

## 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 The researcher must either wait until the pending submission has been approved, or the previous submission can be withdrawn so that the new amendment request can be initiated.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.

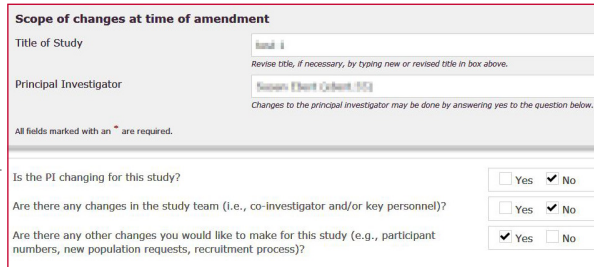


## Scope of Changes at the Time of Amendment:

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.



The screenshot shows a form titled "Scope of changes at time of amendment". It includes fields for "Title of Study" (with a "Final" label and a note to "Revise title, if necessary, by typing new or revised title in box above.") and "Principal Investigator" (with a "Susan Elbert Colburn, MD" label and a note that "Changes to the principal investigator may be done by answering yes to the question below."). Below these fields is a note: "All fields marked with an \* are required." The form contains three questions with radio button options for "Yes" and "No":  
1. "Is the PI changing for this study?" with "Yes" selected.  
2. "Are there any changes in the study team (i.e., co-investigator and/or key personnel)?" with "Yes" selected.  
3. "Are there any other changes you would like to make for this study (e.g., participant numbers, new population requests, recruitment process)?" with "Yes" selected.

**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.

### Principal Investigator

Proposed PIs must meet the qualifications listed on [Qualifications for service as a PI](#). All Ohio State University investigators must complete the required web-based course (CITI) in the protection of human research subjects and the online Conflict of Interest disclosure prior to IRB review. See [Human Subjects Protections Training, eCOI](#), or contact ORRP for more information.

All fields marked with an \* are required.

New PI name\*

Please enter the full name or lastname.# of the principal investigator, then select the name from the list that appears. Principal investigators not appearing on the list must register first. To register, have the principal investigator follow the [instructions provided](#) to complete the user registration form. Only they may complete the registration form. For assistance contact the [help desk](#).

Provide rationale for change in PI\*

For information about data transfer when an investigator leaves the university, see [Research Data Policy](#).

You have entered 0 of 3000 characters.

Explain the proposed PI's qualifications to assume responsibility for the research\*

You have entered 0 of 3000 characters.

Has the sponsor or funding source of the study been notified of the change in PI?\*  Yes  No  Not Applicable

Will the former PI continue to have a role in the research?\*

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  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.

### New Study Team Member

Click "Save & Continue" to confirm addition of the study team member.

All fields marked with an \* are required.

Team member search\*

Please enter the full name or lastname.# of the team member, then select the name from the list that appears. Study team members not appearing on the list must register first. To register, have the team member follow the [instructions provided](#) to complete the user registration form. Only they may complete the registration form. For assistance contact the [help desk](#).

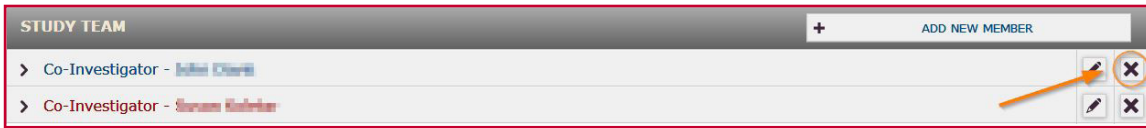
Team member designation\*  Co-Investigator  Key Personnel  Additional Contact (receives study correspondence from ORRP)

Research role/activities performed for study\*  Select All  Protocol development/study design  Recruitment  Assess participant eligibility  Obtain consent/parental permission/assent  Interview participants/administer surveys  Process samples  Conduct follow-up visits  Data collection/entry/coding  Data analysis/interpretation  Reporting results  Manuscript preparation  Maintain regulatory documentation  Access participant Protected Health Information (PHI)

Other activity description

**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.

### New External (non-Ohio State) Co-Investigators & Key Personnel

All fields marked with an \* are required. Click 'Save & Continue' to confirm adding them as a team member. If any of the information is incorrect, please have the collaborator visit the [user registration application](#) to update their information.

**i** If the external collaborator has a sponsored guest account with Ohio State, you can add him/her by searching in the box below. If he/she does not appear or does not have a sponsored guest account, complete the requested contact information in the form below. At the time of screening of the submission, ORRP staff will work with the investigator to execute any necessary agreements for the addition of this external collaborator.

Person search\*

Please enter the full name or lastname, # of the team member then select them from the list that appears. If the team member does not appear in the provided list, please instead fill in their contact information in the form below.

#### Contact Information

First Name\*

Last Name\*

Organization\*

Phone\*

Email\*

Address Line 1

Address Line 2

City\*

State

Country

## 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.

**Proposed Changes**

Select all appropriate pages below that correspond to revisions being made to the study. When applicable, form pages should be revised to reflect changes and/or new information, in addition to revising associated documents. For migrated studies, because only basic data were migrated it may be necessary to import additional information to revise the study.

**i** Note: Leave this section blank for document changes only.

All fields marked with an \* are required.

Will changes be made to any of the following? (check all applicable pages; leave blank for document changes only)

- Funding
- Location of Research
- Multi-Site Study
- Summary, Background, and Objectives
- Research Methods and Activities
- Duration
- Number of Participants
- Participant Population
- Participant Identification
- Incentives to Participate
- Alternatives to Participation
- Informed Consent Process
- Confidentiality of data
- HIPAA Research Authorization
- Reasonably Anticipated Benefits
- Risks, Harms, and Discomforts
- Assessment of Risks and Benefits
- Monitoring

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.

**Document Changes**

In the appropriate upload boxes below, provide two versions of all revised documents: one with change(s) underlined (“tracked”) and one with the change(s) incorporated (“clean”). If the currently approved version is not shown, that version should also be provided. Note: This should be necessary only for migrated studies.  
If there is not an appropriate upload box below for the revised document, enter the document on the “Other Files/Comments” page (found later in the application).  
Upload both a tracked and clean version of each revised document.

▲ Please upload a version of each revised document with change(s) underlined (or “tracked”) and one version of each document with change(s) incorporated (clean).

Research Protocol	<p>UPLOADED FILES</p> <p>IRB approved documents cannot be removed except by DRRP staff.</p> <p><a href="#">View Approved Documents</a></p> <p>Uploaded by <a href="#">Paul H. Williams</a> on 08/17/2015</p>
Informed Consent Process	<p>UPLOADED FILES</p> <p>IRB approved documents cannot be removed except by DRRP staff.</p> <p><a href="#">View Approved Documents</a></p> <p>Uploaded by <a href="#">Paul H. Williams</a> on 08/17/2015</p>
HIPAA Research Authorization	<p>UPLOADED FILES</p> <p>IRB approved documents cannot be removed except by DRRP staff.</p> <p><a href="#">View Approved Documents</a></p> <p>Uploaded by <a href="#">Paul H. Williams</a> on 08/17/2015</p>
Participant Identification, Recruitment, and Selection (e.g., ads, flyers, telephone or other oral script, radio/TV scripts, internet solicitations)	<p>UPLOADED FILES</p> <p>IRB approved documents cannot be removed except by DRRP staff.</p> <p><a href="#">View Approved Documents</a></p> <p>Uploaded by <a href="#">Paul H. Williams</a> on 08/17/2015</p>
Instruments (e.g., questionnaires or surveys completed by participants)	<p>UPLOADED FILES</p> <p>IRB approved documents cannot be removed except by DRRP staff.</p> <p><a href="#">View Approved Documents</a></p> <p>Uploaded by <a href="#">Paul H. Williams</a> on 08/17/2015</p>

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).

**Supplemental Questions**

At the beginning of the application, you indicated changes to the research in the following areas:

- Participant Population

**i** Be as specific as possible when describing changes. A rationale must be provided for each change made in the application form and/or uploaded documents. If the currently approved information for this aspect of the research is not shown, that information should also be provided. Note: This should be necessary only for migrated studies. Clearly distinguish what is currently approved from the proposed change(s).

All fields marked with an \* are required.

Describe the change(s) to the research and provide a rationale for each change.\*

**i** A rationale summary must be provided for all changes made in the application form pages as well as uploaded documents.

Will there be any changes in the risk(s) to participants?\*

Yes  No

Will there be any change in the benefit(s) to the participants?\*

Yes  No

*Compensation is not to be a considered a benefit.*

Could the proposed change(s) affect participants’ willingness to take part in the research?\*

Yes  No

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.

**Other Files/Comments**

This page should be used to provide ORRP or the IRB with additional information related to the current submission.

The general comments text area can be used to provide clarification to ORRP staff or the IRB members.

The general upload box below should be used to upload any additional documents necessary for this submission that were not already captured previously in the form. Examples of documents which may be uploaded include the detailed cover letter response for modifications or deferrals, IRB approvals for external sites at the time of continuing review, or a memo to IRB reviewers from the investigator.

All fields marked with an \* are required.

UPLOADED FILES

*No files have been uploaded.*

Click Select Files to add files to this form

SELECT FILES

Additional comments for this submission.

You have entered 0 of 3000 characters.

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.



### Finding Errors...

You have completed the continuing review form. To ensure a faster approval process, your study submission has been checked for errors or incomplete information. These must be remedied prior to study submission.

▲ 29 errors require your attention.

#### PLEASE REMEDY THE FOLLOWING PRIOR TO SUBMISSION.

You must specify the new Principal Investigator.	Principal Investigator Change >
You must provide rationale for change in PI.	Principal Investigator Change >
You must explain the proposed PI's qualifications.	Principal Investigator Change >
You must specify whether the sponsor has been notified of the change in PI.	Principal Investigator Change >
You must specify whether the former PI will continue to have a role in the research.	Principal Investigator Change >

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.