

In accordance with federal regulations, the IRB shall review and have authority to approve, require modifications in (to secure **IRB approval**), or disapprove all research activities covered by this policy, including exempt research activities under §__.104 for which limited IRB review is a condition of exemption (under §__.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7), and (8)).

IRB determinations are based on specific ethical and regulatory criteria to protect the rights, safety and welfare of participants.

1.0 Applicability.

When conducting review of research at a convened meeting or by the expedited method, federal regulations require the IRB to make the following determinations to approve research. The IRB applies these criteria to review of new research, as well as ongoing studies (continuing review, amendments, and unanticipated problems). The IRB applies additional criteria when research involves children or other vulnerable groups, or requests for a waiver or alteration of the requirement for informed consent.

2.0 Criteria for IRB approval of research.

In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

2.1 Risks to subjects are minimized:

- By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and
- Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2.2 Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

2.3 Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

2.4 Informed consent. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §____.116.

2.4.1 General Requirements for Informed Consent (§____.116):

- (1) Before involving a human subject in research covered by this policy, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative.
- (2) 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.
- (3) The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative.
- (4) The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
- (5) Except for broad consent:
 - (i) 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.
 - (ii) Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate.
- (6) No informed consent may include any exculpatory language through which the subject or the legally authorize representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

2.4.2 Elements of Informed Consent: Unless a waiver or alteration is approved, informed consent must contain the basic elements of informed consent as well as additional elements when appropriate. Please see SOP 9.2 Documentation of Informed Consent.

2.5 Documentation of Informed Consent. Informed consent will be appropriately documented or appropriately waived in accordance with §____.117. See also SOP 9.2 Documentation of Informed Consent or SOP 9.3 Waiver or Alteration of Informed Consent.

2.6 Data Monitoring. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

2.7 Privacy and Confidentiality. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

2.3.1 Privacy and confidentiality standards will be based on the current guidance issued by the Secretary of HHS.

2.8 Coercion and Undue Influence. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Refer to HRPP Section 10 Vulnerable Groups for more information.

3.0 Criteria for Limited IRB Review.

3.1 Exemption Category 2(iii) and Category 3(c) – The IRB shall make the following determination:

- When appropriate, there are adequate provision to protect the privacy of subjects and to maintain the confidentiality of data.

3.2 Exemption Category 7 - The IRB shall make the following determinations:

- **Broad consent** for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of §___.116(a)(1)-(4), (a)(6), and (d).
 - ii. **Broad consent is appropriately documented** or waiver of documentation is appropriate, in accordance with §___.117; and
 - iii. If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain confidentiality of data.

See also SOP 9.5 Broad Consent.

3.3 Exemption Category 8 – The IRB shall make the following determinations:

- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- That the research to be conducted is within the scope of the broad consent.

4.0 Local research context.

When reviewing research conducted at site(s) geographically or culturally different from NDSU, or for which the board does not regularly conduct reviews, eth IRB must consider unique aspects of the locality and culture to ensure protection of human subjects.

4.1 Requirement for sufficient information.

The IRB must either possess or obtain sufficient information regarding the local context and how it will impact subject protections as related to the review criteria. This information could include, but is not limited to:

- The participant population,
- Local laws, standards, customs and culture,
- Language(s) understood by prospective participants or their legally authorized representative.

The requirement for this information may be satisfied by individuals with extended, direct experience with the site, community, culture, subject population or research institution including an IRB member, external consultant or member of the research team.

The IRB may obtain oral or written information from consultants, or may request they attend a convened meeting to provide information regarding the local research context of the research site. Consultants may not vote on approval of the project. Refer to SOP 7.3 Expedited Review and 7.4 Full Board Review for more information. The IRB documents the process by obtaining written materials, and/or documenting discussion that demonstrate sufficient knowledge of local context.

4.2 Collaborative review.

NDSU may rely on the review of another IRB with sufficient knowledge of local research context. This collaborative review arrangement is subject to criteria described in SOP 2.3 Collaborative, Multi-site or Off-site research.

4.3 Research involving more than minimal risk.

When research involves more than minimal risk, the IRB may determine that additional measures are necessary to obtain sufficient knowledge of the local research context. Such measures may include systematic reciprocal and documented interchange between the IRB and the local research site by:

- Periodic visits to the site by one or more IRB members,
- Periodic discussion with appropriate consultants,
- Regular interactions with one or more institutional liaisons, and
- Review of relevant written materials.

5.0 Review of funding proposals.

When NDSU serves as the primary awardee of a federally funded project involving human subjects, the IRB reviews and complete funding proposal to verify consistency with the approved IRB protocol. Although funding proposals may not contain detailed descriptions of human subject involvement, where the application describes such detail (e.g., procedures, interventions, subject populations, or research sites), the IRB determines whether or not information is consistent with the IRB protocol. Long-term or multi-phased projects may require submission of multiple protocols, and/or future amendments as the project progresses.

Proposal review may be performed at a convened meeting, or by the expedited method; either concurrently with or after the initial review of the protocol. The IRB documents the review and retains a link to the grant record. Refer to HRPP Section 13 Sponsored Research for more information.

DEFINITIONS:

Benefit: something of health-related, psychosocial, or other value to a participant or society as a whole (e.g., contribution to generalizable knowledge) that results from the research.

Confidentiality: pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission.

IRB approval: the determination of the IRB that research has met the appropriate approval criteria and may be conducted within the constraints set forth by the IRB and by other institutional and federal requirements.

Minimal risk: the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Privacy: having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

REFERENCES:

§ ____.109 and [21 CFR 56.109](#) IRB Review of Research
§ ____.111 and [21 CFR 56.111](#) Criteria for IRB Approval of Research
FederalWide Assurance Terms
OHRP Guidance, Local Research Context
OHRP Guidance, Written Procedures
OHRP IRB Guidebook, Chapter III, Basic IRB Review
OHRP Guidance, IRB Review of Applications for HHS Support

RELATED FORMS:

IRB Protocol Application
Review Guide

RELATED HRPP STANDARD OPERATING PROCEDURES:

- 2.3 Collaborative, Multi-site and Off-site Research
- 7.3 Expedited Review
- 7.4 Full Board Review
- 8.1 Risks and Benefits
- 8.2 Privacy and Confidentiality
- 8.3 Data Safety Monitoring
- 9.1 Consent Process
- 9.2 Documentation of Informed Consent
- 9.3 Waiver or Alteration of Informed Consent Requirements
- 9.5 Broad Consent
- 10.1 Vulnerable Groups: Children
- 10.2 Vulnerable Groups: Prisoners
- 10.3 Vulnerable Groups: Other Vulnerable Groups
- 13.1 Certification of IRB Approval