Continuing review will be conducted in accordance with Health and Human Services regulations at 45 CFR §46.109(e) and OHRP guidance on continuing review (July 11, 2002).

Expedited and full board protocols are approved at intervals appropriate to the degree of risk, but no less than once per year. Research certified as exempt does not require continuing review, but is generally certified for a period of 3 years; refer to 7.1 Exempt Determinations for procedures on recertification of exempt status.

1.0 Continuing review/completion report submission process.

1.1 Notification of pending expiration of IRB approval.
The current project approval period is documented on the initial approval letter, as well as subsequent continuing review reports. Approximately 2 months prior to a project’s IRB approval expiration date, HRPP staff send a courtesy renewal reminder to the principal investigator (PI). Investigators are responsible for timely submission of the Continuing Review/Completion Report form, due by the first day of the month prior to the month that approval expires. For example, if a project’s approval will expire April 15th; HRPP staff will typically send a reminder to the PI in early February, with the report due by March 1st.

1.2 Content of report.
PIs are responsible for completion and submission of the Continuing Review/Completion Report. Reports should include, at a minimum, the following information:

- number of participants enrolled during the report period, and the cumulative number since initial approval,
- brief summary of research results to date,
- summary of unanticipated problems and available information regarding adverse events (in some cases, could include a statement that there have been no unanticipated problems, or that these have occurred at a frequency and severity as documented in the research protocol and informed consent document,
- summary of any withdrawal of participants since the last review,
- summary of any complaints since the last review,
- summary of recent literature that may be relevant to the research,
- summary of amendments or modifications since the last review,
- any relevant multi-center reports,
- any relevant information pertaining to risks, such as data safety monitoring reports,
- a copy of any current informed consent document(s), and any newly proposed consent document(s), if applicable,
- a copy of any relevant funding proposals or reports, if applicable.

1.3 Ongoing Projects.
Research projects that continue to enroll, or collect information from participants, or analyze identifiable data are considered currently active. Investigators must submit the Continuing Review/Completion Report form, and any applicable attachments, by the due date listed to allow for IRB review and approval prior to the expiration date. PIs may submit Continuing Review Reports and required supplemental materials electronically via their official NDSU.
email. Hard copy submissions are also acceptable, these must be signed by the PI. Review of long term projects must include submission of an updated protocol form (using the current form version) at least every 5 years, to verify the currently approved research procedures. Projects that remain active only for data analysis do not require an updated protocol form.

1.4 Completed, Abandoned, or Inactive Projects.
Research projects are considered inactive and may be closed if research interventions are complete, no additional data will be collected from participants, and no identifiable information will be retained for analysis. The PI must submit the Continuing Review/Completion Report form prior to the expiration date to close the project. The closure report is reviewed by qualified HRPP staff, IRB chair or designee.

1.5 Overdue reports.
If a report is not filed by the due date, HRPP staff send an overdue notice to the PI, and a copy to the department chair and director or dean. The overdue notice explains the consequences for failure to renew approval prior to the expiration date, including halting all research activities involving human subjects.

1.5.1 Currently active projects.
If the project is to remain active, the PI must submit the continuing review report immediately, to avoid a lapse in IRB approval. See section 5.0, Lapse of approval, below.

1.5.2 Completed projects.
If a project is complete, a completion report is required to close the protocol. If not received prior to the expiration date, project approval has lapsed. See section 5.0, Lapse of approval, below.

2.0 IRB Review Process.

2.1 Pre-review procedures.
Qualified HRPP staff screen the report to verify documentation of training for the research team, and ensure the application is complete, including any relevant attachments. If incomplete, the missing information is requested from the investigator prior to assigning for review; all communication is documented in the protocol file.

If information in the report indicates possible increased risks to subjects, HRPP staff will promptly forward to the IRB Chair or designee to determine whether or not the project should be suspended, pending a review by the convened board. Refer to procedures as outlined in SOP 7.7 Unanticipated Problems and Serious Adverse Events, and 12.4 Reporting Noncompliance, Suspensions, Terminations, and Unanticipated Problems.

2.2 Expedited review.
Eligible projects may undergo continuing review by the expedited method, as described in 7.3 Expedited Review:

2.2.1 Protocols previously reviewed by the expedited method.
Ongoing protocols previously reviewed by the expedited method may also undergo continuing review by the expedited method as long as the project remains eligible for
one or more of the allowable categories, and no new risks that are more than minimal have been identified.

2.2.2 Protocols previously reviewed at a convened meeting.
Ongoing protocols previously reviewed by the full board may undergo expedited continuing review under one of the following review categories:

**Expedited category #8.**
Continuing review of research previously approved by the convened IRB as follows: (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis.

**Expedited category #9.**
Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply, but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Qualified HRPP staff may consult with the IRB chair/designee to determine eligibility for continuing review by the expedited method. The applicable category of expedited review is documented in the protocol file.

In accordance with 7.3 Expedited Review, the IRB Chair/designee, or other experienced member performs the review, utilizing the criteria described in 2.4 below. Reviewer(s) are provided with the continuing review report, applicable attachments (i.e., consent document(s), funding proposals or reports, updated protocol forms, etc.), and provided access to the complete approved protocol file. Generally, reviewers will have 5 working days to return their determination to the HRPP office.

2.3 Full board review.
Projects that were initially reviewed at a convened meeting would generally require continuing review at a convened meeting unless the research qualifies for expedited review Categories 8 or 9 as outlined in 2.2.2. In addition, those projects for which reports indicate an increase in the risks originally anticipated, to more than minimal, or those no longer eligible under one or more categories of expedited review, will undergo continuing review by the full board.

In accordance with 7.4 Full Board Review, the ongoing project is reviewed at a convened meeting, utilizing the criteria described in 2.4 below. One experienced member is selected as a primary reviewer, and is responsible for providing a review summary at the convened meeting. All members receive the continuing review report, applicable attachments (i.e., consent document(s), funding proposals or reports, updated protocol forms, etc.), and are provided online access to the complete approved protocol file and relevant IRB meeting minutes at least 5 working days prior to the meeting.

2.4 IRB review criteria.
Continuing review must be substantive and meaningful regardless of the review process utilized. Criteria for continuing approval include: the initial criteria for approval, as outlined in 7.2 Criteria for IRB Approval, as well as:

2.4.1 Risk assessment and monitoring.
The IRB considers whether any new information has emerged - either from the research itself or other sources – that could alter the previous determinations, particularly with respect to risk to participants. This may include reports of unanticipated problems or safety monitoring reports.

2.4.2 Adequacy of the consent process.
The IRB reviews a copy of the current consent document(s) submitted by the investigator to verify that the most recently approved version is being used, and it contains the most accurate and complete information about the research. The IRB also ensures that any significant new findings that would relate to a participant’s willingness to continue in the research are communicated to them.

2.4.3 Investigator and institutional issues.
The IRB considers any changes in an investigator’s situation or qualifications, as well as any complaints related to their research. Continued acceptability of the proposed research, with respect to institutional resources or local laws, as well as any audit reports are also important in determinations for continuing approval.

2.4.4 Research progress.
The IRB reviews information about the study’s progress, including participant enrollment and withdrawals to determine consistency with the initially approved protocol, as well as the presence of any problems with the conduct of the research. If apparent discrepancies are present, the IRB may request that an audit is necessary to verify that no material changes have occurred in the research since previous IRB review; refer to 12.2 Directed Audits of Research for criteria and process. In addition, the IRB reviews external funding proposals or reports to verify consistency with information provided in the protocol and continuing review report.

2.5 Approval period.
The IRB determines the approval period appropriate to the degree of risk, as described in SOPs 7.3 Expedited Review and 7.4 Full Board Review.

The IRB approval period would normally be kept constant for each subsequent continuing review, provided that the IRB reviews and approves the research within 30 days prior to the expiration date. If continuing review and approval occurs more than 30 days prior to the expiration date, the renewal anniversary date must be re-set.

For example, if a protocol was originally approved (or approved with minor modifications) on October 15 of the current year, approval will expire October 14 of the following year - assuming a typical approval period of no more than one year. If the IRB reviews and approves the ongoing project anytime within 30-days of the expiration date, the anniversary date may be retained. However, if the IRB reviews and approves the ongoing project on more than 30-days prior to the expiration date, the anniversary date will be reset based on the new review date.
3.0 IRB actions and notification:
Several outcomes of IRB review are possible:

3.1 Approved as submitted.
The IRB may determine that the research continues to meet all required criteria for approval. IRB Chair or designee, assigned reviewer or HRPP staff sign approval of the continuing review report, documenting the new approval period, and category of expedited review, if applicable. HRPP staff forward a copy of the signed approved Continuing Review Form to the investigator for their records.

3.2 Approved with conditions.
The IRB may determine that specific revisions and/or additional clarification or documentation are required in order for the research to meet the criteria for continuing approval. Qualified HRPP staff notify the investigator in writing, outlining the revisions and/or additional documentation or clarification required by the reviewer(s) for approval. Upon receipt (prior to the expiration date), the responsive materials are forwarded to the IRB Chair/desigee or assigned reviewer (which may include HRPP staff), to determine that conditions have been satisfied; further review at a convened meeting is not required. If acceptable, approval is documented in the protocol file. HRPP staff notify the investigator of approval as described in 3.1 above.

3.3 Deferral.
The IRB may determine that insufficient information has been provided, or substantive modifications are needed in order to meet the criteria for continuing approval of the research. Qualified HRPP staff notify the investigator in writing, outlining the reasons for deferral, and including a description of the additional information or revisions needed for review. Upon receipt of the additional information, it is re-assigned for continuing review at the next convened meeting. If approval will lapse prior to the meeting, all research activities must cease and a new protocol must be re-filed for review as described in 5.0 below.

3.4 Disapproval.
The convened IRB may determine that the research does not meet the criteria for continuing approval, and/or would place participants at unacceptable levels of risk. Qualified HRPP staff notify the investigator in writing, outlining the reasons for the disapproval.

A project undergoing continuing review may only be disapproved by the full board at a convened meeting; designated reviewers performing expedited review may, however, vote to refer a protocol for review at the next convened meeting.

Qualified HRPP staff notify the investigator, in writing, of the IRB review action. The IRB is notified of continuing reviews approved by expedited procedures in a report of actions taken outside a convened meeting. The report is provided to all regular and alternate members who have an opportunity to review the list and ask questions about the actions performed outside of full board deliberations.

5.0 Lapse of approval.
IRB approval will lapse if a report has not been submitted, and the research reviewed and approved by the IRB prior to the expiration date. All research activities involving human subjects must cease, unless the IRB chair/designee has determined, in consultation with the
investigator, that it would be harmful for currently enrolled participants to discontinue their participation.

HRPP staff notify the PI of the expiration in writing, with copies to department chair/head, director or dean, and Sponsored Programs Administration, if externally funded. Expired projects may be subject to a directed audit to verify that research interventions involving human subjects have not continued beyond the approval period.

The principal investigator remains responsible for submission of a completion report for the expired project, which may be re-initiated only with submission of a new protocol for IRB review. The IRB will not review and approve any of the investigator’s future new protocol submissions prior to receipt of the completion report for the expired project.

It should be noted that expiration of IRB approval occurs automatically, without any direct action on the part of the IRB. This event is not considered equivalent to the IRB actions of suspending or terminating approval of a project; therefore, expiration of IRB approval for a project is not subject to additional reporting requirements, unless an issue of reportable noncompliance or an unanticipated problem has been identified.

**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.

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:**

FederalWide Assurance Terms
45CFR46.103(b)(4) Written IRB procedures
21CFR56.108(a) IRB functions and operations
45CFR46.109 and 21CFR56.109 IRB review of research
45CFR46.111 and 21CFR56.111 Criteria for IRB approval of Research
Categories of Research Eligible for Expedited Review
OHRP Guidance on IRB Continuing Review of Research
OHRP Guidance on IRB Approval of Research with Conditions

**RELATED FORMS:**

Continuing Review/ Completion Report Form
Continuing Review Guides

**RELATED HRPP STANDARD OPERATING PROCEDURES:**

7.2 Criteria for IRB Approval
7.3 Expedited Review
7.4 Full Board Review
7.5 Protocol Amendments
7.7 Unanticipated Problems and Serious Adverse Events
12.4 Reporting Noncompliance, Suspensions, Terminations and Unanticipated Problems