

In accordance with federal regulations, the IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove proposed research involving human subjects. These determinations will be based on specific ethical and regulatory criteria to protect the rights, safety and welfare of participants. The criteria are applied to new, continuing, or amended protocol reviews conducted at either a convened meeting (full board review procedure), or by the expedited review procedure. Additional criteria may apply when research will involve children or other vulnerable groups.

### 1.0 Research Risks:

#### 1.1 Risk Assessment.

The IRB will make a decision based on common sense and sound professional judgment as to whether or not the proposed research places the participant at risk of harm. A participant is considered to be at risk if he/she is exposed to the possibility of harm, whether physical, psychological, sociological, economic or other, as a consequence of any activity that goes beyond the application of those established methods necessary to meet his/her needs. Refer to Section 8 Research Risks and Harms for more information.

#### 1.2 Risk and benefit evaluation.

In order to approve research, the IRB shall determine that 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 making this determination, the IRB will categorize the level of potential risk as either: 1) no more than minimal risk, 2) a minor increase over minimal risk, or 3) more than a minor increase over minimal risk. Potential benefits of the project will be categorized as either: 1) no prospect of direct benefit to individuals, but likely to yield generalizable knowledge, or 2) prospect of direct benefit to individuals

The IRB will also consider the fact that certain subject populations (e.g., children, pregnant women, prisoners, mentally disabled, physically disabled) may be at greater risk than others. 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 (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

##### 1.2.1 Non-therapeutic intervention.

In research involving a non-therapeutic intervention, the potential of risk to the participant must be outweighed or balanced by the potential benefit to the subject and/or by the knowledge to be gained.

### 1.2.2 Therapeutic research.

In therapeutic research involving more than minimal risk, the potential risk should be outweighed or balanced by the potential benefit to the participant. In addition, the relation of the anticipated benefit to the risk must be at least as favorable to the subject in the non-research context. No participant is allowed to continue in a research protocol if another therapy of proven better quality becomes available to the subject.

### 1.2.3 Standard therapy and research.

In research where a standard therapy not a part of the research protocol is employed solely for the benefit of the participant along with additional procedure performed solely for research purposes, the anticipated benefits of the therapy cannot be used to justify exposing participants to the risks associated with the research procedures. Such risks can only be justified in light of the potential benefits of the research procedures. Conversely, only the risks associated with the research procedures should be used in determining the risk/benefit ratio.

### 1.2.4 No therapeutic alternative.

In research involving a therapy employed for the potential benefit of a participant suffering from a life-threatening illness, the risk of serious adverse effects may be acceptable providing there are no other therapeutic alternatives available to the subject that offer a more favorable risk/benefit ratio.

### 1.2.5 No direct benefits to participants.

In research where no direct benefits to the participant are anticipated, the IRB will evaluate whether the risks and/or discomfort presented by procedures performed solely to obtain generalizable knowledge are ethically acceptable.

## 1.3 Minimizing risks and harms:

In order to approve research, the IRB shall determine that all possible risks and harms to subjects will be minimized:

- by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
- whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes
- by verifying that investigators have appropriate qualifications and/or licensure to carry out the procedures involving human participants with an acceptable degree of potential risk; a cv or resume may be requested
- by verifying that investigators have adequate facilities and equipment to conduct the research with an acceptable degree of potential risk

## 2.0 Subject Selection and Recruitment:

In order to approve research, the IRB shall determine that the selection of participants is equitable. In making this assessment the IRB will consider the following issues. Refer to *Section 9 Informed Consent and Subject Selection* for more information.

- appropriateness of the choice of potential participants for the research question, the inclusion and exclusion criteria, and methods for screening potential participants.

- setting in which the research will be conducted, and 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 (ie, children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons)

### 3.0 Obtaining Informed Consent:

In order to approve research, the IRB shall determine that legally effective informed consent will be sought from each potential participant or their legal representative, unless a waiver or alteration of this requirement is approved. In making this determination, the IRB will consider the following issues (refer to Section 9 Informed Consent and Subject Selection for more information.)

- setting in which the research will be conducted, and the setting and timing of the process to seek the consent of subjects allows sufficient time to consider participation
- potential for any coercion or undue influence to participate, which may occur in the context of dual relationships/roles, and/or excessive compensation schemes
- additional protections for vulnerable groups, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons to protect them from coercion and undue influence
- information given to potential participants is presented in a language understandable to the least educated potential participants or their representatives, avoiding technical terms and jargon, and including all required elements
- no written or verbal consent process includes exculpatory language through which participants are made to waive or appear to waive any legal rights, or releases, or appears to release the investigator, sponsor, or institution from liability for negligence

### 4.0 Documentation of Informed Consent:

In order to approve research, the IRB shall determine that informed consent will be appropriately documented, unless a waiver of the requirement is approved. Refer to *Section 9 Informed Consent and Subject Selection* for more information.

### 5.0 Data Safety Monitoring:

When appropriate, in order to approve research, the IRB shall determine that the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. Refer to *Section 11.7 Clinical Research* for more information.

### 6.0 Protecting Privacy of Participants:

When appropriate, in order to approve research, the IRB shall determine that the project has adequate provisions to protect the privacy of participants. For more information, refer to *Section 8.8 Research Risks and Harms - Privacy*.

#### 7.0 Maintaining Confidentiality of Data:

When appropriate, in order to approve research, the IRB shall determine that the project has adequate provisions to maintain the confidentiality of data. For more information, refer to *Section 8.9 Research Risks and Harms - Confidentiality*.

#### 8.0 Protections for Vulnerable Populations:

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, the IRB shall determine that additional safeguards have been included in the study to protect the rights and welfare of these subjects. Refer to Section 10 Vulnerable Groups for more information.

#### 9.0 Knowledge of Local Research Context:

When research will be conducted at sites geographically removed from NDSU, or locations for which the IRB does not regularly review research, information on local context shall be obtained from consultants. Such consultants should not be a part of the research team, but should have personal knowledge of the local context, obtained through extended, direct experience with the research institution or site, populations, and surrounding community. Alternatively, this requirement could be met through an NDSU IRB member with such personal knowledge, through a review by the site's IRB, or a letter of permission/cooperation from the site's management or administration.

10.0 Review of application for federal grants.....

#### **DEFINITIONS:**

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

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 the research has been reviewed and may be conducted within the constraints set forth by the IRB and by other institutional and federal requirements

#### **REFERENCES:**

[45CFR46.109](#) and 21CFR56.109 IRB Review of Research  
[45CFR46.111](#) and 21CFR56.111 Criteria for IRB Approval of Research  
[FederalWideAssurance Terms](#)  
[OHRP guidance: Local Research Context](#)  
[OHRP guidance on Written Procedures](#)  
45CFR46.107 (a) and 21CFR107(a) IRB Membership  
OPRR IRB Guidebook

**RELATED FORMS:**

IRB Protocol Form  
Participant informed consent template and instructions  
Protocol Submission Checklist  
IRB Reviewer Checklists

**RELATED HRPP SECTIONS:**

2     Applicability  
7.3   Expedited Review  
7.4   Full Board Review  
8     Research Risks and Harms  
9     Informed Consent and Subject Selection  
10    Vulnerable Groups