Institutional Review Board

Researcher Handbook

Northwestern State University
Natchitoches, LA 71497

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*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.[1]

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 need.

--*Principal Investigator (PI)*: The person primarily responsible for designing and implementing the research protocol.

NOTE: NSU policy allows the student to serve as the study PI, but a Faculty Advisor from the student's major department must be assigned to oversee the study activities that the student conducts, especially activities involving the human subjects who participate in the study.

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

All NSU-sponsored research protocols involving human subjects 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 [2] must complete the required training courses at CITIprogram.org or have currently valid (unexpired) training certificates. 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)**. [3]
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 the 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 specific plan will require more time later to provide the necessary information.
3. *Determination of Human Subjects Research*: The PI must complete the Non- human Subjects Research Questionnaire (or NHSR) [4]; the IRB will determine if the protocol plan (see Step #2) involves "human subjects research"—*as defined by*

[1] See *The Belmont Report* (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

[2] All persons involved in the administration of a human subjects research protocol, including the PI (and any Co-PIs), faculty advisors (if applicable), and approving agents (e.g, dept. heads, research coordinators, and/or Deans) must complete the two training courses before a protocol can be reviewed by the NSU IRB.

[3] CITI Program offers several different COI courses; the NSU IRB recommends the "Conflicts of Commitment and Conscience" course for all principal investigators, faculty advisors, and Approving Agents. However, any of the COI courses will be accepted.

[4] NSU Nursing personnel (faculty, staff, and students) will complete a different document, the Quality Improvement Survey, which is submitted to the Nursing Scientific Review Committee along with the protocol application.

federal law—and must undergo IRB review. There are two possible determinations:

a. **Non-human Subjects Research**: 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 NHSR letter. STOP HERE; DO NOT proceed to Step #4.
b. **Human Subjects Research**: 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 forms. PROCEED to Step #4.

4. *IRB Protocol Application*: The PI completes the required IRB Application forms (Parts A & B), which will be sent through the Exempt, Expedited, or Full Board 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 in the application form must be answered with specific information. Incomplete information will result in the application being returned for revisions.
   b. **Do not leave any section or question blank**: A blank section or question also results in the application being returned for revisions.
5. *Protocol Information Checklist*: The PI completes this checklist (in Part A of the IRB Protocol Application) to ensure that all required materials are completed and included.[5]
6. *Approving Agents:* The PI must obtain the approval of their assigned faculty advisor (if applicable), research coordinator,[6] department head, and/or Dean.
7. *Application Submission*: The PI submits the application to the NSU IRB submission system.[7]
   a. **Save each file separately**: When submitting an IRB application, save each document (e.g., Informed Consent form, survey instrument, site permission letter, etc.) as a separate file. Do not save the documents in one file.
   b. **Use PDF format**: For each separate file, save it in Adobe PDF format. Do not use any other file format.
8. *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 protocol may begin. The letter will include the protocol completion date (see #9, below).
   b. **Conditional Approval**: Before the protocol may begin, the PI must revise application to meet the conditions required by the IRB. The application may

[5] The Protocol Information Checklist is included with the IRB application form (see Step #4).
[6] For Nursing personnel, the Nursing Scientific Review Committee serves as the research coordinator. [7] See Part III. for instructions to submit the IRB application materials to the NSU IRB.

be resubmitted at any time and does not have to meet the regular IRB deadlines. However, if all conditions are not met, the IRB Director & Chair may elect to have the entire IRB membership or a subcommittee review the application to determine the recommended action. Procedures for conditional protocol reviews include:

i. Resubmit the entire IRB protocol application with the specified changes;
ii. Obtain all appropriate signatures;[8]
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 resubmitted protocol reviews include:

i. Resubmit the entire application with the specified changes;
ii. Obtain the appropriate signatures;
iii. Provide all required supplemental documentation.[9]

9. *Protocol Close* [10]: No later than 10 business days (not including holidays) after the protocol is closed by the PI or the protocol completion date is reached [11] (whichever occurs first), the PI must notify the IRB Office that the study is officially closed. *To extend the completion date, see Section C.2.*

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

C. Changes in Active Protocols [12]

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 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 may continue.

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

[8] For both Conditional Approval and Resubmit applications, all approving agents must sign the revised application.

[9] A resubmitted protocol will be reviewed as a new application.

[10] "Protocol Close" occurs when all recruitment and data collection from human subjects have ceased and all human subjects have been dismissed from the study.

[11] Full Board protocols have an assigned completion date, typically one year 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.

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

inform them in writing of the situation. The PI must then complete an Adverse Event Report with recommended 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. If disapproved, the protocol will be terminated immediately.

4. *Continuing Review*: If, during a continuing review of a Full Board-approved protocol, the IRB reviewer 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 of the situation. The PI must then complete the Continuing Review form and submit it to the IRB. The protocol cannot recommence until the IRB approves. If disapproved, the protocol is terminated immediately.

III. NSU IRB Online Application Submission Systems: Procedures:

a. Nursing students, faculty, and staff: the application is first routed to the Nursing Scientific Review Committee (SRC). Once the protocol is approved by the SRC and the CONSAH Dean, the application is automatically sent to the IRB for review. IRB approval is required before the protocol may begin.
b. Allied Health students, faculty, and staff: the application is routed directly to the IRB via Sitero-Mentor.
c. Other NSU students, faculty, and staff: the application is routed directly to the IRB via Sitero-Mentor.

2. Log in to Sitero-Mentor: https://www.axiommentor.com/login/axlogin.cfm
3. Instructions on how to use the system are available on the NSU IRB webpage.
4. For further information, contact the NSU IRB Office.

IV. Supplemental Documentation: Types and Creation Guidelines

When & How to Create Supplemental Documents

I. Introduction

When applying to the NSU IRB for approval to conduct a research study with human subjects, there are a number of documents that may be needed to support the information given in the IRB Application Form. This Guidelines document describes: 1. when the document is needed; 2. the information needed for the document.

NOTE: Keep in mind that a specific supplemental document is only required for a specific study design. A particular IRB application may include a few supplemental documents but not all of them. Choose the document types that apply to your study. *If unsure, consult with the NSU IRB Office.*

II. Types of Supplemental Documents & When Needed [1]

--Informed Consent/Assent Forms: Recommended for all NSU IRB studies. [2]

[1] CITI Program certificates are not supplemental documentation. The NSU IRB receives this information directly from CITI Program.

[2] Under federal law, the Informed Consent, Assent, and Debriefing forms are not required for all human subjects study types. However, the NSU IRB recommends their use whenever possible and appropriate.

--Data Collection Instruments (Surveys, spreadsheets, or similar types): Required whenever used in a study.

--Debriefing Forms: Recommended for all NSU IRB studies (see Footnote #2). --

Grant Funding Documents: Required for all studies awarded grant funding. --

Permission Letters (Site, Data, or Instrument permission): Required whenever property owned by someone other than the researcher is used in a study. See sample letter in the Appendices.

--Recruiting Materials: Required whenever recruiting materials of any type—

e.g., posters, flyers, letters, emails, or videos—are used to ask people to participate in a study.

III. Information Needed for each Supplemental Document Type

A. Informed Consent/Assent Forms (see Appendices for complete details)

B. Data Collection Instruments

i. For a Survey (including online), provide a complete copy of all questions to be asked. If follow-up questions will be used, provide examples of possible questions.

ii. For an interview (individual or focus group), provide a complete list of questions. If follow-up questions will be used, provide examples of possible questions.

iii. For a Spreadsheet, include a copy of the file with the label used for each data category.

C. Debriefing Forms (see Appendix on Informed Consent)

D. Grant Funding: Provide a copy of the signed and dated grant award letter. (If the award is pending, provide a copy of the grant application form.)

E. Permission letters (Site, Data, or Instrument*; see Sample Permission Letter, p. 9*)

i. A statement granting permission to the researcher to do _____ with the letter signer's property.

ii. Name and title of person granting permission.

iii. Signed and dated (digital or handwritten signature).

(NOTE: See Appendices for sample permission letter)

F. Recruiting Materials

i. For each separate recruiting announcement, include the complete text.

ii. If audio/visual media are used, provide the complete text and a link to the a/v announcement.

San Torino High School
San Torino, LA

Dr Jane Doe, Principal
San Torino High School
San Torino, LA
12345

February 22, 2023

Dear Gary Graduate,

Based on my review of the proposed research by Gary Graduate, I give permission for him to conduct a research project entitled "*Attitudes about Students' Knowledge of English Grammar and the Impact of Those Attitudes on Students Academic Performance*" on site at San Torino High School. As part of this study, I authorize the researcher to conduct one-on-one interviews with the teachers and administer, record, and transcribe the results.

We understand that our organization's responsibilities include provision of the preselected teachers names and email addresses. We reserve the right to withdraw from the study at any time if our circumstances change.

We understand that the research will include recorded interviews with the teachers as deemed necessary.

This authorization covers the time period of the 2022-2023 school year.

I confirm that I authorize to approve research in this setting.

I understand that the data collected will remain coded and may not be provided to anyone outside of the research team without permission from the Northwestern State University Institutional Review Board.

Sincerely,
Dr Jane Doe, Principal
(123) 456-7899

V. Appendices

Appendix A

NSU IRB Application & Review Process: Additional Information

Informed Consent Form: Guidelines
Social, Behavioral, & Educational Research
(Rev. 2023.07.18)

I. Required Elements*

A. A statement that the activity involves 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 participant 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; phone: 318-357-5228) in case the potential participant has questions.
M. One of the following two statements 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 if desired (see https://www.hhs.gov/ohrp/regulations-and-policy/regulations/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 of the study, organized as bullet points. This section could include (from Required Elements, see page 1) sections A., B., 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: Times 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 subjects. For example, 10-year- old study participants have different reading needs 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.

NOTE: The NSU IRB recommends that the target "Grade Level Score" score (for studies involving average adult human subjects) is 8th & 9th grade; the equivalent "Reading Score" is 60-70. [See the chart at the bottom of the web page for the complete readability scoring scale.]

   F. When the target Grade Level Score is reached (or lower), take a screenshot of the readability calculator web page 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: 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:

- 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.)

- Will you seek assent with a written form and/or an oral briefing? (For children younger than age 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.)

Content elements include:

- All of the required elements shown in the NSU IRB "Informed Consent Form: Guidelines" document are included in the Assent Form or oral script.

- 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 2nd or 3rd 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 copy of the form shall be given to the person who signed it or to the legally authorized representative.
- The copy with the original signature will be kept with the principal investigator's research records.

Debriefing Form: Guidelines

(Rev. 2023.07.17)

The Debriefing Statement is provided to study subjects after study is completion. The purpose is to inform the subject of the purpose of the study and its methods, allow the opportunity to withdraw from the study, provide contact 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. See the "Guidelines: Informed Consent Form" document (in the Appendices) to calculate readability.

The Debriefing Statement must include the following:

1. The questions, hypotheses, 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 hypotheses.

4. An opportunity to withdraw their data from the study.

5. A 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 results, 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.*

9. Thank subjects for their participation in the study

Appendix B

NSU IRB Training Policy

Previous Policy (1/01/2019-5/31/2022)				*Revised Policy* (As of 6/01/2022)*	
PI Type	Field	1st Certificate	2nd	1st Cert.	2nd
Faculty/Staff	Biomedical	Biomed.	RCR**	~~HSR-Bio.~~	COI^
"	Soc./Behav.	S&BR	RCR**	~~HSR-SBE~~	COI^
Student	Biomed.	Biomed.	None	~~HSR-Bio.~~	COI^
"	Soc./Behav.	S&BR	None	~~HSR-SBE~~	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 NSU PI 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). [13]

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

CITIprogram.org Certificates [14]

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. Dept. of Agriculture

Rev. 2023.07.13

[13] The IRB reserves the right to require additional training for a specified protocol.
[14] Recertification policy: The NSU IRB requires recertification within five years of the certificate award date. The NSU College of Nursing and School of Allied Health (CONSAH) requires recertification within three years of the award date.

CITI Program
Site Registration and
Training Course Enrollment

Step-by-Step Instructions: Principal Investigator (PI), Co-PIs, and Approving Agents
(NOTE: See also the video version: https://www.nsula.edu/irb)

The purpose of this document is to provide detailed information on how to

A. complete new member registration with CITIprogram.org;
B. enroll in the IRB-required training courses.

NOTE: If you have completed CITI training previously, log in with your current CITI credentials; however, be sure to identify your affiliation with NSU; see Part B., Step #4 (below) for more information.

TIP: Each step in the process is indicated in some way in the CITIprogram.org system; however, if you get lost or stuck, you can refer back to these steps. You can also contact the IRB Office for help at irb@nsula.edu; 318-357-5228.

A. New Member Registration
   1. Go to https://about.citiprogram.org/;
   2. Click the "Register" button (upper right-hand corner of the page);
   3. In the box titled, "Select your Organizational Affiliation," type "Northwestern State" and click NSU's name when it pops up.
   4. Click the checkbox, "I agree to the Terms of Service and Privacy Policy for accessing CITI Program materials."

NOTE: Be sure to check the box in "Select Your Organizational Affiliation," not in "Independent Learner Registration."

   5. Click the checkbox, "I affirm that I am an affiliate of Northwestern State University."
   6. Click the button, "Continue to Create Your CITI Program Username/Password."
   7. Follow the steps to set up your login credentials.

B. Required Training Courses Enrollment
   1. Log in to CITIprogram.org using your credentials.
   2. Your member homepage will appear: "Welcome, [First Name]."
   3. The first section of the page is titled, "Institutional Courses."
   4. Click the button labeled, "Northwestern State University: View Courses."

TIP: If the button shows a different institution, click the "Add Affiliation" button to identify Northwestern State U., then complete step #4.

   5. On the next page, click the link labeled, "Add a course."
   6. The next page is titled, "Select Curriculum: Northwestern State University." A brief 8-question survey will be shown.
   7. For "Question 1: Human Subjects Research," click the radio button labeled appropriate for your academic field (either "Social & Behavioral Research Investigators" OR "Biomedical Research Investigators").

NOTE: A student PI should confirm with their faculty advisor the correct choice for Question 1.

   8. Scroll down to "Question 6: Conflicts of Interest," and click the radio button labeled, "Yes."

TIP: For the remaining questions, you may answer as you wish or leave them blank.

   9. At the bottom of the Select Curriculum page, click "Submit."
   10. Your member homepage will appear again. Under the section, "Courses Ready to Begin," the courses selected in the "Select Curriculum" page will be listed.

GO TO NEXT PAGE

NOTE: The course titles listed on the member homepage are a bit different from those shown in the survey; the two required courses as listed on the member homepage are as follows:

"Social & Behavioral Research: Stage 1 - Basic Course" OR "Biomedical Research – Basic Course";
"Conflicts of Interest: Stage 1 - Basic Course."

**If one or both of these titles are not listed on your member homepage, go back to the survey and take it again.

11. Click the "Start Now" button to begin the training.

TIP: You can stop at any point and continue the training later; CITIprogram.org keeps track of your progress and indicates how much of the training is left to complete.

12. When a training course is completed successfully, the "View – Print – Share Record" button will appear on your member homepage. Click that button to generate the completion certificate.

NOTE: It is recommended that you keep a copy of each training certificate for your own records. Except in special cases, it is not necessary to submit the certificates to the NSU IRB; CITI Program sends the completion notifications directly to the IRB. Contact the IRB Office if you have any questions.

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Additional Training Resources

for Researchers

I. CITI Program Training—Additional Topics [15] [16]

   a. Conflicts of Interest (COI):

      a. Financial Conflicts of Interest: Overview, Investigator Responsibilities, and COI Rules – Course ID 15070

      b. Institutional Conflicts 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.

II. NSU IRB Resources

   a. Researcher Handbook (available on the NSU IRB website)

   b. Website: https://www.nsula.edu/irb/

III. NSU Resources

   a. Faculty Handbook (2021, p. 26-27)

   b. Student Handbook (2022-23, p. 59)

IV. Federal Resources: U.S. Office of Human Research Protections (OHRP)

   a. Homepage: https://www.hhs.gov/ohrp/index.html

   b. Regulations/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

[15] These additional topics cannot replace the NSU IRB-required researcher training courses (see the NSU IRB Training Policy for details).

[16] These optional training course topics listed are suggestions only; see the CITIprogram.org web site for the current catalog.

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.

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. "Ethics and Clinical Research." (1966). Henry K. Beecher, M.D. *New England Journal of Medicine.*

d. "The Declaration of Helsinki." (1964). World Medical Association.

e. "The Nuremburg Code." (1947).

Rev. 2022.08.18

Appendix C

Contacts

I. NSU Offices

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HRPP/IRB Office: Dr. Jim Mischler, Director. 318-357-5228; irb@nsula.edu; http://www.nsula.edu/irb

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Student Affairs: Dr. Yonna Pasch, Director. 318-357-6128; https://www.nsula.edu/studentexperience/

II. Federal Offices

Office of Human Research Protections (OHRP): https://www.hhs.gov/ohrp/index.html

U. S. Department of Health and Human Services (HHS): https://www.hhs.gov/

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