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 will state if there are participants already enrolled. The reviewers will consider if participants need to be re-consented.

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.

The wording in the amendment describing what is being changed must be clear and complete. In other words would you be able to understand what is being changed by this wording if it is reviewed six months from now? If personnel are being changed they must be named in this section in addition to the personnel section, what are the procedures being changed, what wording has been added or deleted?

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, it 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 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.
New information that could affect willingness to continue may include such information as new side effects, or an improved or alternate treatment has been discovered.

If there are revisions or changes that need to be made, you may amend the application as part of the continuing review. 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 should ascertain that the numbers add up.

The form will then request how many were enrolled since the last continuing review approval. The main point is we have to show due diligence in acquiring more than the usual info for protocols that might involve vulnerable populations.