Title: SARMC Institutional Review Board: Continuing Review

Policy Statement: Periodic review of research activities is necessary to determine whether approval should be continued or withdrawn. All research projects must be reviewed at least annually; by regulation, approval of a research study can be given for a period of no more than one year (365 days). The IRB has the authority to require a review to occur more frequently and will provide the rationale in writing to the Principal Investigator. Approval of studies will expire and accrual will be temporarily closed if the IRB does not receive and approve a Research Study Annual Re-Approval (continuing review) Form from the investigator within the interval specified by the IRB.

Procedure:

I. Continuing Review
Continuing review shall occur for as long as the research remains active, even if the research is closed for enrollment. The frequency of review will be determined by the IRB, but will be no less than annually. Continuing review occurs even when the remaining research activities are limited to the analyses of protected health information.

The IRB shall make a determination of the approval period as well as a determination of the need for additional supervision or oversight on a study-by-study basis. The following criteria will be used to determine the frequency and type of periodic monitoring:

- Nature of the methods, treatments or interventions under study;
- Health and background of potential participants;
- Nature of the risks involved and potential benefits;
- Past history of the research activities of either the Principal Investigator or the research entity.

II. Continuing Review Process
The Research Integrity office will send out renewal reminder letters for those studies coming due at least 30 days prior to the expiration date. It is important to note that it is ultimately the investigator’s responsibility to submit the continuing review in a timely fashion to avoid involuntary administrative expiration of the study under authority of the IRB. The IRB is not responsible for the timely submission. Principal Investigators and study team members should be periodically monitoring their research studies, and should be aware of upcoming scheduled continuing review due dates.
A completed annual re-approval application and the following attachments must be submitted prior to review by the IRB:

1. Current IRB approved informed consent;
2. Any abstracts or publications resulting from this research;
3. Adverse event summary (if applicable).

Re-approval applications are typically reviewed at a full board convened meeting, although continuing review may be done via expedited review in which case, expedited review criteria must be met.

During the convened meeting the IRB may decide to require that the research be modified or halted altogether. Special precautions or requirements may be imposed or previously imposed special requirements may be relaxed due to new information. The IRB will also determine whether a research study requires verification from other sources other than the investigators that no material changes have occurred since previous IRB review. The external verification process will be documented and the outcome of the external verification will be provided to the Principal Investigator.

After the IRB meeting, an approval letter will be issued and include the following information:

- The date of IRB approval and when the approval will expire;
- The frequency of continuing review;
- A reminder that the Principal Investigator must report any changes in protocol or informed consent;
- Notification that the Principal Investigator must promptly report any adverse events;
- A request for additional information, if applicable, or clarifications that are required to address questions that arose during the meeting.
- The informed consent document will be date stamped as approved and included with the letter.

Note: Review of a change in the protocol does not alter the date by which the continuing review must occur.

II. Lapse in Continuing Review
IRB regulations make no provisions for any grace period for lapsed continuing review. Failure to provide a timely continuing review report could lead to study suspension, a loss of funding, publication sanctions and/or reporting of noncompliance to sponsors or funding agencies.

The IRB approval is considered to have lapsed at midnight on the expiry date of the approval. Once a lapse in continuing review has occurred, all research activity must be stopped unless the IRB finds that it is in the best interest of the participants to continue with the study.
The IRB will provide written notice of the expiration to the Principal Investigator indicating that the research must stop and that the study approval is expired. After receipt of the expiration notice from the IRB, the Principal Investigator may submit a written request to the IRB chair to continue the research for current subjects involved in procedures. The IRB chair shall determine which participants, if any, may continue and what procedures may be performed. The decision made by the IRB chair will be documented and a letter sent to the Principal Investigator.

In the case of research that is stopped, the Principal Investigator must re-submit a new application to the IRB, along with all appropriate materials if he/she wishes to continue the research and participant recruitment. The submission and review process will take place as if the research protocol was a new study.

III. Authority of the IRB

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB requirements, or has been associated with unexpected serious harm to participants.

If the IRB decides to suspend or terminate its approval of a research project, the IRB shall report its decision promptly to the investigator(s), appropriate institutional officials, sponsor and the department or agency head (or designated office, such as OPRR or FDA) as applicable. The IRB letter must include a statement of the reasons for the suspension or termination.

Related Policies: Information the Investigator Provides to the Institutional Review Board (IRB)

Related Forms: Research Study Annual Re-Approval Application; Request for Expedited Review

http://www.saintalphonsus.org/forms-and-resources

References:


http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html