

Continuing review is required on an annual or more often basis.
Continuing review allows reflection on study progress, study events, and outside events.
Continuing review raises the question, "Given the new information, is the study still approvable?"

RESPONSIBILITY:

It is the investigator's responsibility to make sure that renewal is sought early enough to allow time for IRB review prior to the expiration date.

IRC sends a *courtesy* notice of impending expiration together with information about continuing review requirements. The notice should be about four to six weeks before the expiration date.

CONTINUING REVIEW PROCEDURES

1. Prepare and submit in time
 - in time for scheduled meeting (plus extra time for questions) if full board
 - at least two weeks before expiration for expedited process
2. Prepare requested information
 - Many questions on the continuing review form are open-ended. We want some thought given to the answer.
 - We ask for breakdown by gender and ethnicity. If specific data was not captured, please make an estimate of percentages. Both inappropriate inclusion and inappropriate exclusion of populations are issues of equity.

CONTINUING REVIEW ISSUES

1. Have the risks or the benefits changed?
2. Have the alternatives or options or treatment changed?
3. What is the status of the study?
 - enrollment open (percent enrolled?) or closed?
 - how near is completion?
4. Discuss participation by the numbers?
 - Number screened and enrolled
 - Of those enrolled: continuing, completed, lost, withdrawn, other
 - Of those enrolled: gender and ethnic breakdowns
5. Experience - what worked and what didn't
 - complaints?
 - successes?
 - monitoring visits?
 - consent form communicative?
Consent procedures sufficient?
6. Were there any modifications to protocol? Will there be any?

APPROVAL PERIOD

Approval is for a maximum of one year. The one year period for full board reviews begins on the date of the *last Full Board Review* regardless of the extent of correspondence or time that passed between that date and the date contingencies are removed and approval is granted. OHRP GUIDANCE IS AT:

<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/contrev2002.htm>

There are three important dates:

- Full Board Review: the most recent review date OR
- Contingency removal: the date the reviewer last considered the request
- Approval Start: date of the approval letter.
- Expiration: date stated in the approval letter

Reasons to approve for less than a year include

- the level of risk
- the nature of the study (e.g. a limit to the number of dose escalations)
- the investigator's history with the IRB
- rapidly changing standards

Grace periods: The regulations make no provision for any grace period. However, if application made in time results in an earlier than one year period, the IRB may extend approval to one year from the prior expiration date.

Modifications do not ordinarily alter the continuing review date.

CONSEQUENCES OF FAILURE TO SUBMIT CONTINUING REVIEW MATERIALS IN TIME FOR IRB REVIEW.

- The study will expire on the expiration date.
- No further enrollment is possible.
- Subjects may be seen only for follow-up visits to assure safety.
- Continued enrollment or intervention is considered serious non-compliance.
- Investigators are given the expiration date at the time of approval. A claim that no renewal notice was received, is insufficient excuse.

