Amendment and Renewal Guide for Reviewers

Office of Research Integrity & Compliance | Version 2
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This document is intended to outline general areas that should be examined by IRB members when reviewing amendment and continuing review/renewal submissions. If further assistance or clarification is required, please contact the ORIC at 304-293-7073, or at IRB@mail.wvu.edu.

Amendments

If a researcher wishes to modify an approved WVU IRB expedited or full board protocol – an amendment must be submitted in the electronic system. Amendments for acknowledged exempt protocols should not be submitted, unless the proposed modification will present an increase in risk to the participants. To be sure that an exempt amendment is not required, consult with the ORIC.

Amendments are submitted as one of the following:

1. **Minor Amendments –** changes to the approved IRB protocol that does not increase the risk to the subject for participating in the research. Typical changes in a minor amendment include:
   - Adding or removing study personnel
   - Address changes
   - Wording changes to the protocol, consent forms, or surveys
   - Minor procedural changes
   - Changes to the recruitment strategy

Minor amendments may be reviewed using the expedited processes, regardless of whether the initial protocol was reviewed and approved using the expedited or Full Board processes. The PI should state if they plan to re-consent the subjects already enrolled on the study (if applicable) and justify why or why not.

2. **Major Amendments –** changes to the approved IRB protocol that increases the risk to the subject, or could increase the risk to the subject, while participating in the research. Typical changes in a major amendment include:
   - An increase in risk of any form
   - Change of drug administration guidelines
   - Change in treatment(s)
   - The addition of a vulnerable population (e.g. children, prisoners, pregnant women, mentally handicapped)

Major amendments must be reviewed by the Full Board. The PI should state if they plan to re-consent the subjects already enrolled on the study (if applicable) and justify why or why not.

Amendment Form

The amendment form is located on the *Protocol Summary* tab, at the top of the *Questionnaire* section. In this form, the wording describing what is being changed must be clear and complete. The reviewer should be able to understand what is being changed by this wording if the amendment is reviewed six months from now.

If personnel are being changed, they must be named in this section in addition changing the personnel section. It should explain if there are new procedures, what these are, what wording has been added or deleted?

Any changes described in the amendment must be incorporated into the protocol, e.g. into the 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. Any old attachments need to be replaced by the new ones.

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. Acknowledgements can be found in the *Protocol History* of the study.

Continuing Reviews/Renewals

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. Please take into consideration the time necessary to submit, review, revise (if applicable), and approve the renewal. It is suggested that the renewal process begin at least four (4) weeks in advance of the expiration date.

When reviewing a full board or a clinical trial renewal, the review can be done using expedited processes if one of the following are met:

1. Closed to enrollment more than 12 months ago and no further treatment is being conducted; or
2. Study is in the data analysis stage; or
3. If there has been no enrollment to date and there is no increase in risks.

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. The PI must explain how this new information will be disseminated to subjects. If with a letter or addendum consent, the document must be included in the attachments.

Amendments with Renewals

If there are revisions or changes that need to be made, an amendment may be 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. The reviewer should compare this to the total number requested to ensure that the PI has not gone over the number requested.

The form will then request how many were enrolled since the last continuing review approval.