Informed Consent for Human Research

Policy Approval Authority: President

Responsible Division: Division of Research and Innovation Partnerships

Responsible Office: Office of Research Compliance, Integrity, and Safety

Responsible Officer (title only): Vice President for Research and Innovation Partnerships

Contact Person: Patricia Wallace

Purpose

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 participant’s consent throughout the course of the study. In some cases, the investigator may need to proactively verify that the participant understands the consent materials.

Policy Narrative

**DEFINITIONS**

**A. *LEGALLY AUTHORIZED REPRESENTATIVE (LAR):*** "an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject’s participation in the procedure(s) involved in the research." (45 CFR 46.102(i)).

***(See the NIU IRB policy “***Research Involving Persons with Impaired Consent Capacity” for the NIU institutional policy on who may provide consent for persons with impaired consent capacity.)

**I. GENERAL REQUIREMENTS FOR INFORMED CONSENT**

A. 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. (Note: The IRB *may* approve a protocol which conducts screening for recruitment or to determine eligibility without informed consent for that screening if one of two conditions is met: 1) screening data is obtained through oral or written communication with the prospective subjects OR 2) the investigator will obtain identifiable private information for screening by accessing records or identifiable biospecimens.)

B. Informed consent should only be obtained under circumstances that provide the prospective subject or the legally authorized representative (LAR) sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.

C. The information that is given to the subject or the LAR should be in language that is understandable to the subject or the LAR. This means that the consent language should be free of words and terminology that are not readily understood by a lay reader. If potential subjects do not speak or readily understand English, the consent information should be provided in the language they are most fluent in.

D. The prospective subject or the LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate and an opportunity to discuss that information.

E. Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research. This should include a brief description of the following: a statement that the study involves research, a statement that participation is voluntary, an explanation of the purpose of the research, the duration of participation, the research procedures, the potential benefits of the study (to the participant or the field in general), and the potential risks. This part of the informed consent must be organized and presented in a way that facilitates comprehension (e.g., bullet points are acceptable).

F. Informed consent as a whole must present information in sufficient detail relating to the research and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject’s or the LAR’s understanding of the reasons why one might or might not want to participate in the research.

G. No informed consent may include any exculpatory language through which the subject or the LAR appears to waive any of the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

**II. BASIC ELEMENTS FOR INFORMED CONSENT**

A. In addition to the “key information” section at the beginning of the informed consent, the following basic elements of informed consent are required to be provided in the course of the consent process:

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 any procedures that are experimental

2. A description of any reasonably foreseeable risks or discomforts to the subject

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

4. A 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) The limitations (if any) to these confidentiality procedures such as legal reporting requirements for specific diseases and in the case of suspected child, sexual, or elder abuse.

6. For research involving more than minimal risk, or risk of physical harm, a statement that Northern Illinois University policy does not provide for compensation or medical treatment of injuries that may occur as a result of participation in research activities, and that the preceding statement shall not be construed as a waiver of any legal rights or redress which the participant may have.

7. Identification of whom to contact for answers to questions about the research and the research participants’ rights, and whom to contact if the participant sustains a research-related injury. For student researchers, this contact information must also include their faculty mentor’s contact information.

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 to withdraw will not involve a penalty or loss of benefits to which the participant is otherwise entitled.

9. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

(a) A statement that the identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research without additional informed consent from the subject or LAR, if this might be a possibility **OR**

 (b) a statement that the subject’s information or biospecimens collected as a part of the research, even if identifiers are removed, will not be used or distributed for further research studies.

B. **When appropriate**, the following additional elements of informed consent must also be adequately provided to the participant or LAR:

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

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. A statement that the subject’s biospecimens (even if the identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit

9. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)

10. 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. At most, the web site will include a summary of the results. You can search this web site at any time.”

**III. GENERAL REQUIREMENTS FOR BROAD CONSENT FOR THE STORAGE, MAINTENANCE, AND SECONDARY USE OF IDENTIFIABLE PRIVATE INFORMATION OR BIOSPECIMENS**

Researchers who wish to store or maintain identifiable private information or identifiable biospecimens which were collected either for research studies or for nonresearch purposes have the option of using broad consent to obtain permission from the subjects or their LARs to store or maintain the identifiable private information or identifiable biospecimens. This includes the storage or maintenance of audiotapes or videotapes.

If the subject or LAR is asked to provide broad consent, the following shall be provided to each subject or the subject’s LAR:

A. Before a participant becomes involved in research, investigators must obtain either the legally informed consent of the participant (or the participant’s LAR) or have Institutional Review Board (IRB) approval for a waiver of informed consent.

B. Informed consent should only be obtained under circumstances that provide the prospective subject or the LAR sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.

C. The information that is given to the subject or the LAR should be in language that is understandable to the subject or the LAR. This means that the consent language should be free of words and terminology that is not readily understood by a lay reader. If potential subjects do not speak or readily understand English, the consent information should be provided in the language they are most fluent in.

D. The prospective subject or the LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

E. No informed consent may include any exculpatory language through which the subject or the LAR appears to waive any of the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

**IV. BASIC ELEMENTS FOR BROAD CONSENT**

A. The following basic elements of broad consent are required to be provided in the course of the broad consent process:

1. A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted

2. A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of the identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens

3. A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (the period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (the period of time could be indefinite)

4. Unless the subject or LAR will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject’s identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies

5. Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject

6. An explanation of whom to contact for answers to questions about the subject’s rights and about storage and use of the subject’s identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm

7. A description of any reasonably foreseeable risks or discomforts to the subject

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

9. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained

10. 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 to withdraw will not involve a penalty or loss of benefits to which the participant is otherwise entitled

11. If appropriate, a statement that the subject’s biospecimens (even if the identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit

12. If appropriate, for biospecimens, whether the research uses will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen)

**V. DOCUMENTATION OF INFORMED CONSENT**

Unless waived by the IRB, the informed consent information will be provided in writing and will be signed (including in an electronic format) 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.

**VI. 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; **OR**

3. The subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects, and provided there is an appropriate alternative mechanism for documentation that informed consent was obtained.

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.

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

The IRB may not omit or alter any of the requirements for broad consent. If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of that identifiable private information or identifiable biospecimens.

With the exception of broad consent, the IRB may approve a consent procedure that omits some, 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;

e. if the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format

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.

**VIII. Waiver of consent for screening, recruiting, or determining eligibility**

An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject’s LAR, if either of the following conditions are met:

1. The investigator will obtain information through oral or written communication with the prospective subject or LAR

**OR**

1. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

This waiver of consent for screening, recruiting, or determining eligibility does not apply to procedures other than oral or written communication or existing private information or identifiable biospecimens. Other types of screening procedures, such as taking blood pressure, blood draws, conducting hearing screenings, using physical sensors, collection of saliva, etc. still require prospective informed consent of the participants.

**IX. 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 be conducted 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 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.

When appropriate, the consent process for studies involving deceiving the participants regarding the nature or purposes of the research may include prospective authorization of the deception. Where authorization of deception is used, the consent process will inform the participants that they will be unaware of or misled regarding the nature or purposes of the research.

**X. 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 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

**XI. ADDITIONAL CONSENT REQUIREMENTS**

The IRB may require the investigator(s) provide additional information in the informed consent other than the 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.

Procedural History of the Policy

**Approved by the convened Institutional Review Board and the VP for Research in August 2023.**