	University of Puerto Rico Medical Sciences Campus Human Research Subjects Protection Office	Effective: 9/1/2008
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PROCEDURES FOR CONTINUING REVIEW

Purpose:

Federal regulations require continuing review of approved research at intervals appropriate to the degree of risk, but not less than once per year.

Applicability:

Investigators, IRB Members, IRB Staff

Sources:

45 CFR 46.109, 113
21 CFR 56.109 (f)

Policy:

The IRB shall conduct periodic continuing review of all approved research projects as deemed necessary, but not less than annually. Continuing review must be substantive and meaningful and must follow the same approval criteria as that for initial review. Investigators are responsible for timely submitting documentation for continuing reviews, or a progress report to close a study file. IRB does not allow for the conduct of research beyond the expiration date of IRB approval.

It is the responsibility of the Principal Investigator to notify the IRB when a

study is completed or is being closed. It is important to note that all research activities involving human subjects, including data analysis with individually identifiable or coded private information, must be complete in order to request to terminate IRB approval for a study. A Final Study Report may be submitted at any time during the review period.

Procedure:

Investigators are required to complete continuing review applications through the IRB management electronic software (IRBWISE). To facilitate timely submission of continuing reviews requests, courtesy electronic reminders that continuing review is required will be sent to investigators prior to the expiration date of the current IRB approval. Investigators must give OPPHI sufficient time to arrange that continuing reviews are seen by the same IRB panel that approved the original proposal and are required to submit renewal requests through the IRBWISE system at least six weeks (1.5 months) before approval expiration date. All sections of the IRBWISE application must be completed. The application must include report and assessment of adverse events (AE) as described in AE reporting policy. In the case of procedural protocol changes a separate amendment application must be submitted. For projects that were planned to be conducted during one year or less, investigators must submit a progress report in a continuing review application to close the file at end of the study. Approved studies that are not submitted for continuing review will be administratively closed after IRB approval period expires.

The IRB must determine that all of the requirements (45 CFR 46.111 and 21 CFR 56.111) are satisfied:

Criteria for IRB approval of Research

The IRB reviews research in accordance with current Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA) regulations. The main purpose of the IRB is to protect the rights and welfare of human subjects who take part in research. More specifically, the IRB assures that:

(1) Risks to subjects are minimized.
(2) Risks to subjects are reasonable in relation to any benefits that might be expected from taking part in a research study and to the importance of the knowledge that may result.
(3) Selection of subjects is fair and equitable.

(4) Participation is voluntary and informed consent is obtained from each prospective subject or where appropriate, from the subject's legally authorized representative.
(5) The research plan provides for monitoring the data collected to ensure the safety of subjects.
(6) There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Full Board-Primary reviewer system

In conducting continuing review of research not eligible for expedited review, primary reviewer should at least receive and review a protocol summary and a status report on the progress of the research that includes:

- the number of subjects accrued;
- a summary of any unanticipated problems and available information regarding adverse events (in many cases, such a summary could be a simple brief statement that there have been no unanticipated problems and that adverse events have occurred at the expected frequency and level of severity as documented in the research protocol, the informed consent document, and any investigator brochure);
- a summary of any withdrawal of subjects from the research since the last IRB review;
- a summary of any complaints about the research since the last IRB review;
- a summary of any recent literature that may be relevant to the research and any amendments or modifications to the research since the last IRB review;
- any relevant multi-center trial reports;
- any other relevant information, especially information about risks associated with the research; and
- a copy of the current informed consent document (not stamped).

All other protocol related documents are available through the IRBWISE system.

When reviewing the current informed consent document(s), the IRB should ensure the following:

- The currently approved or proposed consent document is still accurate and complete;
- Any significant new findings that may relate to the subject's willingness to continue participation are provided to the subject in accordance with HHS regulations at 45 CFR 46.116(b)(5).

Review of currently approved or newly proposed consent documents must occur during the scheduled continuing review of research by the IRB, but informed consent documents should be reviewed whenever new information becomes available that would require modification of information in the informed consent document.

Expedited review

When reviewing research under an expedited review procedure, the IRB Chair (or designated IRB member(s)) should receive and review all of the above referenced documentation. The complete protocol will be available through IRBWISE.

When the study is a clinical trial that is subject to oversight by a monitoring entity (e.g., the research sponsor, a coordinating or statistical center, or a DSMB/DMC), local investigators should submit to IRBs a current report from the monitoring entity.

Closing IRB Approved Research

It is the responsibility of the Principal Investigator to notify the IRB and OPPHI when a study is completed or is being closed. It is important to note that all research activities involving human subjects, including data analysis with individually identifiable or coded private information, must be complete in order to terminate IRB approval for a study. A Final Study Report may be submitted at any time during the review period.

Expiration of IRB approval

Once a project approval period expires, the Principal Investigator is given an additional 30 days from the expiration date to submit a Continuing Review Report. The IRB chair issues a letter to the investigator indicating that none of the following activities can occur: (1) collection, use, or

reporting of any data; (2) performance of any study interventions, unless the IRB finds that it is in the best interests of individual subjects to continue participating in research interventions or interactions; (3) enrollment or screening of any new subjects; and/or (4) receiving any study funding. There is no grace period extending approval for the conduct of research beyond the expiration date. For any project that is allowed to expire and for which a Continuing Review is not received within 30 days of expiration, the project will be moved from "expired" status to "closed" status. To conduct further research on this project, the PI must re-submit the project according to the guidelines for new project submissions.