

INFORMED CONSENT: GENERAL REQUIREMENTS AND DOCUMENTATION

SOP #:	701	VERSION #:	1	EFFECTIVE DATE:	6/1/14	SUPERSEDES DOCUMENT:	5/1/09
THIS POLICY PERTAINS TO:			ALL RESEARCH SUBMITTED TO THE IRB				
RESPONSIBILITY FOR EXECUTING POLICY:		ASSOCIATE VICE PRESIDENT FOR RESEARCH AND ECONOMIC DEVELOPMENT, IRB CHAIRPERSON, IRB MEMBERS					
LAST REVIEWED ON:		/ /		RESULTS:	REVISED		
APPROVAL AUTHORITY:		Associate Vice President for Research and Economic Development					
APPROVED BY:						DATE:	3/1/14

1. POLICY

Except as described in SOP 702, Investigators may not enroll human subjects in research unless they have obtained the legally effective, written, informed consent of the subject or the subject’s legally authorized representative. Investigators are responsible for ensuring that the subjects, or their representatives, are given sufficient opportunity to consider whether or not to participate and must seek to avoid coercion or undue influence. The IRB is responsible for evaluating the informed consent process. The IRB may request to observe the informed consent process to ensure adequate consent, especially when the research involves particularly vulnerable populations.

The informed consent of a subject is a privilege freely granted by a subject. He or she is under no obligation to participate no matter how worthy the research objectives. Furthermore, while obtaining the signature of a subject is an event, obtaining consent is a process that leads to the signature and that is to be continued throughout the project.

The IRB requires documentation of informed consent by use of a written informed consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative. Only the most recently approved, date stamped consent form is to be used. In studies involving children, the legally authorized representative is the parent or the child’s court-appointed guardian. In studies involving cognitively impaired adults, the legally authorized representative is a designated proxy (such as a Durable Power of Attorney for Health Care), court-appointed guardian, spouse, adult child, parent, or adult sibling, in that order.

A waiver of the requirement of informed consent may be obtained only under the conditions described in SOP 702. Documentation of informed consent applies to all research projects that qualify for expedited and Full IRB review.

2. SPECIFIC POLICY

2.1 The Consent Form May be Either of the Following:

1. A written consent document that embodies the elements of informed consent described in 21 CFR 50.25 and 45 CFR 46.116(a). This form may be read to the subject or the subject's legally authorized representative, but, in any event, the Investigator shall give either the subject or the representative adequate opportunity to read and reflect upon it before it is signed. The subject must also be given a copy of the signed form.

2. A "short form" written consent document stating that the elements of informed consent as required above have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be an impartial witness to the oral presentation. The IRB must approve a written summary of what is to be said to the subject or representative. The subject or the representative signs only the short form itself. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining the consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative in addition to a copy of the short form. For participants who do not speak English, the witness will be conversant in both English and the language of the participant.

2.2 Required Elements of Informed Consent

In seeking informed consent the following information shall be provided to each subject:

1. A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others which may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about the research and whom to contact in the event of a research-related injury to the subject; and
8. A statement that subjects can contact the IRB office for answers to questions about research subjects' rights, concerns or complaints about the research, or if research staff is unavailable or the subject wants to talk with someone else.
9. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

2.3 Additional Elements of Informed Consent

When appropriate, one or more of the following elements of information shall also be provided to each subject:

1. A statement that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable.

A statement that the particular treatment or procedure may involve risks to the embryo or fetus if the subject is or may become pregnant, which are currently unforeseeable.

- Required for medical research.

- Add for non-medical research whenever the risks of the intervention are not well known.
 - Required for medical research involving women of child bearing potential, unless the risks to the embryo or fetus are well known.
 - Add for non-medical research whenever the research involves women of child bearing potential and the effects of the intervention on an embryo or fetus are not well known
2. Anticipated circumstances under which the subject's participation may be terminated by the Investigator without regard to the subject's consent;
 - Required for medical research.
 3. Any additional costs to the subject that may result from participation in the research;
 - Required.
 4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
 - Required when early withdrawal by participants may place them at increased risk of harm.
 5. 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;
 - Required for medical research.
 - Add for non-medical research whenever new information may be discovered during the course of the study that may affect participants' willingness to continue in the research. and;
 6. The approximate number of subjects involved in the study.
 - Required.

2.4 Other Requirements

1. Second person: The language of the consent document should be in the second person style so the consent form conveys a dialogue with information being provided and that there is a choice to be made by the subject rather than presumption of the subject's consent with the use of the first person style.
2. Language should be simple: The information provided in the informed consent documents must be in language understandable to the subject. The informed consent document should be written at about an eighth grade reading level, and should not include complex language that would not be understandable to all subjects. Technical and scientific terms should be adequately explained using common or lay terminology.
3. Exculpatory language: Informed consent documents may not contain any exculpatory language through which the subject is made to waive or appear to waive legal rights or releases or appears to release the Investigator, the Sponsor, or the University of North Dakota from liability for negligence.
4. FDA-regulated test articles: For all research involving test articles regulated by the FDA, informed consent documents must include a statement that the purpose of the study includes evaluation of both the safety and the effectiveness of the test article. The consent form must also include a statement that the FDA has access to the subject's medical records.

5. **Questions and Concerns:** The informed consent needs to contain contact numbers for the Investigator and IRB to ensure that the subject can contact the appropriate people with questions, concerns or complaints.
6. **Compensation:** Payment to research participants should not be considered a benefit, but a recruitment incentive or compensation. The compensation should not be such that it would be considered coercive or unduly influence subjects to enroll into a study or stay in a study. All information concerning the compensation, including the amount and schedule of payments should be included in the consent document. The compensation should be prorated rather than contingent upon completion of the study. If compensation is class extra-credit, an alternative means of obtaining credit must be made available to the students who wish not to volunteer as a research subject. The alternative means of obtaining credit must be comparable in time and effort.
7. **Withdrawal from a clinical trial:** When participants withdraw from a clinical trial, the IRB determines:
 - When a participant withdraws from a study, the data collected on the participant to the point of withdrawal remains part of the study database and may not be removed. The consent document cannot give the participant the option of having data removed.
 - A researcher may ask a participant who is withdrawing whether the participant wishes to provide continued follow-up and further data collection subsequent to their withdrawal from the interventional portion of the study. Under this circumstance, the discussion with the participant distinguishes between study-related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through non-invasive chart review, and address the maintenance of privacy and confidentiality of the participant's information.
 - The researcher must obtain the participant's consent for this limited participation in the study (assuming such a situation was not described in the original consent document). The IRB must approve the consent document.
 - If a participant withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the researcher must not access for purposes related to the study the participant's medical record or other confidential records requiring the participant's consent. However, a researcher may review study data related to the participant collected prior to the participant's withdrawal from the study, and may consult public records, such as those establishing survival status.

2.5 Additional Consent Information for Different Types of Studies

1. **Studies involving blood samples.** The consent form should contain a statement such as, "Blood samples will be obtained by venipuncture. This method involves inserting a needle into a vein in the arm and withdrawing a sample of blood. It is routinely used to obtain blood for physical examinations. Venipuncture is accompanied by minor discomfort at the site of the needle entry and may result in slight bruising and a feeling of faintness. In this study a trained technician will obtain a 30 ml (about 2 tablespoons) sample of your blood that will be analyzed for..."
2. **Studies involving blood, tissue or body fluid for possible genetic research.** If the research involves the use of a subject's blood, tissue or body fluid for current or future genetic

- research, the researcher should modify the consent form to explain subjects' rights, including:
- a. the fact that the specimens will be maintained without identifiers;
 - b. the risk level to the subject if they agree to participate;
 - c. where the specimens will be stored;
 - d. who owns the specimens, and
 - e. how the specimens will be used in the future.
3. Studies that involve physical risk. The consent form should indicate how research related injuries will be handled. The University does not have a plan to cover research-related injuries. If a study involves physical risk, assess the risk and add a statement such as, "The University has no plan to provide treatment for research related injury and no plan to provide payment in the event of a medical problem." If emergency treatment for research-related injuries is arranged by (for example) having a medical doctor available for emergency treatment, that should be stated, but a disclaimer for extended care should be put into the consent form, such as "You will be charged for continuing medical care and hospitalization for research-related injuries. The University has no plan to provide financial compensation."
 4. Studies that involve a risk to a fetus: The female participant must be informed of the risk and the methods to be used (such as a pregnancy test) to minimize the risk.
 5. Studies that involve drugs: The participants must be given a statement of known side effects, warned about possible drug interactions (including interactions with alcohol), and warned about activities that may be dangerous (such as driving with a drug that has a sedative effect).
 6. Studies that involve psychological risk: The principles that apply to studies that involve psychological risk or mental stress are similar to those that involve physical risk. Participants should be informed of the risk and told that the University has no plan to provide treatment. They should be given the names and telephone numbers of agencies that may alleviate their mental concerns, such as a crisis hot line. If the Principal Investigator or the faculty sponsor of a Student Investigator is qualified to treat mental health problems, that person may be listed as a resource.
 7. Studies that involve sensitive topics: Participants should be told that some of the questions are of a personal or sensitive nature and should be given examples of the topics or questions. They should also be told that they can skip a question if they do not wish to answer it. If questionnaires or interviews may generate reports of child physical or sexual abuse, the participant must be informed whether the researcher is legally required to report this information to Child Protective Services. If the questionnaire or interview may generate reports that the participant plans to harm him or herself or others, the participant must be told whether the Investigator is ethically required to report that information to the local police department. Even if the PI is not a mandatory reporter, the IRB encourages Investigators to include this information. This information about the legal obligations to report abuse and threats of harm to oneself or others may be omitted if the responses are anonymous. In the event that the Privacy rule is more restrictive than the procedures described in the consent requirements, the more restrictive rule must be followed.
 8. Studies that involve deception: Where deception is a necessary part of an experiment, the IRB will generally require that a preliminary consent be obtained, in which the

Investigator informs the subject of the research. After the experiment, the subject should be informed of the deception and its purpose. We recognize that there are rare instances in which no consent can be obtained or debriefing done. Deception requires that a PI get formal approval of a waiver of informed consent, due to the initial consent being used.

9. Studies that involve audio or video recordings:

Participants must be told:

- a. that the interviews or sessions will be audio or video recorded;
- b. that the cassettes will be coded so that no personally identifying information is visible on them;
- c. that the recordings will be kept in a secure place (e.g., a locked file cabinet in the Investigator's office);
- d. that recordings will be heard or viewed only for research purposes by the Investigator and his or her associates; and
- e. that recordings will be erased after they are transcribed or coded.

If the researcher wishes to keep the recordings because of the requirements of his/her professional organization with respect to data or because the researcher may wish to review them for additional analyses at a later time, the statement about erasing them should be omitted and replaced with a statement that recordings will be retained for possible future analysis. If the researcher wishes to present the recordings at a convention or to use them for other educational purposes, he/she should get special permission to do so by adding, after the signature lines on the consent form, the following statement, "We may wish to present some of the recordings from this study at scientific conventions or as demonstrations in classrooms. Please sign below if you are willing to allow us to do so with the recording of your performance." Additionally, a second signature line should be added with the preface, "I hereby give permission for the video (audio) recording made for this research study to be also used for educational purposes." This procedure makes it possible for a participant to agree to being recorded for research purposes and to maintain the confidentiality of the information on that recording.

10. Cover Letters: Cover letters, rather than consent forms, may be used for some categories of minimal-risk research such as survey or questionnaire research. Cover letters are most frequently used for survey or questionnaire studies. The cover letter should state the purpose of the research, the expected number of respondents, a description of the topic of the survey and the content of the questions on the survey, a statement about confidentiality or anonymity, and a statement about how the participant may obtain additional information about the study. The cover letter should also state that participation is voluntary, and refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.

11. National Institute of Justice-funded research:

- The confidentiality statement on the consent form must state that confidentiality can only be broken if the participant reports immediate harm to participants or others.
- Under a privacy certificate, researchers and research staff do not have to report child and/or elder abuse unless the participant signs another consent form to allow child and/or elder abuse reporting.

3. RESPONSIBILITIES

Primary reviewers are responsible for careful review of all informed consent documents and for communicating revisions at the IRB meeting needed to bring documents into compliance. IRB Members/Alternates are responsible for review of informed consent documents prior to the IRB meeting.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 50
45 CFR 46.116, 46.117
[FDA Information Sheets, 1998](#)

5. ATTACHMENTS

IC 701-A Informed Consent Checklist
IC 701-B Informed Consent Document Template: Non-Medical

6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task
<i>Primary Reviewer, IRB members</i>	Review proposed ICFs and confirms that all required elements are present. If elements are missing, return consent document to Investigator with request for revision and suggested language (where appropriate).