Amendments

If a researcher proposes any changes to their approved protocol, an amendment must be submitted.

Amendments that include an increase of risk, change of drug, administration or treatment, addition or increase of a vulnerable population, etc. constitute a major amendment. Major amendments are for full board review. The PI should state if there are participants already enrolled and if they feel re-consent is needed.

Minor amendments may be reviewed by expedited review, regardless whether the initial protocol was a full board review. The amount of changes in the protocol does not determine major versus minor. Minor amendments include administrative changes, address changes, telephone changes, wording changes to the protocol, consent or surveys, minor procedure or recruitment changes.

The wording in the amendment describing what is being changed must be clear and complete. In other words, it should be very clear what is being changed, exactly where the protocol submission is revised to reflect the changes, and what new wording or attachments have been added. For example:

1) The wording should reflect if there is any increase in risks, and if participants need to be re-consented.
2) What procedures are being changed, what wording has been added or deleted and where?
3) If personnel are being changed, they must be named in this section, in addition to the personnel section. If the new personnel will obtain consent and/or are co-investigators they need to be added to the consent form.
4) Any changes described in the amendment must be incorporated into the protocol, e.g. questionnaire and new or revised attachments, as appropriate. If the sponsor’s protocol is changed, the new revised protocol needs to replace the old one. The KC application must be updated to reflect the changes described in the amendment.

If a deviation/violation or adverse event caused an amendment to the protocol, that event should be submitted, reviewed, and acknowledged separately in the KC system in the History of the study.
Continuing Reviews

It is the investigator’s responsibility to ensure that a continuing review is approved prior to the expiration date. By federal regulation, no extension to the original approval period may be granted. The KC system will send multiple reminders automatically to both the PI and to all of the aggregators. As a PI, take into consideration the time necessary to submit a renewal and have the IRB review and approve the renewal and then begin the submission process accordingly.

The protocol will expire on the expiration date, even if a renewal has been submitted, but not approved. Once the protocol expires, no research activities may take place, (i.e. advertisements must be removed, no more consenting of subjects, no subject enrollment, no data collection/analysis, no surveys [electronic or paper], etc.).

If the protocol was originally reviewed as a full board, it will continue to be reviewed per full board review. If it was expedited it will continue to be reviewed per expedited review, unless there is an increase of risk.

Continuing reviews may contain revisions to the study.

KC Section for Continuing Review/Renewal within the questionnaire

To avoid an error message, answer all of the questions in the form, even if it is an n/a.

The current status of the study:
For a full board or a clinical trial study: If the study was closed to enrollment more than 12 months ago or if there has been no enrollment to date and there is no increase in risks, the review may be expedited. Please ignore “Neither (If closed please see the questions below)” option.

When answering the question referring to new information that could affect willingness of participants to continue, you should include such information, such as new side effects, or an improved or alternate treatment has been discovered.

If there are revisions or changes that need to be made as part of the renewal, you may amend the application at this point. Any changes must be incorporated into the protocol, e.g. Sections in the questionnaire and new/revised attachments, as appropriate.
The form requests the total number of subjects enrolled since the beginning of the study. If there has been enrollment, the number should then be broken down into specifics, such as race and gender. The reviewer will ascertain that the numbers add up.

You will then be asked how many were enrolled since the last continuing review approval.