

Guide to the IRB Submission Process for Student Investigators

NOVA SOUTHEASTERN UNIVERSITY
INSTITUTIONAL REVIEW BOARD



IMPORTANT NOTICE:

- ▶ Research activities may **NOT** begin until the Principal Investigator has received an official IRB approval memo from the IRB Office.
 - An email or verbal statement of approval does **NOT** constitute official IRB approval.
- ▶ Investigators need official IRB approval to do **ANY** of the following research activities:
 - Contact potential participants.
 - Consent potential participants.
 - Enroll participants into the research study.
 - Obtain any data from or about participants.
 - Conduct any data analysis with participant data.
- ▶ Research begun prior to receiving official IRB approval is non-compliance and will be investigated by the IRB Office.

Steps for a Student Principal Investigator (PI)

1. Review the '[Information for Investigators](#)' page of the IRB website.
2. Obtain thesis/dissertation or faculty advisor approval.
3. Complete the required CITI Human Subjects Protection Training.
4. Create an IRBManager account and complete profile.
5. Submit the *Researcher Qualification xForm*.
6. Submit the *New Protocol Submission xForm* for IRB review.
7. Receive official IRB approval and begin research activities.
8. Follow all post-approval requirements.

NOTE: Forms are referred to as “xForms” in the IRBManager system.

1. Review Information for Investigators webpage.

- ▶ Before beginning the IRB process, review all the information on the '[Information for Investigators](#)' page of the IRB website.
- ▶ This page contains information regarding the steps in the IRB process and what is required from you, the investigator.
- ▶ Read this information carefully. If you have questions regarding the IRB process, please contact your [College Representative](#) for further guidance.

2. Obtain thesis/dissertation or faculty advisor approval.

- ▶ As a student you may not begin the IRB Process until you have either:
 - a. Obtained thesis/dissertation proposal approval.
 - b. Obtained approval from Faculty Advisor (if research is unrelated to thesis/dissertation).
- ▶ Once you have obtained the above departmental approval, you may begin the IRB submission process.

3. Complete the required CITI Human Subjects Protection Training

- ▶ **Required** for all study personnel, including thesis advisors/dissertation chairs.
- ▶ This training is a federal requirement to ensure that research activities are conducted in an ethical manner that protects the rights of human participants.
- ▶ This training must be taken every 3 years per NSU IRB policy.
- ▶ Further guidance can be found on our website at www.nova.edu/irb on the 'CITI Training' page.
- ▶ Register for CITI at www.citiprogram.org/.

4. Create an IRBManager account and complete profile

- ▶ The NSU IRB Office uses an electronic submission system called IRBManager which can be accessed at <https://nova.my.irbmanager.com/Login.aspx>.
- ▶ In order to submit a protocol for review, you must create an IRBManager account.
- ▶ After creating an account, you must complete your IRBManager profile.
- ▶ Further guidance can be found on the [IRBManager](#) page of the IRB website.

5. Submit the *Researcher Qualification xForm*

- ▶ The *Researcher Qualification Form* is where you provide your qualifications and your CITI Training information.
- ▶ All study personnel are **required** to complete and submit this xForm prior to submitting a protocol for review.
- ▶ Further guidance can be found on the [IRBManager](#) page of the IRB website.

6. Submit the *New Protocol Submission xForm* for IRB Review

- ▶ The *New Protocol Submission xForm* must be submitted to the IRB Office so your research protocol can be reviewed.
- ▶ Once you have submitted this xForm it will undergo the IRB Review Process as outlined in the next slide.
- ▶ Further guidance can be found on the [IRBManager](#) page of the IRB website.
- ▶ If you have questions, please contact your [College Representative](#).
- ▶ Visit the [Office for Human Research Protections \(OHRP\)](#) webpage to find decision charts that will assist with determining the level of IRB review.

NOTE: Submitting this xForm does not constitute IRB approval.

The review process is as follows*:

1. Review by Faculty Advisor/Dissertation Chair
2. Review by College Representative
3. Review by the IRB Office
4. Review by the IRB Chair

*The [IRB Process Maps](#) provide a visual overview of the IRB process.

NOTE: At any stage in the review process, a submission may be sent back to the PI for revisions.

7. Receive IRB Approval and begin research activities.

- ▶ Upon approved, you will received the following via email:
 - ▶ Official NSU IRB approval memo.
 - ▶ Stamped documents such as recruitment flyers and consent documents, etc. (for studies reviewed via expedited or full procedures)
- ▶ Once you have received these documents, research activities may begin.

NOTE: An email or verbal statement of approval does not constitute official IRB approval of your research protocol.

REMINDER:

Investigators may **NOT** approach **any** participants or work with their data until they have received an official IRB approval memo and stamped documents such as recruitment flyers and consent documents.

8. After you have received IRB approval

The following are post-approval requirements:

- ▶ File an Amendment xForm prior to implementing any changes to your study.
- ▶ Once a year, file the Continuing Review xForm if the study is still collecting or analyzing data.
- ▶ Submit a Closing Report xForm upon completion of all data related activities, including data analysis.
- ▶ Further guidance regarding the completion of these xForms can be found on the [IRBManager](#) page of the IRB website.

For more information

Visit the IRB website at:

www.nova.edu/irb

Our website has information to assist with:

- ▶ [CITI Human Subjects Protection Training](#)
- ▶ [IRBManager](#)
- ▶ [Information for Investigators & the IRB Submission Process](#)
- ▶ [Contacting your College Representative](#)
- ▶ [Reviewing NSU IRB Policies & Procedures](#)