Guidance: Components of informed consent

Criteria #4: Informed consent will be sought from each prospective subject or the subject's legally authorized representative unless this requirement is waived by the IRB.

Criteria #5: Informed consent will be appropriately documented as required by local, state and federal regulations unless the requirement is waived by the IRB.

Informed consent is the process by which potential participants are provided important information about the research study. Obtaining written consent from individuals ensures investigators have provided the necessary and required information for one to make a fully informed choice to enroll as a research participant. It is important that issues of coercion and undue influence are considered. To minimize these, the IRB considers many factors:

- language used to recruit prospective subjects;
- Timing and circumstances under which consent is obtained
- Relationship between the individual obtaining consent and the potential research participant;
- qualifications of individuals obtaining informed consent
- whether oral or written, the consent may not include any exculpatory language
- Informed consent may not include language that appears to waive subjects' legal rights or appears to release the investigator or anyone else involved in the study from liability or negligence
- Consent forms and scripts must be clearly written and understandable to subjects
- Scientific, technical, professional jargon, and medical terms must be clearly defined
- The reading level should be appropriate to the targeted subject population
- Plans to document and retain consent forms is appropriate and ensures participant privacy is retained

The IRB informed consent form templates are designed to ensure that documentation of informed consent includes federally mandated basic and additional elements of informed consent. Below is guidance on sections and required elements for each. The information and recommendation that follow are taken from the *Code of Federal Regulations, Department of Health and Human Services for the Protection of Human Subjects §46.116*.

WHO, WHAT & WHY

- Specify who is conducting the research and their affiliation with Northeastern University. Northeastern has a policy on who may serve as a principal investigator, found here.
- Include a statement that the study involves research.
- Explain the purpose(s) of the research.

- Describe the procedures to be followed and the duration of participation.
- When appropriate, state the approximate number of subjects involved in the study.

VOLUNTARINESS

- Include a statement that participation is voluntary.
- Include a statement indicating that the subject may refuse to participate or may discontinue participation at any time during the project without penalty or loss of benefits to which the subject is otherwise entitled.
- Describe any compensation the participant will receive and when applicable, how compensation will be prorated
- When appropriate, include a statement that "the decision to participate, decline, or withdraw from participation will have no effect on the subject's grades at, status at, or future relations with the University of Illinois."
- When appropriate, state any anticipated circumstances under which the subject's participation may be terminated by the researcher without regard to the subject's consent.
- When appropriate, state the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

RISKS & BENEFITS

- Include a description of any reasonably foreseeable risks or discomforts.
- Include a description of possible benefits to the subject or to others, which may reasonably be expected from the research.
- If research involves treatment, disclose any appropriate alternative procedures or courses of treatment that might be advantageous.
- When appropriate, 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.
- When appropriate, 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.
- When applicable include the statement "The University of Illinois does not provide medical or hospitalization insurance coverage for participants in this research study nor will the University of Illinois provide compensation for any injury sustained as a result of participation in this research study, except as required by law."

CONFIDENTIALITY

- Describe the extent, if any, to which confidentiality of records will be maintained. If you cannot assure privacy or confidentiality, state that explicitly.
- State how results will be disseminated.
- When appropriate, state that research records may be inspected by the FDA.

CONTACT INFORMATION

- The name(s), title(s), and contact information (phone and e-mail) of the person(s) to contact for answers to questions about the research and the name, title, and contact information of the responsible project investigator, if different.
- Add the following contact statement, If you have any questions about your rights as a research subject, including concerns, complaints, or to offer input, you may contact the Human Research Protection Program at IRBReview@northeastern.edu.

ABOVE THE SIGNATURE LINE

- State that subjects will be given a copy of the consent form or may print a copy if consent is online.
- Include a statement such as "I have read and understand the above consent form and voluntarily agree to participate in this study."
- When appropriate, include a statement that "I am 18 years of age or older."
- When applicable, yes/no checkboxes to being audiotaped, videotaped, or photographed (if such recording is optional and has not already been specified as a requirement for participation).
- When applicable, yes/no checkboxes to being contacted for future research participation.

RETENTION OF INFORMED CONSENT DOCUMENTS

- Documentation of informed consent of subjects must be retained for at least three years after the research is completed.
- During those three years, records must be accessible for inspection and copying by authorized representatives of the University or Office of Human Research Protections, should the need arise.
- Once the three-year period has passed, informed consent records must be sufficiently destroyed, such as by shredding. Recycling or throwing away the documents does not meet OHRP's standard of "sufficiently destroyed."