Before a participant becomes involved in research investigators must obtain either the legally informed consent of the participant or the participant’s legally authorized representative, or have Institutional Review Board (IRB) approval for a waiver of informed consent. Although this policy largely addresses the content required for informed consent, consent for participation is a process which may involve providing participants with additional information as necessary and ensuring continuing participants consent throughout the course of the study. In some cases, the investigator may need to proactively verify that the participant understands the consent materials.

DEFINITIONS

A. LEGALLY AUTHORIZED REPRESENTATIVE: An individual, or judicial or other body, authorized under applicable law to consent on behalf of a prospective participant to the participant’s participation in the procedure(s) involved in the research

B. SURROGATE PERMISSION: Permission for an individual to participate in research given by an appropriate surrogate (e.g., next of kin–spouse, parent, child, sibling) when an individual is assessed as not capable of providing fully informed and legally effective consent and state law does not define the appropriate legally authorized representative for research purposes.

INFORMED CONSENT REQUIREMENTS

To be legally effective, informed consent should:
1. be in language understandable to the subject or the representative;
2. be obtained under circumstances that offer the subject or the representative sufficient opportunity to consider whether the subject should or should not participate; and
3. not include exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the research investigator, the sponsor, the institution or its agents from liability for negligence.
4. be conducted in a manner designed to minimize any potential for coercion or undue influence.
The following eight basic elements of informed consent are required to be provided in the course of the consent process (45 CFR 46.116):

1. A statement that the study involves research, an explanation of the purpose of the research, the expected duration of participation, a description of the procedures, and identification of the experimental procedures.

2. A description of any reasonably foreseeable risks or discomforts.

3. A description of any benefits to the participant or to others that might be reasonably expected from the research.

4.Disclosure of appropriate alternative procedures or courses of treatment, if any, that may be advantageous to the participant.

5. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained including as appropriate:

   (a) what records may be examined by the sponsor, the IRB, other University personnel, the Food and Drug Administration (FDA), or other regulatory agencies,

   (b) whether or not the data collected will be retained, and, if so, for what purpose and for what period of time, or when the data will be de-identified and/or destroyed,

   (c) what procedures will be put in place to ensure that unauthorized individuals will not have access to this information, and (d) the limitations (if any) to these confidentiality procedures such as legal reporting requirements for specific diseases and in the case of suspected child or elder abuse.

6. For research involving more than minimal risk, an explanation as to whether or not any compensation and medical treatment are available if injury occurs to the participant and if so, what they consist of or where further information may be obtained.

7. Identification of whom to contact for answers to questions about the research and the research participants’ rights including whom to contact when the investigator may be unavailable or to discuss any other questions, complaints or concerns and whom to contact if the participant sustains a research-related injury.

8. A statement that research participation is voluntary, that the participant may discontinue participation at any time, and that the participant’s refusal to take part or withdrawal will not involve a penalty or loss of benefits to which the participant is otherwise entitled.

When appropriate, the following additional elements of informed consent must also be adequately provided to the participant or representative:

1. A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) which are unknown or currently unforeseeable.
2. Anticipated circumstances under which the volunteer’s participation may be terminated by the investigator without regard to the participant’s consent or willingness to continue to participate.

3. Any additional costs to the participant that may result from taking part in the research, including whether or not such costs may be billed to a third party payer.

4. The amount and schedule of payments for participating in the research.

5. The consequences of the participant’s decision to withdraw from the research and procedures for safe and orderly termination of participation, if applicable.

6. A statement that significant new findings developed during the course of the research which may relate to the participant’s willingness to continue to participate will be provided to the participant.

7. The approximate number of participants involved in the study.

8. If the study is registered on clinicaltrials.gov: 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. A most, the web site will include a summary of the results. You can search this web site at any time.

DOCUMENTATION OF INFORMED CONSENT

Unless waived by the IRB, the informed consent information will be provided in writing and will be signed by the participant or their legally authorized representative or surrogate. For a research project that is also subject to FDA regulations, the individual obtaining the informed consent must also sign and date the form. The informed consent form that is given to the participant must be marked with the approval and expiration date as determined by the IRB. The researcher must retain all signed informed consent forms for three years after the completion of the research. Participants must be provided with a copy of the consent document to keep.

WAIVER OF DOCUMENTATION OF INFORMED CONSENT

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all of the participants if it finds and documents the following:

1. That the research (or a specific part of the research, such as recruitment) presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context. This condition also applies to FDA regulated research OR

2. That the only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. In such a case, each participant will be asked whether the participant wants documentation linking the participant to the research, and the participant's wishes will govern. This condition is not applicable to FDA regulated research.
In research projects where the IRB has waived the signature of informed consent, the investigator(s) must still provide all of the required elements of informed consent to the participants, and the IRB may require the investigator(s) provide participants with a written copy of the consent information to be given. The IRB will review a written description of the information that will be provided to the participants to ensure that all of the required elements of informed consent are included.

**WAIVER OF SOME OR ALL OF THE REQUIRED ELEMENTS OF INFORMED CONSENT**

The IRB may approve a consent procedure that omits or alters some or all of the elements of informed consent only if 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;
   c. possible changes in or alternatives to those programs or procedures;
   d. or possible changes in methods or levels of payment for benefits or services under those programs;
   AND
   a. the research could not practicably be carried out without the waiver or alteration;
   b. the research is not FDA-regulated

OR

2. The research meets the following criteria
   a. 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
   AND
   a. The research is not FDA-regulated

NOTE: When the FDA regulations apply to a research project, the IRB may not waive or alter the consent process.

**Studies involving deception**

Studies which will not fully disclose the purpose, nature or other aspects of the study to potential participants at the time of informed consent may do so only when the deception is deemed necessary by the IRB for the conduct of the research. Because studies involving deception involve incomplete disclosure of some of the eight basic elements of consent the requirements, the IRB must determine that the conditions for waiver of consent described in this policy are met.
Participants in a study involving the use of deception or incomplete disclosure should be provided with information about the nature of the deception and/or incomplete disclosure after the completion of the study unless debriefing is not possible or would cause unacceptable risk to the subjects. During the debriefing, subjects must have the opportunity to ask questions and be given the opportunity to withdraw from the study or have their data removed.

Studies using incomplete disclosure or deception should do so to the minimum extent required for the purposes of the study.

NON-ENGLISH SPEAKING AND/OR ILLITERATE PARTICIPANTS

When some or all of the prospective participants do not speak or readily understand English, the participant must be provided information throughout the study in their own language. The informed consent must be a written consent document drafted in language understandable to the participant.

Alternatively, oral presentation of informed consent information may be used with persons who do not speak (or cannot read) English. In such cases, an oral presentation and a short form written document may be provided in a language readily understandable to the participant, and the English language informed consent document approved by the IRB may serve as the basis for the oral presentation.

When using the short form consent:

1. The short form consent must state that the elements of disclosure required by regulation have been presented orally to the participant or his/her Legally Authorized Representative (LAR).

2. The form must embody the basic and appropriate additional elements of disclosure.

3. There must be a witness to the oral presentation. The interpreter may serve as a witness.

4. For participants who do not speak English, the interpreter presenting the consent information must be conversant in both English and the language of the participant.

5. The participant or his/her LAR must sign the short form consent. If the study is FDA-regulated, the participant or LAR must also date the short form consent

6. The interpreter obtaining consent and the witness (who may be the same person) must sign the short form consent and the summary (full consent document in English).

7. The researcher must sign the summary (full consent document in English).

8. Copies of the short form and the summary (full consent document) must be given to the participant or his/her LAR, as appropriate.

The IRB must receive and approve prior to their use, all foreign language versions of the short form document and any other translated documents presented to the participants.
ADDITIONAL CONSENT REQUIREMENTS

The IRB may require the investigator(s) provide additional information in the informed consent other than the eight required elements if it deems them necessary to protect the rights and wellbeing of the participants.

Video/Audiotaping Procedures

Projects involving the use of videotaping or audiotaping must make specific mention of this in the consent documents. The subject must have the choice of whether to participate in the video or audiotaping procedures. This consent is separate and distinct from consent to participate in the project, therefore, separate signature and date lines are required. If the IRB has approved a waiver of the written signature of consent, the investigator must ensure that either the written consent information or the oral consent process addresses consent to be recorded separately from consent to participate in the research.

Additional Requirements for Children and Other Special Populations

Additional consent requirements for children, pregnant women and fetuses, and prisoners are specified in the separate NIU IRB policies specific for those populations.