Nova Southeastern University
IRB - Consent Form Checklist

This form is intended to assist the researcher in creating consent and assent forms.

Informed consent is one of the primary ethical requirements for research with human subjects; it reflects the basic principle of respect for persons. No investigator may involve a human being as a subject in research, as defined in the Nova Southeastern University Institutional Review Board policy, unless the investigator has obtained the subject's informed consent. The process of informed consent is constituted on two essential elements: (1) the subject has the information he or she requires to make an effective decision, and (2) the subject's participation is not coerced, i.e. his or her consent is voluntary.

The checklist below is provided to ensure that each of the following components is included in your consent form. The IRB also recommends reviewing the template and model information at **http://www.nova.edu/irb/manual/forms.html**. You do **not** have to submit a copy of this form.

Item	Component
☐	The consent form is written in a language understandable to the subject or his/her legal representative.
☐	The consent form is written in a consistent voice to describe the participants, preferably second with the exception of the Voluntary Consent section, which is written in the first person. The researcher may use the 3rd person or the 1st person to describe him/herself.
☐	First page of the consent/assent form is on original Nova Southeastern University letterhead, except in cases of collaborative projects when the letterhead from a hospital, university, etc. is acceptable
☐	If the research is externally funded, the funding agency is listed under funding source.
☐	The title of the study and the name, address, and telephone number of the investigator(s) is listed.
☐	If the principal investigator is a student, the address and phone number of his/her advisor(s), clinical Supervisor(s) are listed. Site information (address) of where research will be collected or research activities will occur with subjects if this information is different than the address of investigator/co-investigator or there are multiple sites.
☐	The IRB's phone number 954-262-5369, Toll Free: 866-499-0790 and the email address (**IRB@nsu.nova.edu**) are listed.
☐	A statement that the study involves research and an explanation of the purpose of the research is included.
☐	A concrete description of the study procedures, including the amount of time subjects are being asked to contribute and the nature of the questions or data to be collected, is included. Any procedures which are experimental are identified and any alternative procedures disclosed. Information about financial agreements with the investigators must be discussed. Audio and Video tape information (if applicable) in keeping with the paragraphs provided in the model forms.
☐	A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
☐	A description of any risks and possible discomforts to the subjects, if any, is included.
☐	For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained. Include a statement as to who will be responsible for the costs related to medical expenses associated with research-related injuries.
☐	A description of any benefits to the subjects or to others which may reasonably be expected from the research is included. If no benefits are expected, this is stated.
☐	If subjects will be compensated for their participation, a statement has been included addressing this.
☐	Any additional costs to the subject that may result from participation in the research.
☐	A statement describing the extent to which confidentiality will be maintained is included in addition to a clause that states that all information obtained is strictly confidential unless disclosure is required by law.
☐	As a part of the confidentiality section, a statement that the NSU-IRB and other regulatory agencies may review research records.
☐	A statement regarding the use, or non-use, of Protected Health Information (PHI) if the study involves PHI.
☐	A statement regarding the use, or non-use, of information from student records if the study involves student records.
☐	A statement that participation is voluntary, that refusal to join the study or to leave the study involves no penalty, and that the subject may discontinue participation at any time. This statement must be followed by an explanation of how data collected will be managed if a participant decides to leave (e.g., destroyed at any time, except in situations that violate state and/or federal laws and regulations, kept until the conclusion of the study, etc.).

☐	A statement indicating who the subject can contact for any questions about the study including whom to contact for answers to pertinent questions about the research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
☐	A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.
☐	The consent form contains no language through which the subject is made to waive any of his/her legal rights or which releases the investigator, the sponsor, or the institution from liability for negligence.
☐	The entire paragraph under Section VI-Voluntary Consent on the consent form appears in **boldface** and reads "**I have read the preceding consent form, or it has been read to me, and I fully understand the contents of this document and voluntarily consent to participate in the research study entitled "(fill in title of study)". All of my questions concerning the research have been answered. I hereby agree to participate in this research study. If I have any questions in the future about this study they will be answered by (fill in name). (If applicable: I also voluntarily agree to the release of my PHI as described in this document.) A copy of this form has been given to me. This consent ends at the conclusion of this study.**"
☐	A space for the subject's signature, the date, the signature of a witness is provided, the date. Space is also provided for the signature of an authorized representative, date, and the basis for that representation if applicable.
☐	An assent form is included for subjects 7-17 years of age. This may be either be a child assent, an adolescent assent, or both (depending on the age range of subjects).
☐	Flyers, brochures, advertisements, or other recruitment materials are attached. **Recruitment material must have Nova Southeastern University on them.**
☐	If the language of the consent form/assent form is other than English, a certified copy of the Informed Consent Form in that language is included **or** the investigator may wait until notified by the IRB to have the consent form translated.
☐	All consent pages are numbered to reflect the current page and the total number of pages (Page X of X). All pages, except the signature page, contain a space indicated for initials and date.

When appropriate, one or more of the following elements of information shall also be provided to the subject:

☐	A statement that the particular treatment or procedures may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable
☐	Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
☐	The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
☐	The approximate number of subjects involved in the study.