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).

<u>The Debriefing Statement must include the following:</u>

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.