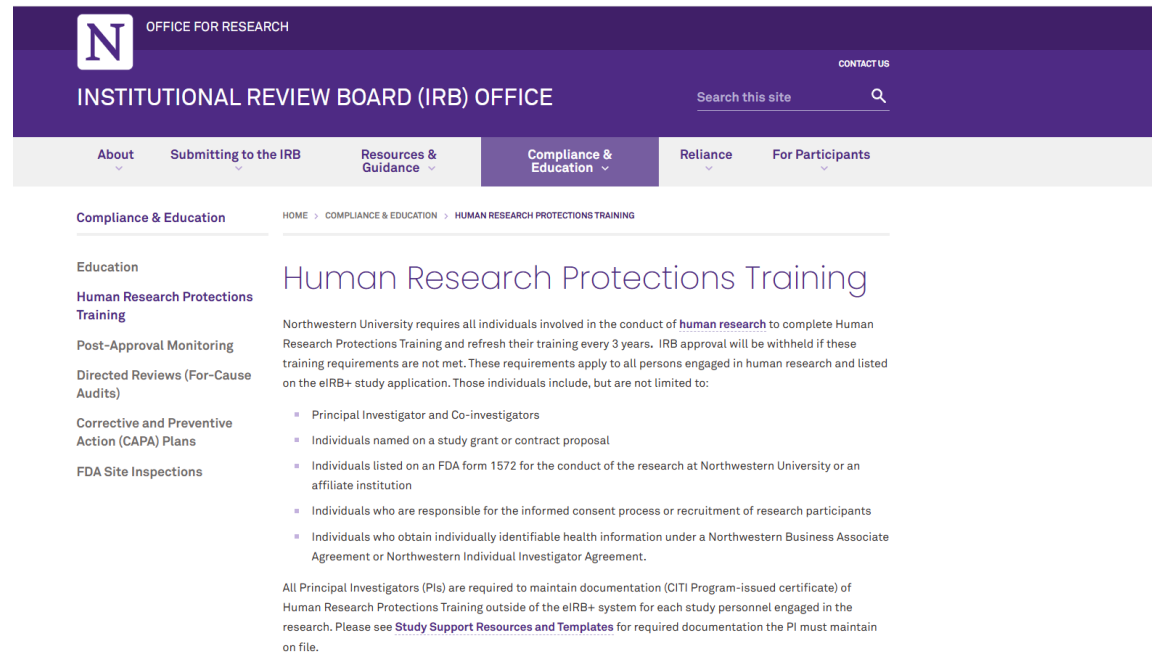
Overview of NU IRB resources

Allow time for questions

What are the pre-IRB application startup needs?

1. NU IRB Required: Human Research Protections Training Certification (good for 3 years)

<https://irb.northwestern.edu/compliance-education/human-research-protections-training/>



The screenshot shows the Northwestern University Institutional Review Board (IRB) Office website. The header is purple with the 'N' logo and 'OFFICE FOR RESEARCH' text. Below the header, the main navigation bar includes 'About', 'Submitting to the IRB', 'Resources & Guidance', 'Compliance & Education' (highlighted), 'Reliance', and 'For Participants'. The page title is 'Human Research Protections Training'. The main content area explains that Northwestern University requires all individuals involved in human research to complete Human Research Protections Training and refresh it every 3 years. It lists the following individuals who are required to complete training:

- Principal Investigator and Co-investigators
- Individuals named on a study grant or contract proposal
- Individuals listed on an FDA form 1572 for the conduct of the research at Northwestern University or an affiliate institution
- Individuals who are responsible for the informed consent process or recruitment of research participants
- Individuals who obtain individually identifiable health information under a Northwestern Business Associate Agreement or Northwestern Individual Investigator Agreement.

All Principal Investigators (PIs) are required to maintain documentation (CITI Program-issued certificate) of Human Research Protections Training outside of the eIRB+ system for each study personnel engaged in the research. Please see [Study Support Resources and Templates](#) for required documentation the PI must maintain on file.

Collaborative Institutional Training Initiative (CITI) Program

<https://www.citiprogram.org/?pageID=668>

What are the pre-IRB application startup needs?



English ▾

LOG IN

LOG IN THROUGH MY ORGANIZATION

REGISTER

i Due to planned maintenance, the CITI Program website will be unavailable on Friday, March 14th from 8 p.m. to 12 a.m. U.S. Eastern Time (5 p.m. to 9 p.m. U.S. Pacific). We apologize for the inconvenience.

Organizations listed here use "Single Sign On" (SSO) for CITI Program access.

SSO requires a username and password issued by the organization.

If your organization is not listed here, it does not use Single Sign On. Click on the "Log In" tab (if you already have a CITI Program account) or the "Register" tab (if you are new to CITI Program and creating an account for the first time).

To find your organization, enter its name in the box below, then pick from the list of choices provided. 🗨

Northwestern University

Northwestern University

Continue To SSO Login / Instructions

[See our full list of SSO-enabled organizations](#)

What are the pre-IRB application startup needs?

While you are at it...

The screenshot shows a user interface for viewing courses. At the top, there is a search bar labeled "Show Courses for:" with "Northwestern University" selected in a dropdown menu and a blue "Institution List" button. Below this, the page is titled "Northwestern University". There are three main sections: "Active Courses", "Courses Ready to Begin", and "Completed Courses". Each section has a "Learner Tools" link. The "Completed Courses" section contains two course entries. The first entry is "CITI Good Clinical Practice" (Stage 1 - Basic Course) with a "Post-Course Survey" link and a "Passed 25-Oct-2022" status. It has two buttons: "Review Course" (blue) and "View - Print - Share Record" (yellow). The second entry is "Health Privacy Issues for Researchers" (Stage 1 - Basic Course).

Show Courses for: Northwestern University [Institution List](#)

Northwestern University


Active Courses [Learner Tools](#)


You have no active courses for this Institution.

Courses Ready to Begin [Learner Tools](#)

You have no courses ready to begin for this Institution.

Completed Courses [Learner Tools](#)

Northwestern University
CITI Good Clinical Practice
Stage 1 - Basic Course
[Post-Course Survey](#) 
Passed 25-Oct-2022 [Review Course](#) [View - Print - Share Record](#)

Northwestern University
Health Privacy Issues for Researchers
Stage 1 - Basic Course
[Post-Course Survey](#) 

What are the pre-IRB application startup needs?

<https://www.nucats.northwestern.edu/training/good-clinical-practice.html>

[Feinberg Home](#) > [NUCATS Home](#) > [Training](#) > [Good Clinical Practice Training](#)

Training

[Training Overview](#)

▶ **Good Clinical Practice Training**

[Investigator Development](#)

[Research Staff Development](#)

[Funding Opportunities](#)

[Art of Science Communication Course](#)

Good Clinical Practice Training

Good Clinical Practice (GCP) is an international, ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki and that the clinical trial data are credible.

Northwestern University and the Feinberg School of Medicine require GCP training for all investigators, co-investigators and study personnel listed on the Northwestern University IRB application and involved in research defined as follows by the **NIH clinical trial definition**: "A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes."

What are the pre-IRB application startup needs?

2. NUIRB required: eIRB+ Registration

<https://irb.northwestern.edu/submitting-to-the-irb/eirb/>



REGISTER

New to eIRB+? Registration instructions are available.

REGISTER



LOGIN

Click here to access eIRB+ and login.

LOGIN

Elements of the NU IRB Application

Login and Create New Study

[https://eirbplus.northwestern.edu/IRB/sd/Rooms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity\[OID\[5C3E6DF4AA49DF408616C9B82E714D46\]\]](https://eirbplus.northwestern.edu/IRB/sd/Rooms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity[OID[5C3E6DF4AA49DF408616C9B82E714D46]])

The Legacy eIRB system (for studies approved prior to November 2014) has been retired. If you have questions about materials previously stored in the Legacy system, contact the IRB Office at irb@northwestern.edu.

NetID:

Password:

Login

Remember me

After signing in to this site, you are bound by the terms and conditions set forth when you received your account.



Review Board Office



My Inbox

Home

IRB

Create New Study

Report New Information

Submissions

My Inbox

My Studies

My Inbox

Filter ?

ID

▼

Enter text to search for

Go

+ Add Filter

✕ Clear All

ID

Name

Date Created

▼ Date Modified

Owner

State

Full Study Title

Root Study Exp. Date

PI first

PI last

Elements of the NU IRB Application

Basic Information Items 1-5

« Back

Save Print

Continue »

Basic Information

1. * Title of study:

2. * Short title:

3. * Brief description: ?

4. * Which selection best describes your study?

Social Behavioral

Biomedical

[Clear](#)

5. * Principal investigator:

Sharnia Lashley

Help

Brief Description

In a few words, summarize:

- The central question the research is intended to answer
- The primary objectives
- The methods used

For example:

This is a <drug study, vaccine study, chart review, bio-specimen analysis, survey, or questionnaire study> that will examine...

Elements of the NU IRB Application

Basic Information Items 6-8

6. * Will an external IRB act as the IRB of record for this study? **Note: You will NOT be able to change this answer once you save/continue past this page. If you answer incorrectly you will need to discard this study and create a new study.**

Yes No [Clear](#)

7. * What kind of study is this?

If Northwestern University and any other site are engaged in Human Research, the study is either Multi-site or Collaborative. Sites could be affiliated or non-affiliated (e.g., one or more NM sites, SRALab, University of Phoenix, or other participating sites in an Industry sponsored study).

If you are a sub-award recipient of any Federal funds (e.g., NIH agencies and centers) and you will conduct non-exempt Human Research, then the prime award recipient is an Engaged site, and the study is either Multi-site or Collaborative.

Single Site study (Only one site is engaged in Human Research, e.g. only Northwestern University, or only NMHC, or only SRALab)

Collaborative study (Each site engaged in Human Research will conduct a portion of the study)

Multi-Site study (More than one site engaged in Human Research will conduct the entire study)

[Clear](#)

Note: Site vs. Location - A Site is engaged in Human Research where a Location is a place where researchers go to conduct the research, but where the Location is not engaged in the research. (Example: When researchers conduct interviews with participants at a coffee shop, the coffee shop is a Location because the employees of the coffee shop are not engaged in the research.)

8. * Attach the protocol:

[+ Add](#)

Document	Category	Date Modified	Document History
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There are no items to display

Elements of the NU IRB Application

Sources of Funding and Other Support

You Are Here: [xIRB Tatebe VIBRANT](#)

« Back

Sources of Funding and Other Support

Identify each organization supplying funding for the study from a specific NU department/division that is providing funding for the study.

1. * Identify each organization supplying funding for the study

+ Add

Funding Source	Sponsor's Funding ID
There are no items to display	

« Back

Add Funding Source - Google Chrome

eirbplus.northwestern.edu/IRB/sd/CommonAdministration/Choosers/Entity/CustomDataType/DataEntry/Form?postbac...

Add Funding Source

If this project has external funding, use the CERES chooser in question 1 to select the correct grant, contract, or other mechanism funding the study. Confirm this information with the research or finance administrators in your department if you are unsure of the correct grant or contract CERES number for this study.

When you select the CERES record, questions 2 through 5 will automatically be filled in with the correct information.

If this project is **not** funded through CERES, or you cannot find the correct grant, then complete questions 2 through 5 manually, as applicable.

If funding/support for your study is only from NU (no external funding sources), select your NU department/division from the drop-down menu in question 2. See the help links below for more information.

1. * Is this research funded by an external sponsor (an agency, department, foundation or other funding source external to Northwestern University) that has awarded funding to NU, or through a sub-award?

NOTE: If your project has external funding, but that funding did not go through NU (e.g. SRALab or Lurie Children's is managing the grant), please select "No" to this question AND upload an attachment in question 5 to show how the funding is routed.

Yes No [Clear](#)

2. * Funding/Support Organization: ?

button below and indicate in question

Contin

Contin

Elements of the NU IRB Application

Study Team Members

The screenshot displays the 'Study Team Members' section of the NU IRB application. The main page includes a navigation bar with 'Back', 'Save', 'Exit', 'Hide/Show Errors', 'Print', 'Jump To', and 'Continue' buttons. The 'Study Team Members' section contains instructions for listing co-investigators and study team members, a '+ Add' button, and two empty tables with headers 'Name' and 'Roles' and 'Name' and 'Institution'. A modal window titled 'Add Study Team Member' is open, showing a form with three required fields: 'Study team member' (with a dropdown menu showing 'Sharnia Lashley'), 'Role in research' (with radio buttons for 'Co-Investigator' and 'Study Team Member'), and 'Is the team member involved in the consent process?' (with radio buttons for 'Yes' and 'No'). The modal also includes 'OK', 'OK and Add Another', and 'Cancel' buttons.

Study Team Members

List all co-investigators and study team members in the application. Information must be listed. For each individual added, their name, title, and role in research; individuals are considered to be co-investigators if they are not listed in the Northwestern University COI office.

Please note, minors (persons under age 18) are not allowed to be listed as study team members.

1. To be considered an "internal" study team member, individuals must be registered in eIRB+ with their Northwestern University email address. Individuals who are not registered in eIRB+ are likely because they have not yet registered in eIRB+. For more information, see <https://irb.northwestern.edu/submittin>

+ Add

Name	Roles
There are no items to display	

2. External Study Team Members

If Northwestern will serve as the IRB of record for the study, external investigators will be under the supervision of the IRB of record. If Adding Northwestern Volunteers/Interns, students, faculty, staff, etc. (e.g., NMHC, Shirley Ryan AbilityLab, etc.) and their roles in research, Supporting Documents. More Information

+ Add

Name	Institution
There are no items to display	

Add Study Team Member

1. * **Study team member:** ?
Sharnia Lashley

2. * **Role in research:** (check only one option)
 Co-Investigator
 Study Team Member

3. * **Is the team member involved in the consent process?**
 Yes No [Clear](#)

* Required

OK OK and Add Another Cancel

Elements of the NU IRB Application

Local Site Documents



Edit: IRB Submission - IRBSITE00002757

You Are Here: xIRB Tatebe VIBRANT

« Back

Save

Exit

Hide/Show Errors

Print

Jump To

Continue »

Site-Specific Documents

1. Consent forms: ?

+ Add

Document	Category	Date Modified	Document History
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There are no items to display

2. Recruitment materials: (add all material to be seen or heard by potential participants, including ads) ?

+ Add

Document	Category	Date Modified	Document History
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There are no items to display

3. Supporting Documents: (any study-related documents not attached elsewhere)

+ Add

Document	Category	Date Modified	Document History
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There are no items to display

Elements of the NU IRB Application

Sites



Edit: IRB Submission - IRBSITE00002757

You Are Here: xIRB Tatebe VIBRANT

<< Back

Save

Exit

Hide/Show Errors

Print

Jump To

Continue >>

Sites

1. Please specify Northwestern and Northwestern Affiliate study site(s):

- Northwestern University (NU) – Evanston
- Northwestern University (NU) – Chicago
- Northwestern University (NU) – Qatar
- Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Childrens)
- Clinical Research Unit (CRU)
- Northwestern Memorial HealthCare (NMHC) and/or its affiliates (NMH, NMG, NLF)
- Shirley Ryan AbilityLab (SRALab)
- Robert H. Lurie Comprehensive Cancer Center and/or its affiliates
- The Family Institute

Elements of the NU IRB Application

RSS Cancer Research and Operational Data Items 1-3

Update RSS Data

If you have received instructions from Feinberg to update specific RSS fields now, you can do so below. Otherwise you should confirm all of your RSS information is correct each time you submit a Modification.

RSS: Cancer Research

* 1. Is this a cancer-relevant human subjects research study?

Yes No [Clear](#)

RSS: Operational Data

* 1. Will you or your study team access or collect Protected Health Information (PHI) from NMHC?

Yes No [Clear](#)

* 2. Does your research include the use of students, residents and fellows at the Feinberg School of Medicine as participants? If so, please be aware that you must seek prior approval. For additional guidance please see [this document](#). Please contact Dr. Diane Wayne at dwayne@northwestern.edu for more information.

Yes No [Clear](#)

3. Community Engagement in Research

Please answer the following questions about community participation in your research. If you need assistance with this section or to learn about resources to support community engagement in your research, contact the Center for Community Health (cch-consult@northwestern.edu). Be sure to include 'RSS CCH Data Form Help' in the subject line of your email.

5a. In which of the following ways will non-academic organizations (including clinical sites affiliated with Northwestern) or community partners (e.g. community or faith-based organizations, foundation, government, social service organization) participate in this research? *Select all that apply.*

- Participating on an advisory board or other governing body for the study
- Designing the study proposal or protocol (e.g. assessing feasibility, design of study questions, etc.)
- Developing the intervention (e.g. drug, device, framework, approach, technology, etc.)
- Providing a location or space for research recruitment, data collection or intervention delivery
- Recruiting participants, including obtaining consent
- Delivering study intervention
- Acquiring/collecting specimens or data, including permission to use electronic data
- Analyzing data
- Interpreting findings
- Assisting with dissemination activities
- N/A - No organizations, including clinical sites and community partners, will participate in this research in any capacity
- Other, please specify:

Elements of the NU IRB Application

RSS NMHC site information

Organization Name	Zip Code	City and Country
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There are no items to display

RSS: Northwestern Memorial HealthCare (NMHC)

For help with this form please contact the NMHC Office of Research at nmoor@nm.org. Be sure to include 'RSS NMHC Data Form Help' in the subject line of your email.

1. Northwestern Memorial HealthCare (NMHC) Site(s):

NM Memorial Hospital

Northwestern Medical Group (NMG) / Regional Medical Group (RMG)

Other NMHC Affiliate

a. If other, please specify:

2. [Question 2 no longer applicable]

3. Will equipment, software and/or hardware be brought to NMHC for this study?

Yes

No

Unknown at Time of Submission

[Clear](#)

a. If Yes to question 3, describe the equipment:

b. If Yes to question 3, indicate the NMHC Department where equipment will be housed:

c. If Yes to question 3, do you anticipate any IT involvement in this project (e.g. hardware, software, etc.)?

Yes No [Clear](#)

Elements of the NU IRB Application

RSS NMHC site information continued and Data Security

5. Indicate the ancillary service areas where the research will be conducted:

Interventional Radiology

Investigational Drug Services Pharmacy (IDS)

Mathews Center for Cellular Therapy (MCCT)

Northwestern Medicine Developmental Therapeutics Institute (NMDTI)

Northwestern Memorial Hospital Clinical Research Unit (NMH CRU)

Nuclear Medicine

Pathology/CSRC

Radiology/Medical Imaging (ex. MRI, CT, Ultrasound)

Rube Walker Blood Center

6. I understand that most third-party insurance carriers, including Medicare and the Illinois Department of Public Aid, will not cover investigational/experimental services. Accordingly, I acknowledge Northwestern Medicine may not be held liable for absorbing the cost of research charges, without the expressed written authorization of the Hospital.

Per Northwestern Medicine Policy 5.0034, I understand the Hospital reserves the right to conduct periodic audits to ensure compliance with established policies and procedures and I agree to support the Hospital with these efforts in a timely manner and make available all required records. Additionally, I understand that failure to comply with all applicable federal/state laws and Northwestern Medicine policies/procedures related to this research may include disciplinary action up to and including termination of research at the Hospital.

I agree: Yes No [Clear](#)

RSS: Data Security

For questions about the 'Data Security' section of the form, please contact FSMIT-policy@northwestern.edu. Be sure to include 'RSS Data Security Form Help' in the subject line of your email.

* Attest that all sections of the Data Security Plan are complete, using the following Data Security Plan template:

Data Security Plan form

* Upload the Data Security Plan for this study:

[None]

Technology Resources

Please address all questions and requests for IT resources required (e.g., storage and storage estimates, backup storage, archiving storage, granting access to date) of the Data Security Plan to FSMHHELP@northwestern.edu.

Data Security Plans

Please address all questions, request for clarification and all other forms of assistance regarding Data Security Plans to FSMIT-policy@northwestern.edu.

Please visit our Frequently Asked Questions (FAQ) for Data Security Plans:

<https://www.feinberg.northwestern.edu/it/policies/information-security/data-security-plans.html>

Elements of the NU IRB Application

Notify the PI to Submit

The screenshot shows a web application interface with a sidebar on the left and a main content area. The sidebar contains several buttons: 'Edit Site', 'Printer Version', 'View Differences', 'Submit', 'Assign Primary Contact', 'Add Comment', 'Discard', and 'Notify PI to Submit'. The 'Notify PI to Submit' button is highlighted with a checkmark icon. The main content area displays a dialog box titled 'Notify PI to Submit'. The dialog box contains the following text:

Execute this activity to notify the PI that the submission is ready to review and submit to the IRB. You may enter comments for the PI below.

IMPORTANT: If the PI is Feinberg faculty or the project uses Northwestern Memorial Hospital as a site, please ensure you have completed the RSS form before you forward this submission to the PI. If the RSS form is not completed, the PI will receive an error message upon submission.

Comments:

Below the text is a large text input field. At the bottom right of the dialog box are two buttons: 'OK' and 'Cancel'. The background of the application shows a table with a 'COI' column and a 'complete' button.

NU IRB Resources

Website Resources and Guidance - Protocol Templates

The screenshot shows a web browser window with the URL irb.northwestern.edu/resources-guidance/protocol-templates-forms/. The browser tabs include "Work with footers and headers", "Protocol Templates & Forms: In", "xIRB VIBRANT", "GlobalProtect", and "Good Clinical Practice Training:". The browser's address bar shows the URL and search engines like Google Lens. The website's navigation menu includes "About", "Submitting to the IRB", "Resources & Guidance" (which is highlighted), "Compliance & Education", "Reliance", and "For Participants".

Resources & Guidance

HOME > RESOURCES & GUIDANCE > PROTOCOL TEMPLATES & FORMS

Protocol Templates & Forms

Is your study human research?

- [Human Research Determination Form \(HRP-503\)](#) 📄: (Rev. 11-01-2023) Researchers can self-determine whether their activities are human research. If you are unable to determine whether your activities meet the regulatory definition of “research” with “human subjects,” [QR](#) if you would like/need the IRB to evaluate your study to provide an official determination that your activity is not human subjects research, complete this form.
- [Guidance on the Use of Public Use Data](#) 📄: Researchers using specified “public use” data sets for secondary analysis may not need to submit to the IRB for review since publicly available data does not constitute

Resources & Guidance

- Protocol Templates & Forms
- Consent Templates & HIPAA Requirements
- Study Support Resources
- Recruitment Materials & Guidelines
- Policies & Guidance
- Checklists & Worksheets
- SOPs

NU IRB Resources

Website Resources and Guidance - Protocol Templates

Which protocol template should you use?


The IRB Office has developed protocol templates for use by the Northwestern University research community to describe research/human research activities.

- Consult our [Protocol Conversion Guide 11-9-2014](#) for important information about using templates with new submissions or converting templates for previously approved research.
- When developing the recruitment sections of your protocols please refer to our [Recruitment Materials and Guidelines](#) webpage.

Biomedical Research Templates

- [Biomedical Protocol Template \(HRP-593\)](#): (Rev. 12-01-2024) This document is intended for use primarily by those conducting biomedical research.
- [Local Protocol Addendum Template \(HRP-508\)](#): (Rev. 11-01-2023) This document is intended for use when local information is not represented in the main protocol document received from a study sponsor or non-Northwestern University research collaborator. The Local Protocol Addendum should be uploaded along with the main protocol document in eIRB+ and modified as necessary throughout the duration of the study to account for local changes to the research.
- [Data and Specimen Analysis Protocol \(HRP-1704\)](#): (Rev. 03-01-2025) This document is intended for use primarily by those involved in analysis of data and/or specimens.

Social and Behavioral Research Templates

- [Social Behavioral Protocol Template \(HRP-583\)](#): (Rev. 11-01-2024) This document is intended for use primarily by those conducting social, behavioral, or educational research. If your research involves physical procedures or devices, you may need to  sections that are contained in the biomedical template protocol.



NU IRB Resources

Website Resources and Guidance - Consent Form Templates and Language

Resources & Guidance

HOME > RESOURCES & GUIDANCE > CONSENT TEMPLATES & HIPAA REQUIREMENTS

Protocol Templates & Forms

Consent Templates & HIPAA Requirements

Biomedical & Social Behavioral
Consent Templates

Consent & HIPAA Requirements

Suggested Consent Language

Limited English Proficiency and Non-
English Speaking Participants

Study Support Resources

Recruitment Materials &
Guidelines

Policies & Guidance

Consent Templates & HIPAA Requirements

CONSENT TEMPLATES

DOWNLOAD CONSENT TEMPLATES

CONSENT & HIPAA REQUIREMENTS

REVIEW REQUIREMENTS

SUGGESTED CONSENT LANGUAGE

VIEW SUGGESTIONS

LIMITED ENGLISH PROFICIENCY
AND NON-ENGLISH SPEAKING
PARTICIPANTS

LEARN MORE

NU IRB Resources

Website Resources and Guidance – Biomedical Consent Form Template page 1

Instructions are in red font- delete everything in red font and replace with applicable language pertinent to your study.

The footer of the informed consent document template includes a "**Consent Subtitle**" section to designate the subtitle and version of each consent document used in the study (e.g., Main, Genetic, Screening, Treatment Group, etc.). Abbreviate lengthy subtitles. When a study uses only a single consent document, this item in the footer may be deleted. The "**Consent Version**" **MUST** be completed and is utilized as a document tracking system for **any** change to the document. The version designation must take the form of a date (e.g., 06/01/2020 Consent subtitle) & version should match with the document file name.

The consent form should be written in language understandable to a layperson. Please use simple language and sentence structure. Avoid overly technical language. See the [NCCN Informed Consent Language Database](#) to assist with lay language descriptions of risks and procedures in clinical research.

From the IRB website, please use [IRB suggested language](#) for specific situations and procedures.

Title of Research Study: [insert title of research study here with protocol number, if applicable]

Principal Investigator: [insert name of principal investigator]

Supported By: [List all monetary and/or non-monetary support for this research. If none, state, e.g., Northwestern University, the Shirley Ryan AbilityLab, etc.] This research is supported by _____.

Financial Interest Disclosure: [Include if there is a financial interest to disclose. Otherwise, delete.] The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study:

[Include if the investigator is also the participant's treating physician. Otherwise, delete.] Your doctor, who is also responsible for this research study, [or, If your doctor is also the person responsible for this research study, please note that your doctor is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

NU IRB and Office of Research Resources

Website - Principal Investigator Responsibilities, Eligibility, and Permissions

<https://irb.northwestern.edu/submitting-to-the-irb/initial-studies/principal-investigator-eligibility-and-permissions.html>

STATUS/TITLE	IRB			SPONSORED RESEARCH			IACUC		
	Eligible	Case by Case	Not Eligible	Eligible	Case by Case	Not Eligible	Eligible	Case by Case	Not Eligible
Curators	x			x				x	
Instructors	x			x				x	
Librarians	x			x				x	
Non-tenure-track research and/or clinical faculty (full, associate, and assistant professors)	x			x			x		
Tenure-track faculty (full, associate, and assistant professors)	x			x			x		
Senior research investigators (Faculty with emeritus status or who are tenured and retired but wish to continue at PI)	x			x			x		
Adjunct Faculty		x		x				x	
Lecturers		x			x			x	
Contributed Services Faculty		x			x			x	
Health System Clinicians		x			x			x	
Visiting Faculty		x			x			x	
Visiting Scholars		x			x			x	
Postdoctoral Scholars*		x			x				x
Research Assistants and Grad Students			x		x				x
Residents			x			x			x
Research Associates			x			x			x
Undergraduate Students			x			x			x

* Inclusive of Postdoctoral Scholars (Trainee), Postdoctoral Fellows - National Research Service Award (NRSA) (Trainee), Visiting


NU IRB Resources

Website Recruitment Materials and Guidelines

<https://irb.northwestern.edu/resources-guidance/recruitment-materials-guidelines.html>

Required Elements

- Study title and IRB study number
- The word “research.” Make it clear that this is a research study
- “Northwestern University”
- The PI’s name
- A contact name with either a phone number or e-mail address
- Eligibility criteria, if applicable, should be noted briefly. Especially if payment depends on meeting these criteria. For example, “*English speaking only*,” “*Women only*,” etc.
- State whether participants will be paid for their time and effort
 - Acceptable:
 - “*You will be compensated for your participation.*”
 - “*You will receive a gift card to X for [amt.] for your participation.*”
 - “*Participants will be compensated.*”
- The amount of payment may be included but should not be the most prominent element on the page. Compensation should not be excessive considering the nature of the project. Payment should be stated as a range of amounts or stated as “*at least*” or “*up to*” for payments dependent on the amount of participation.

For additional guidance on recruitment materials, refer to [HRP-315 WORKSHEET Advertisements \(Recruitment Materials\)](#) 

NU IRB Resources

myHR Learn Web-Based Training: Navigating Human Research Ethics & Regulatory Review with the Institutional Review Board Office

The screenshot shows a web browser window displaying a training completion page. The browser's address bar shows the URL: learn.northwestern.edu/Saba/Web_spf/PRODTNT074/app/me/ledetail/crty00000000481076?url=common%2Flearningeventdetail%2Fcrty00000000481076%3Fcontext%3Duser&learnerId%3Demplo00000000035105&returnPage%3DMyPlan?learner...

The page has three tabs: "Paths", "Overview & Other Information", and "History". The "Paths" tab is active and shows a progress bar at the top indicating "100% Path Completed". Below the progress bar, a message states: "This path was used to acquire the certification."

The main content area lists 11 modules, each with a status and completion count:

- Module 1 Introduction to Navigating Human Research Ethics & Regulatory Review: Required (Complete 1 of 1) 1/1
- Module 2 Human Research Foundations: Optional 1/1
- Module 3 Key Concepts: Optional 1/1
- Module 4 Understanding Review and Approval: Optional 1/1
- Module 5 Vulnerable Populations: Optional 1/1
- Module 6 Informed Consent: Optional 1/1
- Module 7 HIPAA and Biomedical Research: Optional 1/1
- Module 8 Human Research Timeline: Optional 1/1
- Module 9 Compliance and Education: Optional 1/1
- Module 10 Reliance: Optional 1/1
- Module 11 Resources: Required (Complete 1 of 1) 1/1

At the bottom of the page, there is an "Overview" section with the text: "An overview of the most salient topics in human research protections and tips on conducting that work in the context of Northwestern University."

The Windows taskbar at the bottom shows the system tray with a temperature of 37°F, the name "Sunny", and the date and time: 8:06 AM 3/13/2025.

Lastly, thank you for your time and attention. Questions?

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