

**Nova Southeastern University  
Institutional Review Board  
Policies and Procedures**

**Informed Consent**

**Effective 10/11/2007; Revised 11/08/2007, 10/14/2010, 02/17/2011, 09/16/2011**

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**Purpose:**

To establish policy and procedures related to informed consent documents.

**Definitions:**

None

**Policy:**

1. General Items

The Principal Investigator (PI) is required to submit informed consent forms in keeping with NSU requirements and federal regulations. An Informed Consent Form Checklist and model consent and assent forms are available on the IRB website ([www.nova.edu/irb](http://www.nova.edu/irb)) to assist researchers in completing consent forms that are in keeping with NSU requirements.

2. The NSU IRB will ensure that the general elements of informed consent as defined by the Office of Human Research Protections (OHRP) and the Food and Drug Administration (FDA) are included. Therefore the consent document must contain the following elements:

1. Information about the research including
  - a statement that the study involves research
  - an explanation of the purpose(s) of the research
  - the expected duration of the subject's participation
  - a description of the procedures to be followed
  - identification of any procedures which are experimental.
2. A description of any reasonably foreseeable risks or discomforts to the subject.
3. 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.
4. A description of any benefits to the subject or to others which may reasonably be expected from the research.
5. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
6. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

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7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
9. 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."

When appropriate, one or more of the following elements of informed consent shall also be provided:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.
  2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
  3. Any additional costs to the subject that may result from participation in the research.
  4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
  5. 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.
  6. The approximate number of subjects involved in the study.
3. The NSU IRB may, at its discretion, require elements in the informed consent that exceed the requirements of the OHRP and the FDA.

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4. Researchers conducting human-subjects research outside of the state of Florida shall review and adhere to applicable law, particularly those regulations that apply to wards and minors. The IRB may require researchers to provide documentation with respect to local laws and may also conduct information searches to determine appropriate local laws.

5. Cooperative Research

For studies conducted at cooperative research sites where another IRB exists, the PI should contact that IRB to discuss its consent form requirements. The NSU IRB permits consent forms to be modified to reflect both the NSU IRB requirements and the requirements of the other IRB as long as these are not contradictory. In these cases, the headings and layout of the informed consent document may differ from NSU's format, so long as all substantive elements are included. In instances where the other IRB will not allow NSU items to be incorporated into the consent, the NSU IRB will typically require two versions of each consent/assent—one reflecting NSU's requirements and the other reflecting the other IRBs.

6. Translations and Translation Services

1. The policy on translation of informed consent documents applies to all consent forms, regardless of whether reviewed at the center level, by expedited or full review.
2. The IRB chair may appoint an individual who is fluent in reading the foreign language of the translated consent to verify accuracy of the translation of the informed consent protocol. This individual may not be associated with the study nor have contributed to the translation. Centers may nominate persons they believe are qualified to perform these services. If there is no such designee, the principal investigator is required to submit consent materials translated by a certified translator. The IRB Director shall maintain a list of the individuals appointed by the Chair to provide verification of translation accuracy and provide that information to investigators at their request. The individual reviewing the document will follow a standardized procedure for ensuring that the translated materials reflect the original English version.
3. Translation of the informed consent document is not required until the English language version has been accepted and the PI is informed that he/she should submit the translated version to the IRB office. Approval is granted after both the English and translated versions are received and approved.

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7. Use of Approved Consent Versions

To ensure that the proper versions of the consent/assent forms are used, investigators will distribute only copies of the stamped, approved version of these forms.

8. Standardized Format

To facilitate review and subject ease of understanding of material, the NSU IRB has adopted, and investigators shall use, a standardized layout of consent and assent forms. Exceptions are permitted for cooperative research (see item 5 above) and as noted below in this section.

A consent form may be either:

1. A written consent document that embodies the elements of informed consent noted above. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or
2. The IRB may approve a short form written consent document stating that the elements of informed consent noted above have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

9. Alteration of Consent Procedures

The IRB may approve a consent procedure that does not include or alters some or all of the elements of informed consent set forth above, or the IRB may waive the requirement to obtain informed consent, provided the IRB finds and documents that:

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
  - a. public benefit or service programs;
  - b. procedures for obtaining benefits or services under those programs;

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- c. possible changes in or alternatives to those programs or procedures; or
  - d. possible changes in methods or levels of payment for benefits or services under those programs; and
2. The research could not practicably be carried out without the waiver or alteration.

Additionally, the IRB can grant alteration/waiver of informed if it is determined that:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

These waivers may not be granted in the case of research involving non-viable neonates.

10. **Waiver of Requirement for Signed Informed Consent**

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

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The researcher is reminded that this waiver is of the subject signing the informed consent. The subject still must consent to participate, be given appropriate information about the study, and have the ability to decline participation without repercussions.

11. Exception from Consent Requirements for FDA Regulated Products

Obtaining informed consent may be waived if both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing all of the following:

1. Subject is in a life-threatening situation necessitating use of test article
2. Consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from, the subject
3. Time is not sufficient to obtain consent from subject's legal representative
4. There is available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject.

If immediate use of the test article is required to save the life of the subject and time is not sufficient to obtain independent determination by another physician before using the test article, a determination by the investigator shall be made. This determination by the investigator is to be reviewed and evaluated by a physician who is not participating in the investigation within five (5) days after the use of article.

The documentation required for the exception under FDA regulations must be submitted by the investigator to the IRB within five (5) working days after the use of the test article.

12. Re-consenting of Subjects/Participants

In instances when a consent form has been changed via amendment or as a result of updating to meet current NSU IRB requirements, once the amended consent form has been approved by the IRB the principal investigator or a member of the research team must re-consent active subjects/participants at the discretion of the IRB or the expedited/exempt reviewer. Active subjects/participants are those who still have research-related interventions or activities to complete. The IRB, when appropriate, may require the investigator to re-consent subjects who are only active for long-term follow-up if the revised consent form provides information that may be meaningful to the subject.

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Subjects/participants do not have to be re-consented if the only change to a consent form is the approval/continuing review dates on the stamp.

**References:**

45 CFR 46.111(4 – 5)  
45 CFR 46.116  
45 CFR 46.117  
21 CFR 50.25(a)  
21 CFR 50.25(b)  
21 CFR 50.20

**Procedures:**

1. The PI must use the NSU IRB Informed Consent Form Checklist to verify that the consent form(s) adhere both to NSU requirements and to federal regulations. For FDA regulated studies, the consent form must also include a space for the assigned subject number.
2. The PI must submit the draft consent documents and assent forms for review at the time of initial review. At the time of continuing review, the PI must submit the consent/assent forms currently being used—that were previously approved by the IRB.
3. When translated consent/assent forms are needed, after the English version of the informed consent(s)/assent(s) document is/are approved, the PI will be asked to provide a translated version. If the IRB does not have an individual designated by the Chair to review the language of the informed consent, then the PI will provide a certified translation. In the case of certified translations, the PI may be asked to also provide evidence of the certification/credential of the translator.
4. The IRB member or other NSU faculty/staff member reviewing translated consents will use the Review of Translated Consent(s) Form to document his/her review of translated consent(s)/assent(s). A copy of the completed form will be included in the protocol's file.
5. The IRB returns stamped, signed, and dated consent/assents form(s). The PI provides executed copies of the consent or assent form to research participants, and retains a copy for his or her own records.