

Prior to their involvement in non-exempt research, participants, or their legally authorized representatives, must signify consent by signing a written document that includes all relevant information about the research.

1.0 Consent document.

The legally effective process of informed consent, as described in *9.1 Consent Process*, must be documented by use of a written consent form approved by the IRB and signed by the participant, or their representative, unless the IRB has otherwise waived the requirement.

1.1 Format.

Prepare the consent document according to the following guidelines:

- written in simple, layperson's terms, free of scientific jargon (unless clearly defined) in a language that is understandable to potential participants or their representatives (a 6th – 8th grade reading level is recommended for the average, adult population)
- written in 2nd person language, addressing the participant directly as 'you'
- printed on NDSU department letterhead, or with the NDSU department name and address prominently displayed on the document
- containing all required, and any additional elements, as described below
- pages are numbered (i.e., pg 1 of 4), with a version date in the footer

Utilize either the suggested templates for consent documents (available on the IRB website), or an alternate format meeting these guidelines.

1.2 Required elements of consent. The consent document must contain the following required information, unless otherwise waived by the IRB:

1.2.1 Information about the research.

- statement that the study involves research
- explanation of the purposes of the research
- explanation of subject selection, if applicable
- expected duration of the subjects' participation
- description of the procedures to be followed
- identification of any procedures that are experimental

1.2.2 Risks and discomforts. A description of any reasonably foreseeable risks or discomforts related solely to the research. This explanation should be based on information in the protocol, other information, or relevant literature.

1.2.3 Benefits. A description of any reasonably expected benefits to the subject directly, as well as to others. Benefits should not be overstated; if participants are not expected to benefit directly, this should be stated.

1.2.4 Voluntariness. A statement that their participation is voluntary, and that refusal to participate, or to withdraw early will involve no penalty or loss of benefits to which they're otherwise entitled.

1.2.5 Alternatives. If applicable, include a brief description of any alternative procedures or course of treatment that might be available to the subject. *(Primarily relevant for biomedical research, although maybe applicable if behavioral interventions are proposed).*

1.2.6 Confidentiality. A statement describing the extent, if any, to which confidentiality of their records will be maintained. Include any responsibility for mandated reporting (i.e., child abuse), if applicable to the research. If the study is subject to FDA regulation, state that FDA officials may also access their records.

1.2.7 Compensation. A statement describing the amount of compensation offered in return for research participation. Include a description of any partial compensation, as well as the approximate chances of winning a raffle or drawing, as applicable. If applicable, include any equal, non-research alternatives for earning compensation (i.e., extra course credit).

1.2.8 Treatment for injury. *(Only applicable if research involves more than minimal risk)* Provide contact information for reporting injuries. Explain whether medical treatment is available for such injuries, and, if so, describe this treatment or tell where further information may be obtained. Include any referrals for local counseling services, if applicable.

1.2.9 Contact information for researcher. Provide contact information for questions about the research.

1.2.10 Contact information for the NDSU IRB office. Provide the IRB office contact information for questions about their rights as a research participant, or to report a problem or concern.

1.3 Additional elements of informed consent.

When appropriate, the consent document must include the following additional information:

1.3.1 Unforeseeable risks. A statement that the particular treatment or procedure may involve risks to them (or embryo or fetus if they are or may become pregnant) which are currently unforeseeable.

1.3.2 Termination of enrollment. Describe anticipated circumstances under which their participation may be terminated by the investigator without regard to their consent (ie, if they fail to follow instructions).

1.3.3 Costs. Describe any additional costs that may result from their participation in the research, and who is responsible for these costs.

1.3.4 Consequences for early withdrawal. If their decision to withdraw from the research would be deleterious to their health or welfare, describe these consequences as well as the procedures for orderly termination of their participation.

1.3.5 New findings. Indicate that they will be informed if any significant new findings develop during the course of the research that may impact their willingness to continue participation.

1.3.6 Number of participants. Include the approximate number of subjects in a study, if this would be significant to their decision to participate.

1.3.7 Statement of IRB approval. Consent documents may be stamped by the IRB office to signify IRB approval of a study. However, when use of a stamp is not feasible, (i.e., for consent documents posted online), a statement of NDSU IRB approval may be included in the written document, along with the applicable protocol number.

1.3.8 Sponsor name. Include the name of the sponsor, if the research is supported by external funding.

1.4 Signature requirement.

Informed consent is documented with the signature of the participant (or their representative), as well as the researcher obtaining their consent on the written document. A copy of the signed document must be offered to the participant. If obtaining a signature is not feasible for a research study, the IRB may determine that this requirement may be waived; refer to *9.3 Waiver or Alteration of the Requirements for Informed Consent*.

2.0 Consent of legally authorized representative.

When adult participants lack the capacity to consent, a legally authorized representative must give consent for their participation in research, unless the IRB has otherwise waived the requirement. Draft the consent document in a manner reflecting that it is the representative, rather than the participant, being asked to provide their permission for research participation.

3.0 Short Form Written Consent.

An alternate method for documenting informed consent is available, and may be preferable for non-English speaking or illiterate participants.

3.1 Oral presentation.

Present the elements of informed consent orally to the participant, or their representative. An impartial witness must be present during the presentation. An impartial witness is someone not associated with the research who can attest to the adequacy of the consent process as well as the subject's voluntary consent.

3.2 Written summary.

The IRB must approve a written summary of the oral presentation. The witness and the researcher obtaining consent sign the summary after the oral presentation. A copy is then given to the subject.

3.3 Short form.

The subject and the witness sign a short form, stating that the required elements of consent have been presented orally. A copy is given to the subject.

4.0 Consent for optional procedures.

A layered consent form can be used for research requiring participants to make various choices. For example, participants may be asked to choose whether or not to allow video or audio taping, donation of excess tissues, use of their real names, etc. Provide these options on the consent form as separate boxes for participants to check or mark their choice as 'yes' or 'no'.

5.0 Retention of consent forms.

The investigator must retain signed copies of the consent documents in a secure manner for 3 years beyond the termination of the study, unless otherwise specified by federal and/or state regulations or sponsor requirements. Should the investigator leave NDSU before the end of this period, the forms must then be maintained by the department of record unless otherwise specified.

6.0 IRB Review of Consent Documentation.

As part of the criteria for IRB approval, the IRB reviews and approves the consent documents prior to use. This review ensures that all required, and any additional elements are included, and the document is understandable to the proposed participant population. If the consent document will be translated into the participant's native language, the IRB must receive a copy of both the English and translated versions, and may require verification that the two documents are equivalent.

7.0 Waiver of the requirement to obtain documentation of informed consent.

Research involving incomplete disclosure, use of deception, elimination of the entire consent process, elimination of a signature requirement, or some other alteration to the informed consent requirements must get a waiver from the IRB. The IRB will make additional determinations in order to approve such a waiver or any alteration of informed consent requirements; refer to *9.3 Waiver or Alteration of Informed Consent Requirements*.

DEFINITIONS:

Informed consent: the voluntary agreement of a participant to take part in research, after being provided with sufficient information about the study, in a language and terminology understandable to them, and sufficient opportunity to consider their decision.

Legally authorized representative: an individual authorized by a judicial body or other appropriate body to give consent on behalf of a prospective subject to the subject's participation in research. May include: a health care agent (named as a durable power for health care decision maker while the subject had competency), or a court-appointed guardian.

REFERENCES:

[45CFR46.116](#) General requirements for informed consent
[45CFR46.117](#) Documentation of informed consent
[21CFR50, Subpart B](#) Informed Consent of Human Subjects
[45CFR46.111](#) and [21CFR56.111](#) Criteria for IRB approval of Research
[45CFR46.109](#) and [21CFR56.109](#) IRB review of research
[OHRP guidance on Written Procedures](#)

OHRP FAQs: [Informed Consent](#)
FDA Information Sheet, [A Guide to Informed Consent](#)

RELATED [FORMS](#):

IRB Protocol Form
Informed Consent Waiver Request Attachment form
Informed Consent Templates

RELATED HRPP SECTIONS:

9.1 Consent Process
9.3 Waiver or Alteration of Informed Consent Requirements
9.4 Children as Research Participants