

Institutional Review Board

# Researcher Handbook



2024-25

*Approved 2024.03.11*

**New in the 2024-25 Edition**

<u>Title</u>	<u>Brief Description</u>	<u>Page #</u>
NSU Site Request	To request permission for NSU employees and/or students to participate in a human subject study.	<i>9-10</i>
Individual Investigator Agreement	To apply to serve as a member of an NSU-sponsored study team (for researchers not currently affiliated with <u>any</u> institution).	<i>10</i>
Public Data Sets Policy <b>(NOTE: Not yet approved by NSU IRB)</b>	To apply to obtain NHR (Not human Subjects Research Determination) for a study employing Public Data Sets (PDS).	<i>16</i>
Data Use Policy	To request permission to use data from NSU-owned databases in a human subject study.	<i>16</i>

## NSU IRB Review Process

### Reviewer Checklist

1. Read the 2024-25 NSU IRB Research Handbook (this document).
2. Register with CITIprogram.org; complete the required training certificates.
3. Plan the study in detail from beginning to end (consult with the NSU IRB Office).
4. Watch the NSU IRB YouTube video (<https://www.youtube.com/@NSUIRB>).
5. Log in to Mentor (see the NSU IRB website for instructions:  
<https://www.nsula.edu/irb>).
6. Fill out the appropriate IRB application\* and electronically sign it.
7. Wait for the NSU IRB approval decision
8. If the study is approved: begin the research work.  
*If not yet approved: Make the required revisions, resubmit the application, and wait for the approval decision.\*\**
9. Close the study in Mentor (Occurs when data collection from ALL human subjects ends).
10. Store all study data safely and securely for a minimum of three years.

\*All researchers who seek approval from the NSU IRB to conduct a study *with one or more human subjects* must, **at minimum**, fill out either the Quality Improvement Application or the NHRD Determination Questionnaire. The Exempt, Expedited, and Full Board application forms are much longer, take more time and effort to complete, and require an extended time frame to review.

*The NSU IRB does not recommend filling out the longer forms unless the researcher is certain that the study requires it. If uncertain, contact the NSU IRB Office for consultation.*

\*\*The study cannot begin until the researcher receives the official NSU IRB approval letter.

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# NSU IRB REVIEW PROCESS

**Required**

**If Necessary**

**STEP 1**



**NHSR  
Review**



**STEP 2**



**Intake  
Review\***



**STEP 3**



**Formal  
Review**



**STEP 5**



**Study  
Closed**



**STEP 4**



**Post-  
approval  
Monitoring**



\*Intake Review = Paperwork completion check.



## I. NSU Institutional Review Board: Mission

The mission of the Northwestern State University Institutional Review Board (IRB) is to ensure the rights and welfare of every person who may be involved in NSU-sponsored research as a human subject. Our guiding values are “respect for persons,” “benevolence,” and “justice,” the ethical principles first described in *The Belmont Report*, which has informed U.S. federal law and public policy concerning research with human subjects for more than four decades.<sup>1</sup>

## II. NSU IRB Review System

### A. Definitions of Key Terms (listed in the order first used in this Handbook)

--*Research Protocol*: Any systematic procedure for gathering and/or analyzing data to explore or investigate a specific research question or program improvement need.

--*Human Subject*: A living person who engages in the protocol to provide data, intended to help investigate the research question or program improvement under study.

--*Principal Investigator (PI)*: The person primarily responsible for designing and implementing the research protocol (NOTE: A Co-PI is not the same as the PI).

NOTE: NSU standard practice allows a student researcher to serve as the study PI, but NSU IRB policy requires that a Faculty Advisor approved by the student’s major department must be assigned to oversee the protocol activities that the student conducts, especially all activities involving the human subjects who will participate in the study.

### B. The Review Process: Step-by-Step-Overview

All NSU-sponsored research protocols involving any human subject in any way must be approved by the NSU IRB before any protocol activities may begin. This includes the recruitment of human subjects and the collection of study data (e.g., surveys, focus groups, one-on-one interviews, etc.), whether administered face-to-face or online.

1. *Training*: All NSU personnel responsible for planning, implementing, overseeing, and/or approving the research protocol<sup>2</sup> must complete the required training courses at [CITIprogram.org](https://www.citi-program.org) or have currently valid (unexpired) training certificates while the study is active. As of 6/1/2022, the required courses are:

a. **The appropriate research ethics course**: Complete either “Social & Behavioral Research” or “Biomedical Research.”

b. **Conflicts of Interest (COI)**.<sup>3</sup>

2. *Protocol Plan*: The systematic study of a research question or quality improvement need requires a specific, step-by-step, protocol plan. Use the information gained in training (see Step #1, above) to plan for the protection of human subjects and document those plans in detail. Applying for NSU IRB approval without a detailed plan will require more time later to provide the necessary information.

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<sup>1</sup> See *The Belmont Page* (1978). For the federal law that governs U.S. IRBs (45 CFR Part 46; also known as “The Common Rule”), see <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html>

<sup>2</sup> All persons involved in the administration of a human subject research protocol, including the PI (and any Co-PIs) and faculty advisors (if applicable) must complete the two training courses before a protocol can be reviewed by the NSU IRB.

<sup>3</sup> CITI Program offers several different COI courses; the NSU IRB recommends the “Conflicts of Commitment and Conscience” course for all principal investigators and faculty advisors. However, any of the COI courses offered by CITI Program will be accepted by the NSU IRB.

3. *Determination of Human Subjects Research:* The PI must complete the Non-human Subjects Research (NHSR) Determination Questionnaire; the IRB will determine if the protocol (see Step #2) involves “human subjects research”--*as defined by federal law*--and must undergo IRB review. There are two possible determinations:
  - a. **Non-human Subjects Research (NHSR):** If the IRB Office determines that the protocol as planned does not involve human subjects research as defined in the federal regulations, a letter will be sent to the PI stating that decision. In that case, NSU IRB review is not required; the protocol may begin after receiving the official NHSR letter. STOP HERE; DO NOT proceed to Step #4.<sup>4</sup>
  - b. **Human Subjects Research (HSR):** If the IRB Office determines that the protocol as planned does involve human subjects research, a letter will be sent to the PI stating that decision. In that case, NSU IRB review is required, and the PI must submit the required IRB application form. PROCEED to Step #4.
4. *IRB Protocol Application:* The PI completes the appropriate IRB Application form, which will be sent through the NSU IRB review process.
  - a. **Do not write “Not Applicable”:** When completing the forms, do not write “Not Applicable” to answer any question. All requests for information on the application form must be answered with specific information. Incomplete information will result in the application being returned for revision.
  - b. **Do not leave any section or question blank:** A blank section or question also results in the application being returned for revision.
5. *Approving Agents:* The PI must obtain the approval of their assigned faculty advisor, research coordinator,<sup>5</sup> department head, and/or Dean. The correct Agent may depend on the research policy of the NSU academic department or College.
6. *Application Submission:* The PI submits the application, and all required supplemental documents to the NSU IRB submission system.<sup>6</sup>
  - a. **Save each file separately:** When submitting an IRB application, save each supplemental document (e.g., Informed Consent forms, survey instrument. Site permission letter, etc.) as a separate file. Do not save the documents one file.<sup>7</sup>
  - b. **Use PDF format:** For each separate file, save it in Adobe PDF format. Do not use any other file format.
7. *IRB Decision Letter:* A letter communicating the IRB decision regarding the protocol will be sent to the PI (and the faculty advisor, if applicable). The IRB decision will be one of the following:
  - a. **Approval:** The NSU IRB approved the protocol as written and the study may begin. The letter may include the Protocol Close Date (see #8 and #9, below).

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<sup>4</sup> NSU has a new policy for one type of NHSR study, called “Public Data Sets.” See the “Appendices” for more information.

<sup>5</sup> For College of Nursing faculty, staff, and students, the Nursing Scientific Research Committee (SRC) serves as the research coordinator.

<sup>6</sup> See Part III for instructions to submit the IRB application materials to the NSU IRB.

<sup>7</sup> NSU has a new policy called “Data Use,” which involves one type of supplemental documentation. See the “Appendices” for more information.

- b. **Conditional Approval:** Before the protocol may begin, the PI must revise application to meet the conditions required by the IRB. The application may be resubmitted at any time and does not have to meet the regular IRB deadlines. However, if all conditions are not met, the HRPP Director or IRB Chair may elect to have the entire IRB membership, or a subcommittee review the application to determine the recommended action. Procedures for conditional approval include:
  - i. Resubmit the entire IRB protocol application with the specified changes;
  - ii. Provide all appropriate signatures;<sup>8</sup>
  - iii. Provide all required supplemental documentation.
- c. **Resubmit:** The PI must revise the entire application to address the issues identified by the IRB and resubmit under the appropriate guidelines for either “Full Board” or “Expedited” review. Procedures for submitted protocol reviews include:
  - i. Resubmit the entire application with specified changes;
  - ii. Obtain the appropriate signatures;
  - iii. Provide all required supplemental documentation.<sup>9</sup>

8. *Protocol Close*<sup>10</sup>: No later than 10 business days (not including holidays) after the protocol is closed by the PI or the protocol Close Date is reached<sup>11</sup> (whichever occurs first), the PI must notify the IRB Office that the study is officially closed. *To extend the Close Date, see Section C.2.*

9. *Protocol Data Management:* After the protocol officially closes, all data generated from the human participants must be stored and maintained securely for three years and accessible only to the PI (and Co-PIs, if applicable).

### C. Changes in Active Protocols<sup>12</sup>

- 1. *Amendments:* Any change to an IRB-approved and currently active protocol must also be approved by the NSU IRB. The PI must suspend the protocol immediately, complete the Amendment Request form, and submit it to the IRB for approval. The protocol cannot recommence until written approval for the Amendment is received.
- 2. *Continuation of an Approved Protocol:* If a previously approved Full Board protocol needs to continue past the original completion date, the PI must submit the Amendment Request form. The NSU IRB must approve the application before the protocol can continue.

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<sup>8</sup> For both Conditional Approval and Resubmit applications, the required Approving Agent(s) must sign the revised application.

<sup>9</sup> A resubmitted protocol will be reviewed as a new application.

<sup>10</sup> “Protocol Close” occurs when all recruitment of and data collection activities from human subjects have ceased and all human subjects have been dismissed from the study.

<sup>11</sup> Full Board protocols have an assigned Close Date, typically 365 days after the approval date. Exempt protocols do not have a completion date and can continue indefinitely; however, the PI must still inform the IRB of the protocol close.

<sup>12</sup> The forms mentioned in Section C. 1. 4 are located on the NSU IRB website: <https://www.nsula.edu/irb>



3. *Adverse Events*: If adverse events or effects on any participant are detected at any time during the study by the PI, other research personnel, human subjects, or IRB members, the protocol must be suspended and the NSU IRB Office informed immediately. The HRPP Director will contact the appropriate personnel (i.e., PI faculty advisor, dept. head, Dean, and/or the Institutional Official) and inform them in writing. The PI must then complete an Adverse Event Report to recommend action(s) to resolve the situation and submit it to the NSU IRB. The protocol cannot recommence until the IRB approves the PI's recommendations (NOTE: The HRPP Director and/or IRB Chair can also make additional recommendations or amend the PI's recommendations). If disapproved, the protocol is terminated immediately.
4. *Continuing Review*: If, during a continuing review of a Full Board-approved protocol, the IRB reviewer(s) finds areas of concern, the protocol must be suspended immediately. The HRPP Director will contact the appropriate personnel (i.e., PI, faculty advisor, dept. head, Dean, and/or the Institutional Official) and inform them in writing. The PI must then complete the Continuing Review form and submit it to the IRB. The protocol cannot recommence until the IRB approves the Continuing Review. If disapproved, the protocol is terminated immediately.

### III. NSU IRB Online Application Submission Systems (Sitero Mentor): Procedures

- a. Nursing students, faculty, and staff: the application filled out in Mentor is first routed to the Nursing Scientific Research Committee (SRC). Once the protocol is approved by the SRC and the CONSAH Dean, the application is routed to the NSU IRB for review. IRB approval is required before the protocol may begin.
- b. Allied Health students, faculty, and staff: the application in Mentor is routed directly to the IRB.
- c. All other NSU students, faculty, and staff: the application in Mentor is routed directly to the IRB.

(NOTE: To Log in to Sitero Mentor: <https://www.axiommentor.com/login/axlogin.cfm>. Instructions on how to use the Mentor system are available on the NSU IRB webpage (<https://www.nsula.edu/irb>) and YouTube channel (<http://www.youtube.com/@NSUIRB>).

### IV. Unaffiliated Researchers

#### A. NSU Site Request for External Investigators Proposal Policy

If a researcher not affiliated with NSU as a faculty, staff, or student wishes to use NSU students and/or personnel for a human subject research study, the following procedure is required to request that approval:

- i. The researcher must have approval (or seeking approval) for the study from another IRB. The approval letter from the other IRB must be filed in the NSU IRB application file in Mentor prior to the start of the study.
- ii. The researcher must send a letter (or email) from their institutional account to [irb@nsula.edu](mailto:irb@nsula.edu) requesting the site approval. The message must include:

1. A description of the study purpose
2. The location of the study (at a specific NSU campus location or online)
3. The human participants to recruit (e.g., NSU undergraduate students, School of Business faculty)
4. The study procedure (e.g., participants will fill out a 15-minute survey)
5. The data categories to be collected, how the data will be collected (e.g., online in Survey Monkey), and whether any data is personally identifiable information (PII).

If the above information is provided at least 60 days before the study start date, the NSU IRB will consider the site request and provide a signed and dated letter communicating the decision.

B. Individual Investigator Agreement (IAA)

- i. For researchers who are not NSU faculty, staff, or students, and who are not affiliated with any other research institution, the NSU IRB requires that the researcher reviews and signs an Individual Investigator Agreement (IIA). The IIA form is available from the NSU IRB Office.
- ii. The document provides university and NSU IRB policies concerning the conduct of researchers who work on university-sponsored research studies. The researcher must agree to all stipulations shown in the IIA and follow them throughout the course of the research until the study Close Date. The document is only valid when it has the electronic signature of both the researcher and the NSU IRB Institutional Official (IO), who authorizes the work of all researchers at the university.

## Appendices

### Appendix A

#### **NSU IRB Application & Review Process: Additional Information**

##### Informed Consent Form: Guidelines Social, Behavioral, & Education Research

- I. Required Elements
  - A. A statement that the activity involved a research study.
  - B. An explanation of the purpose(s) of the study.
  - C. A statement concerning any conflicts of interest for the researcher (s).
  - D. The expected length of the study (days, weeks, or months);
  - E. A brief description of the research procedures to be followed and identification of any procedures that are experimental.
  - F. A description of any reasonably foreseeable risks or discomforts to the participant.
  - G. A description of any benefits to the participant or others which may reasonably be expected from the research (NOTE: If none, say so).
  - H. A statement describing the procedures designed to maintain confidentiality and privacy of the participant's records.
  - I. A statement that participation is voluntary and refusal to participate will not involve any penalty or loss of benefits.
  - J. A statement that the participation may drop out of the study at any time without penalty.
  - K. A statement that the participant may request to have their data removed from the study.
  - L. Contact information for the researcher (email) and the NSU IRB Office (email: [irb@nsula.edu](mailto:irb@nsula.edu); phone: (318-357-5228) in case the potential participant has questions.
  - M. One of the following two statement concerning identifiable private information:
    1. A statement that identifiers may be removed from private information and that such data could be used in future research studies.
    2. A statement that the participant's data, even if identifiers are removed, will not be used or distributed for future research studies.

\*Other, optional elements/information can be included in the Informed Consent/Assent form is desired (see <https://www.hhs.gov/ohrp/regulations-and-policy/regulation/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116>, especially Part C, for more information). *The general guideline: Include everything that the potential participant needs to know in order to make an informed decision about whether to participate in the study or not.*

## **Informed Consent/Assent Form: Guidelines**

### **Organization & Formatting**

- I. Organization
  - A. The Informed Consent form has three major sections:
    - i. Key information
    - ii. Detailed Information
    - iii. Signatures page
  - B. Major sections- Descriptions
    - i. Key Information: A brief summary of the most important aspects (from Required Element, see page 1) sections A., B., C., D., E., H., and I. The bullet points should be limited to 5-7 items of one to two sentences each.
    - ii. Detailed Information: Complete information for all Required Elements. This section could be multiple pages in length, but shorter is better (see Section III., below).
    - iii. Signatures page:
      - a. A statement that the person who signs the form has read it, understood it, is satisfied that all questions and concerns have been answered, and agrees to all requirements for the study.
      - b. Signature and date lines for the participant and the researcher; signatures indicate agreement to implement the Consent Form.
- II. Formatting
  - A. Font: 12. Color: Black. Style: Time New Roman
  - B. Margins: At least 1 inch on all four sides of the page; wider margins may improve readability.
  - C. Line spacing: At least 1; more may be better.
  - D. Paragraphs: Double-space between paragraphs.
  - E. Whitespace: Enough to make reading easier.
- III. Readability

The Informed Consent Form must be readable for the intended human subjects. 10-year-old study participants have different reading abilities than 30-year-olds. To check for readability:

  - A. Go to this web page: <https://charactercalculator.com/flesch-reading-ease/>.
  - B. Copy the text of the Informed Consent form into the readability score calculation box.
  - C. The readability scores will appear immediately (there are four of them).
  - D. If the “Grade Level Score” is too high for the intended subjects, revise the text until the desired score is achieved (*see NOTE below*).
  - E. As much as is possible, use common, everyday vocabulary (not technical terms), short, active voice sentences, and words with only one or two syllables. Technical terms used must be defined in a way that the reader can understand.

NOTE: For studies involving average adult human subjects, the NSU IRB recommends that the target “Grade Level Score” score is 8<sup>th</sup> & 9<sup>th</sup> grade; the equivalent “Reading Score” is 60-70

(called “Plain English”). See the chart at the bottom of the webpage for the complete readability scoring scale.

- F. When the target Grade Level Score is reached (or lower), take a screenshot of the readability calculator webpage and include all four scores (Reading Score; Reading Level; Grade Level Score: and Reading Note). Save the screenshot in a PDF file and include it as a supplemental document with the IRB application.

### **Child Assent Form: Additional Guidelines**

If participants in your study will be minors, you will need to develop an Assent Form for the minors to complete *in addition to* an Informed Consent Form for parents/guardians to sign.

An assent form is different from an informed consent form and is specifically designed to simply indicate that the minor is willing to participate in the study and understands what he or she will be expected to do as part of the study.

#### **Process questions include:**

- a. Will you obtain signed assent or request a Waiver of Informed Consent? (Note that unless a waiver is justified by the PI and approved by the NSU IRB, informed consent shall always be documented by the use of a written consent form approved by the NSU IRB and signed by the participant's legally authorized representative.)
- b. Will you seek assent with a written form and/or an oral briefing? (For children younger than 7, it may not be possible for them to read and comprehend a written document that asks them to assent to participate in a study. In that case, an oral briefing is required.)

#### **Contents elements include:**

- a. All of the required elements shown in the NSU IRB "Informed Consent Form: Guidelines for" document are included in the Assent Form or oral script.
- b. In addition, all of the following elements must be included in the Assent Form or oral script before submission to the NSU IRB for review:
  - All of the information in the Assent Form or oral script is consistent with the information in the study protocol.
  - The form or oral script is written in an easy-to-read format that uses language and vocabulary appropriate to the age of the participants. (A good guideline: the assent form should be written at a 2<sup>nd</sup> or 3<sup>rd</sup> grade reading level.)
  - A final assent statement and place for date and signature is included. (OR, if Waiver of Informed Consent is sought, a place to indicate assent is included.)

#### **Procedure elements include:**

- a. A copy of the form shall be given to the person who signed it—the child or the legally authorized representative.
- b. The copy with the original signature will be kept with the principal investigator's research records.

### **Debriefing Form: Guidelines**

The Debriefing Statement is provided to study subjects after study is completed. The purpose is to inform the subject of the purpose of the study and its methods, allow the opportunity to withdraw their data from the study, provide information for the researcher and the NSU IRB, and to thank the subject for their involvement in the study.

The Debriefing Statement must be written **in non-technical language**; if technical terms must be used, define them in everyday language whenever possible. The Debriefing Form must also be checked for readability before being distributed to the study subjects. To calculate readability, see the “Guidelines: Informed Consent/Assent Forms” document (Appendices).

The Debriefing Statement must include the following:

1. The questions, hypothesis, and issues that motivated the research.
2. The background leading to the research question being studied.
3. An explanation of how the data gathered from that participant will be used to address the hypothesis
4. An opportunity to withdraw their data from the study.
5. An opportunity to be informed of the results of the study. You can say, “If you would like to receive a report of this research when it is completed (or a summary of the findings), please contact *(name)* at *(e-mail.)*”
6. Contact information for the researcher (to request a copy of the study result, request to drop their data from the study, etc.)
7. Contact information for the NSU IRB in case there are questions about the research.
8. An accessible reference for further reading. *This reference must be found easily by the research participants via the web and must be written in non-technical language.*
9. Thank the human subject for participating in the study.

### **Research with Public Data Sets**

The collection and use of data from public data sets (PDS) is not considered human subject research if the following three criteria are met:

- a. The researcher will NOT merge any of the PDS so that individuals might be identified.
- b. The researcher will NOT enhance any PDS with personally identifiable data (PII) or potentially identifiable data.
- c. The data host does NOT require the researcher or the researcher's institution to sign a Data Use Agreement.

If the above three criteria are met and the research will involve data collected from the NSU IRB Approved PDS List, the study will qualify for NHSR designation.

NOTE: The current Approved Public Data Sets List is located on the NSU IRB web page: <https://www.nsula.edu/irb>.

### **Data Use Policy**

Data from NSU-owned databases can be approved for use in an NSU IRB-approved research study if the following three criteria are met:

- a. The data must not include NSU students or personnel under 18 years old or any student, faculty, or staff member who has requested "Confidential" status for their NSU data.
- b. The NSU IRB must approve the collection and use of the data for the study, in accordance with federal regulations regarding data privacy and human subject protections.
- c. The data categories requested must be approved by the University Registrar.

If the above criteria are met, the data will be approved for use in the study. The Registrar will then authorize the dissemination of the requested data to the principal investigator (PI).



## Appendix B

### NSU IRB Training Policy

(Rev. 2023. 07. 13)

<i>Previous Policy (1/01/2019-5/31/2022)</i>				<i>Revised Policy* (As of 6/01/2022)</i>	
<b>PI Type</b>	<b>Field</b>	<b>1<sup>st</sup> Certificate</b>	<b>2<sup>nd</sup></b>	<b>1<sup>st</sup> Certificate</b>	<b>2<sup>nd</sup></b>
Faculty/staff	Biomed.	Biomed.	RCR**	Biomed.	COI^
Faculty/staff	Soc./Behav.	S&BR	None	S&BR	COI^
Student	Biomed.	Biomed.	None	Biomed.	COI^
Student	Soc./Behav.	S&BR	None	S&BR	COI^
IRB Member	Any	IRB Member#	None	IRB Member#	COI^

#### Notes

\*A current NSU PI will follow the Previous Policy until the RCR certificate expires; a new PI (as of 6/01/2022) will follow the Revised Policy.

\*\*Under the Revised Policy, RCR is no longer required but is still recommended. NOTE: NIH, NSF, and USDA require RCR training for grant-funded studies.

^^“Conflicts of Commitment and Conscience” certificate is recommended for NSU PIs and all IRB members: “Financial COI” certificate is required when a PI and/or the institution has a *financial interest* in the protocol (e.g., grant funding; intellectual property).<sup>13</sup>

#“IRB Member” certificate is for those w/IRB voting privileges; IRB Chair and Institutional Official (IO) roles require separate certificates from CITIprogram.org.

#### CITIprogram.org Certificates<sup>14</sup>

Biomed. = Biomedical Research

S&BR = Social & Behavioral Research

RCR = Responsible Conduct of Research

COI = Conflicts of Interest

#### Other Abbreviations

PI = Principal Investigator

NIH = National Institutes of Health

NSF = National Science Foundation

USDA = U.S. Department of Agriculture

<sup>13</sup> The IRB reserves the right to require additional training for a specified protocol.

<sup>14</sup> Recertification policy: the NSU IRB requires recertification within five years of the certificate award date.

## Additional Training Resources For Researchers

- I. CITI Program Training- Additional Topics<sup>15 16</sup>
  - A. Conflicts of Interest (COI):
    - a. Financial Conflicts of Interest: Overview, Investigator Responsibilities, and COI Rules- Course ID 15070
    - b. Institutional Conflict of Interest- Course ID 16765
  - B. Information Privacy and Security (IPS)- Course varies by academic discipline.
  - C. Research Practices
    - a. Responsible Conduct of Research (RCR)- Course varies by academic discipline. [NOTE: RCR training is required by some grant-funding agencies.]
    - b. Good Clinical Practice (GCP)- Course varies by academic discipline.

[NOTE: Additional CITI Program training, on a variety of subjects related to effective research practices, is available in their Webinar series. To enroll in a webinar, follow the procedure for enrolling in a certificate course. The list of current webinars is displayed on the enrollment page. Important: *CITI Program does not offer a formal completion certificate for the webinars.*]

- II. NSU IRB Resources
  - a. Researcher Handbook (available on the NSU IRB website; see below)
  - b. YouTube Channel: <http://www.youtube.com/@NSUIRB>
  - c. Website: <https://www.nsula.edu/irb/>
- III. NSU Resources
  - a. Faculty Handbook (University policies regarding human subjects research)
  - b. Student Handbook (University policies regarding students as human subjects)
- IV. Federal Resources: U.S. Office of Human Research Protections (OHRP)
  - a. Homepage: <https://www.hhs.gov/ohrp/index.html>
  - b. Regulation/Policy: <https://www.hhs.gov/ohrp/regulations-and-policy/index.html>
  - c. Education and Outreach: <https://www.hhs.gov/ohrp/education-and-outreach/index.html>
  - d. OHRP YouTube channel: “How IRBs Protect Human Research Participants.” (2018). <https://m.youtube.com/watch?v=U8fme1boEbE>. [NOTE: This is one example: additional videos are available.]
- V. Print Resources
  - a. Protecting Participants and Facilitating Social and Behavioral Sciences Research. (2003). The National Academies Press.

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<sup>15</sup> These additional topics cannot replace the NSU IRB-required researcher training courses (for details, see the [Appendices, “NSU IRB Training Policy”](#)).

<sup>16</sup> These optional training course topics listed are suggestions only; see the [CITIprogram.org](http://CITIprogram.org) web site for the current catalog.

- b. Human Research Protections: Working with the IRB. (2015). Patricia H. Arford, Ph.D., R.N.
- VI. Historical Resources (All are available online for free)
  - a. “50 Years on, the Lessons of the Tuskegee Syphilis Study Still Reverberate.” (2022). *Ars Technica*.
  - b. “The Belmont Report.” (1978). *National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research*.
  - c. “The Declaration of Helsinki.” (1964). World Medical Association.
  - d. “The Nuremburg Code.” (1947).

(rev. 2022.08. 18)

## Appendix C

### Contacts

#### I. NSU Offices

- a. HRPP/IRB Office: Dr. Jim Mischler, Director. 318-357-5228; [irb@nsula.edu](mailto:irb@nsula.edu); <https://www.nsula.edu/irb>
- b. Nursing Scientific Review Committee (SRC): Dr. Susan Steele-Moses, 318-677-3139; [steelemoses@nsula.edu](mailto:steelemoses@nsula.edu)
- c. Student Affairs: Dr. Yonna Pasch, Director. 318-357-6128; <https://www.nsula.edu/studentexperience/>
- d. NSU Institutional Official (IO): Dr. Greg Handel, Provost. 318-357-5361; [handelg@nsula.edu](mailto:handelg@nsula.edu); <https://www.nsula.edu/provost/>

#### II. Federal Offices

- a. Office of Human Research Protections (OHRP): <https://www.hhs.gov/ohrp/index.html>
- b. U.S. Department of Health and Human Services (HHS): <https://www.hhs.gov/>

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