



Researcher Guide for Amendments & Renewals

Office of Research Integrity & Compliance

Version 2

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This document is intended to help researchers create and submit modifications, 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 the ORIC at 304-293-7073, or at IRB@mail.wvu.edu.

Contents

- Amendments..... 1
- Creating, Completing, and Submitting an Amendment..... 2
 - Creating an Amendment..... 2
 - Completing an Amendment..... 3
 - Submitting an Amendment..... 3
- Continuing Reviews..... 4
- Creating, Completing, and Submitting a Continuing Review/Renewal 4
 - Creating a Continuing Review 4
 - Completing a Continuing Review 5
 - Submitting a Continuing Review 5

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:

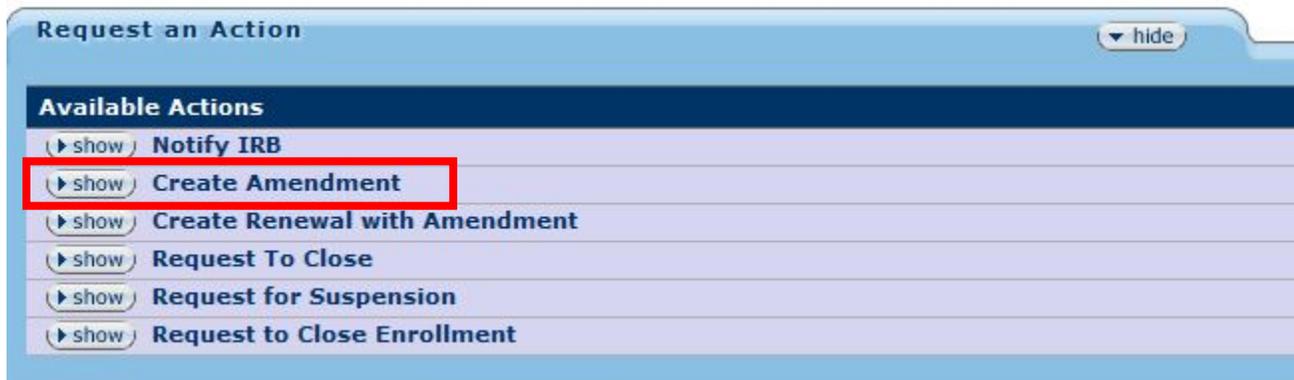
- /// An increase in risk of any form
- /// Change of drug administration guidelines
- /// Change in treatment(s)
- /// The addition of a vulnerable population (e.g. children, prisoners, pregnant women, mentally handicapped)

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.

Creating, Completing, and Submitting an Amendment

Creating an Amendment

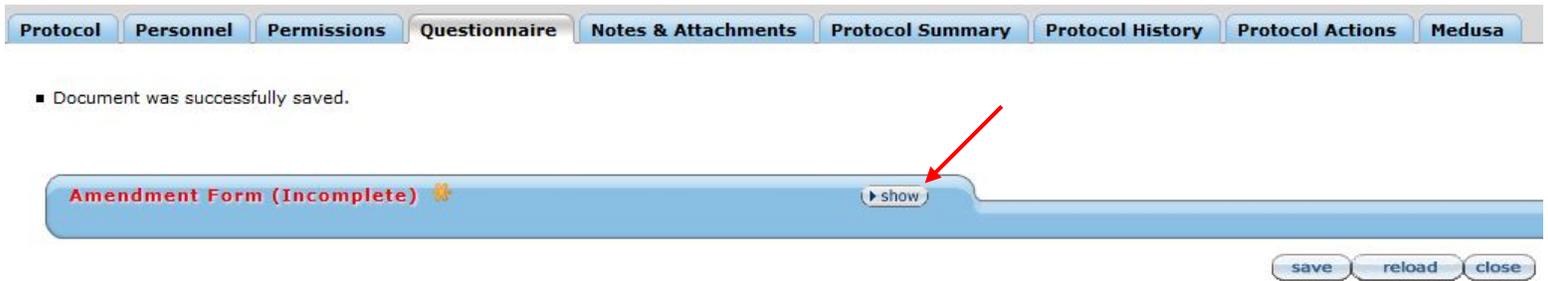
These submissions must be created within the protocol you wish to amend. After searching and opening the protocol, using the “Edit” option, move to the *Protocol Actions* tab. Under “Available Actions” there will be the options “Create an Amendment”.



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 created will have the same 10-digit protocol number with the addition of an “A00#” at the end. For example, if it is the second amendment you are submitting for a protocol, the amendment document will have an “A002” at the end of your protocol number.

Completing an Amendment

The amendment document is where all of the modifications are to 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, please do so in detail. See the example below:

- /// 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”

Be sure to make the changes to 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 caused an amendment to the protocol, that event needs to be submitted and reviewed separately in the electronic system. Follow the *Reportable Events & Notifying the IRB* guide on the ORIC website.

Submitting an Amendment

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

Unlike initial protocols, Amendments do not need to be approved by the PI’s Unit Administrator. Once the PI approves the submission, the ORIC will be notified of the submission and the review process will begin. If a Co-investigator or study personnel are submitting the amendment, the application will not be received by the ORIC until the PI approves the submission.

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

Continuing Reviews

As the expiration date for a WVU IRB protocol nears, the PI should consider submitting a Continuing Review application for review. Any research that is actively recruiting, enrolling, has study procedures being conducted, or is analyzing data needs to submit a Continuing Review application to the IRB. This application, once reviewed and approved, will renew WVU IRB approval for a specified period of time.

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 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.

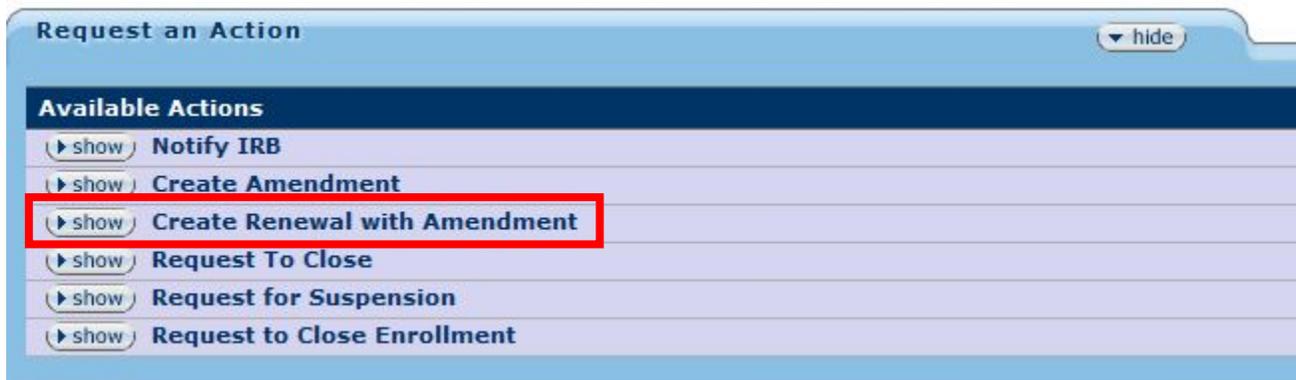
The protocol will expire on the set expiration date, regardless of if the renewal has been submitted for review. Once the protocol expires, no research activities may take place (e.g. remove recruitment materials, no consenting participants, no data collection or analysis).

The review procedures for a continuing review is 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 the 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 and opening the protocol, using the “Edit” option, move to the *Protocol Actions* tab. Under “Available Actions” there will be the options “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 created will have the same 10-digit protocol number with the addition of an “R00#” at the end. For example, if it is the second continuing review you are submitting for a protocol, the renewal document will have an “R002” at the end of your protocol number.

Completing a Continuing Review

The continuing review application can contain information necessary for the renewal of a protocol, and amendments or modifications can also be made. This prevents investigators from needing to submit more than one application at a time. Continuing reviews *cannot* be submitted with amendments.

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



Be sure to make the changes if you are including an amendment with the renewal protocol; for example, if you say you are changing your recruitment plan, make the change in the corresponding section of the Questionnaire.

Submitting a Continuing Review

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

Unlike initial protocols, Continuing Reviews do not need to be approved by the PI's Unit Administrator. Once the PI approves the submission, the ORIC will be notified of the submission and the review process will begin. . If a Co-investigator or study personnel are submitting the continuing review, the application will not be received by the ORIC until the PI approves the submission.

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