

PRESENTING AMENDMENT REQUESTS

When does an amendment require full committee review?

The federal regulations permit use of an expedited review procedure for "minor changes in previously approved research during the period (of one year or less) for which approval is authorized" (45 CFR Part 46.110(b)(2)).

What is a "minor change"?

Routine changes to a study, such as changes in staff, tweaking of questionnaire items, requests for additional identifiable records, correction of minor errors in consent forms, etc., usually qualify for expedited review.

"Minor changes", if approved, would not appreciably alter the risk/benefit assessment and generally are consistent with the overall objectives of the research.

How is the decision made?

Review Section staff determine whether an amendment request requires full committee review shortly after receipt. Generally, this involves review of the project file to assess current project status, how the amendment alters approved procedures, risks and benefits, etc. Review Section staff typically review all "minor" changes to study procedures without the input of the Primary Reviewer. The Primary Reviewer receives PDF copies of all amendment requests and disposition letters (whether approved as submitted, conditionally approved, or deferred).

Special protections:

If a study amendment involves a study population for which there are special protections under the regulations (pregnant women/fetus, prisoners, children), and the Review Board had not previously considered inclusion of and protections for these sub-populations, the amendment may be referred to a convened meeting for consideration. Full committee review may also be required if the amendment may alter a previous full committee risk/benefit analysis of research procedures involving these populations.

Previous expedited review:

Occasionally, an amendment request for research originally reviewed under expedited review procedures requires full committee review.

Example: A researcher submitted an application for identifiable records, which was reviewed under expedited review procedures and approved. Two years later, the researcher submits an amendment to contact a subset of his study population to conduct a short survey of subjects' experiences obtaining health care for a rare condition.

In this particular case, this amendment requires full committee review because the researcher wishes to use confidential agency records to identify and contact subjects. It does not meet the criteria for expedited review in the *Washington State Agency Policy for Protection of Human Research Subjects*.

Unable to approve through an expedited review procedure:

If one or more reviewers cannot agree on approval of a proposed amendment, there are usually two options:

- 1) defer review and request additional information from the investigator, or
- 2) refer the amendment to full committee.

Study amendments reviewed under an expedited review procedure *cannot* be disapproved by a subcommittee. Disapprovals, just like all other potential dispositions, require a majority vote of the full committee.

What should I consider in reviewing an amendment request?

The *same* criteria for evaluating potential risks/harms to subjects, potential benefits, informed consent, and procedures to minimize risks/harms apply to amendment requests as were considered during initial review of a research proposal.

Questions to consider:

- Has the investigator clearly explained the reasoning behind any proposed changes? Does the amendment "make sense" and fit into the overall goals and objectives of the research?
- Are the proposed changes clearly and adequately described?
- Do the proposed changes have an impact on subjects already enrolled in the research?
- Would the potential risks/harms to subjects change in any way under the revised procedures? Would risks/harms be lessened or increase?
- Does the amendment add to the time required to complete research procedures?
- Are potential risks/harms adequately described in consent documents? Do these documents require (further) revision, such as changes to length of study participation, data collection intervals, changes in incentives, etc?

What is the approval period for amendments?

Approval of study amendments remains consistent with the anniversary date of the study. For example, if a study has an anniversary date of November 24th, any amendment reviewed and approved during the current approval period has the same anniversary date -- November 24th.

Approval periods are extended for the study *as a whole*. So even though an amendment may be approved in June, continuation review of the study -- which includes review of the recently-approved amendment -- would occur prior to expiration of study approval on November 24th.

Hints for Presenting Amendment Requests

- ❖ Use the Study Amendment 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 the presentation ***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 Amendment Request. Reviewers should not read from the report itself at the IRB meeting.
- ❖ If you have questions before the meeting, contact IRB staff working on the study. This person is always listed in the meeting agenda.