In accordance with federal regulations, the IRB shall review and have authority to approve, require modifications in (to secure IRB approval), or disapprove proposed research involving human subjects. 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 Risks and benefits.

2.1 Research risks.
The IRB considers all reasonably foreseeable types of risks and discomforts of the research:

- physical risks (e.g. pain, injury, discomfort, allergic reactions, etc.),
- psychological risks (e.g. stress, depression, guilt, loss of self-esteem, etc.),
- sociological risks (e.g. embarrassment, damage to reputation, etc.),
- economic risks (e.g. loss of employment or health insurance, etc.),
- legal risks (e.g. criminal prosecution, etc.).

In addition, the IRB determines the level of risk of the research as:

- no more than minimal risk,
- a minor increase over minimal risk, or
- more than a minor increase over minimal risk.

2.2. Minimize risks.
In order to approve research, the IRB determines that risks to subjects are minimized by using procedures which are consistent with sound research design and do not unnecessarily expose subjects to risk, and when appropriate, by using procedures already being performed on subjects for diagnostic or treatment purposes. A variety of measures may be employed to minimize research risks. Refer to SOP 8.1 Risks and Benefits for more information.

2.3 Risk/benefit ratio.
In order to approve research, the IRB determines that risks to subjects are reasonable in relation to anticipated benefits to subjects, if any, and the importance of the knowledge that may reasonably be expected to result. Several considerations in evaluating risk/benefit ratio include, but are not limited to:
vulnerable groups may be at greater risk than others, scientific merit is an important consideration when the study design contributes to unnecessary risks, where accepted standard medical care is available, research procedures require a comparable risk/benefit ratio.

The IRB considers 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 does not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility. Refer to SOP 8.1 Risks and Benefits for more information.

3.0 Subject selection.
In order to approve research, the IRB determines that the selection of participants is equitable. In making this assessment the IRB considers the following issues:

- appropriateness of the choice of potential participants for the research question,
- inclusion and exclusion criteria,
- methods for screening potential participants,
- setting in which the research is conducted,
- the setting and timing of the recruitment process,
- the appropriateness of any documents used to invite potential participants,
- potential for any coercion or undue influence to participate, which may occur in the context of dual relationships/roles, excessive compensation schemes, or vulnerability of groups chosen as potential participants (e.g. children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons).

Refer to HRPP Section 9 Requirements for Informed Consent and Section 10 Vulnerable Groups for more information.

4.0 Informed Consent.
In order to approve research, the IRB determines that legally effective informed consent will be sought from each potential participant or their representative, unless the requirement is waived.

4.1 Consent process.
The IRB considers the adequacy of the consent process to ensure voluntariness, as well as understanding, given the proposed participants and research setting. When an investigator requests a waiver or alteration of the consent requirement, the IRB considers criteria based on necessity, minimal risk, rights and welfare and debriefing in order to approve the request. Refer to HRPP Section 9 Requirements for Informed Consent for more information and additional required determinations.

4.2 Documentation.
In order to approve research, the IRB determines that informed consent will be appropriately documented, unless a waiver of the requirement has been requested. The IRB reviews the consent document to ensure all required elements, as well as any additional elements are
included, and appropriate documentation will be obtained. When an investigator requests a waiver of documentation of consent, the IRB considers criteria based on minimal risk, confidentiality concerns, and any other requirements for signatures in order to approve the request. Refer to HRPP Section 9 Requirements for Informed Consent for more information and additional requirements.

5.0 Data safety monitoring.
When appropriate, in order to approve research, the IRB determines that the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. Refer to SOP 8.3 Data Safety Monitoring for more information.

6.0 Privacy and confidentiality.
When appropriate, in order to approve research, the IRB determines that the project has adequate provisions to protect the privacy of participants, and the confidentiality of their information.

6.1 Privacy.
Participants’ privacy may be a concern when research will involve observation or recording of individuals without their knowledge, private records, or sensitive questions. Privacy risks may include social, legal or economic risks, which may be minimized by limiting collection of identifiable or sensitive information, data security controls, use of private settings for data collection, or debriefing procedures. Refer to SOP 8.2 Privacy and Confidentiality for more information.

6.2 Confidentiality.
When appropriate, in order to approve research, the IRB determines that the project has adequate provisions to maintain the confidentiality of participants’ data. A breach of confidential research data may involve social, legal or economic risks to participants when the data is sensitive and may be linked to participants through direct or indirect identifiers. Direct identifiers include but are not limited to: names, codes, medical record numbers and/or employee ID numbers, voice or video recordings, etc. Indirect identifiers exist when individual identities may be deduced using a combination of data fields (e.g. gender, race, zip code, etc.). Measures to protect confidentiality may include adequate data safeguarding procedures (e.g. password protection, firewalls, and/or encryption), limiting or avoiding collection of identifiers, or obtaining a Certificate of Confidentiality. Refer to SOP 8.2 Privacy and Confidentiality for more information.

7.0 Vulnerable groups.
When research is likely to involve groups of participants who are considered vulnerable to coercion or undue influence, the IRB determines that additional safeguards have been included to protect the rights and welfare of these subjects.

7.1 Categories of vulnerable populations.
Federal regulations recognize specific groups of individuals who may be vulnerable when recruited for research participation:

- children,
- prisoners,
pregnant women, fetuses or neonates,
cognitively impaired persons,
economically or educationally disadvantaged persons.

7.2 Additional protections.
When approving research involving a vulnerable group protected under the federal regulations, the IRB is required to document specific, additional determinations. Examples of additional safeguards to protect vulnerable populations may include:

- permission of a parent/guardian or other legally authorized representative to participate in the research,
- enhanced educational measures to ensure understanding,
- restrictions on types of research conducted with a vulnerable population,
- federal reviews of research.

Refer to HRPP Section 10 Vulnerable Groups for more information.

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

8.1 Requirement for sufficient information.
The IRB must either possess or obtain sufficient information regarding the local context to ensure protection of subjects. This information would include, but is not limited to:

- types of subject populations,
- local laws, standards, customs and culture,
- language(s) understood by prospective subjects,
- method for equitable selection of subjects,
- method for protection of privacy and confidentiality,
- method for minimizing coercion or undue influence in seeking consent,
- safeguards to protect vulnerable populations.

The requirement for this information may be satisfied by individuals with extended, direct experience with the site, community, subject population or research institution:

- IRB member,
- external consultant,
- principal investigator.

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. Consultants are not allowed to vote on approval of the protocol. Refer to SOP 7.3 Expedited Review and SOP 7.4 Full Board Review for more information. The IRB documents the process by obtaining written materials, and/or documenting discussions that demonstrate sufficient knowledge of local context.

8.2 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.

8.3 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.

9.0 Review of funding proposals.
When NDSU serves as primary awardee of a federally funded project involving human subjects, the IRB reviews the 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, research sites), the IRB determines whether or not information is consistent with that in the 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, and may occur concurrently with, or after initial review of the IRB protocol. A copy of the funding proposal and documentation of the review is retained in the IRB protocol. 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 (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 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:
45 CFR 46.111 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 Form
IRB Review Guides

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
10.1 Vulnerable Groups: Children
10.2 Vulnerable Groups: Prisoners
10.3 Vulnerable Groups: Other Vulnerable Groups
13.1 Certification of IRB Approval