Policies and Procedures

SECTION: Human Research Protection Program	NUMBER: 120	
CHAPTER: Institutional Review Board	ISSUED: 2/2000	LATEST REVIEW/REVISION: 11/2018
POLICY: Continuing Review/Project Termination	PAGE 1 OF 6	

1. POLICY

Any research activity that goes through a full board review or is FDA regulated and involves the use of human subjects and has received initial review and approval by the IRB is subject to continuing review and approval. Expedited projects that an initial reviewer provides rationale requesting continuing reviews are also subject to these guidelines. Time intervals for such reviews shall be made at the discretion of the IRB but shall occur no less than annually, as required by the federal regulation [45 CFR 46.108 (b) and 21 CFR 56.108 (c)]. In general, research activity approved through the expedited review process will not be subject to continuing review unless regulated by the U.S. Food and Drug Administration.

2. DEFINITIONS

2.1. Progress Report – A report submitted to the IRB outlining the progress made on the Principal Investigator's human subject's research project

2.2. Continuing Review – The application submitted to the IRB for review of the Principal Investigator's human subject's research project

3. CONTINUING REVIEW

3.1. Investigators shall submit a continuing review when at least one of the following is true:

3.1.1. The research is ongoing

3.1.2. The remaining research activities involve data collection

3.2. Continuing review shall be terminated only when:

3.2.1. The research is permanently closed to the enrollment of new subjects; and

3.2.2. All subjects have completed all research-related interventions; and

3.2.3. Collection and analysis of private identifiable information has been completed.

3.2.4. All subjects have completed all research related interventions, but the analysis of identifiable data is ongoing; and

3.2.5. The research is permanently closed to the enrollment of new subjects All subjects have completed all research-related interventions

The Principal Investigator is wholly responsible for tracking and submission of requested continuing review, per the timelines as established by the IRB.

FAILURE TO SUBMIT A PROGRESS REPORT FOR CONTINUING REVIEW

3.3. On the day the study expires, if no Continuing Review/Termination containing a progress report has been received, notification shall be sent to the Principal Investigator indicating IRB approval has lapsed, and no further research activity may occur.

3.3.1. The final notice requires the Principal Investigator to immediately submit, to the IRB Chair, a list of research subjects for whom stopping research procedures would cause harm. Continuation of research interventions or interactions in already enrolled subjects shall be allowed only when the IRB or IRB Chair determines it is in the best interest of individual subjects to do so. A Continuing Review/Termination containing a progress report shall be submitted to and reviewed by the IRB at the next convened meeting.

3.3.2. If no harm would occur, the project shall be terminated and, if the Principal Investigator wishes to re-open the project, s/he must resubmit it as an initial IRB review or if it is within 60 days of expiration and no research activity has taken place, the investigator may submit a continuing review application and progress report for consideration by the IRB. If the IRB grants approval, the PI may proceed with the project.

3.3.3. If the IRB does not receive the Continuing Review/Termination containing the progress report within 60 days of expiration, the Research Compliance Auditor will be notified by the IRB administrator to conduct a for-cause audit. The audit will be sent to the full board for review. The IRB will not consider any new projects from this Investigator or research team for review until the report has been received.

3.4. A final report shall be submitted on all research projects.

4. CONDUCTING CONTINUING REVIEW

4.1. An IRB administrator shall conduct a preliminary review of progress reports for accuracy and completeness. At the discretion of the IRB administrator, a project may be referred to the Chair or designee for consideration for expedited review (see Section 7 of this policy). If the Chair or designee allows expedited review of the project, the Chair or designee shall follow IRB review responsibilities, as stated in Section 6 of this document.

4.2. If the study is open to enrollment, the current consent document(s) shall be reviewed by the administrative staff. The only modifications allowed at continuing review are updates to page one of the consent to include addition or removal of investigators and updates to address and phone numbers. An administrator may request the investigator to update IRB-approved template changes made to the consent documents since the last approval or renewal of the consent documents.

4.3. If there are any significant new findings that may relate to the subject's willingness to continue participation, in accordance with 45 CFR 46.116(b) (5) and 21 CFR 50.25(b) (5), the consent shall be updated. The currently approved or proposed consent document shall be submitted and shall be reviewed as a separate agenda item under modification, with supporting information for the need to change the consent.

4.4. Investigators shall provide the IRB with all relevant information regarding the conduct of the research. This system is based on trust between the investigators and the IRB. To ensure the research is conducted in compliance with all state and federal regulations for the protection of human subjects, the IRB may require verification of information from sources other than the investigator. Investigators participating in multi-center and/or multi-institution clinical trials may be unable to prepare a meaningful summary of adverse events at the time of continuing review because study-wide information regarding adverse events is not readily available to them. In such circumstances, when the research study is subject to oversight by a monitoring entity (e.g., the research sponsor, a coordinating or statistical center, or a Data Safety Monitoring Board [DSMB]/Data Monitoring Committee [DMC]), investigators shall be asked to submit a current report from the monitoring entity. Such reports include the following (where available):

4.4.1. A statement indicating what information (such as study-wide adverse events, interim findings, and any recent literature that may be relevant to the research) was reviewed by the monitoring entity;

4.4.2. The date of the review; and

4.4.3. The monitoring entity's assessment of the information reviewed.

5. IRB REVIEW RESPONSIBILITIES

5.1. The IRB shall have the responsibility to review and authority to approve, require modification to, table, or disapprove all research activities. Each Board member shall study the project under review to ensure no unnecessary or unacceptable hazards are present and adequate safeguards are provided for the research subjects. IRB members shall receive the Continuing Review/Termination with progress report and all supporting documents sent by the investigator. Any IRB member shall have access to the complete IRB protocol file and relevant IRB minutes prior to or during the convened IRB meeting (see IRB Policy "IRB Review Process").

5.2. If the IRB determines a project requires additional verification from other sources, they may request the Research Compliance Quality Assurance Monitor to review the study. The Monitoring and Education Compliance Program procedures are described in the Research Compliance Quality Assurance Program.

5.3. If a project has been open for three years and has enrolled no subjects, the IRB shall consider sending a letter to the investigator requesting the investigator submit an amendment with definite plans to complete the research or the study will be closed.

5.4. If the project is still open to enrollment but has been dormant for more than three years, the IRB shall consider sending a letter to the investigator requesting the investigator de-identify existing data and close the study.

6. CONDUCTING CONTINUING REVIEW USING THE EXPEDITED PROCEDURE

6.1. The IRB may expedite certain project renewals at the discretion of the Chair or designee. 45 CFR 46.110(b) and 21 CFR 56.110(b) limit the use of expedited review procedures to specific research categories, as follows:

6.1.1. The research was initially approved using the expedited process pre-2018 Revised Common Rule and there have been no modifications to the project changing the criteria for this type of review. At this time, a letter will notify

the researcher that no further continuing reviews are required and that an Annual Review Update form must be submitted annually from the initial date of approval.

6.1.2. For all expedited studies approved post-2018 Revised Common Rule, Continuing Review requirements are eliminated unless FDA regulated or if a reviewer explicitly justifies why continuing review would enhance the protection of research subjects

7. DETERMINING THE CONTINUING REVIEW DATE

7.1. DHHS regulations at 45 CFR 46.109(e) and FDA regulations at 21 CFR 56.109(f) require an IRB conduct continuing review of research at intervals appropriate to the degree of risk, but not less frequently than once per year. The IRB shall decide the frequency of continuing review for each study necessary to ensure the continued protection of the rights and welfare of research subjects. The expiration date for an IRB protocol is the last day of the period for which the protocol is approved.

7.2. Because the regulations make no provision for any grace period extending the conduct of research beyond the expiration date of IRB approval, continuing review of research shall occur before the date when IRB approval expires

8. PROTOCOL TERMINATION (INCLUDING EARLY TERMINATION)

8.1. The Principal Investigator shall submit a Continuing Review/Termination and progress report within the electronic IRB database.

8.2. The IRB administrators shall review the termination report for completeness; a final progress report should be included in the termination report. For a multi-center project, the final progress report may be limited to safety data available at time of termination by the sponsor. For single-center sites, efficacy and project outcome should be included in the progress report. A letter of termination signed by the Chair or designee shall be sent to the Principal Investigator.

8.3. The IRB files shall be maintained in a closed file for three years. The Principal Investigator's file shall be maintained as per Research Compliance F "Retention of University Research and Compliance Records."

9. FAILURE TO OBTAIN AND MAINTAIN PROTECTION OF HUMAN SUBJECT CERTIFICATION AND RE-CERTIFICATION

Investigators and study personnel who do not certify or fail to re-certify for the required CITI Human Subject Protection Training shall not be allowed to participate in human subject research conducted at Creighton University or any of Creighton University's affiliated sites. Training requirements are available on the Education and Training page on the Creighton University Research and Compliance website.