9 Requirement for Informed Consent: 9.2 Documentation of Informed Consent	Effective Date: 1/21/2019 Revised: 10/27/2017

Informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's legally authorized representative unless the research is determined to be exempt under §___.104 or a waiver of this requirement has been granted. A written copy of the informed consent shall be given to the person signing the informed consent form. (§___.117)

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 legally authorized representative (LAR), unless the IRB has otherwise waived the requirement.

1.1 Format.

Prepare the consent document according to the following guidelines:

- Write 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 6^{th} – 8^{th} grade reading level is recommended for the average, adult population),
- Write in 2^{nd} person language, addressing the participant directly as 'you,'
- Print or display on NDSU department letterhead, or with the NDSU department name and address prominently displayed on the document,
- Use all required, and any additional elements, as described below,
- Number pages (e.g., Page 1 of 4), and include a version date and IRB protocol number in the footer.

Suggested templates are available on the IRB website; however, alternative formats may be acceptable as long as all required information is included.

1.2 Key Information. Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. This element may not be waived or altered.

1.3 Basic elements of informed consent. The consent document must contain the following required information, unless otherwise waived by the IRB:

1.3.1 Study Specific Description. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;

1.3.2 Risks: A description of any reasonably foreseeable risks or discomforts to the subject;

1.3.3 Benefits. A description of any benefits to the subject or to others that may reasonably be expected from the research;

1.3.4 Alternatives. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

1.3.5 Confidentiality. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

1.3.6 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;

1.3.7 Contact Information. An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research-related injury to the subject.

- Include contact information for the Principal Investigator and Co-Investigator if applicable.
- Include contact information for the Human Research Protection Program office for questions about participant rights, unresolved questions, concerns or complaints about the research.

1.3.8 Voluntariness. 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; and

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

(i) 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 studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

(ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

1.4 Additional elements of informed consent.

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

1.4.1 Unforeseeable risks. 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.

1.4.2 Termination of enrollment. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the legally authorized representative's consent.

1.4.3 Costs. Any additional costs to the subject that may result from participation in the research;

1.4.4 Consequences for early withdrawal. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

1.4.5 New findings. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;

1.4.6 Number of participants. The approximate number of subjects involved in a study.

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

1.4.8 Clinically relevant research results. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and

1.4.9 Biospecimens. 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).

1.5 Signature requirement.
Informed consent is documented with the signature (including in electronic format) of the participant or their LAR, 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 Informed Consent Requirements.*

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. A consent document may be drafted 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.
Alternate methods for documenting informed consent are available, and may be preferable for non-English speaking or participants with limited literacy.

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 participant'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 participant 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 or their real names, etc. Provide these options on the consent form as separate boxes for participants to check or mark or initial 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 regulations and/or state law 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. Refer to NDSU's Records Management site for more details.

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 have a waiver of the requirement approved 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 (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 the issue, LAR means an individual recognized by **institutional policy** as acceptable for providing consent in the non-research context. (§___.102(i)) Examples of LARs 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:

§___.116 General requirements for informed consent
§___.117 Documentation of informed consent
21CFR50, Subpart B Informed Consent of Human Subjects
§___.111 and 21CFR56.111 Criteria for IRB approval of Research
§___.109 and 21CFR56.109 IRB review of research
OHRP guidance in Written Procedures
OHRP FAQs: Informed Consent
FDA Information Sheet, A Guide to Informed Consent
FDA Final rule, Informed Consent Elements, January 4, 2011 Federal Register, Vol. 76, No. 2

RELATED FORMS:

IRB Protocol Form
Informed Consent Waiver or Alteration Request
Informed Consent Templates

RELATED HRPP SECTIONS AND STANDARD OPERATING PROCEDURES:

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