

In accordance with federal regulations, the IRB shall review 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 not eligible for a claim of exemption or expedited review, will be reviewed at a convened meeting of the board.

1.0 Initial review of proposed research:

1.1 Application materials and submission process.

Investigators complete the protocol form and any relevant attachments, utilizing the most recent version of forms from the IRB web site. Protocol applications must be completed thoroughly, containing sufficient detail regarding procedures involving human subjects to allow for a thorough review. Investigators may utilize guidance and/or checklists available on the IRB website to assist them in preparing a complete application for submission to the IRB office.

The board meets on a monthly basis (or more or less frequently as needed) to conduct reviews and other committee business; a schedule is posted on the website. Completed and signed protocol applications are due at least 2 weeks prior to the next scheduled meeting.

1.2 Pre-review procedures.

HRPP staff process the protocol application, verifying training documentation and ensuring the application is complete, utilizing the submission checklist for documentation.

1.2.1 Incomplete application.

If the application is incomplete, a qualified HRPP staff member, Chair or designee communicates with the investigator (and co-investigator, as applicable) to obtain the necessary information prior to forwarding the application for review. All communication will be documented in the protocol file.

1.2.2 Complete application.

At least 5 – 7 business days prior to the meeting date, qualified HRPP staff forward complete protocol materials, including a copy of the submission checklist and review checklist, to the primary reviewers and board members. Investigators may complete training requirements during the IRB review period, however final approval will be withheld until all research team members provide documented training in the protection of human research participants.

1.2.3 Special representation.

An IRB may 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 will 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 will determine the need for any special representation.

1.3 IRB review procedures.

1.3.1 Selection of primary reviewers.

Qualified HRPP staff or IRB Chair or designee assign the protocol to 2 experienced primary reviewers, based on members' experience and applicable 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 of the protocol. The IRB staff member will notify reviewers of their assignment, and drafts a review checklist including the required determinations and other criteria as applicable. All documentation will be retained in the protocol file.

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 (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 re-assignment may be made. Those members with conflicts should declare the conflict at the beginning of the meeting, and may respond to questions, but should leave the room 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; documentation will be provided to the IRB office and board members. At the convened meeting, primary reviewers summarize their review of the protocol prior to voting and discussion. All board members also receive a complete set of protocol materials, and any member may provide comments, questions, or voice concerns during the discussion.

1.3.2 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 send the investigator(s) a letter to investigator(s) of the date, location, and approximate time of review. Investigators may provide a short overview of the project, and respond to any questions or provide clarification on any aspects of subject protections.

1.3.3 Review process and criteria.

Each protocol is reviewed and discussed to determine if specific federal requirements for IRB approval can be 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 may be required for projects involving vulnerable groups, or a request to waive or alter informed consent requirements.

1.4 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:

1.4.1 Approval.

The IRB may determine that the protocol materials and consent form(s) are satisfactory as presented, and meet all required criteria for approval. Within approximately 5 business day, an HRPP staff member forwards a letter of approval to the investigator, and the research may begin immediately. The letter will include the investigator’s responsibilities, the dates of approval and expiration of approval. The approval is documented in the protocol file and database record.

1.4.2 Approval, contingent on minor modifications.

The IRB may determine that the criteria for approval can only be met if specific, minor modifications and/or alterations are made to the protocol and/or consent form(s). Minor modifications would involve specific changes requiring only simple concurrence by the investigator. A qualified HRPP staff member will compile the board’s requests and notify the investigator in writing within 5 business days with the specific, minor revisions or modifications required for approval; a copy will go to the IRB Chair.

A primary reviewer, IRB Chair or designee, or other experienced member then reviews the revised protocol. If acceptable, HRPP staff then forward a letter of approval to the investigator within 5 business days. If an investigator does not agree with the requested revisions, the protocol may be referred to the full board for review. If the investigator does not provide the revisions to the request within 90 days, the proposed project will be considered inactive and the protocol withdrawn.

1.4.3 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 in writing within 5 business days of the board’s action, outlining the reasons for deferral, and including a description of the additional information or revisions needed for review; a copy will go to the IRB Chair.

The investigator re-submits a revised protocol for review at the next available convened meeting. If the board determines, however, 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.

1.4.5 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 will notify the investigator of the board's action in writing, including the reasons for disapproval of the project, and a description of how they may respond; a copy will go to the IRB Chair.

1.5 Approval period.

The IRB determines the approval period, appropriate to the degree of risk, but not less than once/yr. The typical approval period is 364 days; however, the IRB may determine that some research projects require more frequent review; such as:

- any research involving fetuses;
- any research involving significant risk, and/or a high risk:potential benefit ratio
- any research for which there have been reports of injury or unanticipated problems as a consequence of participating in the research
- any other research the IRB deems appropriate to review on a more frequent basis

The date of approval is the date of the convened meeting at which the board voted for *Approval* or *Approval contingent on minor modifications*. Note that if minor modifications are required, however, the *research may not begin* until these have been accepted by the IRB. The expiration of approval will then be set at no more than 364 days after the approval date.

1.6 Notification to institutional officials.

A copy of the meeting agenda and minutes are made available to the Institutional Official (IO), and/or the Associate VP for Sponsored Programs Administration by posting on a shared computer drive.

1.7 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 of approval. The IRB office will typically send a notice to the investigator approximately 2 months prior to the expiration date; however, timely submission of the report 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 applicable; 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 usually 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 to accrual, completed, or abandoned. Refer to *7.6 Continuing Review* for more information.

2.4 Unanticipated events.

A report is required to the IRB in the event of unanticipated problems involving risks to participants or others. A research-related injury, or a loss of confidential research data are several examples of unanticipated events that would place participants at risk. Refer to *7.8 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:

Investigator: anyone involved in conducting the research; ie, 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.

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

REFERENCES:

[FederalWideAssurance 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 Procedures](#)

RELATED FORMS:

IRB Protocol Form
Participant informed consent/info sheet template and instructions
Protocol Submission Checklist
IRB Review Checklist

RELATED HRPP SECTIONS:

2 Applicability
4.2 IRB Meeting Procedures
6 Conflict of Interest
7.2 Criteria for IRB Approval
7.4 Full Board Review
7.5 Protocol Amendments
7.6 Continuing Review
7.7 Unanticipated Problems and Serious Adverse Events
12 Quality Assurance and Research Compliance