

Approved nonexempt research protocols require continuing IRB review at intervals appropriate to the degree of risk, but no less than once per year. Continuing review is applicable to protocols approved at a convened meeting, as well as those reviewed by expedited methods. Research certified under an exemption category does not require continuing review, but is generally approved for a period of 3 years; refer to 7.1 *Exempt Determinations*.

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:

The report should include, at a minimum, the following information:

- number of participants enrolled during the report period, including 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 subjects 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 other relevant information, especially information pertaining to risks
- a copy of any current informed consent document(s), and any newly proposed consent document(s)
- a copy of any relevant funding proposals or reports

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. Review of long term projects must include submission of an updated protocol form at least every 5 years, to verify the currently approved research procedures.

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 remains responsible for submission of the *Continuing Review/Completion Report* form 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, director or dean, and Sponsored Programs Administration if the project is externally funded. The overdue notice explains the consequences for failure to renew approval prior to the expiration date, including halting all research activities involving human subjects. The PI must then submit the report immediately, to avoid a lapse in IRB approval.

2.0 IRB Review Process:

2.1 Pre-review procedures.

Qualified HRPP staff may 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 may be 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 continuing review under 2 allowable expedited 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 or 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 or 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 (ie, 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. 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 (ie, consent document(s), funding proposals or reports, updated protocol forms, etc), and are provided 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, the IRB must:

- ensure that the project continues to meet the initial criteria for approval, as outlined in 7.2 *Criteria for IRB Approval*

- consider 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 subjects (ie, unanticipated problems)
- ensure that any current or proposed consent document(s) are accurate and complete
- ensure that any significant new findings that would relate to a subject's willingness to continue in the research are provided to them
- determine whether a directed audit would be 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
- (for expedited review) determine that the research qualifies under one or more categories of research eligible for expedited review; document the category of approval
- (for externally funded research) verify that any grant proposals or reports are consistent with information provided in the protocol and continuing review report

2.5 Approval period.

The IRB will determine 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 for which there have been reports of injury or unanticipated problems as a consequence of participating in the research
- any research for which the IRB specifically required a more frequent review period at initial approval
- any other research the IRB deems appropriate to review on a more frequent basis

The IRB 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, 2008, approval will expire October 14, 2009 - assuming a typical approval period of 364 days. If the IRB reviews and approves the ongoing project anytime between September 14 and October 13, 2009, the anniversary date of October 15th may be retained, and the new expiration date would be October 14, 2010. However, if the IRB reviews and approves the ongoing project on September 1, 2009, the anniversary date will be re-set, and the new expiration date would be August 31, 2010.

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, or designated 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 amendment to the investigator for their records.

3.2 Minor modifications required for approval.

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, the revised or supplemental documentation is forwarded to the IRB Chair, designee, or designated reviewer. If determined to be acceptable, 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 will be re-assigned for continuing review.

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 with an attachment to the agenda for the next convened meeting. All members 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 or designee has determined, in consultation with the investigator, that it would be harmful for currently enrolled subjects 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 are subject to a directed audit to verify that research interventions involving human subjects have not continued beyond the approval period.

The 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:

[FederalWideAssurance 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

[OHRP guidance on Written Procedures](#)

[Categories of Research Eligible for Expedited Review](#)

RELATED FORMS:

Continuing Review/Project Completion Form

Continuing Review Checklist

RELATED HRPP SECTIONS:

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