



Researcher Guide for Amendments & Renewals

Office of Human Research Protections

Version 4

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This document is intended to help researchers create and submit amendments and continuing review (renewal) applications to the WVU IRB. Protocols must already be approved in order to create and submit amendments and renewals. If further assistance or clarification is required, please contact WVU OHRP at 304-293-7073, or at IRB@mail.wvu.edu.

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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 *cannot* be submitted for:

- acknowledged exempt protocols
- approved flex protocols
- NHSR submissions.

If there is a significant change to one of these, the protocol no longer qualifies for that type of review, or the level of risk changes, the study team must submit a new initial protocol for review.

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.

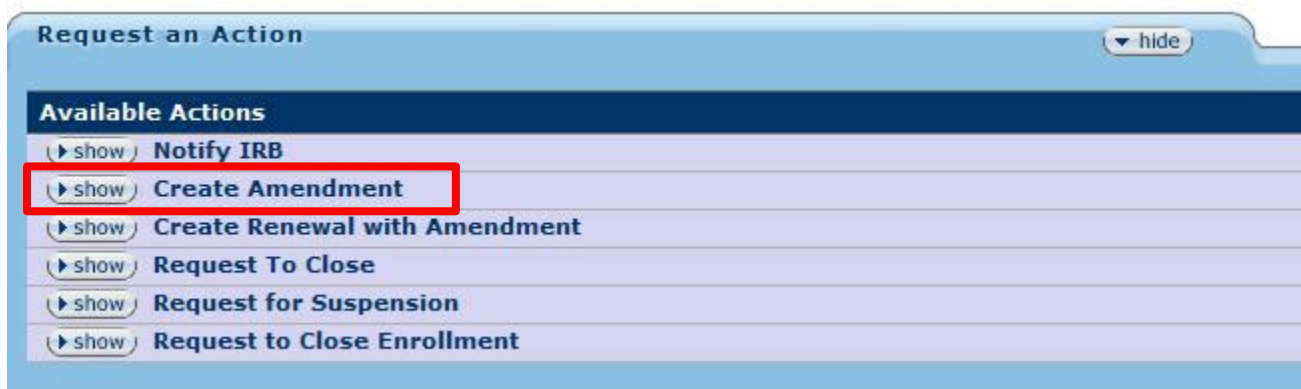
2. **Major Amendments** – changes to the approved IRB protocol which could or will increase the risk to subjects while participating in the research, or which represent a significant change in study procedures. Typical changes in a major amendment include:
- // An increase in risk of any form
 - // Change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

Major amendments for full board studies are reviewed by the full board. Major amendments for expedited protocols may be reviewed using the expedited processes or may be reviewed by the full board, depending on the details of the submitted change. 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.

Creating, Completing, and Submitting an Amendment

Creating an Amendment

These submissions must be created within the protocol you wish to amend. After searching and opening the protocol, using the “Edit” option, move to the *Protocol Actions* tab. Under “Available Actions” there will be the option to “Create Amendment”.



The electronic system will create a copy of the approved WVU IRB protocol, so that no changes are being made to the approved submission on file. The copy created will have the same 10-digit protocol number with the addition of “A00#” at the end. For example, if it is the second amendment you are submitting for a protocol, the amendment document will have “A002” at the end of your protocol number.

Completing an Amendment

The amendment document is where all the modifications must be made. There is an additional section of the *Questionnaire* tab that needs completed – the Amendment Form. Click ‘Show’ to see the additional questions.



Respond to each of the questions asked in this section. When asked to describe the changes being made, provide details. For example:

- /// If you are adding J. Smith, say:
 - “We are adding J. Smith to the protocol to help with recruitment and obtaining consent. J. Smith was also added to the Informed Consent Form”
- /// Do not say:
 - “Adding personnel and changing consent document”
 - “Changing Co-Investigator”

You must also update your protocol. For example, if you say you are changing your recruitment plan, make the change in the corresponding section of the Questionnaire.

If a deviation/violation or adverse event necessitates an amendment to the protocol, that event needs to be submitted and reviewed separately as a Notify IRB submission. The Notify IRB submission cannot be submitted concurrently and must be submitted after the amendment has been reviewed and approved.

Submitting an Amendment

Once the Amendment Form has been completed and the corresponding changes made to the protocol, go to the *Protocol Actions* tab again. Click “Submit for Review”. When asked to select a Type Qualifier – select ‘Other’.

Once the PI approves the submission, it will enter OHRP’s queue for screening and review. If anyone else is submitting the amendment, the PI must approve the submission before it will enter OHRP’s queue.

Any correspondence, such as revision requests or approval letters, can be found in the ‘Correspondence’ section of the *Protocol Summary* page.

Responding to Revisions (if applicable)

Amendments may require revisions prior to approval. If the OHRP screener or IRB reviewer request revisions, a Specific Minor Revisions letter will be sent to the PI and study team. A copy of this letter can be found under “Protocol History.” Please respond to reach revision in the Notes & Attachments section of the WVU+kc protocol submission and change any affected questionnaire questions and/or attachments. The WVU IRB prefers additional changes/updates not be made at this time and instead be submitted as a separate amendment after the amendment in progress is approved. However, if additional changes **must** be made at the time of revisions, the study team **must** update the additional changes in the Amendment questionnaire and include an explanation of the additional changes.

Continuing Reviews

As the expiration date for a WVU IRB protocol nears, the PI should consider submitting a Continuing Review application. Any research that is actively recruiting, enrolling, or conducting study procedures must submit a Continuing Review application to the IRB. This application, once reviewed and approved, will renew WVU IRB approval for a specified

period.

The electronic system will send multiple automatic reminders to both the PI and all personnel listed as an aggregator. These reminders will begin at least 90 days prior to the expiration date.

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 consider the time necessary to submit, review, revise (if applicable), and approve the renewal. Renewals submitted less than 30 days prior to expiration may not be reviewed in time; if so, a new initial submission would be required to continue the project.

The protocol will expire on the set expiration date, regardless of whether the renewal has been submitted for review. Once the protocol expires, no research activities may take place (e.g. no recruiting, no consenting participants, no data collection).

The review procedures for a continuing review are based on the protocol type and how it was originally approved. If the protocol was initially reviewed by the full board, the continuing review must be reviewed the same way. If the protocol was initially reviewed using expedited processes, the protocol will be reviewed in the same manner unless there is an increase in risk.

Creating, Completing, and Submitting a Continuing Review/Renewal

Creating a Continuing Review

These submissions must be created within the protocol you wish to renew. After searching for and opening the protocol, select the "Edit" option then move to the *Protocol Actions* tab. Under "Available Actions" there will be the option "Create Renewal with Amendment."



The electronic system will create a copy of the approved WVU IRB protocol, so that no changes are being made to the approved document on file. The copy will have the same 10-digit protocol number with the addition of "R00#" at the end. For example, if you are submitting the second continuing review for a protocol, the renewal document will have "R002" at the end of the protocol number.

Completing a Continuing Review

The continuing review application contains information necessary for the renewal of a protocol and can also include amendments or modifications. This streamlines the process and reduces the overall number of applications needed. As specific information is needed for continuing review, these *cannot* be submitted within amendment submissions. To submit these items concurrently you must use the continuing review application.

A new section of the *Questionnaire* needs to be completed – the Continuing Review/Renewal form. Click 'Show' to see the additional questions. Respond to all questions in this section, even some do not apply.



Be sure to make relevant changes if you are including an amendment with the renewal submission. For example, if you are changing your recruitment plan, edit the corresponding section of the Questionnaire.

Submitting a Continuing Review

Once the continuing review form is completed, and all the changes proposed in the amendment are made to their corresponding sections, go to the *Protocol Actions* tab again. Click "Submit for Review". When asked to select a Type Qualifier – select 'Other'.

Once the PI approves the submission, it will enter OHRP's queue for screening and review. If anyone else is submitting the amendment, the PI must approve the submission before it will enter OHRP's queue.

Any correspondence, such as revision requests or approval letters, can be found in the 'Correspondence' section of the *Protocol Summary* page.