Office of Human Research Ethics Training Tips

Primary Reviewer Presentation Tips for Continuing Reviews

OHRP Background:

Criteria for IRB Approval of Research Undergoing Continuing Review, HHS regulations set forth the criteria for IRB approval of research https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-continuing-review-2010/index.html

When conducting continuing review, the IRB should:

a. Start with the working presumption that the research, as previously approved, **satisfies all of the above criteria**.
b. **Focus on new information** provided by the investigator, or otherwise available **that would change the risk: benefit ratio** or **require a revision of the protocol** and/or the informed consent document.
c. Disapprove or require modifications in (to secure re-approval of) a research activity that does not meet the 111 regulatory requirements.
d. When conducting continuing review & evaluating if the research continues to satisfy the criteria for IRB approval of research, the IRB should pay particular attention to the following four aspects of the research:
    - Risk assessment and monitoring;
    - Adequacy of informed consent process;
    - Investigator and institutional issues; and
    - Research progress

Primary Reviewer Review:

Note: Focus of a Continuing Review is Activities of the Past Year since the Last Review!

- ***Start by reviewing the consent form.*** It will provide a good summary of the study.
- Assess whether the study is proceeding as expected, using information in the progress report.
- Is the number of subjects enrolled greater than the number the IRB approved?
- Have there been unanticipated problems that suggest a change in risk benefit ratio?
- Are there trends in protocol deviations that may need to be addressed?
- Do Data Safety Monitoring Committee reports suggest issues that may need to be addressed?
- Is there new information that changes risk: benefit ratio?
- Is the consent form adequate and up to date?
- Are there changes requested for the upcoming approval period?

At the Meeting:

- ***Be brief:*** Provide an overview of the key points in your oral presentation:
    - Short description of study design, study objectives & progress of the study—is it going as planned or not.
    - Identification of subjects & enrollment numbers
    - Any changes to study design over the past year.
    - Recommend stipulations.
        - Make the final motion, including period of approval based on level of risk.

Determination of Renewal Approval Period:

- The length of the approval period is based on the level of risk to subjects and/or an analysis of this risk compared to the risk of alternative care, or standard care if such a standard exists.

- The risk assessment of each protocol is done either by expedited procedure or at a convened meeting.

- **Criteria for requiring review more often than annually.**

  Intervals for continuing review, in the absence of problems, are often set to a default of one year. However, the IRB may determine that more frequent intervals are appropriate. The IRB shall consider the following factors in determining the criteria for studies requiring more frequent review:

  - Nature, probability and magnitude of anticipated risks to subjects;
  - Likely medical or psychological condition of the proposed subjects;
  - Overall qualifications of the PI and other members of the research team;
  - Specific experience of the PI and other members of the research team in conducting similar research;
  - Nature and frequency of adverse events observed in similar research at this and other facilities;
  - Vulnerability of the population being studied (this should be understood to include unfamiliarity with the language used on consent forms and other printed matter intended for subjects in the study);
  - Other factors the IRB deems relevant.

- In specifying an approval period of less than one year, the IRB may define the period with either a time interval or a research milestone, e.g., number of subjects enrolled. The minutes should clearly reflect any determination requiring a review more frequently than annually."

Primary Reviewer Draft Outline for Renewal Study Oral Presentations

All Elements May Not Apply to Your Protocol

Study Number:
Phase: ___Pilot ___1 ___2 ___3 ___4
Study Population: ___adults only ___minors ____vulnerable populations who: _____
_____number to be enrolled _____number approved by IRB _____Study Length
Progress during the past year on the study: Remember to focus on the past year's activities only.
Concerns about study progress to date: Is good progress being made, are they behind or ahead or on target?
Study amendments during the past year:
SAEs, UP &/or Protocol Deviations of the past year & any concerns about them:
DSMB, Safety Reports or Interim findings reported:
New scientific information or literature that affects the study design or risk benefit ratio:
Subject withdrawals; reason for the withdrawals; any concerns:
Complaints about the research:
Relevant multi-site reports:
The researcher's current risk-potential benefit assessment based on study results:
Primary Reviewer Questions/Concerns:
Stipulations:

Recommendation: _____Approval ____Approve with Stips ___Defer ____Suspend/Stop

Recommended Approval Period: _____ (Does not have to be 1 year, should be based on risk to subjects)