

**Nova Southeastern University
IRB - Consent Form Checklist
Version Date: 02/17/2010**

This form is intended to assist researchers 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>

Component	Self-Checklist
General Items	
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 3 rd person or the 1 st person to describe him/herself.	
The first page of the consent form is on original Nova Southeastern University letterhead, except in cases of collaborative projects when the letterhead from a hospital, university, etc. is acceptable	
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	
All consent pages are numbered to reflect the current page and the total number of pages (Page X of Y) along with initial and date lines on all pages.	
Consent Form Heading Section	
The title of the study is presented in the manner requested by the IRB, for example "Consent Form for Participation in the Research Study Entitled XYZ"	
If the research is externally funded, the funding agency is listed under funding source or there is an indication of "None" if no funding source exists.	
Space is provided for the IRB to assign a protocol no and reads "IRB protocol #"	
The name, address, and telephone number of the investigator(s) is listed, identifying those individuals who are principal investigators and those who are co-investigators. 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 data 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.	
Include immediately under the addresses of the investigators: For questions/concerns about your research rights, contact: Human Research Oversight Board (Institutional Review Board or IRB) Nova Southeastern University (954) 262-5369/Toll Free: 866-499-0790 IRB@nsu.nova.edu	
Description of the Study	
(Sections - What is the study about? Why are you asking me? What will I be doing if I agree to be in the study?)	
A statement that the study involves research and an explanation of the purpose of the research is included. There must also be a statement that explains the purposes of the research.	
A concrete description of the study procedures to be followed, 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 that are experimental are identified and any alternative procedures disclosed. The approximate number of subjects involved in the study. Include anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent	
A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject must be included.	
Audio or Video Recording	
(Sections – Is there any audio recording? Is there any video recording?)	
Include audio and video tape information (if applicable) in keeping with the paragraphs provided in the model forms.	
Risks	
(Section – What are the dangers to me?)	
A description of any reasonably foreseeable risks and possible discomforts and/or inconveniences to the subjects, if any, is included.	
For research involving more than minimal risk, include an explanation as to whether any compensation and/or any medical treatment is 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.	
Include an explanation of whom to contact for answers to questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.	
Benefits	

(Section – Are there any benefits to me for taking part in this research study?)	
A description of any benefits to the subjects or to others that may reasonably be expected from the research is included. If no benefits are expected, this is stated.	
Compensation and/or Cost	
(Section – Will I get paid for being in the study? Will it cost me anything?)	
If subjects will be compensated for their participation, include a statement addressing this and describing in detail the nature of the compensation and the schedule of compensation if it is prorated or dependent on completion of certain activities.	
Describe any additional costs to the subject that may result from participation in the research.	
Confidentiality	
(Section – How will you keep my information private?)	
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. This section should also include information as to the record retention period. (NOTE: A minimum of 3 years after the study is over is required by the NSU IRB).	
As a part of the confidentiality section, include a statement that the NSU-IRB and other regulatory agencies may review research records. If the principal investigator is a student, there must also be a statement that the dissertation chair/faculty adviser may review the research records.	
For research involving FDA regulated drug (including biological products) and device clinical trials, the following specific statement that clinical trial information will be entered into a databank must be included in the consent form. Submission of clinical trial information to the NIH/National Library of Medicine data bank is required by statute. The statement is to be included in the applicable section that discusses the extent to which confidentiality is to be maintained. The statement is as follows: “A description of this clinical trial will be available on http://www.ClinicalTrials.gov , as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.”	
Academic Information	
(Section – Use of Student/Academic Information)	
Include a statement regarding the use of information from student records if the study involves student records.	
Voluntary Consent	
(Section - What if I want to leave the study?)	
Include a statement that participation is voluntary, that refusal to join the study involves no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. This statement must be followed by an	

<p>explanation of how data collected will be managed if a participant decides to leave (e.g., kept until the conclusion of the study, kept in perpetuity, keep but do not use, etc.). Destruction of data is not permitted. Please see the model and templates for suggested language.</p>	
<p>Additional Information</p> <p>(Section – Other Considerations)</p>	
<p>Include 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.</p>	
<p>The entire Voluntary Consent section on the consent form is completed and appears as follows:</p> <p>By signing below, you indicate that</p> <ul style="list-style-type: none"> • this study has been explained to you • you have read this document or it has been read to you • your questions about this research study have been answered • you have been told that you may ask the researchers any study related questions in the future or contact them in the event of a research-related injury • you have been told that you may ask Institutional Review Board (IRB) personnel questions about your study rights • you are entitled to a copy of this form after you have read and signed it • you voluntarily agree to participate in the study entitled “XYZ” <p>Followed by the appropriate signature lines as outlined below.</p>	
<p>A space for the subject's signature and date, subject’s name to be printed and date, and the signature of the person obtaining consent and date. Space is also provided for the signature of an authorized representative, date, and the basis for that representation, if applicable.</p>	
<p>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). See model and template forms for child and adolescent assents.</p>	
<p>Flyers, brochures, advertisements, or other recruitment materials are attached. Recruitment material must have Nova Southeastern University on them.</p>	
<p>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 with documentation indicating translation by a certified translator or the investigator may wait until notified by the IRB to have the consent form translated.</p>	

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

<p>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</p>	
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currently unforeseeable.	
The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.	