NSU Research Ethics Board

Researcher Handbook

2026-27

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New in the 2026-27 Edition

Title	Brief Description	Page #
International Research Guidelines	Recommendations and advice for conducting NSU-sponsored research studies overseas.	Appendices
Deception Research Policy	Policies and procedures for conducting research studies involving incomplete disclosure to research participants	Appendices

NSU REB Review Process

Researcher Checklist*

1. Read the 2026-27 NSU REB 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 REB Office).
4. Watch instructional videos on the **NSU REB YouTube channel**.
5. Log in to Mentor (see the **NSU REB website** for login instructions).
6. Fill out the appropriate REB application** and electronically sign it.
7. Wait for the NSU REB 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.

*For details on these steps, see Section II., NSU REB Review System.
**There are a total of five different application forms; if unsure about which one is best for your study, contact the REB Office for consultation.
***The study cannot begin until the researcher receives the official NSU REB approval letter.

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REB Review Process

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*Intake Review= Application completion check.

I. NSU Research Ethics Board (REB): Mission

The mission of the Northwestern State University REB 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.

II. NSU REB Review System

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

--*Study 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 study 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 REB 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 Instructions

All NSU-sponsored study protocols involving any human subject in **any** way must be approved by the NSU REB 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 study protocol must complete the required training courses at CITIprogram.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)**.
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 REB approval without a detailed plan will require more time later to provide the necessary information.

3. *Determination of Human Subjects Research*: The PI completes the Not Human Subjects Research (NHSR) Determination Questionnaire; the REB will determine if the protocol (see Step #2) involves "human subjects research"--*as defined by federal law*--and must undergo REB review. There are two possible determinations:

   a. **Not Human Subjects Research (NHSR)**: If the REB 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 REB review is not required; the protocol may begin after receiving

the official NHSR letter. STOP HERE; DO NOT proceed to Step #4.

b. **Human Subjects Research (HSR)**: If the REB 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 REB review is required, and the PI must submit the required HSR application form. PROCEED to Step #4.

4. *REB Protocol Application:* The PI completes the appropriate application form, which will be sent through the REB review process.
   NOTE: **Do not leave any section or question blank**: A blank section or question also results in the application being returned for revision.

5. *Signatures*: The researcher must sign the REB application form and obtain the approval and signature of their assigned Faculty Advisor.

6. *Application Submission*: The PI submits the application form and all required supplemental documents to the NSU REB submission system.[6]
   a. **Save each file separately:** When submitting an REB 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.[7]
   b. **Use PDF format:** For each separate file, save it in Adobe PDF format. Do not use any other file format.

7. *REB Decision Letter*: A letter communicating the REB decision regarding the protocol will be sent to the PI (and the faculty advisor, if applicable). The REB decision will be one of the following:
   a. **Approval**: The NSU REB approved the protocol as written and the study may begin. The letter may include the Protocol Close Date (see #8 and #9, below).
   b. **Conditional Approval**: Before the protocol may begin, the PI must revise the 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 REB deadlines. However, if all conditions are not met, the HRPP Director or REB Chair may elect to have the entire REB membership, or a subcommittee review the application to determine the recommended action. Procedures for conditional approval include:
      i. Resubmit the entire REB protocol application with the specified changes;
      ii. Provide 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 REB and resubmit the application for 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.[9]

8. *Protocol Close*: No later than 10 business days (not including holidays) after the protocol is closed by the PI or the protocol Close Date is reached (whichever occurs first), the PI must notify the REB 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 Approved Protocols[12]
   1. *Amendments*: Any change to an REB-approved and currently active protocol must also be approved by the REB. The PI must suspend the protocol immediately, complete the Amendment Request form, and submit it to the REB 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, approved completion date, the PI must submit the Continuing Review Request form. The NSU REB must approve the application before the protocol can 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 REB members, the protocol must be suspended and the NSU REB 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 REB approves the PI's recommendations (NOTE: The HRPP Director and/or REB Chair can also make additional recommendations or amend the PI's recommendations). If disapproved, the protocol is terminated immediately.
   4. *Continuing Review (CR)*: If, during a continuing review of a Full Board-approved protocol, the REB 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 REB. The protocol cannot recommence until the CR request is approved. If disapproved, the protocol is terminated immediately.

III. NSU REB Online Application Submission System (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 REB for review.
   B. Allied Health students, faculty, and staff: the application in Mentor is routed directly to the REB.
   C. All other NSU students, faculty, and staff: the application in Mentor is routed directly to REB.

(NOTE: Instructions on how to log in to the Mentor system are available on the NSU REB webpage. Step-by-step instructions on completing the REB application are available on the REB YouTube channel.

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 review board. The approval letter from the other REB must be filed in the NSU REB 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 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 REB 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 REB requires that the researcher reviews and signs an Individual Investigator Agreement (IIA). The IIA form is available from the NSU REB Office.

ii. The document provides university and NSU REB 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 Institutional Official (IO), who authorizes the work of all researchers at the university.

Appendices

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

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 (in 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. 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.
   M. Contact information for the researcher (email) and the NSU REB Office (email: irb@nsula.edu; phone: (318-357-5228) in case the potential participant has questions.

*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 or not to participate in the study.*

Informed Consent Forms:

Guidelines for 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://www.readabilit.com/readability/flesch-kincaid-grade-level.
   B. Copy the text of the Informed Consent form into the "Flesch Reading Ease" score calculation textbox.
   C. Click the button, "Check Readability."
   D. The readability scores will appear immediately.
   E. If the "Grade Level Score" is too high for the intended study subjects, revise the text until the desired score is achieved (*see NOTE below).*
   F. 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 REB recommends that the target "Grade Level Score" score is 8th & 9th grade; the equivalent "Reading Score" is 60-70

(called "Plain English").

G. When the target Grade Level Score is reached (or lower), take a screenshot of the readability calculator webpage and include all scores. Save the screenshot in a PDF file and include it as a supplemental document with the REB 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 REB 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 REB "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 REB 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. 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 "Informed Consent/Assent Forms: Guidelines" 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 REBin 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 REB Approved PDS List, the study will qualify for NHSR designation.

NOTE: The current Approved Public Data Sets List is located on the NSU REB web page

NSU Data Use Policy

Data from NSU-owned databases can be approved for use in an NSU REB-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 REB 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).

International Research Guidelines

(Approved January 20, 2026)

NOTE: Researchers can use this information to support their preparations for conducting international research. We encourage researchers to provide the NSU REB with detailed and thorough information for any planned international research site.

Introduction

International research typically includes (i) two or more countries, often with the purpose of comparing responses between them, or (ii) research conducted in a country different from the researcher's country of origin. Research of this nature might be done to devise strategies for diverse cultures, evaluate the cultural appropriateness of measures or procedures, or suggest local adjustments to a global strategy.

Research sponsored by developed-world entities (both public and private) and conducted in the developing world is enmeshed with complex ethical issues. In research settings, people are asked to assume risk and inconvenience in the interest of advancing knowledge designed to benefit individuals and societies.

Codes of research ethics, regulations, laws, policies, and norms guiding researchers aim to minimize the possibility of exploitation of individuals by carefully protecting participant rights and welfare. Widely recognized provisions to protect research participants include:

- Thorough independent review to assure the rigor of the research question and design.
- Assessment of potential risks in relation to benefits and attention to minimizing risks.
- Fair procedures for subject recruitment and selection.
- Informed consent.
- Linguistic, cultural, and social appropriateness.

Preparing New Researchers for International Settings

When most researchers think of international research, they consider the excitement of travel and adventure. International research is also challenging, as it requires researchers to adapt to new ways of life, a change in routine, limited communication with support networks, and a balance of personal beliefs with new customs. Researchers should be properly prepared and trained for the rigors of international research before entering the study site. For example, researchers should:

- Define their research role in the area
    - Consider power dynamics
    - Understand the scope of the work

    - Set realistic expectations and boundaries
- Prepare for linguistic, cultural, and social norms different from their own
    - Conduct background research on the area
    - Study previous research pertaining to the area
    - Communicate with local support for updated information on the area
    - Use cultural training methods and resources related to their research site
    - Work with a trusted translator
- Set a realistic timetable for participants and their data collection
    - Obtain visas, health checks, background checks, and travel items
    - Check for travel advisories
    - Be updated on known infectious diseases
    - Get vaccinated for infectious diseases known to the area
    - Know relevant security and protection resources
- Understand challenges in high-risk areas
    - Obtain proper training to handle known and potential challenges
    - Know available human service and healthcare resources in the area
    - Establish safeguards for individual protection, the protection of research participants, and their data

NOTE: Make sure to register your international travel with the appropriate university and federal government offices. Contact the NSU IRB. For more information.

Translation to the Local Language

The NSU REB does not currently have a policy on translation of informed consent forms and other documents provided to research participants, largely due to cost. The REB strongly recommends translation whenever it is practical. Technology tools, such as artificial intelligence, can aid the translation process at a much lower cost.

Data Security and Privacy

The collection of research data and maintaining its confidentiality and privacy in international settings is both a paramount responsibility and a complex challenge. Researchers should consult with both the NSU REB and personnel residing at the international research site to ensure that data privacy and confidentiality meet required standards. A Data Security Plan will be required by the NSU REB prior to approval of any protocol to be conducted in full or in part outside of the USA.

Data Sharing and Transmission with External Researchers

When conducting research in partnership with another institution, researchers should establish a data-sharing (or "data use") agreement prior to data collection. A data-sharing agreement is a formal agreement that clearly defines what data is being shared, and how the data will be used according to specific terms and conditions as outlined in the agreement. Before conducting any research or sharing data, both parties should discuss anticipated data-sharing, data-use, and data-security issues to document in the agreement. Contact the NSU REB to discuss the formation of an appropriate data-sharing agreement.

Maintain Secure and Private Communications

Communications between researchers in different countries should only be conducted over secure electronic networks (contact the NSU REB for more information). When discussing the research with participants, their identifying information cannot be sent over electronic communications networks, due to security and privacy issues. However, when working across time zones, it may be difficult to set up a time to speak on the phone, especially in an emergency. In these cases, researchers should rely on using pseudonyms or unique codes. Never share the name of a participant or their information in an email or text message, as these communications are not secure.

Guidance for Research Involving Deception or Incomplete Disclosure
(Approved March 16, 2026)

Overview

The NSU REB recognizes that deception and incomplete disclosure may be valuable research methodologies, yet their use presents special challenges to ensure the research is conducted ethically. At times, especially in social and behavioral research, deception or incomplete disclosure is necessary to avoid study bias or to test a hypothesis that requires the participant's misdirection. On the other hand, the regulations for obtaining informed consent from research participants (§45 CFR 46.116), in general, require full disclosure of all elements relevant to the participant's decision about participation in the research. The REB understands that providing adequate consent information does not entail explaining every study aim/hypothesis to potential participants. However, the federal regulations require that the consent process include an explanation of the purposes of the research and a description of the study procedures.

Deception and incomplete disclosure raise concerns as they potentially interfere with the ability of the participant to make a fully informed decision about whether or not to participate in the research. Thus, proposed research involving deception or incomplete disclosure necessitates special considerations by the IRB. To determine when certain restrictions apply, the IRB will consider the extent to which the deception or incomplete disclosure, in any given study, interferes with the 'participant's right to and ability to give fully informed consent.

These guidelines include distinguishing whether "deception" or "incomplete disclosure" (without deception) is involved, whether there is sufficient justification for the use of such measures, and whether there is an appropriate consent and debriefing process in place.

The purpose of the guidelines on the use of deception and incomplete disclosure is to provide researchers, REB staff, and REB members with a common understanding of the following:

- Definitions of deception and incomplete disclosure in research**;**
- When is deception or incomplete disclosure allowed;
- Points to consider when using deception or incomplete disclosure; and
- Debriefing participants when deception or incomplete disclosure is utilized.

What is Deception?

Deception is when researchers purposely mislead participants by providing them with overt misdirection or false information about some aspect of the research, whether in the procedures or the purpose of the research. Examples include:

- Participants are told they are working with a group of other participants on a task, but in actuality, they are the only participant in the study. The other "participants" are confederates or research staff acting as participants or a computer-generated 'other participant', not a real person.
- Participants are told they scored poorly on a task, when in actuality, they are given that feedback regardless of their actual performance. Participants are told something is real when it is made up specifically for the study, such as a journal article or 'research' facts.

What is Incomplete Disclosure?

Incomplete disclosure is when researchers withhold information about some aspect of the research, whether in the procedures or the purpose of the research. An example might include:

- Participants are informed about the purpose of the study in general terms that are true but are not detailed enough to reveal the true objectives of the study.

When is Deception or Incomplete Disclosure permitted?

In keeping with federal regulations and ethical codes, the IRB will consider the following points when reviewing research involving the use of deception or incomplete disclosure:

- Whether the proposed research in general and the specific activity for which the use of deception is proposed are minimal risk.
- Whether the use of deception or incomplete disclosure is justified in the protocol to show that the research cannot be performed in the absence of deception and the benefits of the research will sufficiently outweigh any risks that deception may create.

Research participants cannot be deceived about significant aspects of the research such that it would affect their willingness to participate or that would cause them physical or emotional harm. Participants may not be put in a position to engage in illegal or stigmatizing behavior because of the deception.

Consent Information and Debriefing

The basic principles that guide the ethical conduct of human research support complete informed consent that provides participants with sufficient information in an understandable format to allow them to make an informed decision about whether to participate in a study. Research designs that use deception or incomplete disclosure do not allow participants to provide fully informed consent prospectively.

Investigators should use the following measures to allow participants appropriate autonomy in the consent process for research that involves deception or incomplete disclosure:

- ***Authorized deception:*** Whenever possible, informing participants as part of the consent process that a study will not be described with complete accuracy or that some procedures will be deceptive provides an opportunity to decide whether to participate on these terms.

Sample language for authorized deception:

For scientific reasons, this consent form does not include complete information about the research questions or topics being tested. You will be fully debriefed following your participation in the research, and you will have the right to withdraw your consent at that time. If you withdraw yourconsent, your personal information will be deleted.

OR

We cannot tell you every detail of this study ahead of time, but if you are willing to participate under these conditions, we will explain the procedure to you fully after your participation, and you will have the right to withdraw your consent at that time. If you withdraw your consent, your personal information will be deleted.

Debriefing

Debriefing is intended to mitigate the lack of fully informed consent by explaining the rationale for using deception as a research technique. Deception must be explained to participants (debriefed) as early as is feasible. Many studies that only use incomplete disclosure (without deception) are not required to debrief participants – however, if the incomplete disclosure involves material information that could have significantly influenced individuals' decisions to be in the study, then debriefing should be carried out (for example, if the incomplete disclosure involves not telling participants that the study involves examining correlations between political affiliation and characteristics of empathy). Participants should be given a simple, clear, and informative explanation of the rationale for the use of deception and should have the opportunity to ask questions.

The process of debriefing participants must be explained in your IRB protocol. Your protocol must indicate how participants will be debriefed, who will debrief participants, and when participants will be debriefed. The IRB expects that the person conducting the debriefing process is a member of the research team who has knowledge about the research.

A debriefing sheet/script must be included with the IRB submission documents and should include a detailed description of the ways in which deception/incomplete disclosure was used and why.

Participant option to withdraw data upon debriefing: The researcher can decide, or the IRB may require, that the debriefing include an option for participants to withdraw their data from the study after they learn the true nature of the research. If the study involves deception (or incomplete disclosure) at the time of participant enrollment or consent that could have materially influenced the participant's decision about study participation, and/or the deception/incomplete disclosure would likely be perceived by participants as an invasion of privacy (e.g., videotaping without prior consent), the IRB may require re-consent for the use of data as part of the debriefing process. If the researcher chooses, or the IRB requires, to provide participants with the option to withdraw their data upon being debriefed, the research team will need to keep sufficient identifiers or links to identifiers for participants to exercise this option.

Online Debriefing: Some research requires a debriefing after participants have completed an online survey/task. Online debriefing information should be similar to the debriefing process done during in-lab experiments. The debriefing information should be available immediately after the final survey/task. Participants should be reminded to print a copy of the debriefing information for their records.

Delayed Debriefing: In rare cases, immediately debriefing after a participant has completed study participation would compromise study results (e.g., the study is ongoing and early participants might tell others about it, making it impossible for the researchers to obtain valid/unbiased results from later participants). Under such circumstances, the IRB may approve a delayed debriefing process, such as sending debriefing information to participants via email or regular mail (if

participants' contact information is kept) or giving participants a website URL where they can get debriefing information when the study has been completed.

Debriefing as an Educational Tool: Some University schools or student participant pools recommend that feedback be provided at the study's conclusion to further the participants' education (as opposed to giving information previously withheld or falsified). This is not debriefing in the sense of the IRB ethics review and the regulations. In such cases, the original consent may mention this will be done, and the "Additional Information" document may include bibliographical citations advising participants where they can obtain additional information on the topic if they wish.

Debriefing for studies intending to induce an emotional state: Some studies may deliberately intend to provoke specific emotions in participants by exposing them to stimuli such as audio-visual materials, written scenarios, or experimental tasks. If the emotion being invoked is negative, the study team may need to include procedures intended to mitigate these negative emotions at the end of the study. While this is not debriefing in the sense of the IRB ethics review and the regulations, such procedures may include a document reiterating the purpose of the study procedures or providing resources for participants.

Exceptions to Debriefing: There may be rare instances when debriefing would be inappropriate, such as when the debriefing itself may present an unreasonable risk of harm to the participant without a countervailing benefit. For example, if an individual were selected for participation in a study about group behavior based on a previously measured "negative" behavior such as bias or bigotry or an unattractive physical characteristic, it might not be appropriate for the debriefing to describe the selection process. In such cases, the IRB would not recommend or require detailed debriefing. If you use deception and request not to debrief participants, you must provide a compelling rationale in your protocol for not debriefing.

NSU REB Researcher Training Policy *
(As of 6/01/2022) **

PI Type	Academic Field	Certificate #1	Certificate #2
Faculty/staff	Biomed.	Biomed.	COI^
OR			
Faculty/staff	S&BR	S&BR	COI^
Student	Biomed.	Biomed.	COI^
OR			
Student	S&BR	S&BR	COI^

Notes

*The NSU REB reserves the right to require additional training for a specified protocol.

** NSU policy requires that each certificate is valid for five years. Before the expiration date, the researcher must retake and complete each certificate.

^ The "Conflicts of Commitment and Conscience" certificate is recommended for all NSU PIs. The "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).

CITIprogram.org Certificates[14]
Biomed. = Biomedical Research
S&BR = Social & Behavioral Research
COI = Conflicts of Interest

Other Abbreviations
PI = Principle Investigator

Additional Training Resources
For Researchers (Optional)

I. CITI Program Training- Additional Topics
   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. *CITI Program does not offer a formal completion certificate for the webinars*.]

II. NSU REB Resources
   a. Researcher Handbook (available on the NSU REB website; see below)
   b. NSU REB YouTube channel
   c. NSU REB website

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.
   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).

Contacts

I. NSU Offices

a. HRPP/REB Office: Dr. Jim Mischler, Director. Phone: 318-357-5228; Email: reb@nsula.edu; Website: https://www.nsula.edu/reb

b. Nursing Scientific Review Committee (SRC): Dr. Stacy Joslin, Chair. Phone: 337-423-4907.

c. NSU Student Affairs: Dr. Yonna Pasch, Director. Phone: 318-357-6128; Email: paschy@nsula.edu. Website: https://www.nsula.edu/studentexperience/

d. NSU Institutional Official (IO): Dr. Greg Handel, NSU Executive Vice President and Provost. Phone: 318-357-5361; Email: handelg@nsula.edu;Website: https://www.nsula.edu/provost/

II. Federal Offices

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

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