



**Nova Southeastern University
Standard Operating Procedure for GCP**

Title: <u>Policies on Obtaining Informed Consent</u>		Version # 1
SOP Number: OCR-ICF-002	Effective Date: August 2013	Page 1 of 4

PURPOSE: Information presented to potential and active subjects should be understandable and non-coercive for them to adequately make an informed decision about initial and/or continued participation. Documentation of the process should be of sufficient detail so that the state of informed consent can be easily ascertained. It is essential that the potential subject understands the possible risks and benefits of the study and it is the responsibility of the investigator to ensure that this relevant information is available to the subject in a timely fashion.

POLICIES:

1. Only the Principal Investigator or his/her delegate for this purpose may conduct the informed consent process.
2. The initial informed consent process takes place before any research-related procedures or examinations that otherwise would not be performed.
3. The initial informed consent process shall ideally take place at one of the locations where the research will take place. This will give the subject a chance to be better informed about the research environment.
4. Potential subjects or their legal representative should be offered the opportunity to participate in a study only under circumstances that provide sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.
 - 4.1. The information that is given to the subject or the representative shall be in language that is understandable to the subject or the representative.
 - 4.2. The subject or their representative shall have adequate space, time and privacy to read any and all documents pertaining to initial informed consent before anything is signed.

- 4.3. The subject who is also an established patient of a NSU Health Center must be advised that participation or refusal to participate would not affect current or future care at NSU.
- 4.4. The Principal Investigator must take precautions to ensure that a subject recruited from their practice will be informed that participation is not guaranteed to be therapeutic or beneficial.
5. The NSU IRB or their representative may observe the informed consent process at any time pursuant to their review.

Procedure for Delegating Informed Consent

1. Any delegate authorized by the Principal Investigator to conduct the informed consent process should be adequately trained and credentialed.

Procedure for Obtaining Revised Informed Consent

1. The Principal Investigator, NSU IRB or Sponsor may initiate a proposed change of an Informed Consent Document however all changes must be preapproved by the Sponsor and the NSU IRB has the final authority of the document.
 - 1.1. All revised consent forms should meet requirements as a "stand alone" document. It cannot be a simple paragraph describing the changes
2. No subjects should be presented with a revised consent document until it has been approved by the IRB.
3. The Principal Investigator shall ensure that the most recent IRB approved informed consent form will be used to obtain informed consent from potential research subjects. The most current version of the informed consent will be identified by a version date.
4. Copy of revised IRB approved IC shall be kept in the Investigator Binder.
5. The following classes of subjects shall be asked to sign the revised form.
 - 5.1. New subjects to the study
 - 5.2. Current subjects still actively participating in the study
6. When the IC is revised due to a change in risks and benefits, all active subjects are required to be re-consented at their next scheduled research visit with the revised IC.

Procedure for Obtaining Informed Consent for Patients Unable to give Personal Consent

1. Legal incompetence is defined specifically by different national legislations. Once incompetence has been established informed consent should be obtained from the subject's legal guardian. Usually the guardian is a close relative of the subject that may act on behalf of the Subject. Examples of such cases may include but are not limited to:
 - 1.1. Mental incapacity.
 - 1.2. Illiteracy.
 - 1.3. Specified medical conditions.
2. In the case of a minor child who is capable of reading and writing and of understanding consent, the assent of the child as well as the consent of parent or legal guardian must be obtained.
 - 2.1. This usually applies to a minor of the age of approximately 7 to 17 years old.
3. In the case of a child that is too young to read and write or understand the consent process the IC must be signed by the parent or legal guardian only.
4. In the event of any of the above situations the consenting process remains unchanged from that described for a person capable of giving their own consent with the exception that the person signing the IC for the subject must be present and an active participant in the consenting process.

Procedure for Documenting Informed Consent

1. Unless otherwise waived by the NSU IRB or the Short Form is used, there should be an informed consent form signed AND dated by:
 - 1.1. The subject (or their legal representative)
 - 1.2. And one of the following: a witness, or the person conducting the interview, or the principal investigator.
2. An original signed consent document shall be kept in the research files. In addition, it is also required to have:

- 2.1. One signed copy given to the subject
3. For initial informed consent, a substantial note should be documented indicating that all subject's questions were answered to their satisfaction prior to agreeing to participate and signing of the consent document. Office of Clinical Research recommends using "Documentation of Consent Process" form, attached to this SOP.

Recommendation: The consenting of the subject is an ongoing process, therefore it is recommended at each visit that the subject be queried if they desire to continue participation in the research and make a note in the subject's records.

No research procedures can be initiated prior to obtaining Informed Consent.