

PRESENTING CONTINUATION APPROVAL REQUESTS

Why is continuation review necessary?

Continuation review is one way to monitor a study and to assess whether procedures to protect the rights and welfare of subjects are appropriate.

- Research procedures, subject eligibility, and other aspects of methodology may change over time. This may alter the initial risk/benefit assessment
- Permits the IRB to monitor any areas of concern that were raised during the initial review.
- Gives the IRB an opportunity to revisit the ethical principles in the *Belmont Report*, any special protections or other requirements in 45 CFR Part 46, and institutional policies which may apply.

What happens “behind the scenes”?

Before the Review Board meeting, IRB staff:

- Review recruitment and consent documents currently in use for the research;
- Review the Confidentiality Agreement, if applicable;
- Request any missing information or ask for clarification from the investigator;
- Determine whether studies reviewed by full committee now qualify for expedited continuation review, and whether any projects may be closed;
- Determine whether any research staff need initial human subjects training or a refresher course.

What constitutes “meaningful” continuation review?

The *same* criteria for evaluating potential risks/harms to subjects, potential benefits, informed consent, and procedures to minimize risks/harms apply during continuation review as were considered during initial review of a research proposal. **This assessment does not stop when a study is approved.**

At a minimum, an IRB should review the approved protocol, the approved consent document, amendments, and a status report of:

- ✓ Subject accrual (since last approval period and cumulative),
- ✓ Any unanticipated problems/adverse events that pose risks to subjects or others (including complaints or withdrawals), AND
- ✓ New findings or recent literature, especially information that may relate to a subject's willingness to participate in the research or may change the risk/benefit assessment

What issues should be considered?

Continuation review should be based on the protocol **approved** by the IRB. Primary Reviewers should retain the “approved” application and copies of any amendments reviewed under expedited review authority. These materials will be useful references for presenting at a convened meeting any study amendments and Continuation Approval Requests that require full committee review.

How to identify issues that may be of concern:

- Is the researcher following approved protocols? Are there any discrepancies between the approved protocol and what the researcher reports in the Continuation Approval Request?
- Is study accrual proceeding as planned? If not, could this have an impact on the researcher’s ability to meet study objectives?
- What is the nature of any unanticipated problems/adverse events? Are there multiple reports of problems? Does the researcher explain how problems were resolved?
- Were there any breaches in confidentiality or protocol deviations?
- Do there appear to be a large number of amendments to study procedures and methods since the last approval period?
- Have subjects withdrawn due to reactions to study procedures, research burden, or other reasons?
- Does there appear to be a need for retraining of research staff, either in study procedures or human subjects protection? Why?
- Are potential risks/harms adequately described in consent documents? Do these documents require revision to include new findings, new information about risks/harms, etc?
- Do consent documents require other changes, such as changes to length of study participation, data collection intervals, changes in incentives, etc?

In most cases, researchers are following approved protocols and no issues of concern arise during continuation review.

What is the study approval period?

The IRB should also consider an appropriate approval period, based on risks to subjects and/or any problems or issues of concern with the research.

- Continuation approval may be extended for a period of *no longer* than one year.
 - Example: If a study’s anniversary date is Oct 10th, the next approval period may be extended for no longer than through October 9th of the next calendar year. The

“anniversary date” is the date that a study was granted *conditional approval* by the IRB (whether expedited or full committee review)—not the date that the study received final IRB approval.

- Shorter approval periods and closer monitoring are at the discretion of the IRB. Investigators must be informed of the reason(s) for closer monitoring or a shorter approval period.
- If the IRB extends continuation approval for less than one year, the investigator must submit another Continuation Approval Request *prior* to expiration of study approval.

(Not So Subtle) Hints for Presenting Continuation Approval Requests

- ❖ Use the Continuation Review Worksheet to identify any issues of concern. If a particular item on the Worksheet is *not* a concern, it is not necessary to say so during the presentation.
- ❖ Keep it ***brief*** -- nor more than 5 minutes total. If there are problems/concerns with the research, in most cases IRB staff will have taken this into account and allowed for additional time in the timed agenda.
- ❖ IRB members are assumed to have read the Request. Reviewers should not read from the report itself at the IRB meeting.
- ❖ If you have questions before the meeting, or would like to get copies of any published articles or reports, contact IRB staff working on the study. This person is always listed in the meeting agenda.