Continuing Review Requirements

Background
Health and Human Services (HHS) and Food and Drug Administration regulations require that the IRB shall conduct continuing review of non-exempt research at intervals appropriate to the degree of risk, but not less than once per year. Non-exempt research must undergo continuing review for as long as the project involves human subjects in accordance with OHRP guidance (see SOP entitled “Procedures for Study Closure”). Continuing review of studies eligible for expedited review is conducted by the IRB Co-chair(s). Studies requiring full committee review are conducted through a primary reviewer system.

HSS regulation at 45 CFR 46.103(b)(4) and (5) also require the institution to have written IRB procedures that the IRB will follow for conducting its continuing review of research. Guidance from the Office for Human Research Protections (OHRP) indicates that “continuing review of research must be substantive and meaningful.” OHRP has further clarified these expectations to mean that the IRB must ensure that the approval criteria specified in the regulations at 45 CFR 46.111 and 21 CFR 56.111 are satisfied at the time of continuing review. Specifically, the IRB must make determinations regarding risks, potential benefits, informed consent and safeguards for human subjects.

Submission Requirements
As part of the continuing review process, investigators should submit a completed Continuing Review and Modification Form, that consists of a protocol summary and status report on activities conducted for the research including:

- Changes in personnel;
- Accrual of study participants;
- Enrollment status of participants including:
  - Number of withdrawals, and
  - The reason for the withdrawal.
- Summary of study progress;
- Summary of any new information including current literature that may be relevant to the research;
- Summary of any amendments of modifications since last IRB review;
- Summary of any adverse events and unforeseen problems including:
  - Information about risk associated with the research, and
  - Subject complaints.

Supplemental materials should be submitted along with the form, including:

- Recruitment materials (e.g., flyers, advertisements, scripts, letters, email text, etc.)
- A current informed consent document;
- Description of any proposed modifications;
- An investigator’s brochure, if available, for FDA regulated studies;
- Any other significant information/documents, if applicable, such as reports from a Data Safety and Monitoring Board
Data collection materials (e.g., surveys, interview questions, stimuli, etc.) do not require submission unless any changes have been made or are proposed.

While reviewing the informed consent document the IRB shall determine whether the information provided in the currently approved or proposed consent document is still accurate and complete, and whether any significant new findings that may relate to the subject’s willingness to continue participation should be included in the document.

Full committee continuing review of individual studies will be documented in the meeting minutes and includes the committee determinations regarding previous approval criteria, and the vote. The IRB Co-chair shall document continuing review of the previously noted requirements in writing.

Resources

- Institutional Review Board
- Office of Research Assurances
- 45 CFR 46 Protection of Human Subjects
- 21 CFR 56 Institutional Review Board – Food and Drug Administration