7 IRB Review of Research: 7.4 Full Board Review	Effective Date: **08/15/2008** Revised: **6/12/2009, 5/6/2011, 8/12/2011, 11/14/2012, 5/9/14, 4/9/2021**

In accordance with federal regulations, the IRB reviews proposed and ongoing human research, and grant approval on the basis of specific ethical and regulatory criteria to protect the rights, safety and welfare of participants. Research projects meeting criteria for exemption or expedited review are reviewed outside a convened meeting; however, research involving more than minimal risk or falling outside of one of the exemption or expedited review categories is reviewed by the convened board.

1.0 Initial review of proposed research:

1.1 Application materials and submission process.

Protocol applications are submitted through the IRB Module in Novelution (erac.ndsu.edu). Applications may be started by the Principal or co-investigator. The PI is required to certify application materials prior to submission.

The board meets on a monthly basis (or more or less frequently as needed) to conduct reviews and other committee business; a meeting schedule with associated protocol submission deadlines is posted on the website. An official protocol submission must be received by close of business on the posted deadline to be considered at the next convened meeting.

1.2 Pre-Submission Requirements

All members of the research team must have current CITI training before IRB Processing can begin. Once the PI has submitted (or completed PI certification) members of the research are automatically notified if training requirements must be met. The relevant department chair/head is also notified that department approval is needed.

1.3 Pre-review procedures.

HRPP staff process the protocol application ensuring the application is complete.

1.3.1 Incomplete application.

If the application is incomplete, a qualified HRPP staff member communicates with the investigator(s) to obtain the necessary forms, attachments, or additional information. Official communication is found in the IRB Correspondence panel.

1.3.2 Complete application.

HRPP staff process completed protocol applications and assign for review at the next available convened meeting.

1.3.3 Special representation.

The IRB may choose to invite individuals with competence in special areas to assist in review of issues requiring expertise beyond or in addition to that available on the board. Examples may include, but are not limited to, individuals with experience with cognitively

impaired persons, prisoners, individuals of a particular culture, or locale, etc. These consultants may provide written or verbal information to the IRB on the acceptability of the research with the proposed population, but will not vote with the board. A qualified HRPP staff member, IRB Chair or designee determines the need for any special representation.

1.4 IRB review procedures.

1.4.1 Selection of primary reviewers.

Qualified HRPP staff, IRB Chair or designee assign the protocol to two experienced primary reviewers, based on members' experience, scientific expertise or background, or experience with a subject population. One reviewer is assigned the scientific and technical aspects of the protocol, and another is assigned to review the informed consent process and documentation. After the IRB Administrator assigns reviewers, the Novelution system automatically assigns a 'task' and notifies the assigned reviewers via email.

A member is considered experienced to serve as a primary reviewer when they have completed orientation and training, attended at least 3 IRB meetings, and the Chair or designee has verified that they are sufficiently familiar with the interpretation and application of ethical and regulatory requirements for IRB approval.

No IRB member may participate in review of a protocol for which they have a conflict of interest (investigator or co-investigator, financial, department level, or personal relationship) that would affect their ability to consider the rights and welfare of participants. A reviewer may be selected from a researcher's own department if the reviewer/researcher relationship does not have a perceived power differential (i.e., chair/faculty). If a member has a conflict of interest that is not readily apparent at the time of review assignment, they are to notify the IRB office so a reassignment may be made. Members with conflicts should declare the conflict at the beginning of the meeting, and may respond to questions, but should recuse themselves for deliberation and voting on that protocol. Refer to *Section 6 Conflicts of Interest* for more information.

Primary reviewers may contact the investigators prior to the meeting to clarify any issues; information/documentation of such communication may be provided to the IRB office and board members or summarized during the meeting. At the convened meeting, primary reviewers summarize their review of the protocol prior to discussion and voting. All board members may access the protocol application and relevant materials via Novelution, and any member may provide comments, questions, or voice concerns during the discussion.

1.4.2 Investigator invitation.

Investigators are encouraged to attend (in-person, or via a conference call) that portion of the convened meeting when their protocol is under review. While attendance is not required, direct communication with the board may facilitate the review process. HRPP staff invites the investigator(s) to the meeting via email. Investigators may provide a short overview of the project, and respond to any questions or provide clarification on any aspects of subject protections.

1.4.3 Review process and criteria.

Each protocol is reviewed and discussed to determine if specific federal requirements for IRB approval have been met, as described in *7.2 Criteria for IRB Approval*. These requirements include a consideration of the risk/benefit ratio, subject selection procedures, informed consent process, and privacy and confidentiality protections. Additional considerations are required for projects involving vulnerable groups, or a request to waive or alter informed consent requirements, etc.

1.5 Possible IRB actions and notification.

In accordance with *4.2 IRB Meeting Procedures*, protocols are reviewed at a convened meeting of the board where a majority of members are present, including at least one member whose primary concerns are in nonscientific areas. After discussion with the investigator(s), and preliminary questions and comments from reviewers, the investigators are dismissed. The IRB Chair or designee calls for a "motion to consider" from board members. After further discussion and deliberation, the IRB may take any of the following actions:

1.5.1 Approved as submitted.

The IRB may determine that the protocol materials and consent form(s) are satisfactory as presented, and meet all required criteria for approval. The initial approval date is the date of the IRB meeting at which this determination was made. HRPP staff promptly draft a letter of approval to the investigator in Novelution, and the research may begin once received. The letter includes the investigator's responsibilities, the dates of approval and expiration of approval.

1.5.2 Approved with conditions.

The IRB may determine that the criteria for approval can only be met with specific, minor modifications, alterations or clarifications to the protocol and/or consent form(s). Such conditions would involve specific changes or confirmations, such as:

- confirmation of specific assumptions or understandings regarding how the research will be conducted (e.g., confirmation that the research excludes children)
- submission of additional documentation (e.g., training documentation)
- precise language changes to the protocol or informed consent document(s), or
- substantive changes to the protocol or informed consent documents along with clearly stated parameters that the changes must satisfy (e.g., requiring simplification of the description of risks in the consent document to be at an 8th grade comprehension level).

The IRB may approve a protocol with conditions, with or without the presence of an investigator at the meeting, provided that the conditions are specified as described above. When an investigator attends the IRB meeting and is able to provide specific additional information, the board may approve the protocol with conditions, contingent on incorporation of the additional information and/or specific revisions into the written protocol, consent form(s) or other document(s).

A qualified HRPP staff member promptly notifies the investigator via the Novelution system of the board's conditions required for approval. Requested revisions can be found in the Review Comments panel.

A primary reviewer, IRB Chair or designee, or other experienced member (which may include an HRPP staff member) then reviews the responsive materials to determine that the conditions have been satisfied; further review at a convened meeting is not required. When determined satisfactory, HRPP staff draft a letter of approval to the investigator. The initial approval date is the date on which the responsive materials were determined satisfactory. TIf the investigator does not provide the revisions to the request within 60 days, the proposed project is considered inactive and the protocol withdrawn.

1.5.3 Deferral.
The IRB may determine that the protocol materials contain insufficient information, or would require more than minor modifications to meet criteria for approval. A qualified HRPP staff member notifies the investigator via Novelution of the board's action. Requested revisions/additional information can be found in the Review Comments panel.

The investigator resubmits a revised protocol for review, and the protocol will be scheduled for review at the next available convened meeting. If the board determines that the protocol would involve no more than **minimal risk** and fits within one of the eligible categories for expedited review, the revised protocol may undergo review by the expedited procedure.

1.5.5 Disapproval.
The IRB may determine that the research would place subjects at unacceptable risk relative to benefits, or the research as designed and described is not suitable for the involvement of human participants. A qualified HRPP staff member notifies the investigator of the board's action via Novelution, including the reasons for disapproval of the project. The Board's comments can be found in the Review Comments panel.

1.6 Approval period.
The IRB determines the approval period, appropriate to the degree of risk. The approval period may not exceed one year; however, the IRB may determine that more frequent review is warranted for those projects involving:

- especially vulnerable populations, such as fetuses,
- significant risk, and/or a high risk/benefit ratio,
- prior reports of injury or unanticipated problems as a consequence of participating in the research,
- inexperienced investigator(s),
- novel research interventions.

1.7 Appeals process
The investigator may appeal the IRB determination only if new information becomes available, or evidence is provided that the IRB has failed to follow their own procedures, or incorrectly applied federal regulations, state law, or NDSU policy for the protection of research participants. A written appeal, citing specific federal regulations, NDSU policy or procedures, may be made to the HRPP office or IRB Chair within 10 business days after receipt of communication from the IRB.

In consultation with HRPP staff, the IRB Chair or Chair's designee makes an initial assessment. The IO is notified, and the appeal forwarded to the board for consideration at the next convened meeting. The board's determination is considered final, and communicated in writing to the investigator and other entities as applicable.

1.8 Notification to Institutional Official\.
Meeting agenda and minutes are made available to the Institutional Official (IO) through a Shared Drive, and are also stored via the Novelution IRB Meetings section.

1.9 Other institutional approval.
Some projects may be subject to further review and approval or disapproval by officials of the institution. These officials may not approve the research, however, if it has not been approved by the IRB.

2.0 Post-approval procedures:

2.1 Continuing review.
If a project will continue beyond the initial approval period, continuing IRB review and approval of research must occur prior to the date of expiration. Novelution automatically sends a notice to the principal and co-investigator prior to the expiration date; however, timely submission of the continuing review is the responsibility of the investigator. Normally, if the initial review of a protocol was conducted at a convened meeting, continuing review would also require full review. However, there are limited circumstances where expedited review may be appropriate; refer to *7.6 Continuing Review* for more information.

2.2 Protocol changes.
Prior IRB approval is required for proposed changes to any aspect of the protocol, except when necessary to eliminate apparent immediate hazards to the participants. These changes may include, but are not limited to changes in:

- subject population
- recruitment procedures
- informed consent process
- research or data collection procedures
- research site.

Proposed amendments to a protocol initially reviewed at a convened meeting usually also require review by the convened board, unless they are considered 'minor' changes, which may be eligible for expedited review; refer to *7.5 Protocol Amendments* for more information.

2.3 Project closure.
A report is required to the IRB when a project is closed completed or abandoned. Refer to *7.6 Continuing Review* for more information.

2.4 Adverse or Unanticipated events.
An Adverse Event report is required to the IRB within 72 hours of discovering an adverse event or unanticipated problem involving risks to participants or others, or serious adverse event. A research-related injury or a loss of confidential research data would be examples

of unanticipated events that would place participants at risk. Refer to SOP *7.7 Unanticipated Problems and Serious Adverse Events* for more information.

2.5 Quality assurance and research compliance.
Research projects are subject to random (not-for-cause) or directed (for-cause) audits to ensure compliance with federal regulations and institutional policies. Refer to *Section 12 Quality Assurance and Research Compliance* for more information.

DEFINITIONS:

Principal investigator (PI): an NDSU faculty or staff member who has primary responsibility for the research. When graduate students conduct research, their faculty advisor is considered the PI.

Investigator: anyone involved in conducting the research; i.e., study design or supervision, data collection, obtaining informed consent, performing research procedures, obtaining coded private information or specimens, analyzing data (note that this would *not* include someone whose sole role is providing coded private information or specimens to an investigator).

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.

REFERENCES:

FederalWide Assurance Terms
45CFR46.102 Definitions
45CFR46.103(b)(4) Written IRB procedures
45CFR46.107(e) and 21CFR56.107(e) Conflict of interest
45CFR46.107(f) 21CFR56.107(f) Special representation
45CFR46.108(b) and 21CFR56.108(a) IRB convened meeting
45CFR46.109 and 21CFR56.109 IRB review of research
45CFR46.111 and 21CFR56.111 Criteria for IRB approval of Research
45CFR46.112 and 21CFR56.112 Review by institution
OHRP guidance on Written IRB Procedures
OHRP Guidance on IRB Approval of Research with Conditions

RELATED HRPP SECTIONS:

2 Applicability
4.2 IRB Meeting Procedures
6 Conflict of Interest
7.2 Criteria for IRB Approval
7.3 Expedited Review
7.5 Protocol Amendments
7.6 Continuing Review
7.7 Unanticipated Problems and Serious Adverse Events

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