Office of Research

Buck-IRB Continuing Review User Guide

THE OHIO STATE UNIVERSITY

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

Institutional Review Board

For studies initiated in Buck-IRB, information previously provided will be displayed on some pages and, in most cases, cannot be revised.

For migrated studies, information provided (both in migration and in previous amendments) will be displayed on some pages and, in most cases, cannot be revised. If you discover errors in the migrated data, contact ORRP to correct the record.

Currently approved documents for the study will be visible at points throughout the form. In the continuing review form pages, refer to instructions for guidance on uploading specific documents.

The continuing review application cannot be submitted unless Human Subjects Protection (HSP) training, Responsible Conduct of Research (RCR) training and Conflict of Interest (COI) are current for all study team members (with the exception of those team members being removed from the research).

To Begin Your 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.

Scope of changes at the Time of Continuing Review:

The only changes that can occur during the continuing review are Ohio State personnel changes (PI, co-investigators and key 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 to proceed.

Research Status:

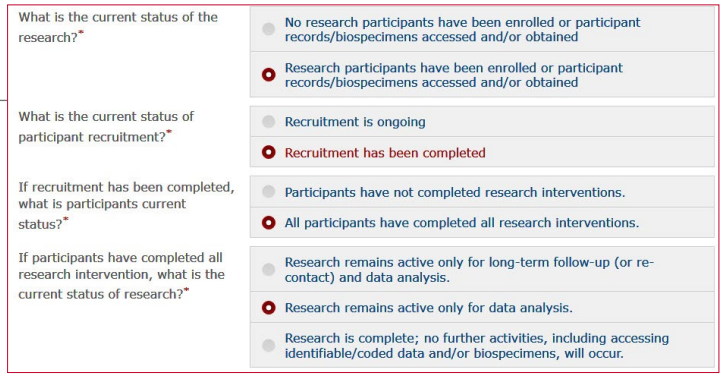
Select the appropriate box to indicate if participants have been enrolled (or records/biospecimens accessed, if applicable).

- **If no participants have been enrolled,** provide an explanation.

> **Note:** This is a required field.

- **If participants have been enrolled,** more questions will appear.

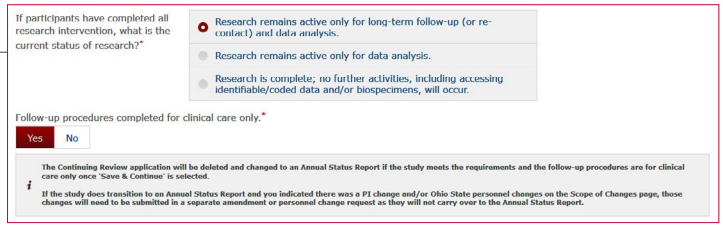
- **If participants have been enrolled, and recruitment has been completed**, make selections based on research activities remaining.



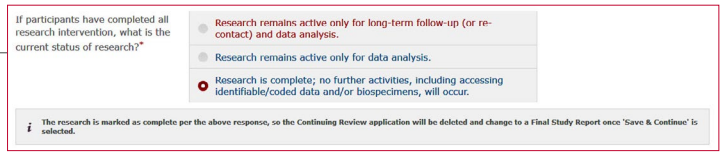
- **Federally-funded studies (not FDA-regulated) with an initial IRB approval date of January 21, 2019 or later may qualify for an annual status report rather than a continuing review.**

  These qualifying studies may transition if:
  - The option “Research remains active only for long-term following (or re-contact) and data analysis” is selected, and the follow-up procedures are completed for clinical care ONLY.
  - Or the option “Research remains active only for data analysis” is selected.

  Studies that do not qualify for transition will remain in the continuing review application.



- **The application will be transitioned to a final study report for studies that select the option** “Research is complete; no further activities, including accessing identifiable/coded data and/or biospecimens, will occur.”

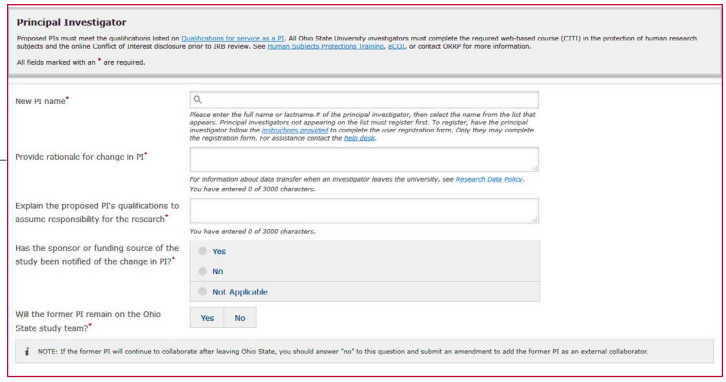


> **Note:** Do NOT select the option “Research is complete; no further activities, including accessing identifiable/coded data and/or biospecimens, will occur.” if any remaining data/biospecimens to be analyzed are still identifiable/coded, or other human subjects research activities need to be conducted.

Click Save & Continue to proceed.

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

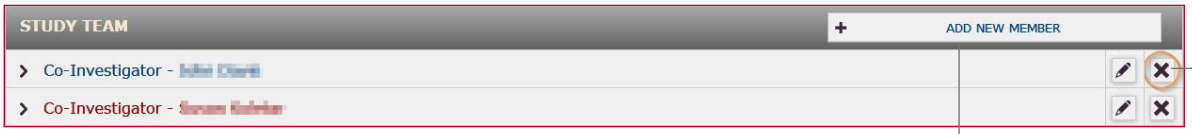
Enter the new PI name in the person look-up and provide the requested information about the change in PI. If the former PI has left the university or is otherwise unavailable, contact ORRP so that the former PI’s department chair can be sent a notification to sign-off on the submission in place of the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



Click Save & Continue to proceed.

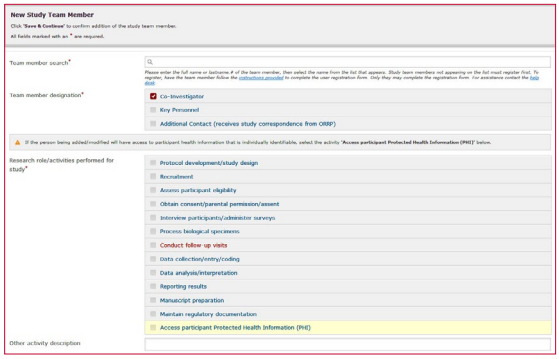
Study Personnel:

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



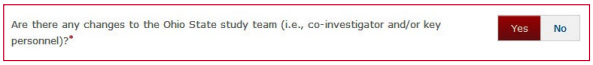
- **To add someone,** click 

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.



Click Save & Continue › to proceed.

If you can only view the study team on this page and can not make changes, then you previously selected "No" to the question about study team changes. To edit this page, go back to the "scope of changes" page and select "Yes" to indicate that you will be requesting personnel changes and resave the page.



Click Continue › to proceed.

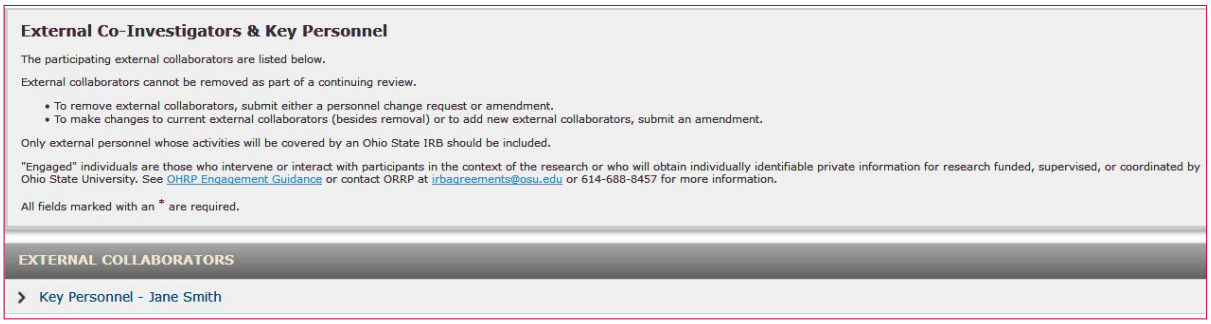
- **To remove a study team member,** click the "X" next to the person's name.

Click Continue › to proceed.

External Co-Investigators & Key Personnel:

This page will display any study team members who are external to Ohio State.

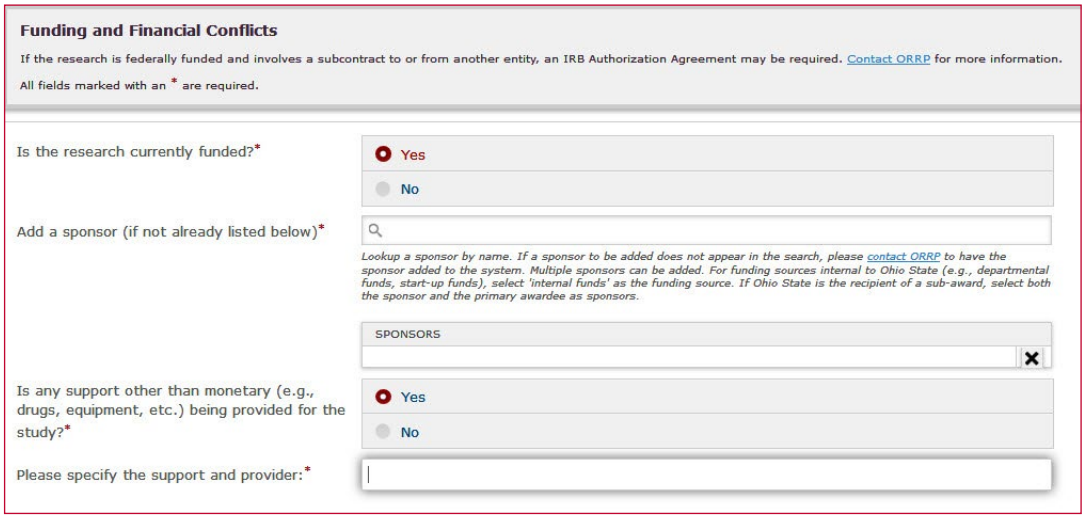
- No changes can be made to external personnel as part of a continuing review.
- A personnel change request can be submitted to remove external collaborators. An amendment is necessary in order to add or revise the role/activities of external collaborators.



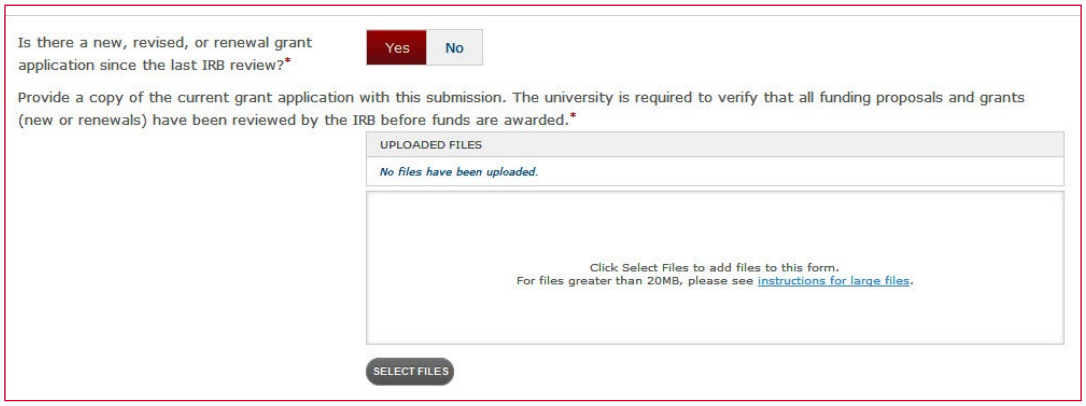
Click Continue › to proceed.

Funding and Financial Conflicts:

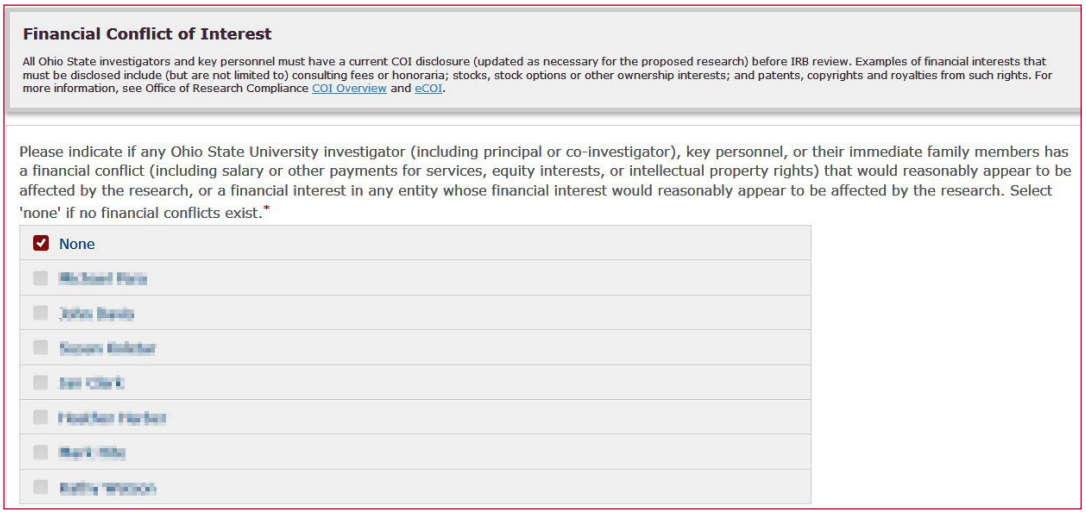
Indicate “Yes” or “No” if the research is currently funded. Answer “Yes” or “No” if other, non-monetary support is provided. If the correct sponsor is already listed, no action is required. If you do not see the appropriate sponsor in the look-up, contact ORRP to request assistance. For any funding sources 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 

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:

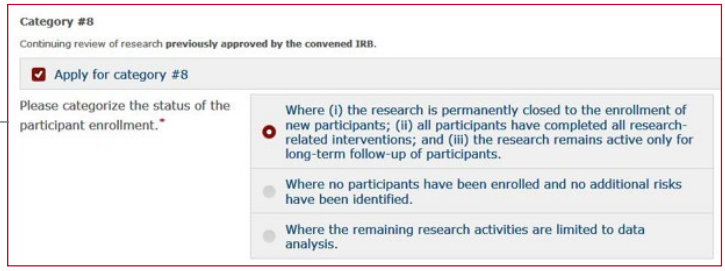
- **For studies initially approved by expedited review under categories 1-7...**
  - Click "Yes" to the question about expedited review.

    Note: "Yes" should be preselected for studies approved by expedited review.

  - Click Save & Continue > to proceed to the "expedited categories" page. Select the appropriate category(ies) for the study. The previously approved categories will be pre-selected. 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.

- **For studies reviewed by the full (convened) 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 Save & Continue > to proceed to the "expedited categories" page. Select "Apply for category #8" and the first option.



  - **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).

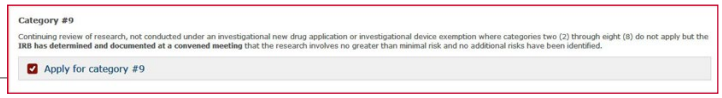
    Click Save & Continue > to proceed to the "expedited categories" page. Select "Apply for category #8" and the second option.

  - **If the research remains open for data analysis only**, click "Yes" for expedited review.

    Click Save & Continue > to proceed to the "expedited categories" page. Select "Apply for category #8" and the third option.

- **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 Save & Continue to proceed to the "expedited categories" page. If none of the options for category 8 apply, select "Apply for category #9" from the list.

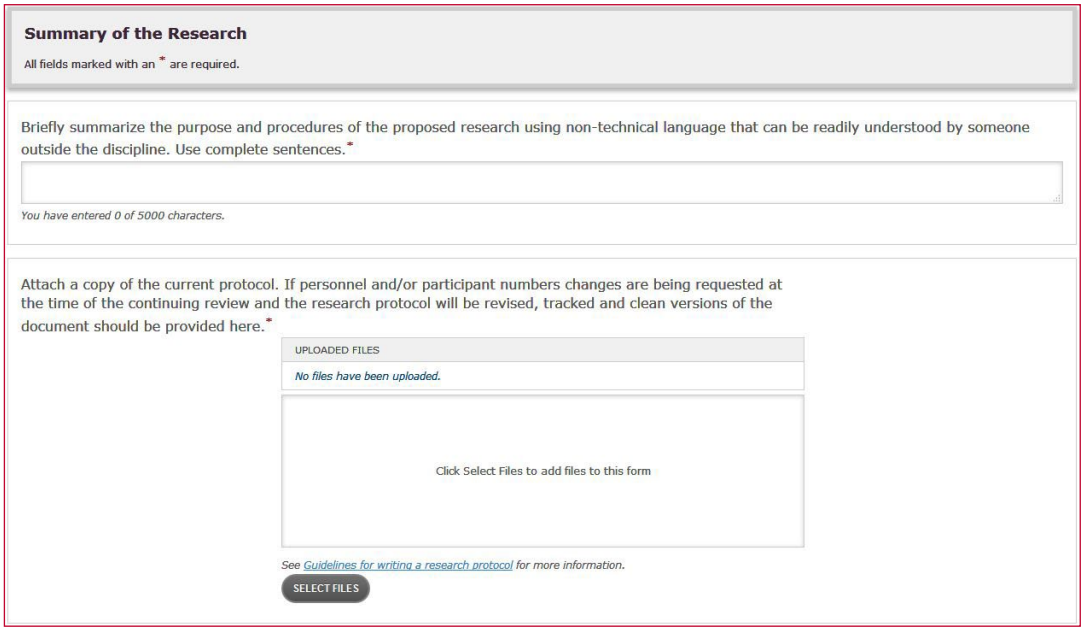


Click Save & Continue to proceed.

Summary of the Research:

The summary is not editable.

- **If you are revising the protocol because of personnel changes or participant numbers**, upload the tracked and "clean" versions of the research protocol.



Click Save & Continue to proceed.

Research Progress:

- Provide the current research progress as described in each box. Check "Not Applicable" if necessary.

> **Note:** If your study is considered multi-site, expect to see a question on this page requesting the progress across all sites. If you do not see a question, contact ORRP so your study can be corrected as multi-site.

- Approved amendments since last review: This section will pre-populate with descriptions and approval dates for any amendments (not counting the separate personnel change requests) that have been approved since the last review. This is not editable.

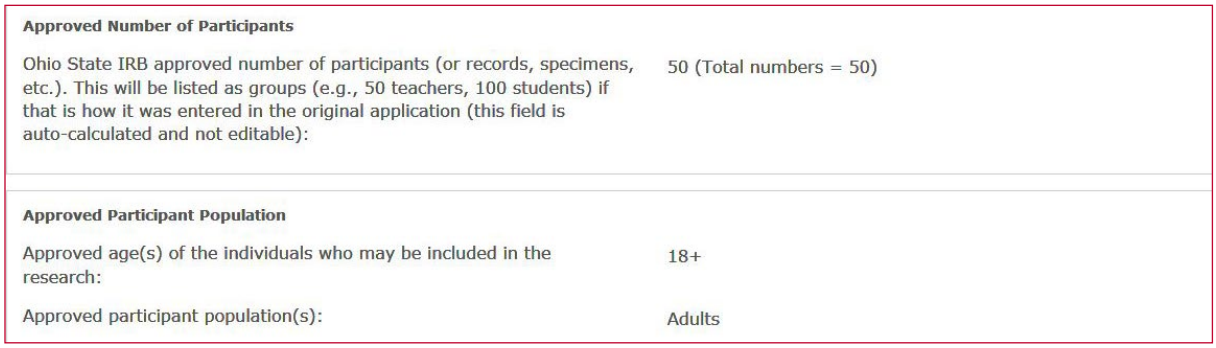
- "Were any changes made to the research that were not previously reported and approved by the IRB" question: If this is answered "Yes", instructions are provided to submit an event report.

- A projected completion date must be provided unless the project is a repository or program protocol.

Click Save & Continue to proceed.

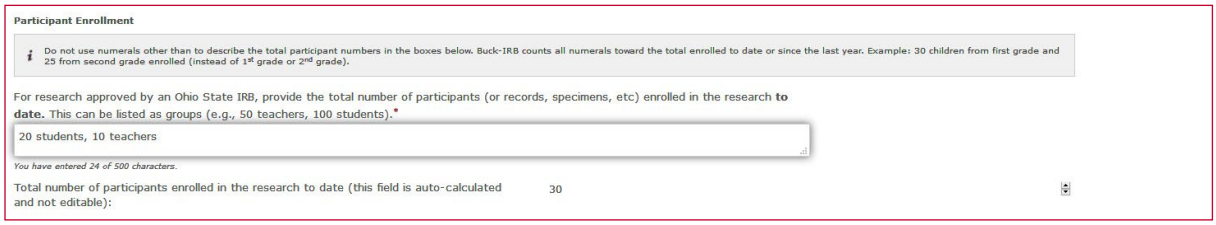
Number of Participants:

The IRB approved number of participants and participant populations are present in the top two boxes on the page. These boxes are not editable.



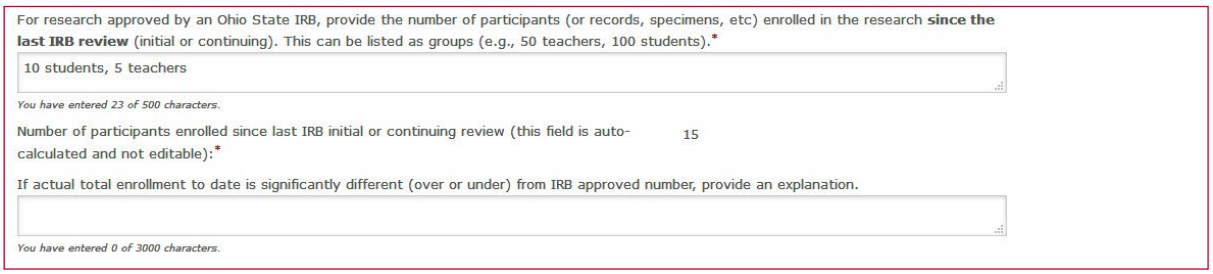
Provide the total number of participants who **have been enrolled in the research to date**. As you begin typing, you will see that another box will pre-fill this same number below your typed answer. The numbers can also be entered in "groups," such as "20 students, 10 teachers." Ensure that the total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

> **Note:** Do not use numbers in the response other than the number of participants, as the system auto-summation will not correctly add if doing so (e.g., instead of "20 10th grade students" state "20 tenth grade students" or "20 students").



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

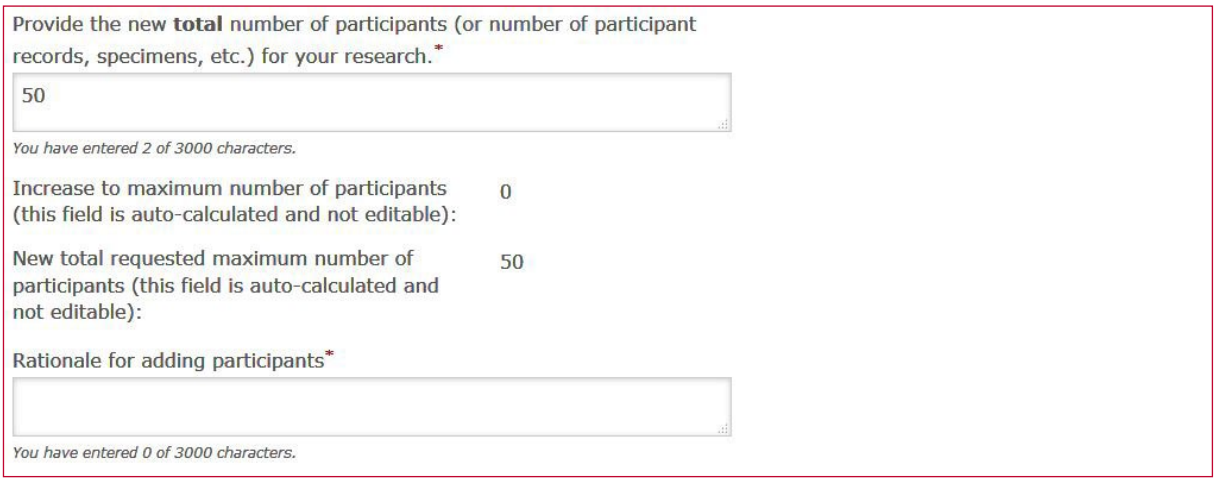
> **Note:** Do not use numbers in the response other than the number of participants, as the system auto-summation will not correctly add if doing so.



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.

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.



Click Save & Continue to proceed.

Informed Consent Process:

- The list at the top of the page will indicate currently approved informed consent processes. This list is not editable. Contact ORRP to resolve any errors.

- The upload box will display all currently approved 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 tracked and “clean” versions in the upload box.

Click Save & Continue to proceed.

HIPAA Research Authorization:

The information on this page regarding the use of protected health information and how authorization requirements will be met is not editable. Contact ORRP to resolve any errors.

Click Save & Continue to proceed.

HIPAA Written Authorization Forms:

- The upload box will display all currently approved authorization documents. If revisions to this document have occurred as a result of personnel changes, provide the current, tracked, and “clean” versions in the upload box.

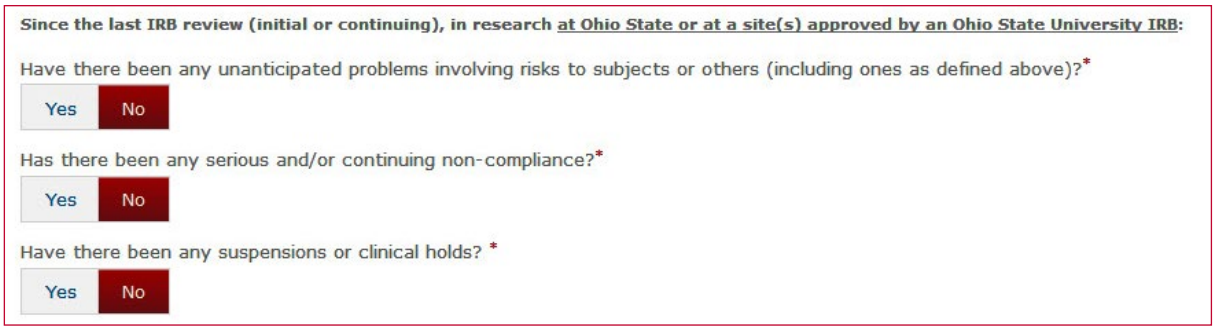
- If using a combined consent & HIPAA authorization form, there is an option on this page to select the combined version (rather than uploading the same form twice).

Click Save & Continue to proceed.

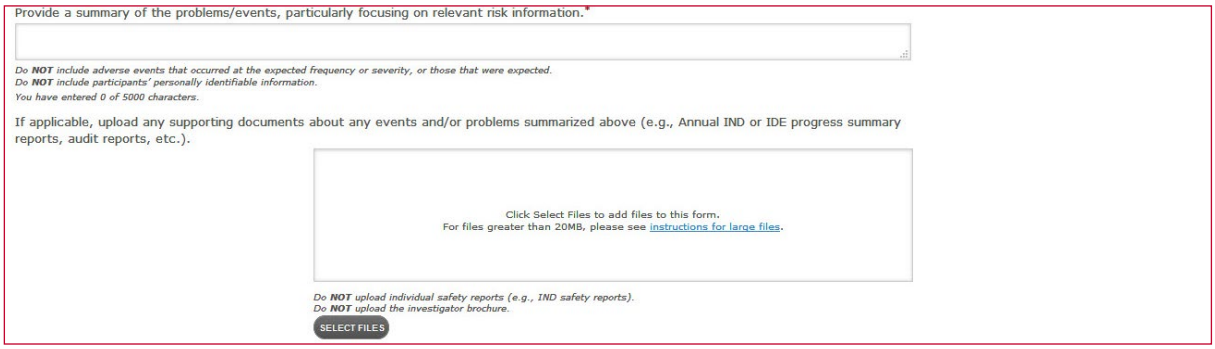
Risk Assessment:

The first three questions deal with unanticipated problems involving risks to subjects or others, serious and/or continuing non-compliance, suspensions and clinical holds.

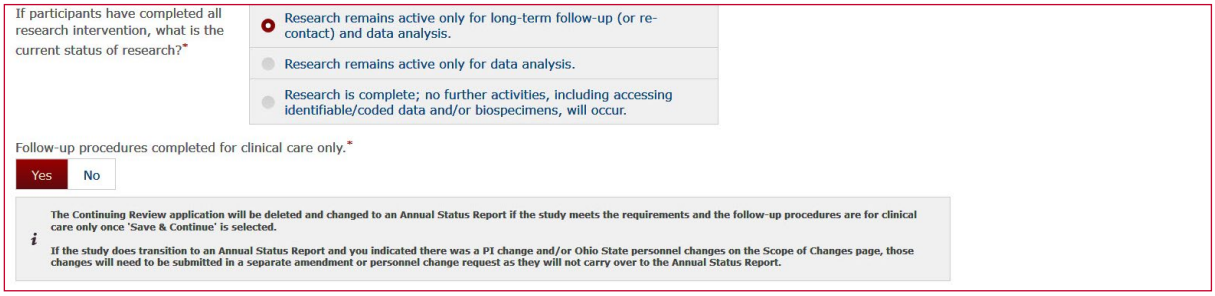
Note: The instructions portion of this page in Buck-IRB provides guidance about clinical holds and unanticpated problems involving risks to subjects or others.



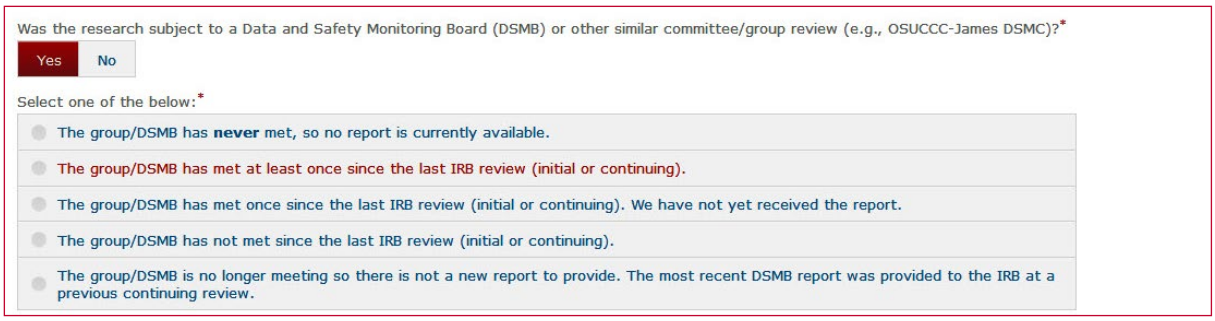
If unanticipated problems, serious and/or continuing non-compliance, suspensions or clinical holds did occur, provide a summary and upload any supporting documentation as necessary.



Indicate if there have been any **unreported** unanticipated problems, serious and/or continuing non-compliance, suspensions or clinical holds. If this is answered "Yes", then instructions to submit an event report will appear.



Indicate if the research was subject to data and safety monitoring board (DSMB) review, and if so, select the appropriate options from the selections that appear. Provide the current report from that review (if available). If there are multiple DSMB reports since the last review, provide a copy of each report.



Indicate if there has been a change in the assessment of risks and benefits, and if so, provide an updated assessment of the overall risks and potential benefits based on study results since the last IRB review.

Click Save & Continue 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 Save & Continue to proceed.

Various Study Docments:

This page displays any currently approved study documents not previously displayed in the application (e.g., data collection forms, surveys, recruitment materials, subject information, etc.). If revisions to these documents have occurred as a result of personnel or participant number changes, provide the tracked and “clean” versions in the upload box.

Click Save & Continue to proceed.

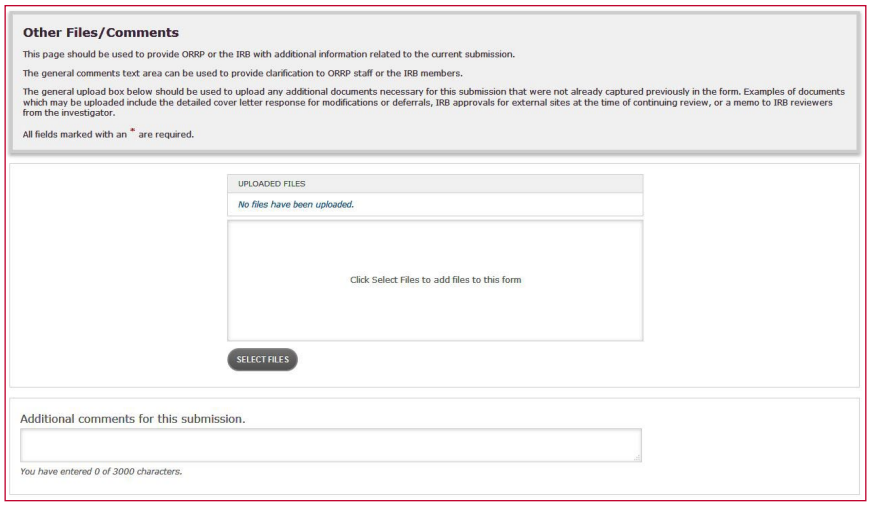
Upload Files Review:

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 Save & Continue 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

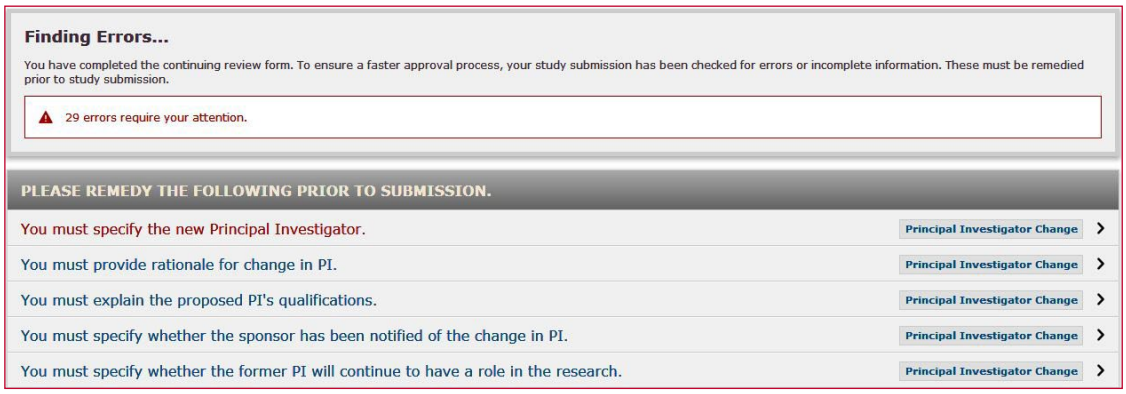


Click Save & Continue to proceed.

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.