Procedure

HUMAN RESEARCH PROTECTIONS PROGRAM

II.K.1

IRB Review Procedures

HRPP Policy and Procedure Committee

March 12, 2003

February 27, 2004; May 28, 2004; August 30, 2004; May 1, 2006;
September 22, 2006; November 10, 2008; May 21, 2010; June 13, 2013;
July 1, 2015

Subject: Procedure for Conducting IRB Continuing Review

Procedure:

This procedure outlines the requirements for continuing review of previously approved human subjects research by the Institutional Review Board (IRB).

I. Investigator Responsibilities.

A. The Investigator completes the "Application for Continuing Review or Study Closure". Additional, detailed instructions are downloaded from the HRPP website at http://www.mc.vanderbilt.edu/irb/.

1. The Investigator verifies all pre-printed information contained within the continuing review application, submitting corrections as needed.
2. The Investigator’s signature is completed on the continuing review application, indicating that he or she is in agreement with all the information being presented for continuing review as the most current and accurate information regarding the status of the study.
3. The Investigator submits a copy of the current IRB date-stamped informed consent documents to the IRB.
4. The Investigator submits the continuing review application and all continuing review documents at a minimum of 4 weeks prior to the expiration date to allow adequate time for IRB review and to avoid any unnecessary delays.

B. The Investigator submits a progress report of the research. This report should include all items listed under C.

C. II.C.4 of HRPP Policy III.K.

D. If a study expires, the Investigator will cease all research activities as instructed in the expiration notice. The Investigator immediately submits continuing review requirements or notifies the IRB of study closure.

E. For Grant Reviews, the Investigator completes the "Application for Grant Continuing Review or Grant Closure". Instructions for this type of continuing review may be downloaded from the HRPP website.

II. IRB Committee Responsibilities.

A. Review Criteria.

1. All continuing review determinations are completed using the criteria found in 45 CFR 46.111 for approval of research. The Primary Reviewer documents the review of criteria using the "Reviewers' Comment Form."
2. Research activities initially reviewed by the IRB Committee are reviewed using standard IRB Committee review (See HRPP Policy III.E and HRPP Procedure III.E.1), unless:
   a) The study has been modified and is now eligible for expedited review as defined in the regulations (e.g., change in risk to minimal); or
   b) The study meets one of the following expedited review criteria:
      (1) The research is permanently closed to the enrollment of new participants; and
      (2) All participants have completed all research-related interventions; and
      (3) The research remains active only for long-term follow-up of participants; or
      (4) No participants have ever been enrolled at any site and no additional risks have been identified; or
      (5) The remaining research activities are limited to data analysis.
3. Research activities that were originally reviewed using expedited criteria may receive continuing review on an expedited basis, unless the research activities no longer meet the expedited criteria for review and approval.

4. Research activities that had previously met criteria for expedited review may change with the review and approval of amendments, such that IRB Committee review would be required at the time of continuing review (e.g., risk has changed to be greater than minimal).

5. In addition to the completed “Application for Continuing Review or Study Closure” and applicable continuing review documents submitted by the Investigator, the Reviewer (Primary and Secondary Reviewers if reviewed at a full, convened IRB meeting) receives a copy of the current, approved IRB Application that includes any prior modifications previously approved by the IRB Committee since the last continuing review and supporting documentation such as a Sponsor’s or Investigator’s protocol, grant, Investigator’s brochure, and copies of any monitoring or audit reports conducted since the last review.

   The entire Committee receives the continuing review application and attached documents, the last IRB approval letter, last approved IRB application and informed consent document.

6. Review of the currently approved consent document must assure that the information is still accurate and complete. Any significant new findings that may relate to the participant’s willingness to continue participation is provided to the participant in an updated consent document. Review of currently approved or proposed consent documents must occur during the scheduled continuing review of research by the IRB, but may be done more frequently if new information becomes available.

B. In an effort to be consistent with OHRP guidance regarding the maintenance of the approval period constant from year to year, the IRB Committee may retain the anniversary date by which the continuing review must occur, provided the following criteria are met:

   1. The continuing review occurs annually; and
   2. The IRB performs the continuing review within 30 days before the IRB approval period expires.

C. If the IRB determines that it needs verification from sources other than the Investigator, that no material changes have occurred since the previous IRB review, the IRB may request an independent assessment of information or data provided in the renewal application.

   1. The scope and extent of such an independent assessment is determined on a case-by-case basis.
   2. Sources for such outside information could include copies of FDA audits, literature searches conducted by a clinical librarian at the Eskind Biomedical Library, site visits conducted by authorized personnel, reports from subjects or study staff, or a directed audit at the direction of the IRB Committee or the HRPP Director.

D. Determining Appropriate Interval for Continuing Review.

   1. Appropriate continuing review intervals are addressed with each review conducted by the IRB.

E. Expired Study.

   1. The IRB Chairperson or designated IRB Committee Member sends a letter to the Investigator notifying of expiration. All research activities must cease when expired (See HRPP Policy II.B).
   2. The IRB addresses on a case-by-case basis, those instances where continued intervention and interaction would seriously jeopardize the safety or well-being of an individual when rendering a formal expiration letter (e.g., discontinuing therapy may cause more harm to the participant or they may receive the same therapy off study).
III. HRPP Regulatory Compliance Analyst (RCA) Responsibilities.

A. Assuring Continuing Review Completion.
   1. The RCA assures the Investigator receives continuing review notification in accordance with HRPP Procedure III.K.2.
   2. When continuing review requirements/documents are not met/received from the Investigator prior to the expiration date, the RCA prepares a notice of expiration for signature by the Chairperson or designated IRB Committee Member.

B. The RCA performs a pre-review of the documents submitted for completeness and to verify the type of continuing review in which the study is eligible and proceeds with preparing the continuing review documents accordingly.
   1. Studies requiring expedited continuing review are forwarded the Chairperson or designated IRB Committee Member for review and approval.
   2. Studies requiring full IRB Committee review are assigned a Primary and Secondary Reviewer and placed on the next available Committee agenda.

C. Letters requesting reviewer revisions and final approval letters are drafted using the appropriate template and forwarded to the Chairperson or designated IRB Committee Member for signature.

D. Appropriate database entries are completed, including Committee notification of approval of expedited continuing reviews on the next available agenda.

References:
HRPP Policy III.D
HRPP Procedure III.D.1
HRPP Policy III.E
HRPP Procedure III.E.1