Subject: Procedure for Amendments to Previously Approved Applications, Claims for Exemption, or Non-Human Subject/Non-Research Determinations

Procedure:
This procedure provides guidance for submission, review and approval of amendments to previously approved applications or claims for exemption.

I. Investigator Responsibilities.
A. The Investigator completes the “Request for Amendment” and include the exact text of the revisions to the application, protocol, informed consent documents (ICDs) or other documents associated with the requested change along with a justification for the change. When there are numerous changes, a summary of the changes is also required with the submission. All revisions must be incorporated into the corresponding documents. Changes to the IRB application and ICDs are to be tracked.
B. If, in the Investigator’s opinion, the risk/benefit ratio has changed, necessitating re-consenting of currently enrolled participants, the Investigator provides an amendment to the currently approved ICDs. The IRB Committee may also request re-consenting of the participants.
C. Any proposed or anticipated changes in an exempt study or in non-human subject/non-research determinations, within one year of the date of IRB approval, must be submitted to the IRB for approval prior to initiation of the change. The research proposal will then be evaluated for appropriate IRB review. If a change in exempt research or non-human subject/non-research determination occurs after the first year of approval, the Investigator completes a new “Request for Exemption” or “Request for Determination of Non-Human Subject or Non-Research”, incorporating the proposed change for IRB review and approval.
D. When the Investigator makes changes to avoid an immediate hazard to the participant, the Investigator completes a “Report of Unanticipated Problems Involving Risk to Participants or Others”. The Investigator is required to submit the form to the IRB with 7 days (See HRPP Policy III.L).

II. IRB Committee Responsibilities.
A. The IRB Chairperson or his/her designee may review and approve research that meets the definition of a minor amendment.
B. When a proposed change in a research study represents a major amendment, the convened IRB Committee must review and approve changes. All Committee members will receive:
1. The cover letter, if applicable;
2. The amendment form;
3. All amended information or additional information including the amended protocol, amended IRB proposal and amended informed consent document if applicable, or the most current informed consent document if not amended; and
4. The last IRB approval letter and the last approved application.
5. The last approved protocol;
6. The last approved Investigator’s Brochure, if applicable;
7. The grant; and
8. Any additional pertinent material (e.g., questionnaires, advertisements, DSMB
III. Compliance Analyst (RCA) Responsibilities.
A. The RCA will review the requested amendment and determine if it reflects a major or minor change.
B. Requested changes meeting the criteria for minor amendments are prepared for review and signature by the IRB Chairperson or his/her designee.
C. Requested changes meeting the criteria for major amendments are prepared for IRB Committee review by assignment of Reviewers, placing the study on the next available Committee agenda and assuring appropriate materials are available. Reviewers are electronically notified once assigned.
D. Letters denoting the IRB Committee determinations are drafted using the appropriate template and forwarded to the Chairperson or his/her designee for signature.
E. The RCA will assist in obtaining any additional information requested by the Committee Chairperson or Reviewer.
F. At any time, the RCA may consult with the IRB Committee Chairperson for assistance in determining the type of review that is required to process the amendment.
G. Amendments requiring modifications in the ICDs must be date-stamped and processed according to HRPP policies and procedures.
H. The RCA will make the appropriate database entries including Committee notification of approval of minor amendments on the next available agenda.