OBJECTIVE

To describe policies and procedures for obtaining and documenting informed consent/assent and for reviewing and requesting waiver of informed consent or waiver of documentation of informed consent for non-exempt human research

GENERAL DESCRIPTION

Informed Consent/Assent Permission: Process and Documentation

For research involving human participants, investigators must obtain the informed consent of prospective subjects before they include these subjects in research. Informed consent is an ongoing educational process that takes place between the investigator and prospective subject, allowing the investigator and the participant to exchange information and ask questions. In most cases, federal regulations require informed consent and documentation of the process. In certain circumstances, the federal regulations allow a waiver of informed consent documentation or of the process.

The consent document is not a substitute for discussion between the investigators and research participants. The Nova Southeastern University (NSU) Institutional Review Board (IRB) will ensure that the process of informed consent complies with federal regulations defined by the Office of Human Research Protections (OHRP) and the Food and Drug Administration (FDA). The NSU informed consent templates include the required elements of informed consent. At its discretion, the NSU IRB may require elements in the informed consent that exceed federal requirements. The investigator may use a short form if approved by the IRB in accord with applicable federal requirements.

Definitions

Assent is defined as affirmative agreement of a child or an individual with impaired consent capacity to participate in research. Failure of participant to object should not be interpreted as assent.

Permission is defined as the agreement of parent(s) or guardian to the participation of their child or ward in research or clinical investigation. Permission includes the element of consent set forth in federal regulations and outlined in the NSU informed consent template.

The terms *child* or *children* refer to all individuals under 18 years of age unless the individual(s) is legally emancipated based on the regulations for the state of Florida and the region the study will be conducted. Individuals under 18 years of age who are not emancipated meet the federal

definition for "child" as defined by the Department of Health and Human Services (DHHS), Food and Drug Administration (FDA), and U.S. Department of Education.

*Legally Authorized Representative (LAR)***:** An individual who has the authority to make research participation decisions on behalf of another.

Guardian: An individual who may serve as an LAR as defined above. These individuals meet the federal definitions for guardian.

Participant's Representative: For purposes of this policy, an individual who is the parent, guardian, or legally authorized representative for a participant as defined in this section.

Waiver of Informed Consent Process

The IRBs have the authority to approve a consent procedure that does not include or which alters some or all of the federally mandated elements of informed consent provided the approved procedure meets applicable federal regulations. A summary of applicable waiver federal regulations and University requirements is as follows:

1. To waive informed consent requirements, the IRB must find and document that the study meets the requirements in 45 CFR 46.116(f)(3).
2. To provide a limited waiver of informed consent requirements for screening purposes, the IRB must find and document that the study meets the requirements in 45 CFR.116(g).

Waiver of Documentation of Informed Consent
(Signed Consent Form Waived (Process Not Waived)

Federal regulations permit an IRB to waive the documentation requirements for obtaining informed consent under special circumstances.

1. Non-FDA-regulated studies: the IRB may waive the requirement to obtain a signed consent form for some or all of the subjects if the study meets the requirements in 45 CFR 46.117(c) and 38 CFR Part 16.117(c).

2. FDA-regulated studies: IRB may waive documentation for some or all of the subjects if the study meets the conditions listed in 21 CFR 56.109(c).

RESPONSIBILITY

Execution of SOP: Principal Investigator (PI)/Research Personnel, Institutional Review Board (IRB) Office Staff, IRB Members, IRB Chairs

PROCEDURES

A. Informed Consent Process and Documentation

1. The investigator submits a proposed informed consent procedure and written form with their protocol submission prior to initiation of research. The investigator indicates in the protocol submission all study personnel who will participate in the informed consent process. All individuals who participant in the informed consent process must be listed as study personnel on the protocol submission.

2. NSU does not allow the IRB Informed Consent Form and HIPAA Authorization for Research Form to be combined into one document. These must be two separate documents and must meet the regulatory requirements for signatures and contents.

3. The NSU IRB has an informed consent template on our website. Investigators are encouraged to use this template unless the IRB grants exceptions or a waiver. The consent template contains the required elements and the additional elements of informed consent as outlined in Section B of this SOP. At its discretion, the NSU IRB may require elements in the informed consent that exceed federal requirements.

4. The IRB reviews the investigator's description of the informed consent process to ensure that the process meets the general requirements of informed consent.

5. The IRB is responsible for reviewing the proposed informed consent process and document(s) to ensure that all applicable federal and NSU requirements are met.

6. The IRB will determine whether disclosure of any investigator conflict of interest is warranted in the informed consent process and document.

7. If the study is not exempt, IRB office staff will affix an approval stamp to every page of informed consent documents upon approval of the protocol submission. Consent documents include, but are not limited to, informed consent/assent forms, participations letters, cover letters, and/or telephone scripts. This stamp will include the protocol number and the approval/expiration dates. Investigators may only enroll subjects using the stamped informed consent documents for non-exempt studies unless the IRB grants a waiver from the requirement for informed consent.

8. The investigator is responsible for ensuring that informed consent is obtained from each research participant or their representative after the participant or the participant's representative has had adequate time to read the form and prior to the participant's participation in any part of the study.

9. The participant or the participant's representative and the person providing the information to the participant sign and date the informed consent document at the time of consent. Only individuals authorized in the approved protocol submission may obtain informed consent and must sign on the line entitled "Name of Person Obtaining Consent and Authorization." The participant or representative signing on the participant's behalf receives a copy of the signed form.

10. The investigator's signature on the informed consent document verifies that the person who explained the study and obtained informed consent is qualified and that the IRB has approved them to do so.

B. Elements of Informed Consent

Required Elements

The following items must be included in the consent form as documentation that the consent process covered these essential principles of Informed Consent:

1. *Research statement*: A statement that provides a description of the research, including that the study is research, the purpose of the research, the duration and nature of the procedures associated with participation, and which, if any, procedures are experimental.

2. *Reasonably foreseeable risks or discomforts*: A statement that describes reasonably foreseeable risks associated with participation, the likelihood of their occurrence, and the effects associated with the risks.

3. *Reasonably expected benefits to subjects or others*: A statement that describes benefits to subjects or others that may reasonably be expected because of their participation in the research including no benefit, if applicable. Payment for participation in a research project is not considered a benefit.

4. *Appropriate alternatives*: A statement that describes with enough detail any alternative procedures or course of treatment that may be deemed beneficial to the participant, as applicable. If no alternatives exist, the consent form must state that there are no

alternatives except not to participate.

5. *Extent of confidentiality*: a statement that describes the extent to which the investigator/study personnel will maintain or not maintain confidentiality of records identifying the subject and describes how the research team will protect subjects' private records during and after the conclusion of proposed research studies.

6. *Compensation or treatment for injury*: For studies with greater than minimal risk, a statement explaining an explanation of possible compensation for injuries, availability of medical treatments, and further information on obtaining such treatment.

7. *Contact information*: a statement that describes contact information for questions about the research, participants' rights, and research-related injuries.

8. *Voluntary participation statement*: A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

Additional Elements

The following items must be included when appropriate but are not required under federal regulations. The IRB may determine that some, or all, of these additional elements are required during the IRB review process:

1. *Unforeseeable risks to subjects, embryos, or fetuses*: A statement that a particular treatment or procedure involves unforeseeable risks to the participant (including embryos or fetuses, if the participant or their partner may become pregnant).

2. *Investigator-initiated termination of participation*: A description of when the researcher may terminate participation without the participant's consent.

3. *Additional costs*: A statement describing any additional costs to the participant that may result from participation in the research.

4. *Early withdrawal/procedures for termination*: A statement describing the consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant.

5. *Significant new findings*: A statement that significant new findings developed during the course of the research, which may relate to the participant's willingness to continue participation will be provided to the participant.

6. *Approximate number of subjects*: A statement that explains the approximate number of subjects to be enrolled in the study, nationwide and locally.

Elements Required by State or Federal Agencies and Other Entities

1. For research involving FDA-regulated drugs or devices to be used in clinical trials, the following statement is required: "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."

2. Other statements required by state law and regulation, depending on where the study will be conducted. The IRB may require researchers to provide documentation with respect to local laws for research that occurs outside the state of Florida and may conduct information searches to determine appropriate local laws.

3. Other statements required by non-NSU Institutional Review Boards that may be responsible for reviewing and approving the study, (i.e., studies conducted at cooperative research sites where an IRB exists). The investigator should contact other IRBs to discuss their consent form requirements.

4. Other statements required as required by sponsored, funding agencies, or other entities with authority over the conduct of the study.

5. Other statements as required by NSU institutional and departmental policies. At its discretion, the NSU IRB may require elements in the informed consent that exceed federal requirements.

C. Use of the Short Form Consent Document

1. The investigator may request to use a short form written consent document stating that study-specific information has been orally described to and understood by the participant or their representative (as required by 45 CFR 46.116) orally to the participant or the participant's representative.

2. Investigators are required to use the NSU Short Form Consent template that is available on the NSU IRB website. Further information regarding the use of short form consent can be found at the beginning of this template.

3. The investigator must submit the following to the IRB for review:
    a. Justification for the use of the short form.
    b. A summary of what will be presented to the participant or their representative.
    c. Assurance that the NSU IRB Consent Short Form will be used.

4. The IRB reviews the request and may approve the short form option for documentation only if the study meets all of the requirements outlined in 45 CFR 46.117(b), and as applicable, 21 CFR 50.27(b) and/or 38 CFR 16.117(b).

5. When the IRB approves use of the short form method:
    a. The investigator must ensure there will be a witness to the oral presentation. For participants who do not speak English, the investigator must ensure the witness is conversant in both English and the language of the participant.
    b. The IRB must approve a written summary of the oral content presented to the participant or the participant's representative, which embodies the basic and appropriate elements of disclosure.
    c. The participant or the participant's representative signs and dates the short form.
    d. The witness signs both the short form and a copy of the summary.
    e. The person actually obtaining consent signs a copy of the summary.
    f. The person obtaining consent gives a copy of the summary to the participant or the participant's representative, in addition to a copy of the short form.

<u>D. Non-English Speaking Subjects</u>

1. Investigators must deliver all information regarding informed consent/assent to potential subjects or their representative in the subject's native language(s) or one that the subject understands.

2. The investigator must provide the IRB and prospective subjects a translated version of the consent/assent form via an amendment <u>after</u> they have received official approval of the English versions.

3. Investigators may not implement translated documents until their amendment have received official approval notification from the IRB.

4. The IRB Office will review translated documents as outlined in Section A of the Protocol Revisions, Annual Status of Research, and Study Closure SOP.

E. Alteration of Informed Consent

1. The IRB may approve a consent procedure that does not include or alters some or all of the elements of informed consent set forth in this SOP.

2. The IRB may grant alteration of informed if it is determined that:
   a. The research involves no more than minimal risk to the participants;
   b. The waiver or alteration will not adversely affect the rights and welfare of the participants;
   c. The research could not practicably be carried out without the waiver or alteration; and
   d. Whenever appropriate, the participants will be provided with additional pertinent information after participation.

3. Investigators are encouraged to consult the Research Involving Deception SOP for further guidance.

4. If the alteration of informed consent is part of a protocol submission reviewed by the convened IRB, IRB office staff will document the alteration of informed consent criteria and approval in the IRB meeting minutes.

5. If the protocol is eligible for expedited review, a notation will be made in the study file by the expedited reviewer documenting whether the study meets each of the criteria for an alteration of informed consent.

F. Waiver of Informed Consent

1. The investigator makes a preliminary decision to seek waiver of informed consent, as specified in the protocol submission.

2. The IRB may waive the requirements or alter elements if it finds and documents:
   a. The research involves no more than minimal risk to the subjects;
   b. The research will not adversely affect the rights and welfare of subjects;
   c. The investigator could not practicably conduct the research without the waiver or alteration; and
   d. Whenever appropriate, study personnel provide participants additional pertinent information after their participation.

3. The IRB may also waive the requirement to obtain informed consent or alter some of the elements if the IRB finds and documents that:
   a. The research or demonstration project is to be conducted by or is subject to approval of state or local government officials and is designed to study, evaluate or examine public benefit of service programs, procedures, methods or levels of payment; AND
   b. The investigator could not practicably conduct the research without the waiver or alteration.

4. If the waiver of informed consent is part of a protocol submission reviewed by the convened IRB, IRB office staff will document the waiver of informed consent criteria and approval in the IRB meeting minutes.

5. If the protocol is eligible for expedited review, a notation will be made in the study file by the expedited reviewer documenting whether the study meets each of the criteria for a waiver of informed consent.

G. Waiver of Documentation of Informed Consent

1. The investigator makes a preliminary decision to seek waiver of the documentation requirements for obtaining informed consent, as specified in the protocol submission.

2. The IRB may waive the documentation requirements to obtain a signed consent if:
   a. Non-FDA-regulated studies: 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. Study personnel must ask each subject whether he/she wants documentation regarding the research; **OR**
   b. Non-FDA-regulated studies: The research presents no more than minimal risk to subjects and involves no procedures for which written consent is normally required (i.e., a cover letter or a phone script). **OR**
   c. FDA-regulated studies: The research presents no more than minimal risk and involves no procedures for which the IRB normally requires written consent.

3. When the IRB waives the requirement to obtain written documentation of informed consent, the IRB reviews a written description of the information that the investigator will give to the participants. The IRB Office recommends investigators use the "Waiver of Documentation of Informed Consent" templates provided on the NSU IRB website.

4. In cases in which the IRB waives the documentation requirement, the IRB has the authority to require the investigator to provide subjects with a written statement regarding the research

5. If the waiver of documentation of informed consent is part of a protocol submission reviewed by the convened IRB, IRB office staff will document the waiver of documentation of informed consent criteria and approval in the IRB meeting minutes.

6. If the protocol is eligible for expedited review, a notation will be made in the study file by the expedited reviewer documenting whether the study meets each of the criteria for a waiver of documentation of informed consent

H. Exception from Consent Requirements for FDA-Regulated Products

1. 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:
   a. Participant is in a life-threatening situation necessitating use of test article
   b. Consent cannot be obtained because of an inability to communicate with, or obtain legally effective consent from, the participant
   c. Time is not sufficient to obtain consent from participant's legal representative
   d. 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 participant.

2. If immediate use of the test article is required to save the life of the participant 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.

3. 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.

I. Limited Waiver of Consent for Screening Purposes

1. The investigator makes a preliminary decision to seek a limited waiver of informed consent, as specified in the protocol submission.

2. The IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening prospective participants without the informed consent if either:
   a. The investigator will obtain information through oral or written communication with the prospective participant or legally authorized representative, or
   b. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

J. Re-consenting of Participants

1. In instances where a consent form has been modified via amendment, upon approval, investigators may be required to re-consent active participants at the discretion of the IRB. Active participants are those who still have research-related interventions or activities to complete.

2. When appropriate, the IRB may require investigators to re-consent participants who are only active for long-term follow-up if the revised consent form provides information that may be meaningful to the participant.

3. Participants/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.

K. Recordkeeping

1. For studies conducted at an NSU clinic, the investigator places a copy of the signed consent form or, if applicable, assent form in the medical record unless the IRB waives the requirement. The investigator must also keep the original signed consent/assent documents, or accurate reproductions, securely throughout the record retention period in accord with the approved protocol submission.

2. For studies conducted in other settings (i.e., not conducted in NSU clinic), the investigator keeps the original signed informed consent/assent documents, or accurate reproductions, in accord with the "Confidentiality/Privacy of Records and Recordkeeping SOP" and study procedures as approved by the IRB.

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