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

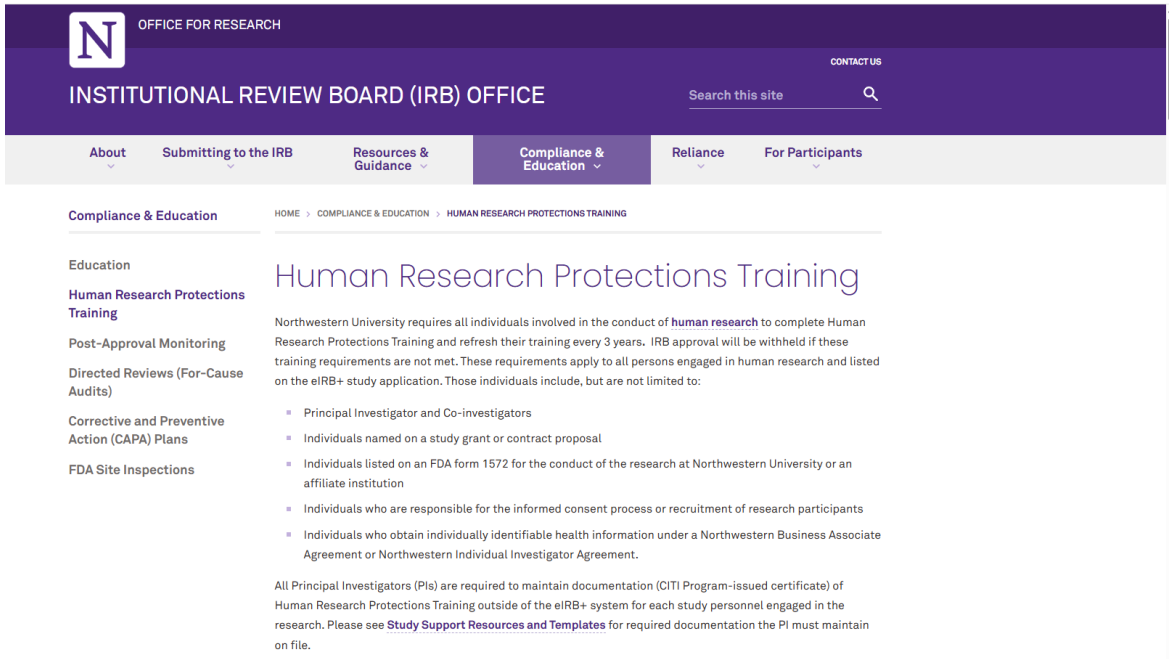
Overview of NU IRB resources

Allow time for questions

What are the pre-IRB application startup needs?

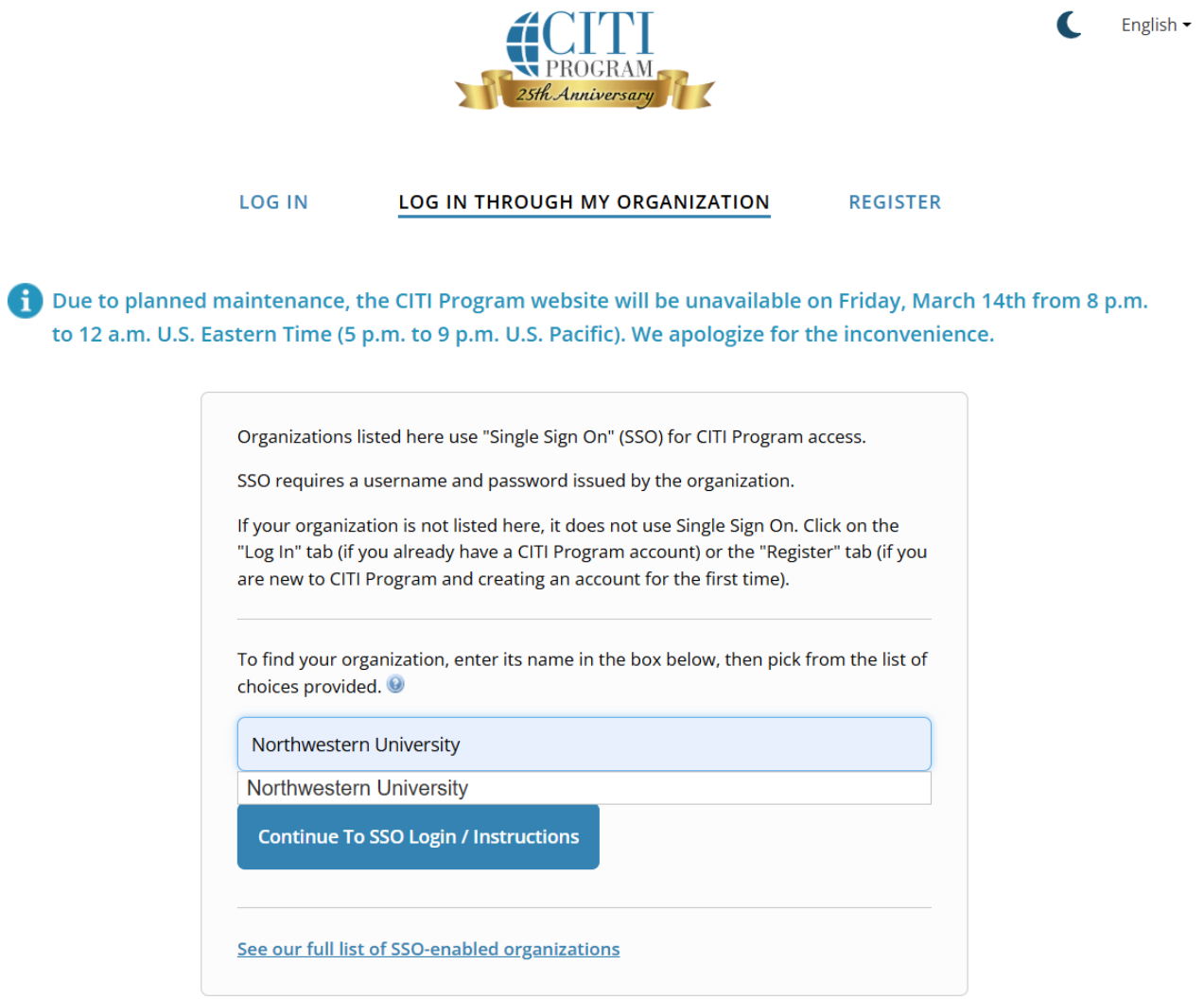
1. NU IRB Required: Human Research Protections Training Certification (good for 3 years)

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



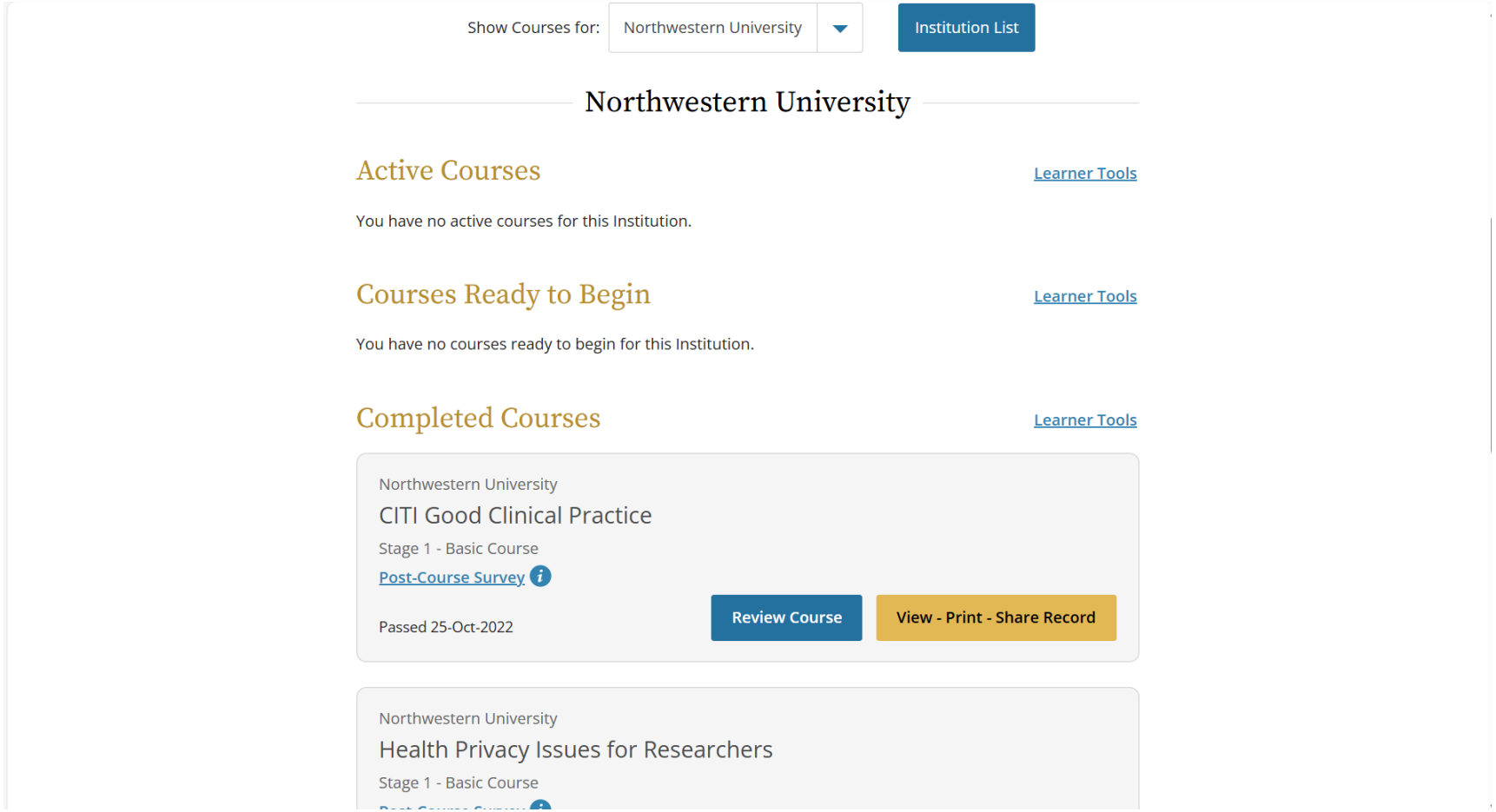
   Collaborative Institutional Training Initiative (CITI) Program
   https://www.citiprogram.org/?pageID=668

What are the pre-IRB application startup needs?



What are the pre-IRB application startup needs?

While you are at it…



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

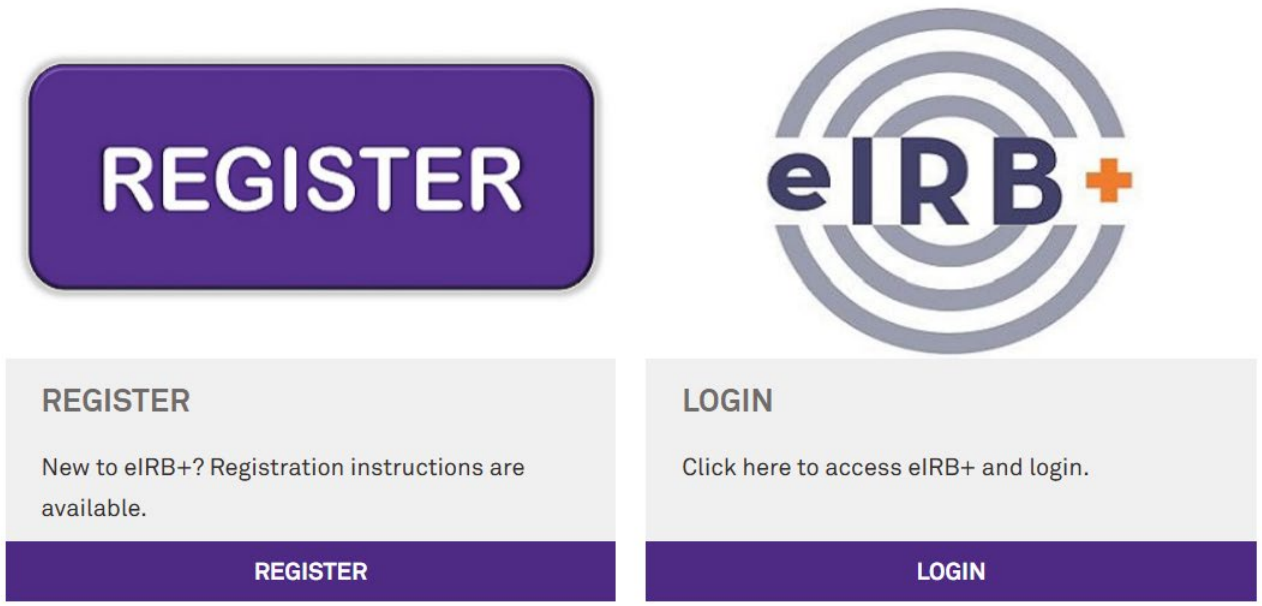
Good Clinical Practice (GCP) is an international, ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial 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

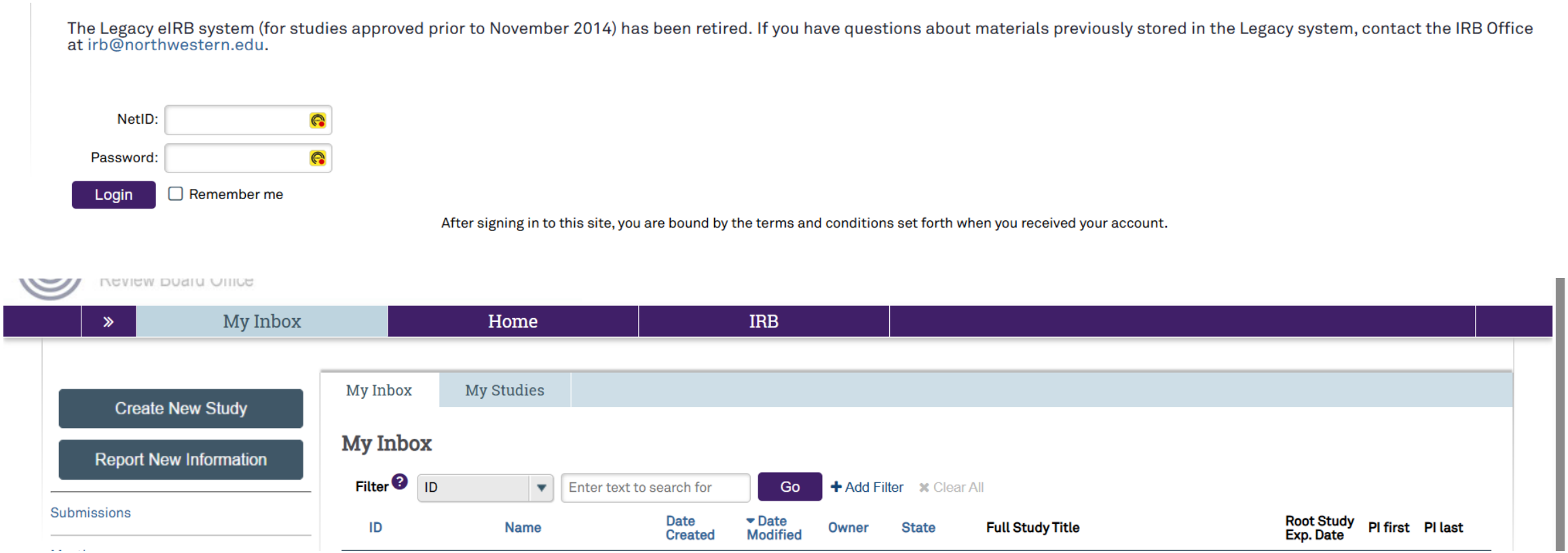
https://irb.northwestern.edu/submitting-to-the-irb/eirb/



Elements of the NU IRB Application

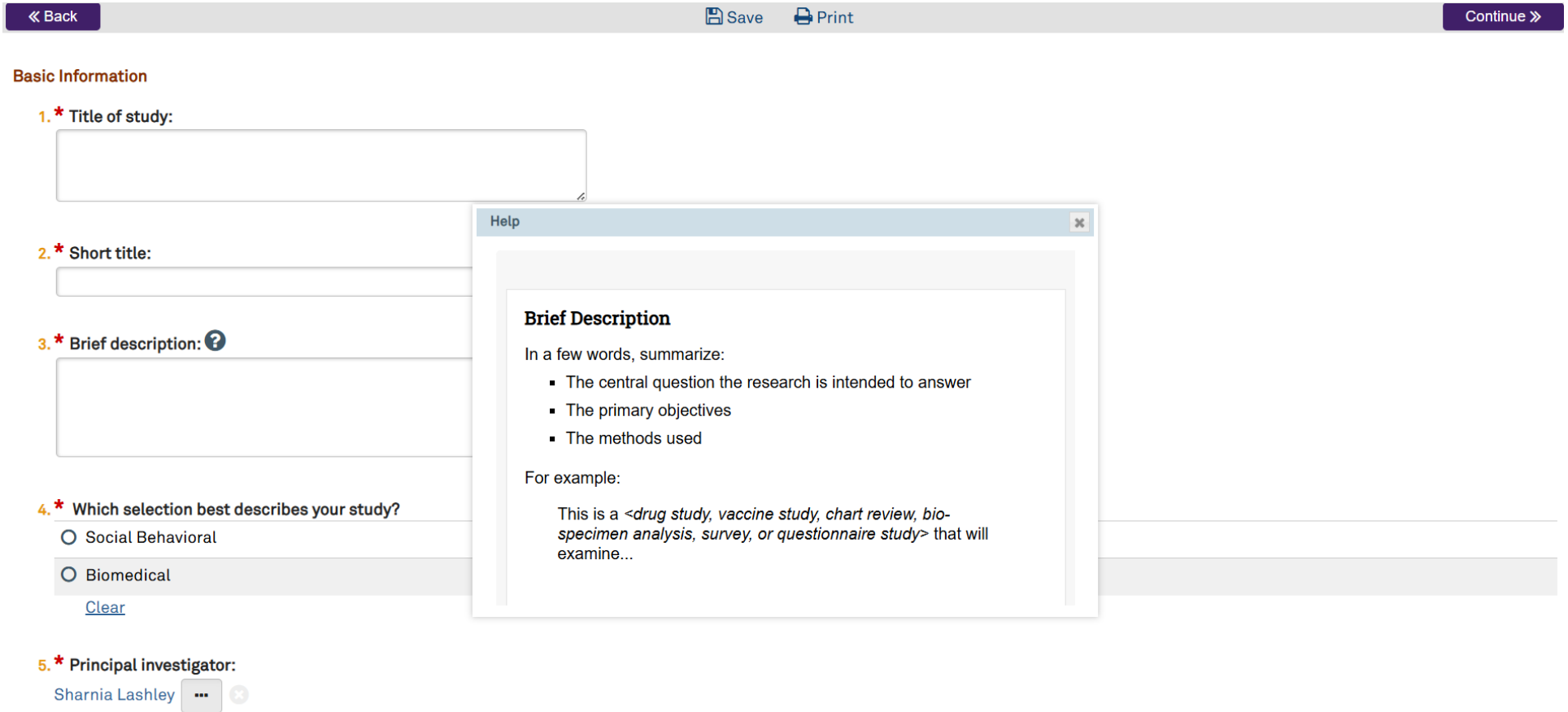
Login and Create New Study

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



Elements of the NU IRB Application

Basic Information Items 1-5



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:**

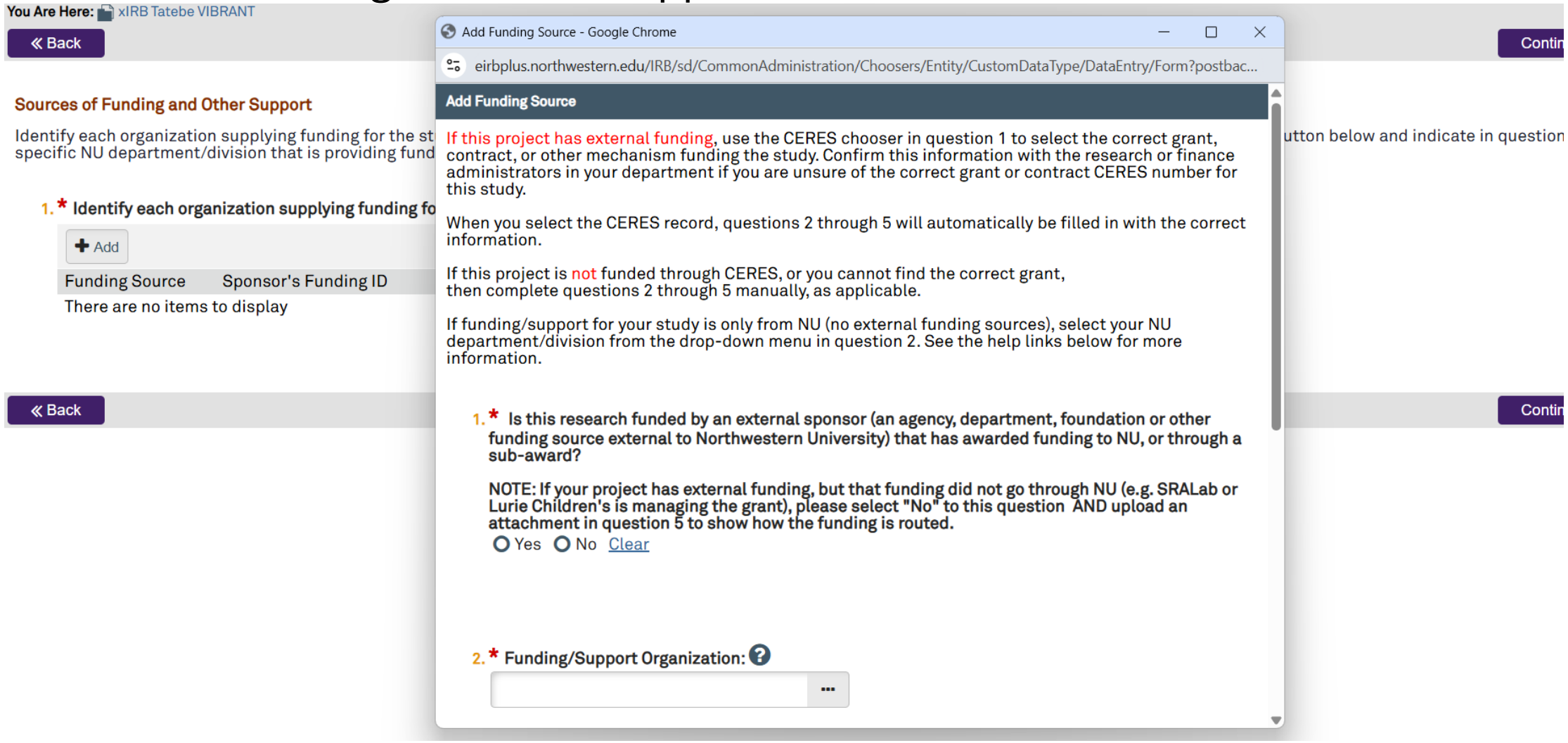
   ✚ Add

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

Protocol templates are available at https://irb.northwestern.edu/resources-guidance/protocol-templates-forms/index.html

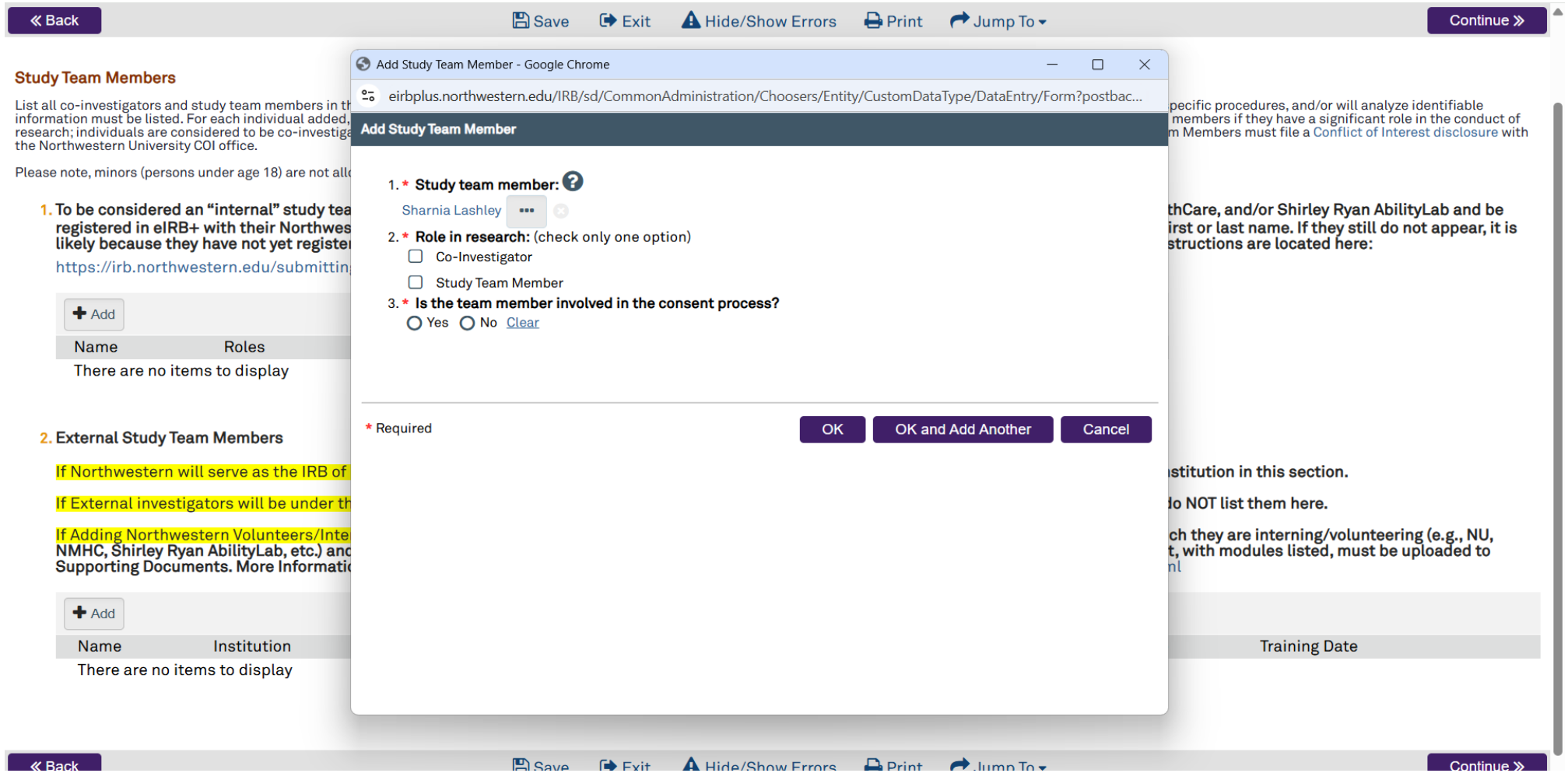
Elements of the NU IRB Application

Sources of Funding and Other Support



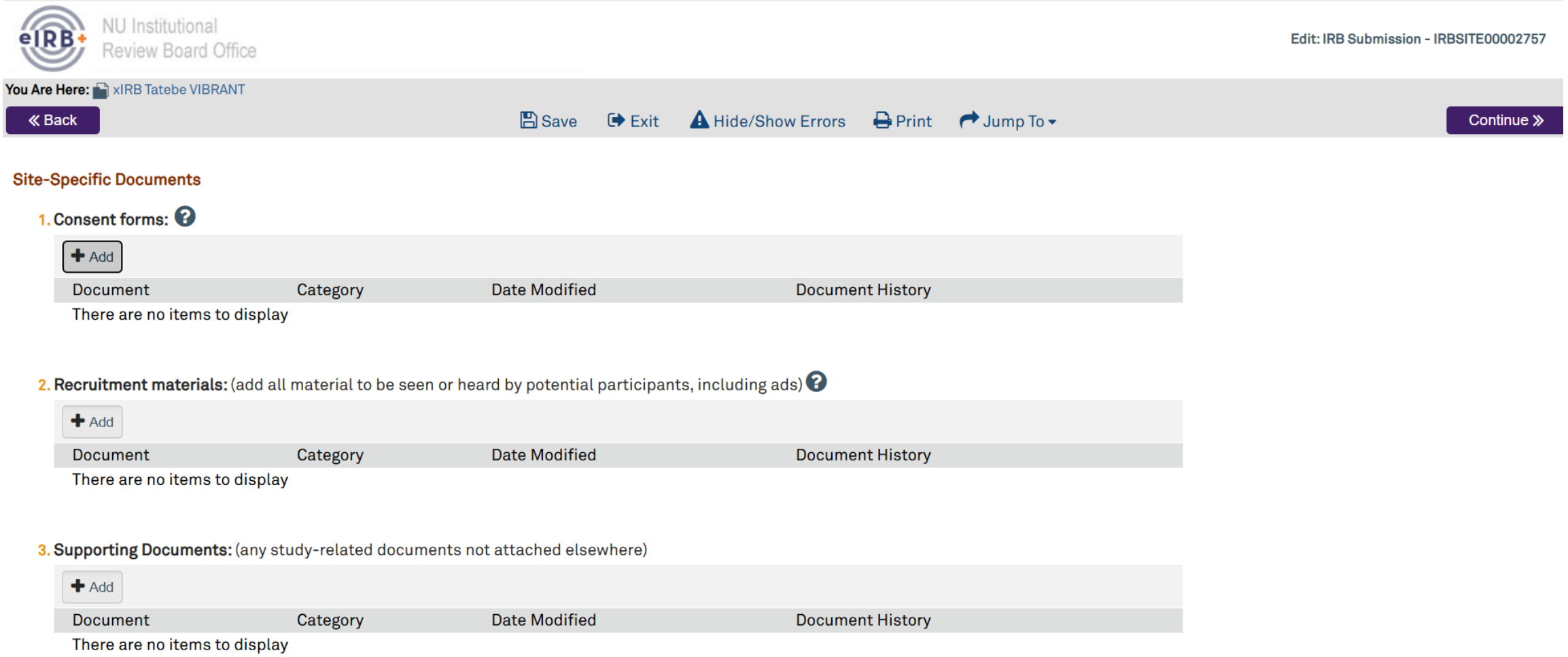
Elements of the NU IRB Application

Study Team Members



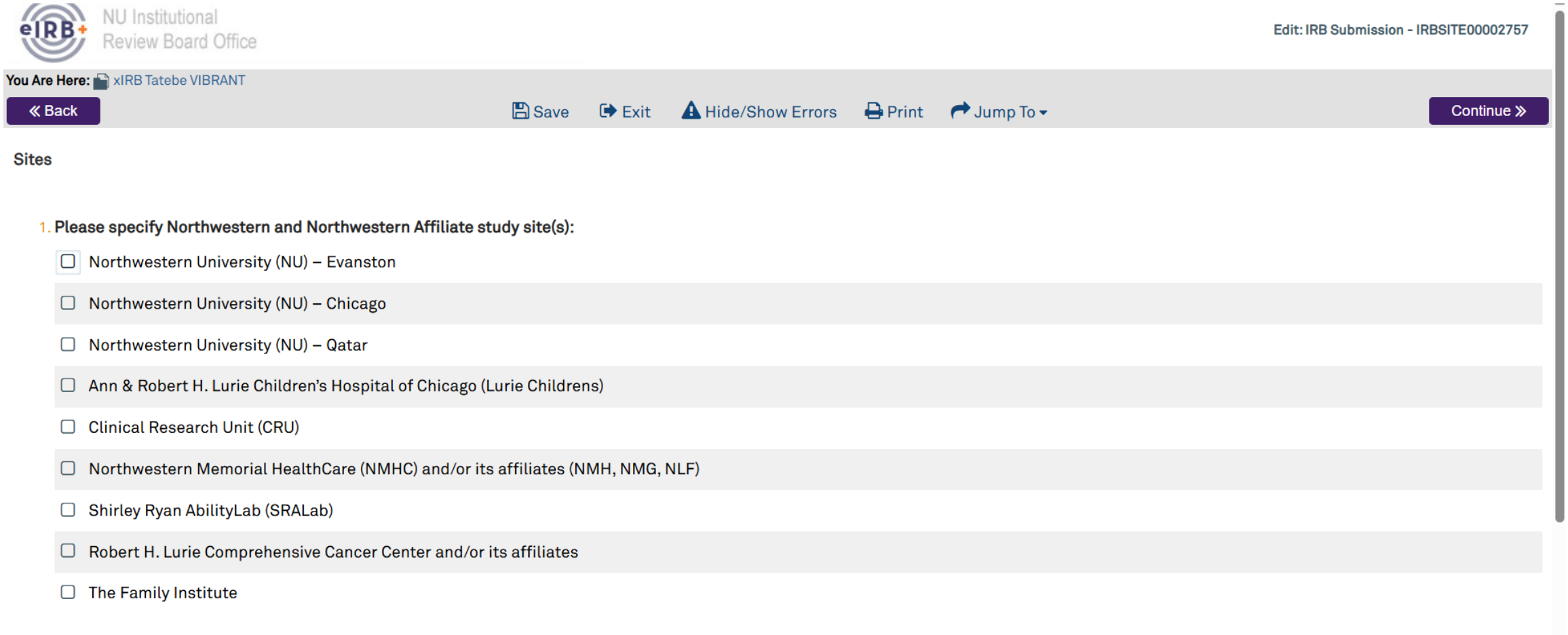
Elements of the NU IRB Application

Local Site Documents



Elements of the NU IRB Application

Sites



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 tl 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
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] Upload

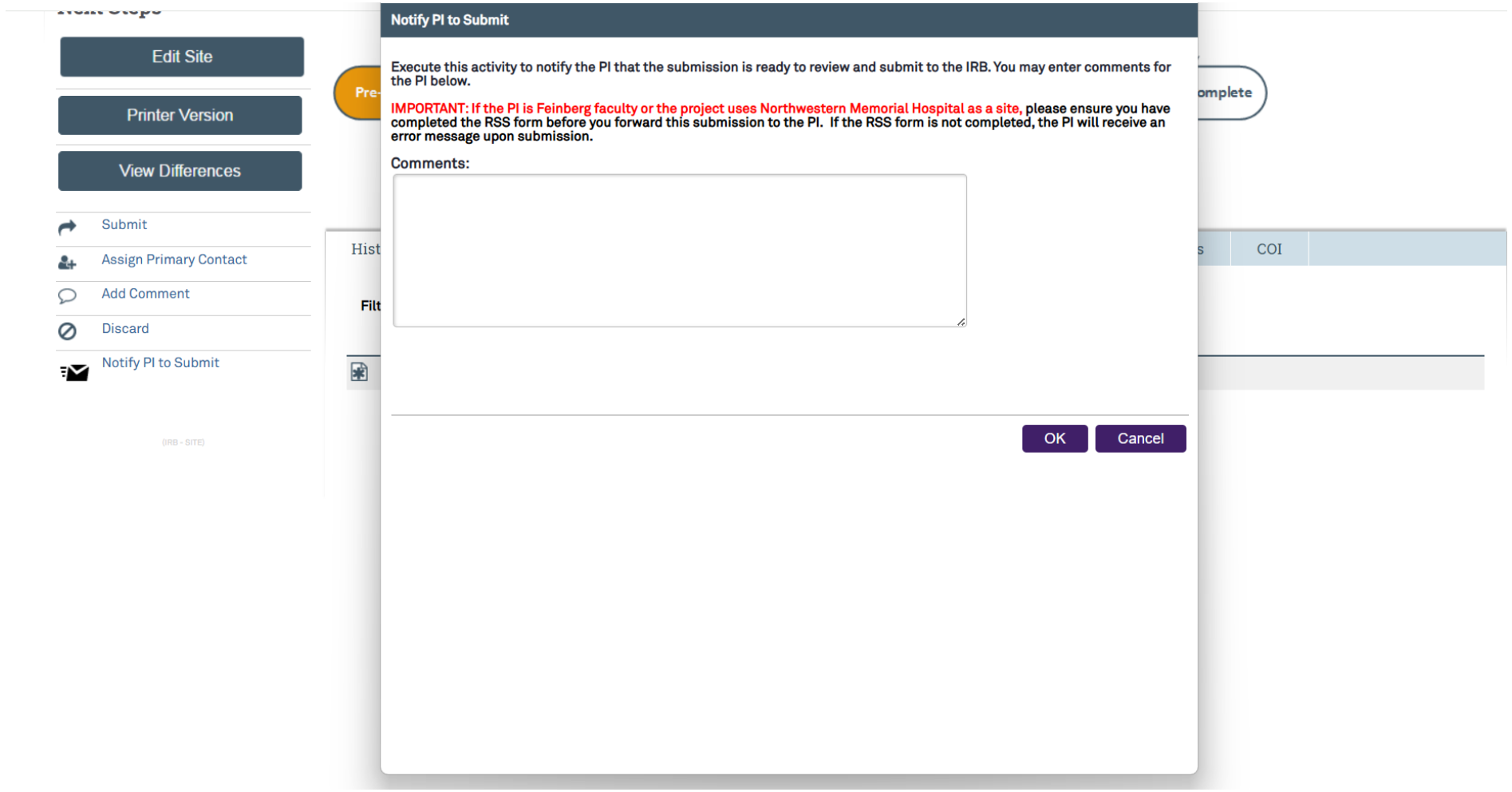
Technology Resources
Please address all questions and requests for IT resources required (e.g., storage and storage estimates, backup storage, archiving storage, granting access to date) of the Data Security Plan to FSMHELP@northwestern.edu.

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

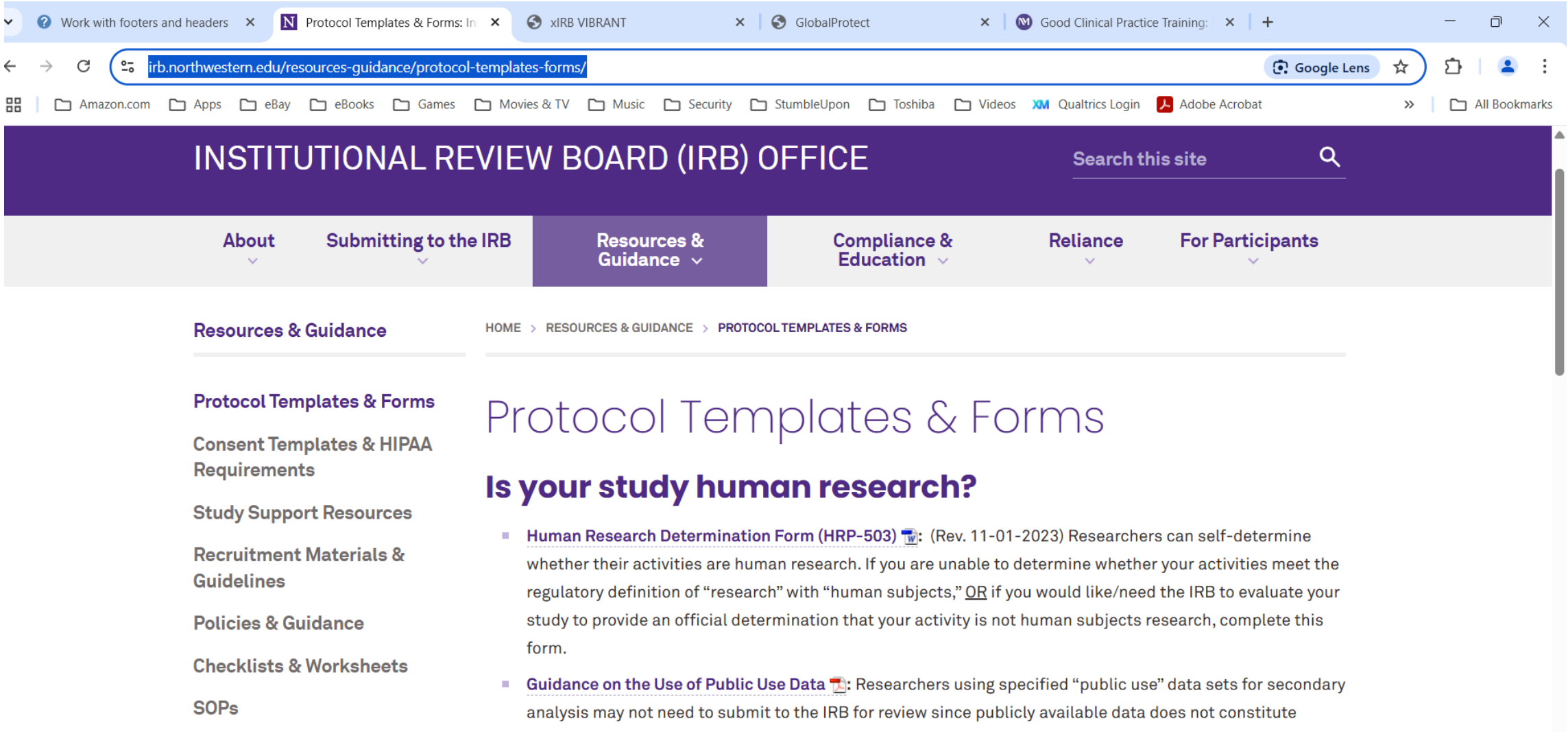
Elements of the NU IRB Application

Notify the PI to Submit



NU IRB Resources

Website Resources and Guidance - Protocol Templates



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.

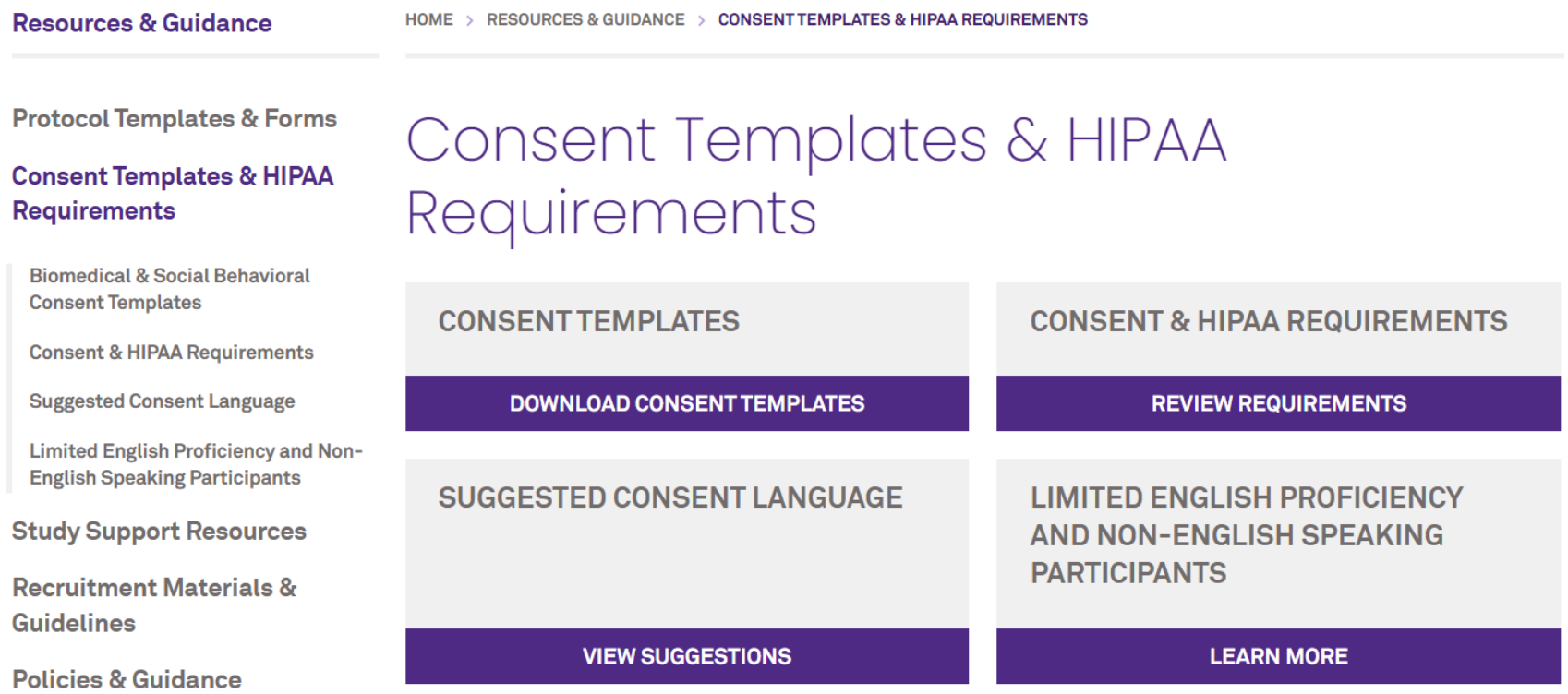
Social and Behavioral Research Templates

- **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 e sections that are contained in the biomedical template protocol.

Zoom

NU IRB Resources

Website Resources and Guidance - Consent Form Templates and Language



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

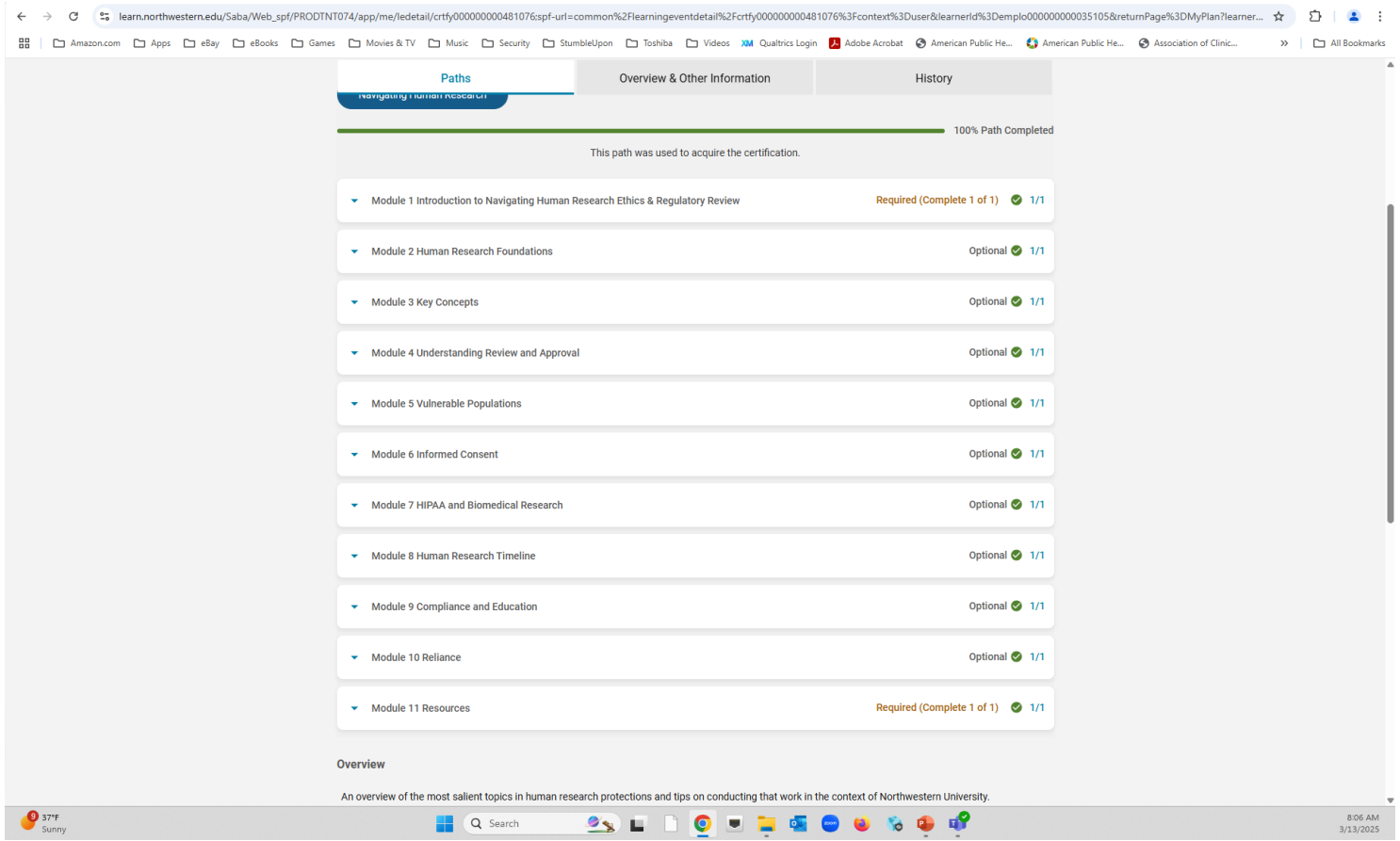
- Study title and IRB study number
- The word "research." Make it clear that this is a research study
- "Northwestern University"
- The PI's name
- A contact name with either a phone number or e-mail address
- Eligibility criteria, if applicable, should be noted briefly. Especially if payment depends 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



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

sharnia.Lashley@northwestern.edu

(312)503-3856