9 Requirements for Informed Consent: 9.1 Consent Process	Effective Date: 1/21/2019 Revised: 10/27/2017

HHS Regulations at 45 CFR 26 require that an investigator obtain the legally effective informed consent of the participant or the participant's legally authorized representative (LAR) unless the research is exempt or an IRB finds that informed consent may be waived.

1.0 Legally effective informed consent.

As autonomous agents, the Belmont report affords that research participants shall "be given the opportunity to choose what shall or shall not happen to them." The process of informed consent involves obtaining the voluntary agreement of individuals to take part in a research study. The consent process begins with the initial contact between the investigator and the subject (e.g., recruitment or subject selection procedures), and continues throughout the research study.

A legally effective consent process will:

1.1 Provide sufficient information.

Prior to a participant's involvement in research, provide potential participants with sufficient information about the research (e.g., its purpose, procedures involved, potentials risks and benefits, etc.) in order to make an informed decision. The 'elements of informed consent' may be communicated to participants: face-to-face, or via phone, video, fax, internet or mail. Allow participants an opportunity to ask any questions prior to, during or after their involvement in the research. Most research projects also require printed information to be provided to subjects.

Refer to *9.2 Documentation of Informed Consent* for a description of the elements of informed consent, and *Informed Consent Templates* on the 'Forms' page of the IRB website.

1.2 Facilitate understanding.

Provide written or oral information about the research project in language understandable to the least educated of potential participants or their representatives. Avoid the use of technical terms and jargon. If technical terms are necessary, provide a lay definition. In general, a 6th to 8th grade reading level is recommended. Adjust the language appropriately for children, participant groups with low literacy levels, cognitively impaired individuals, or individuals with limited English proficiency. Conduct the consent process in a language understandable to the participant, and provide translated written documents when appropriate. The IRB requires verification of any translated documents.

Investigators may also gauge understanding by allowing time for questions, or asking participants to describe the research in their own words.

1.3 Ensure voluntariness.

An investigator shall seek informed consent only under circumstances that provide the prospective subject or the legally authorized representative sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence (45 CFR 46.116(a)(2)). Individuals must be free to decline research participation, or withdraw from participation, refuse to answer questions or complete certain tasks without penalty or loss of other benefits to which they are otherwise entitled.

Informed consent, whether oral or written, may not include any exculpatory language through which the participant or their representative is made to waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, institution or its agents from liability for negligence.

The existence of dual relationships between investigators and potential participants, as well as offers of excessive compensation may also affect the voluntariness of the consent process; see sections 2.0 and 3.0 below.

1.4 Be repeated, supplemented or revised as necessary.
Informed consent is an ongoing process of communication between the investigator and participant. Repeat, supplement, or revise the informed consent process when:

- new information becomes available that may affect the willingness of a subject to continue in the research,
- deficiencies or inaccuracies are identified in the consent process,
- research design or risks have changed,
- a substantial period of time has elapsed between the time consent was obtained and research begins, or the research takes place over an extended time period.

The IRB prospectively reviews and approves all changes to the consent process or documentation, unless the changes are necessary to eliminate apparent immediate hazards to participants.

As part of the review process, the IRB determines that legally effective informed consent will be sought from each potential participant or their legally authorized representative, unless a waiver or alteration of this requirement is granted. Provide a detailed description of the consent process in the protocol application to provide the IRB with sufficient information to make this determination.

2.0 Dual relationships.
Voluntariness may be affected by the existence of an authority relationship between the investigator and potential research subject(s). Potential participants could feel compelled to participate in research for fear of losing status or services with an instructor, employer, or physician, for example. Design research to minimize any potential for undue influence. Slight changes in the study design may alleviate the concern, such as recruiting from a different pool of participants, or involving an objective third-party in the process.

3.0 Compensation.
Voluntariness may be affected by offers of excessive compensation for research participation. Offering monetary or other types of compensation commensurate with a participant's time, effort and inconvenience is acceptable. However, compensation that is either excessive, and/or withheld until completion of the research may cause participants to accept risks that they would not otherwise consider, or affect their ability to voluntarily withdraw.

When research involves an offer of extra or course credit to students, an alternative, non-research method (equal in time and effort to research participation) for obtaining the credit is

required. Include the details of any offer of compensation (and alternatives, if applicable) in the consent. In addition, describe the probability of winning any drawing or raffle to participants.

4.0 Recruitment and subject selection.

The process of informed consent begins with the initial approach to potential participants to invite them to participate in research. This may include use of advertisements, public or private records, or screening tests to select or locate potential participants or determine their eligibility for research.

4.1 Recruitment messages or advertisements.

The IRB prospectively reviews all advertisements, notices, or messages used to invite individuals to take part in research. Provide brief, factual information about the research in the recruitment notice. Typically a recruitment message does not include all the same information required in the consent document.

Recruitment notices in printed or electronic format must include:

- NDSU department name, and contact for the research team
- an indication that the project involves 'research'
- basic information about the research purpose and procedures
- any applicable eligibility or exclusion criteria
- approximate time commitment for participation
- a statement of any compensation that will be offered (if applicable)

Recruitment notices must not:

- over-emphasize compensation
- make a claim for safety or effectiveness
- overstate potential benefits

Sometimes it may be necessary to informally query individuals to determine if an adequate number of eligible participants would be available for a research project. Informal queries of this nature may be made prior to submitting a protocol for review, although a recruitment process may not be initiated prior to IRB approval.

4.2 Screening for eligibility.

Some research studies may include use of inclusion or exclusion criteria to identify eligible research participants. The IRB may approve an "exception" to the consent requirement to determine eligibility for a study. This allows for the Investigator to collect identifiable information or identifiable biospecimens for the purposes of screening, recruiting, or determining eligibility of prospective subjects if:

- the investigator will obtain information through oral or written communication with prospective subject or Legally Authorized Representative, or
- the investigator will obtain identifiable private information or biospecimens by accessing records or stored identifiable biospecimens (___.116(g)(1-2).

The IRB must review and approve the entire research protocol, including the preparatory to research activities. The investigator will protect private identifiable information obtained during the screening, regardless of whether the individual is recruited to take part in the research. If subjects identified during the screening process are successfully recruited to participate, all other consent requirements must be met.

4.3 Use of pre-existing records to select potential participants.
When research will involve use of private records to identify and contact potential research participants, access to the records may be governed by other laws and policies (e.g. private health information - HIPAA, or academic records – FERPA). When individuals will be contacted for an invitation to participate in research on the basis of information in their private records, IRB approval is required prior to accessing the records for research purposes.

In general, researchers who do not otherwise have permissible access to private records should not attempt to contact potential participants directly. Instead, the initial contact should be made only by someone with permissible access to the records; those participants who are interested could then choose to contact the research team to find out more about the project.

5.0 IRB review of consent process.
As part of the criteria for IRB approval of a new protocol, amendment, or continuing review, the IRB reviews the consent process to determine that the legally effective informed consent will be sought from participants, in accordance with the criteria described in section 1.0 above. Refer to *Section 7 IRB Review Process* and *Section 8 Participant Protections* for more information.

6.0 Waiver or alteration of consent requirements.
Some research involves incomplete disclosure, use of deception, elimination of the entire consent process and/or elimination of the signatures. This is considered a waiver or alteration of the informed consent requirements. The IRB must make several additional determinations in order to approve research involving a waiver or alteration of informed consent requirements; refer to *9.3 Waiver or Alteration of Informed Consent Requirements*.

7.0 Consent of legally authorized representatives.
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. This lack of capacity may be temporary or permanent, as a result of trauma, mental illness or cognitive impairments, for example. Research that is likely to encounter subjects with insufficient capacity should describe in the protocol a plan for determining when consent of a legally authorized representative is needed, and how that consent will be obtained. When reviewing research involving cognitively impaired individuals, the IRB must possess appropriate expertise, through its own membership or use of consultants.

8.0 Posting of clinical trial consent form.

8.1 For each clinical trial conducted or supported by a Federal department or agency, the Principal Investigator must post one IRB-approved informed consent form used to enroll subjects on a publicly available Federal Website that will be established as a repository for such informed consent documents.

8.2 If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal

Web site (e.g. confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.

8.3 The PI must post the informed consent form on the designated Federal Website after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

9.0 Consent process for exempt research.

In accordance with the Belmont ethical principle of respect for persons, NDSU requires that all potential research subjects be afforded the opportunity for voluntary consent to research participation, including those invited to take part in research determined by the IRB to be *exempt*.

The same requirements to provide sufficient, understandable information about the research and ensure voluntariness apply, although an 'implied' consent process could be utilized for exempt projects. For example, a participant's positive action (e.g. responding to questions, returning a survey, or performing a research task) may be considered their agreement to participate in research. Providing written information to, or obtaining a signature from participants is typically not required for exempt research, but may be utilized where advisable or required by the IRB.

If obtaining participants' consent would not be feasible, the IRB may waive the requirement, provided an adequate justification is provided. Projects involving public observation, or use of pre-existing materials, records, data, or specimens are examples where eliminating the consent process may be justified. Refer to *7.1 Exempt Determinations* and the templates for Information Sheets and Oral scripts on the IRB website for more information and suggested formats.

DEFINITIONS:

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

Investigator: anyone involved in conducting the research; i.e. study design or supervision, data collection, obtaining informed consent, performing research procedures, obtaining or analyzing coded or identifiable private information or specimens.

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. (45 CFR 46.102(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.

Coercion: occurs when an overt or implicit threat of harm is intentionally presented by one person to another in order to obtain compliance; e.g. an investigator tells a potential subject they will lose access to health services unless they agree to participate in a research project.

Undue influence: occurs through an offer of an excessive or inappropriate reward or other overture in order to obtain compliance (e.g. an investigator promises students extra credit to participate in research, when no other alternatives for extra credit are available). Undue influence can also be subtle (e.g. patients may feel obligated to take part in research if their physician is the investigator, or students may feel pressure to participate if everyone else in a class is doing so). In addition, inducements that are ordinarily acceptable for some populations may become undue influences for vulnerable groups (e.g. economically or educationally disadvantaged, children, prisoners or mentally disabled persons).

REFERENCES:

45 CFR 46.116 General requirements for informed consent
45 CFR 46.111 and 21 CFR 56.111 Criteria for IRB approval of Research
45 CFR 46.109 and 21 CFR 56.109 IRB review of research
21 CFR 50, Subpart B Informed Consent of Human Subjects
OHRP guidance on Written Procedures
OHRP FAQs: Informed Consent
FDA Information Sheet, A Guide to Informed Consent
FDA Information Sheet, Recruiting Subjects
FDA Information Sheet, Screening tests prior to study enrollment
NIH Points to Consider: Impaired decision making capacity

RELATED FORMS:

IRB Protocol Form
IRB Protocol Application for Exemption: Primary Research
IRB Protocol Application: Secondary research for which consent is not required
Informed Consent Waiver or Alteration Request
Informed Consent templates
Protocol Amendment Request

RELATED HRPP SECTIONS:

9.2 Documentation of Informed Consent
9.3 Waiver or Alteration of Informed Consent Requirements
9.4 Children as Research Participants
Section 7 IRB Review Process
Section 8 Participant Protections
11.7 Review of Planned Emergency Research
Section 10 Vulnerable Groups