Information provided during the migration process will be displayed and, in most cases, cannot be revised. If you discover errors in the migrated data, contact ORRP with details of the error(s) to correct the record.

Currently approved documents for the study will be uploaded at specific points throughout the form.

**Note:** After the first continuing review, it will no longer be necessary to upload approved documents into the Buck-IRB system unless they are revised. See document-specific instructions in the continuing review form pages for guidance on uploading documents.

The continuing review submission cannot be submitted unless all CITI and COI are both current for all study team members (with the exception of those team members being removed from the research).

The only changes that can be made at the time of continuing review are study team changes (e.g., PI, co-investigators, key personnel and external personnel) and/or participant numbers. All other revisions require submission of an amendment.

### To Begin Your First Continuing Review:

Click on ‘Start Continuing Review’ at the top left. This option will only be available if the study is 90 days or less from the IRB approval expiration date for the study.

![Start Continuing Review button](image)

### Scope of changes at the Time of Continuing Review:

The only changes that can occur during the continuing review are personnel changes (PI, co-investigators, key personnel and/or external personnel) and changes in participant numbers. Indicate on this page if the PI or other study team members are changing and, if so, whether study documents, such as informed consent forms, recruitment materials, and/or protocol will be revised due to these changes.

**Note:** If after saving this page, you decide to go back at a later point prior to submission to change any ‘Yes’ answers to ‘No’, you will lose any completed information on later pages. However, you are able to change ‘No’ answers to ‘yes’.

Click ![Save & Continue button](image) to proceed.

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

Enter the new PI name in the person look-up and provide the requested information about the change in PI. If the former PI has left the university or is otherwise unavailable, contact ORRP so that the former PI’s department chair can be sent a notification to sign-off on the submission in place of the former PI.

Click ![Save & Continue button](image) to proceed.
**Study Personnel:**

If you selected “No” on the “scope of changes” page to the question about study team changes, you will only see the study team on this page and cannot make changes.

*Note:* Should you wish to make changes, go back to the scope of changes page and change your answer to the second question to indicate that you will be requesting personnel changes and save the page.

Are there any changes in the study team (i.e., co-investigator and/or key personnel)?

Click **Continue** to proceed.

Ohio State study team members can be added or removed from the project.

- **To add someone,** click “Add New Member” 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 **Continue** to proceed.

**External Co-Investigators & Key Personnel:**

If you selected “No” on the “scope of changes” page to the question about study team changes, you will only see the study team on this page and cannot make changes.

*Note:* Should you wish to make changes, go back to the scope of changes page and change your answer to the second question to indicate that you will be requesting personnel changes and save the page.

Are there any changes in the study team (i.e., co-investigator and/or key personnel)?

This page will display any study team members who are external to Ohio State.
If you know that the external person has an Ohio State guest account, the person can be found in the “person search” field. If the team member does not have a guest account, enter the appropriate contact information, designation and role in the blanks provided.

If no changes will be made to add or remove external personnel, click to proceed.

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

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

Click to proceed.

**Funding and Financial Conflicts:**

Indicate if the research is currently funded or not or if other, non-monetary support is provided or not. If the correct sponsor is already listed, no action is required. If you do not see the appropriate sponsor in the look-up, contact ORRP to request assistance. For any funding sources internal to Ohio State, “Internal funds” should be selected.
Indicate if a new or revised grant is available since the last IRB review. If there is a new or revised grant, click “Yes” and upload the grant in the upload box provided.

Indicate any applicable financial conflicts by clicking the specific name of the study team member with a conflict, or click “None.”

Click **Save & Continue** to proceed.

**Location of Research:**

The currently approved location(s) for the study will be listed. Changes to research locations cannot be made at the time of continuing review. If there are errors in the list of approved locations, contact ORRP to request assistance.

Click **Continue** to proceed.

**Expedited Review:**

1. For studies initially approved by expedited review under categories 1-7...
   - Click “Yes” to the question about expedited review.

   Click **Save & Continue** to proceed to the “expedited categories” page. Select the appropriate category(ies) for the study. More than one category can be selected. Categories 8 and 9 should never be selected if the study was initially approved through the expedited review process.
2. For studies reviewed by the full IRB...

- If the study is permanently closed to enrollment and all participants have completed the research interventions, you may select “Yes” to the question of expedited review (even if the research remains active for long-term follow-up and the study was initially determined to be greater than minimal risk).

  Click to proceed to the “expedited categories” page. Select “Apply for category #8” and the first option.

- Click to proceed.

- If no subjects have been enrolled yet and no new risks have been identified, you may select “Yes” to the question of expedited review (even if the study was initially determined to be greater than minimal risk).

  Click to proceed to the “expedited categories” page. Select “Apply for category #8” and the second option.

- Click to proceed.

- If the research remains open for data analysis only, click “Yes” for expedited review

  Click to proceed to the “expedited categories” page. Select “Apply for category #8” and the third option.

- Click to proceed.

- If the study was previously reviewed by the full (convened) IRB and determined to be minimal risk and no additional risks have been identified, you may select “Yes” to the question of expedited review.

  Click to proceed to the “expedited categories” page. If none of the options for category 8 apply, select “Apply for category #9” from the list.

- Click to proceed.
Research Status:
Select the appropriate box to indicate if participants have been enrolled (or records accessed, if applicable).

- If no participants have been enrolled, provide an explanation. This is a required field.
  Click [Save & Continue] to proceed.

- If participants have been enrolled, further details will be requested. If recruitment has been completed, check all that apply in the choices that appear.
  Click [Save & Continue] to proceed.

Summary of the Research:
Provide the current summary of the research.

**Note:** This will not have to be provided again in future continuing reviews for this research

Upload the current IRB-approved protocol in the upload box provided. If you are revising the protocol because of personnel changes or participant numbers, include also the tracked and “clean” versions.

Click [Save & Continue] to proceed.

Research Progress:
Provide the current research progress as described in each box.

**Note:** If your study is considered multi-site, you should expect to see a question on this page requesting the progress across all sites. If you do not, contact ORRP so that your study can be corrected to be noted as multi-site.
A projected completion date must be provided unless the project is a repository or program protocol.

Click [Save & Continue] to proceed.

**Number of Participants:**

The IRB approved number of participants and participant populations are present in the top two boxes on the page. These boxes are not editable. This information was entered during the migration process. If errors were made during migration, contact ORRP to resolve.

| Approved Number of Participants
| Ohio State IRB approved number of participants (or records, specimens, etc.). This will be listed as groups (e.g., 50 teachers, 100 students) if that is how it was entered in the original application (this field is auto-calculated and not editable):
| 50 (Total numbers = 50)

| Approved Participant Population
| Approved age(s) of the individuals who may be included in the research:
| 18+
| Approved participant population(s):
| Adults

Provide the total number of participants who have been enrolled in the research to date. As you begin typing, you will see that another box will pre-fill this same number below your typed answer. The numbers can also be entered in “groups,” such as “20 students, 10 teachers.” Ensure that the total does not count individuals more than once.

| Participant Enrollment
| For research approved by an Ohio State IRB, provide the total number of participants (or records, specimens, etc) enrolled in the research to date. This can be listed as groups (e.g., 50 teachers, 100 students).*
| 20 students, 10 teachers
| You have entered 24 of 500 characters.
| Total number of participants enrolled in the research to date (this field is auto-calculated and not editable):
| 30

In the next field, provide the total number of participants who have enrolled since the last IRB review. As above, there is another box below this field which the system will pre-fill based on your answer.

| Participant Enrollment
| For research approved by an Ohio State IRB, provide the number of participants (or records, specimens, etc) enrolled in the research since the last IRB review (initial or continuing). This can be listed as groups (e.g., 50 teachers, 100 students).*
| 10 students, 5 teachers
| You have entered 23 of 500 characters.
| Number of participants enrolled since last IRB initial or continuing review (this field is auto-calculated and not editable):
| 15

Provide a rationale in the box provided if the number enrolled is significantly different than the IRB approved number.

If enrollment is still ongoing (based on your answer entered on the “research status” page), you will be asked if you wish to request an increase in the approved number of participants. This question will not be present if you indicated that recruitment was complete on the “research status” page.

| Number of Participants Increase Request
| Are you requesting an increase in the number of participants?*
| Yes | No
When entering a request to increase participants, provide the new total number of participants (not the number to be added). The system will populate the increase in the box below. Provide a rationale for the increase in the box provided. This is a required field.

![Increase Participants Form]

Click **Save & Continue** to proceed.

**Informed Consent Process:**

The list at the top of the page will indicate the informed consent processes that were selected at the time of migration. This list is not editable. If errors were made during migration, contact ORRP to resolve.

In the upload box, provide all consent process documents, such as consent forms, verbal scripts, debriefing scripts and assent forms/scripts. If revisions to these documents have occurred as a result of personnel or participant number changes, provide the current, tracked, and “clean” versions in the upload box.

Click **Save & Continue** to proceed.

**Recruitment Process:**

Indicate if recruitment materials were used to enroll participants, and if so, whether the materials are still being used. If still being used, provide copies of all recruitment materials in the upload boxes provided. If revisions to these documents have occurred as a result of personnel changes, provide the current, tracked and “clean” versions in the upload box.

![Recruitment Process Form]
The information on this page regarding the use of protected health information and how authorization requirements will be met is not editable. This information was provided during the migration process. If errors were made during migration, contact ORRP to resolve.

If written authorization will be used, provide the HIPAA authorization form in the upload box. If revisions to this document have occurred as a result of personnel changes, provide the current, tracked and “clean” versions in the upload box.

Indicate if an unanticipated problem involving risks to subjects or others occurred at Ohio State since the last IRB review (initial or continuing). Include any event reports previously submitted to the IRB during this time period that were determined to be unanticipated problems.

**Note:** An unanticipated problem is defined as an unforeseen event (given the nature of the research procedures and subject population) that suggests subjects, research staff or others are placed at greater risk by the research than previously expected. Unanticipated problems involving risks to subjects or others may be medical or non-medical in nature, and include – but are not limited to – serious, unexpected and related adverse drug events and unanticipated adverse device effects.

If unanticipated problems did occur, describe the events and provide any supporting documentation as necessary.
Indicate if any adverse events occurred since the last IRB review (initial or continuing) that were unexpected or occurred at a greater than expected frequency or severity than already described in the protocol and/or consent form(s).

If any such adverse events did occur, describe the events and provide any supporting documentation as necessary.

Provide an assessment of the overall risks and potential benefits based on study results since the last IRB review.

Click to proceed.

**Participant Complaints and Voluntary Withdrawals:**

Indicate if participants made complaints about the research or have voluntarily withdrawn from the research by answering the questions on this page. If yes, provide details regarding the circumstances in the blanks provided.

Click to proceed.
2015 Continuing Review Appendix - Research Involving Storage of Data and/or Specimens:

This appendix must be completed for all ongoing research in 2015. For more information regarding data and/or specimen banking and research use of banked materials, click here.

Indicate if the research involves collecting and storing data and/or specimens for future, as yet unspecified, research.

- If “Yes,” indicate if these procedures are described in another IRB approved research project and, if so, provide the requested information regarding the other IRB approved bank (whether internal or external to Ohio State). If the banking procedures are not described in another IRB research project, provide details regarding the data and/or specimen collection in the appropriate sections, including if collection is ongoing, if informed consent is obtained, whether data and/or specimens are released to other investigators and if the research includes a description of the analyses for collected data and/or specimens.

- If “No,” indicate if the research involves use of data and/or specimens obtained from another bank, repository, registry or database and provide the requested information regarding the source of the data and/or specimens.

Click to proceed.

Data Collection Forms:

Since this is the first continuing review in the Buck-IRB system for a migrated study, all copies of documents still being used must be provided. Provide data collection forms, subject materials, such as information sheets and subject diaries, in the upload box. Do not include case reports forms for multi-site industry-initiated or cooperative group studies.

Click to proceed.

Surveys and Questionnaires:

Since this is the first continuing review in the Buck-IRB system for a migrated study, all copies of documents still being used must be provided. Provide surveys, questionnaires, interview questions, subject stimuli, etc., in the upload box.

Click to proceed.

Upload Files Review:

Review uploaded files on this page to ensure you have submitted all necessary documents. If you have additional files to upload that were not requested on previous pages, upload these documents on the next page. 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.

Click to proceed.

Other Files/Comments:

This page should be used to provide any files that were not captured previously in the form. In addition, a box is provided for any general 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 marked with a red * that were not completed will be listed. Click on the error to go directly to the page with the error.

After you correct 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**, you can go back to the study workspace by clicking **Save & Exit** and will see a **Submit Continuing Review** option on the top left of the left navigation bar.

- **If you are not the PI**, you will see an **Email PI** box on the find errors page to notify the PI that the submission is ready for action.