NSU IRB Application & Review Process: Additional Information

Informed Consent Form: Guidelines
Social, Behavioral, & Educational Research
(Rev. 2024.08.13)

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, brief paragraphs, and/or tables. The Key Information should always include a brief list of the tasks that the human subject will complete and how much time (in total) is needed for those tasks. *NOTE: The Readability Score is required for this section (see Section III., below.)* [See the instructional videos on the NSU IRB webpage for more details.]
  - 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). *NOTE: The Readability Score is not required for this section (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. For more information on this issue, see the following YouTube video: How to Write Key Information in Plain Language.

To check for readability:
- A. Go to the Flesh Kincaid Readability Calculator webpage.
- B. Copy and paste the text of the Key Information section into the Readability Score calculation box. *(NOTE: The Detailed Information section does not require a Readability Score.)*
- 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*).

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 between 60 and 70. [See the chart at the bottom of the web page for the complete readability scoring scale.]

- E. 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