Office of Research

Buck-IRB Amendment User Guide

THE OHIO STATE UNIVERSITY

Office of Responsible Research Practices
1960 Kenny Road, Columbus, OH 43210-1016

Institutional Review Board

General Guidance for Amendments:
The "Start Amendment" option will not be present on the left navigation bar if a continuing review submission or another amendment is pending in Buck-IRB. In general, a new amendment cannot be submitted while a continuing review or amendment is pending (see exceptions below). The researcher must either wait until the pending submission has been approved, or the previous submission can be withdrawn so that the new amendment request can be initiated.

Exceptions:

1. Personnel changes involving Ohio State co-investigators and key personnel that do not necessitate study document changes can be submitted through a process created specifically for personnel changes, rather than by amendment request. These personnel changes can be made at any time, including while other submissions are pending. Click on "Start Personnel Change" to initiate this request. NOTE: PI changes and external collaborator changes can be made by amendment request only.

2. As part of a continuing review submission, the following two types of changes can be requested (and do not require a separate amendment request): Increases in the number of study participants and personnel changes.

Amendment submissions that include personnel changes cannot be submitted until CITI training and COI disclosures are current for all study team members (with the exception of team members being removed from the study). Amendment submissions without personnel changes will not be screened for study team CITI and COI compliance by the Buck-IRB system.

To Begin a New Amendment:

Click on "Start Amendment" in the left navigation bar.

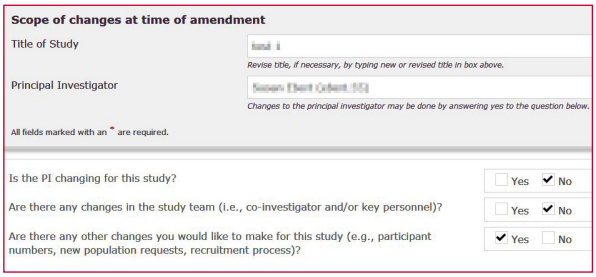
Scope of Changes at the Time of Amendment:

Indicate any requested changes in PI or other study team members. Check "Yes" if study documents, such as the protocol, consent forms, or recruitment materials will be revised as a result of these changes.

Check "Yes" to the last question if you will be making any other changes, including revisions to study documents.

Click 

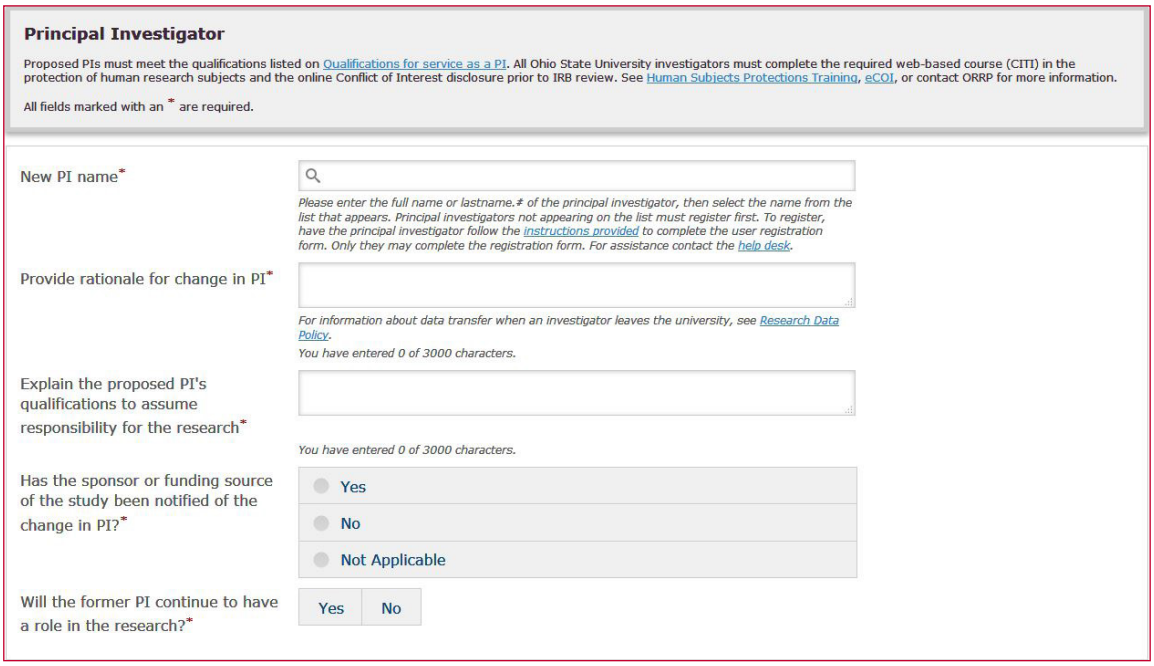
to proceed.



Note: After saving this page, you cannot go back and change the answer to the last question (regarding "other changes") from "Yes" to "No" without losing information entered on later pages. To proceed without making "other changes," the only option is to start the amendment over. You can, however, change the answer to "Yes" (if you originally selected "No" in the last question) and add "other changes" without starting over or losing information.

Principal Investigator (will be present only if PI change is requested):

Enter the new PI name, then select the individual using the lookup tool and provide the requested information about the change in PI.



Contact ORRP to determine whether external agreements are needed if the former PI is leaving the university and will continue to have a role in the research.

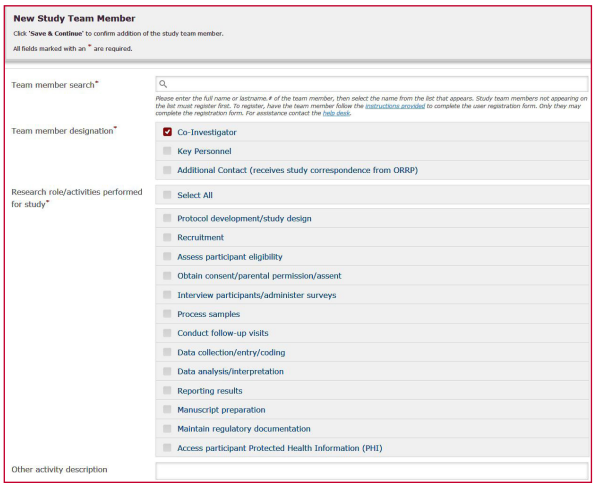
Contact ORRP if the former PI has left the university (or is otherwise unavailable) to request that the former PI's department chair is notified to review and sign-off on the submission (as applicable) in place of the former PI.

Click Save & Continue › to proceed.

Study Personnel:

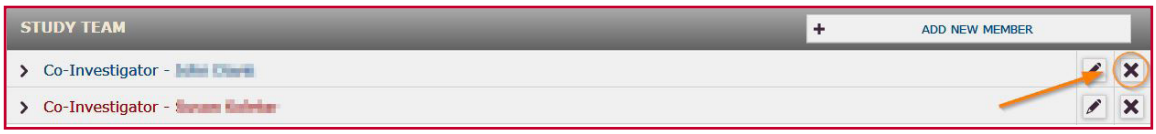
Ohio State co-investigators and key personnel can be added or removed from the study on this page.

To add someone, click "Add New Member" and use the look-up tool to select this individual. Indicate the designation (co-investigator or key personnel) and activities of the new study team member. More than one role can be selected.



Note: The activities selected for team members on this page will be considered during IRB review of the amendment or personnel change request.

To remove a study team member, click the “X” next to the person’s name.



Note: If you selected “No” on the “scope of changes at time of amendment” page to the question about study team changes, you will not see the study personnel page. Should you wish to make personnel changes, go back to the “scope of changes” page, and change your answer to indicate that you will be requesting personnel changes. Save this page.

Click Save & Continue to proceed.

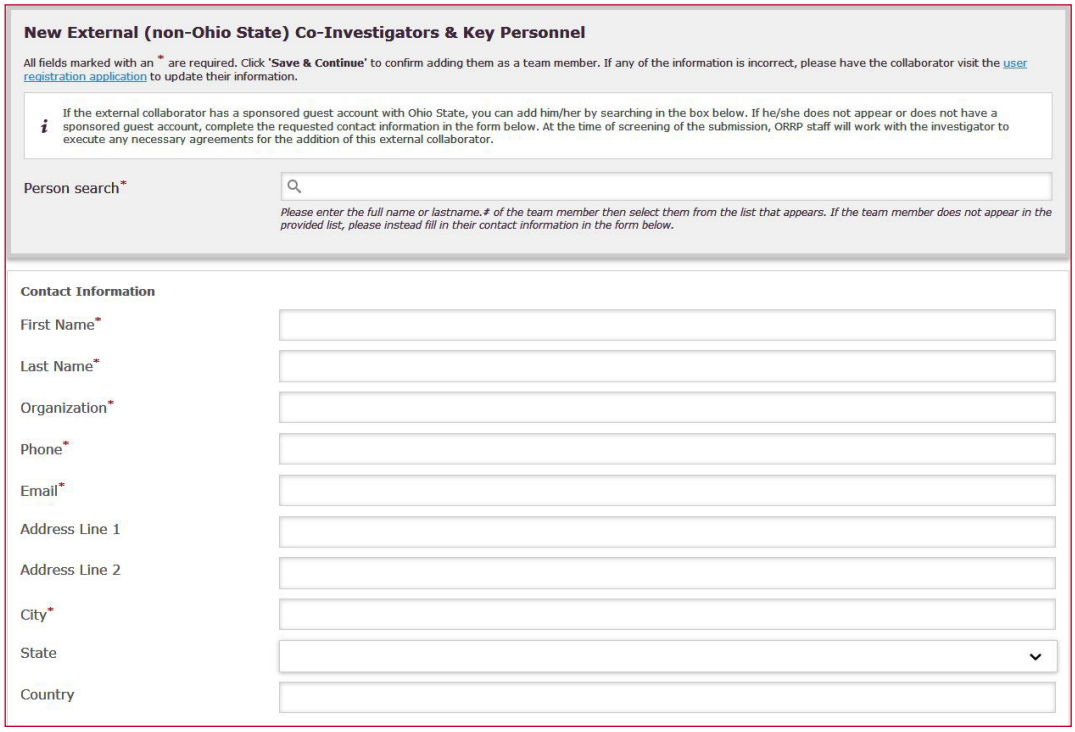
External Co-Investigators & Key Personnel:

This page will display any study team members who are external to Ohio State. If no changes will be made to add or remove external personnel, click Continue to proceed.

If a new external collaborator will be added, click + ADD NEW COLLABORATOR to add a new external person to the study team.

If you know that the external collaborator has an Ohio State guest account, the individual can be found in the “Person Search” field. If the individual does not have a guest account, enter the appropriate contact information, designation, and role in the blanks provided.

Note: If you selected “No” on the “scope of changes at time of amendment” page to the question about study team changes, you will not see the external collaborators page. Should you wish to make changes to external personnel, go back to the “scope of changes” page, and change your answer to indicate that you will be requesting personnel changes. Save this page.



Proposed Changes:

The “Proposed Changes” page will be enabled (i.e., available to you) if you checked “Yes” to making “other changes” on the “scope of changes at time of amendment” page. Select the aspects of the

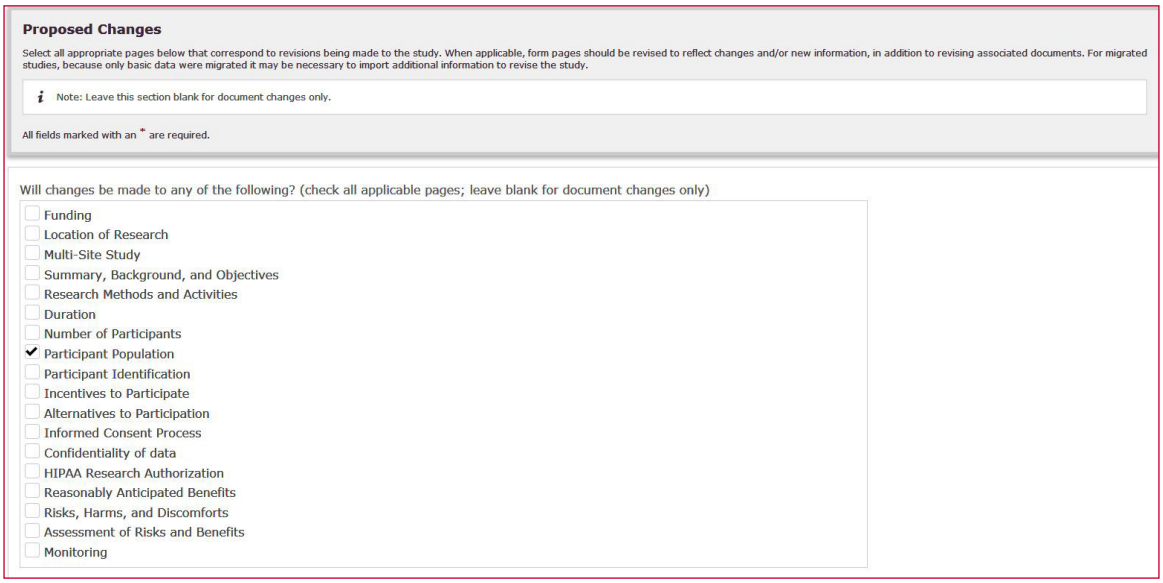
study (e.g., Research Methods and Activities) you would like to change. These selections will determine which pages in the Buck-IRB application will be enabled for revisions. When applicable, form pages should be revised to reflect changes and/or new information, in addition to revising associated documents.

When initiating an amendment, the study team should think about all areas of the application that could require revisions as a result of the change. For example, if an investigator wishes to add a new arm/ experiment to the study, it may be necessary to edit multiple sections of the Buck-IRB application, such as Summary, Background, and Objectives; Research Methods and Activities; Number of Participants; and Participant Identification.

For studies initiated in Buck-IRB, all currently approved information will be present for revision on the enabled pages. For migrated studies, it may be necessary to import additional information when revising the study (because only basic study data were migrated initially), to provide appropriate context for the requested change. **Clearly distinguish what is currently approved from the proposed change(s).**

Do not check any boxes if the amendment does not necessitate changes to any of the Buck-IRB application pages listed.

> **Note:** Only new documents and versions of documents that are being revised in the current amendment should be uploaded. Do not upload documents that are not relevant to the current submission. Do not combine multiple documents (e.g., protocol and consent form) into one. Do not upload the same document in more than one box.



Click Save & Continue to proceed.

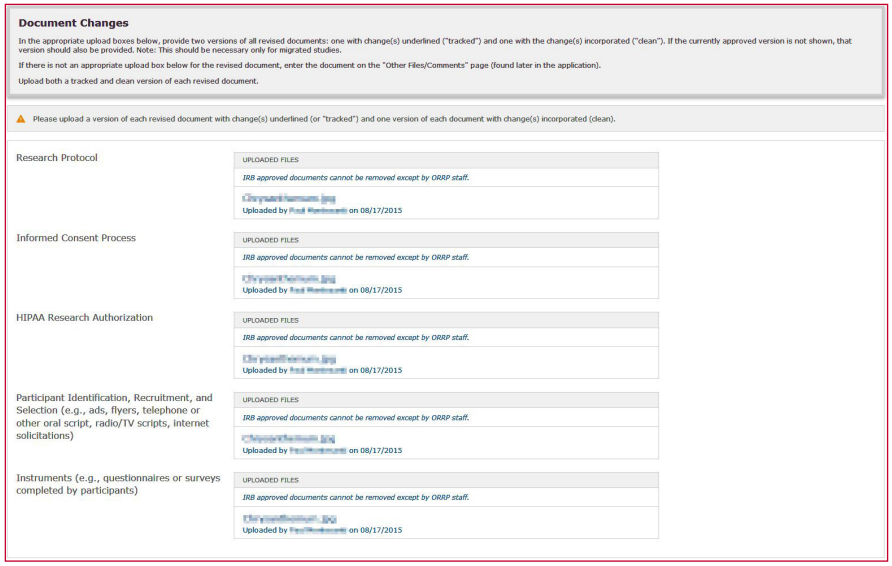
Document Changes:

On this page, upload new documents and/or “tracked” (changes underlined) and “clean” (changes incorporated) versions of approved documents being revised. For migrated studies that have not yet undergone continuing IRB review, the *currently approved version* of a document being revised should also be uploaded with the “tracked” and “clean” versions. For studies initiated in Buck-IRB, currently approved documents will be shown in the appropriate upload boxes and do not need to be uploaded again. As applicable, clearly label documents you upload as “tracked,” “clean,” or “current.”

> **Note:** Only new documents and versions of documents that are being revised in the current amendment should be uploaded. Do not upload documents that are not relevant to the current submission. Do not combine multiple documents (e.g., protocol and consent form) into one. Do not upload the same document in more than one box.

You cannot remove currently approved documents from the upload boxes for studies initiated in Buck-IRB. To request that an approved document is deleted (rather than revised), include this request in the description and rationale for changes on the “Supplemental Questions” page.

Note: Nothing is needed on this page if no documents are being added or revised.



Click Save & Continue to proceed.

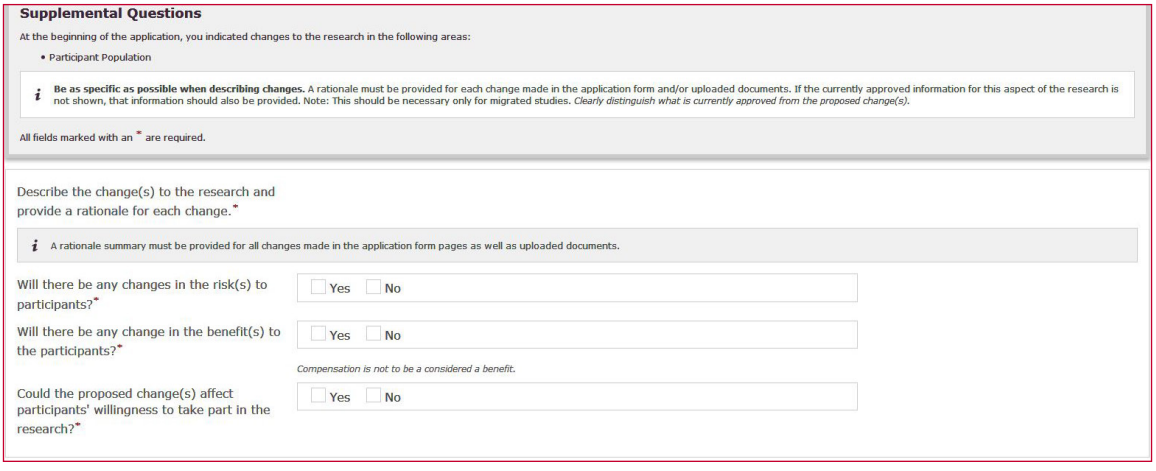
Supplemental Questions:

This page is used to describe the changes being requested.

Describe all requested changes (including document changes), and provide a rationale for each change in the first box. Use this box also to list any approved documents that will no longer be used and should be deleted.

Answer the remaining questions regarding whether the change will alter the risks and/or benefits of the study and whether the change could affect subjects’ willingness to participate.

If you answer “Yes” to the last question, you must describe how participants will be informed of the change (e.g., through a revised consent form or letter).



Click Save & Continue to proceed.

Application Pages:

Selections made on the “Proposed Changes” page will enable applicable pages for revision at this point in Buck-IRB.

> **Note:** For studies initiated in Buck-IRB, all currently approved information will be present for revision on the enabled pages. For migrated studies, it may be necessary to import additional information when making revisions (because only basic study data were migrated initially), to provide appropriate context for the requested change. **Clearly distinguish what is currently approved from the proposed change(s).**

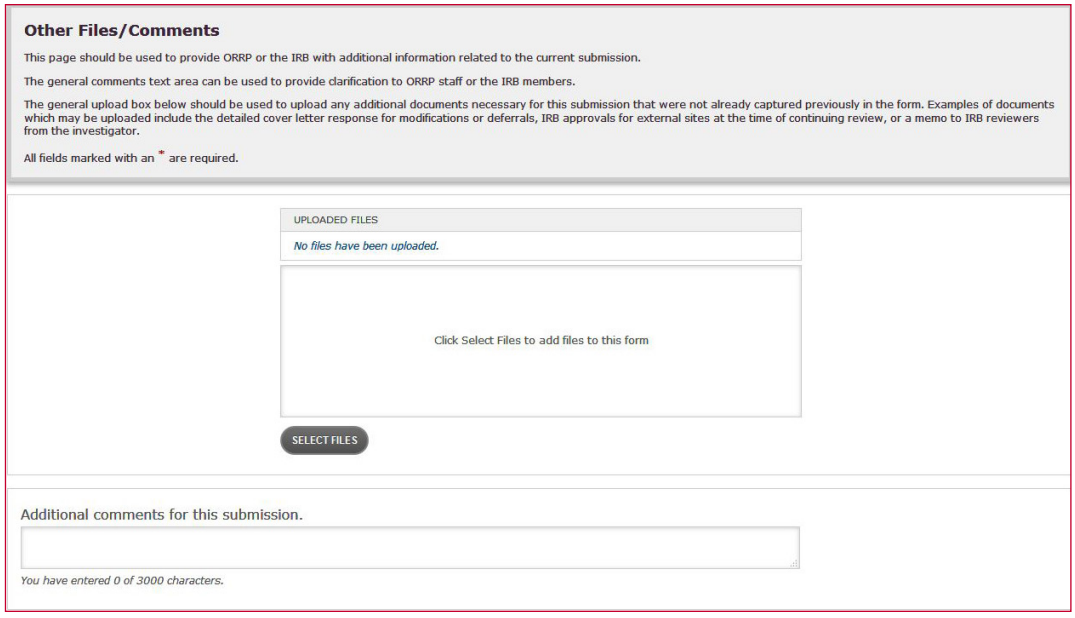
Upload Files Review:

Review uploaded files on this page to ensure you have submitted all necessary documents. Confirm that duplicate files have not been uploaded. To correct errors in an upload box, click the box name to be taken back to the page containing the upload box and can make any necessary revisions. If you have additional files to upload that were not requested on previous pages, upload these documents on the next page, “Other Files/Comments” (see below).

Click Save & Continue to proceed.

Other Files/Comments:

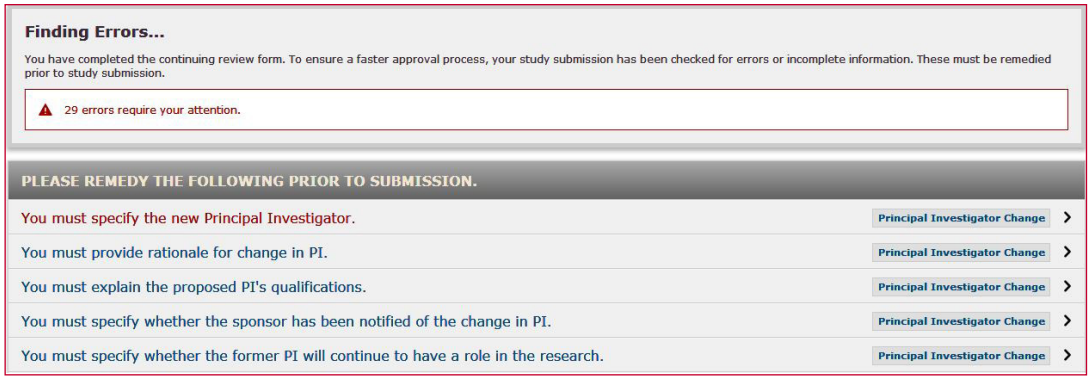
Use this page to provide any files that were not uploaded previously in the form. A box is provided for any additional comments about the submission you wish to provide to ORRP staff and/or IRB members.



Click Save & Continue to proceed.

Find Errors:

On the “Find Errors” page, any form sections that were not completed will be marked with a red *. Click on the error to go directly to the page with the error. After correcting the error, click Save & Continue to return to the “Find Errors” page.



Once all errors have been corrected, the form is ready for submission.

- **If you are the PI**, go back to the study workspace by clicking Save & Exit and will see the Submit Amendment option at the top left of the left navigation bar.
- **If you are not the PI**, use the Email PI box on the "Find Errors" page to notify the PI that the submission is ready for action.

Note: The PI is the only member of the study team who can submit the amendment.