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. Although there are exceptions (see below), a new amendment cannot be submitted while a continuing review or amendment is pending. The researcher must either wait until the pending submission has been approved, or the previous submission can be withdrawn so that the new amendment request can be initiated.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. Researchers can submit a Personnel Change Request involving Ohio State co-investigators and key personnel that do not necessitate study document revisions, rather than submitting an amendment. Personnel Change Requests can be submitted at any time, including while other submissions are pending. External collaborators can only be removed in Personnel Change Requests. Submit an amendment if the researchers wish to add or modify the activities of an external collaborator or make a PI change.

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 Ohio State personnel changes.

Amendment submissions that include personnel changes cannot be submitted until Human Subjects Protection training, Responsible Conduct of Research training and Conflict of Interest (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 training and COI compliance by the Buck-IRB system.

To Begin a New Amendment:
Click Start Amendment in the left navigation bar.

Scope of Changes at Time of Amendment:
Indicate any requested changes in PI or other Ohio State 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 Save & Continue 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,” start the amendment over. However, by selecting “Yes” (if you originally selected “No” in the last question) “other changes” can be added 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 to proceed.

Study Personnel:

Ohio State study team members can be added or removed from the project. When making personnel changes, remember to revise study documents due to the changes. Upload the revised documents on the “document changes” page later in the application.

• To add someone, click + and select the person from the look-up. Indicate the designation and roles/activities of the new study team member. More than one role/activity can be selected.

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

Click 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 cannot see the external collaborators page, then you either previously selected “No” to the question about making other changes on the “scope of changes” page and/or did not select “External Collaborators” on the “proposed changes” page. To edit external personnel, go back to the “scope of changes” page and select “Yes” to indicate that you will be requesting personnel changes and resave the page. Then select “External Collaborators” on the “proposed changes” page and resave.

For questions about the Ohio State IRB covering external collaborators, contact IRBAgreements@osu.edu.
**Proposed Changes:**

The “Proposed Changes” page will be enabled if you select “Yes” to making “other changes” on the “scope of changes” page. Once you select the aspects of the study that are changing (e.g., Research Methods and Activities), the Buck-IRB application will enable the appropriate pages 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 change. **Clearly distinguish what is currently approved from the proposed change(s).**

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

You cannot undo selections made on this page once the submission is under review.

**Proposed Changes:**

<table>
<thead>
<tr>
<th>Proposed Changes:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Will changes be made to any of the following? (check all applicable pages; leave blank for document changes only)</td>
</tr>
<tr>
<td>0. Funding</td>
</tr>
<tr>
<td>0. General Information</td>
</tr>
<tr>
<td>0. Multi-Site Study</td>
</tr>
<tr>
<td>0. Location of Research</td>
</tr>
<tr>
<td>0. Institutional Approvals</td>
</tr>
<tr>
<td>0. Summary, Background, and Objectives</td>
</tr>
<tr>
<td>0. Research Methods and Activities</td>
</tr>
<tr>
<td>0. Duration</td>
</tr>
<tr>
<td>0. Number of Participants</td>
</tr>
<tr>
<td>0. Participant Population</td>
</tr>
<tr>
<td>0. Participant Identification</td>
</tr>
<tr>
<td>0. Informed Consent Process</td>
</tr>
<tr>
<td>0. Participant Privacy</td>
</tr>
<tr>
<td>0. Confidentiality of Data</td>
</tr>
<tr>
<td>0. HIPAA Research Authorization</td>
</tr>
<tr>
<td>0. Responsible Anticipated Beneficiaries</td>
</tr>
<tr>
<td>0. Risk, Harm, and Discomforts</td>
</tr>
<tr>
<td>0. Assessment of Risk and Benefits</td>
</tr>
<tr>
<td>0. Monitoring</td>
</tr>
<tr>
<td>0. Participant Costs / Reimbursements</td>
</tr>
</tbody>
</table>

Click **Save & Continue** to proceed.

**Document Changes:**

On this page, upload new documents and/or “tracked” (changes tracked) and “clean” (changes incorporated) versions of approved documents being revised. 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” or “clean.”

**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. 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 documents are not being added or revised.

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**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).

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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 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 then make the 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 additional comments about the submission you wish to provide to ORRP staff and/or IRB members.

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**, navigate to the “study workspace” by clicking [Submit Amendment]. In the “study workspace” you will see the option on the top of the left-hand “action menu.”

- **If you are not the PI**, use the box on the “Find Errors” page to notify the PI that the amendment is ready for submission.

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

- **To add someone**, click and select the person from the look-up. Indicate the designation and roles/activities of the new study team member. More than one role/activity can be selected.