


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.
- 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.

Note: This is a required field.

What is the current status of the research?*	<input checked="" type="radio"/> No research participants have been enrolled or participant records/biospecimens accessed and/or obtained
	<input type="radio"/> Research participants have been enrolled or participant records/biospecimens accessed and/or obtained
Explain:*	<input type="text"/>
You have entered 0 of 3000 characters.	

What is the current status of the research?*	<input type="radio"/> No research participants have been enrolled or participant records/biospecimens accessed and/or obtained
	<input checked="" type="radio"/> Research participants have been enrolled or participant records/biospecimens accessed and/or obtained
What is the current status of participant recruitment?*	<input type="radio"/> Recruitment is ongoing
	<input checked="" type="radio"/> Recruitment has been completed
If recruitment has been completed, what is participants current status?*	<input type="radio"/> Participants have not completed research interventions.
	<input checked="" type="radio"/> All participants have completed all research interventions.
If participants have completed all research intervention, what is the current status of research?*	<input type="radio"/> Research remains active only for long-term follow-up (or re-contact) and data analysis.
	<input checked="" type="radio"/> Research remains active only for data analysis.
	<input type="radio"/> Research is complete; no further activities, including accessing identifiable/coded data and/or biospecimens, will occur.

- 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.

If participants have completed all research intervention, what is the current status of research?*

☒ Research remains active only for long-term follow-up (or re-contact) and data analysis.

☐ Research remains active only for data analysis.

☐ Research is complete; no further activities, including accessing identifiable/coded data and/or biospecimens, will occur.

Follow-up procedures completed for clinical care only.*

☒ Yes ☐ No

The Continuing Review application will be deleted and changed to an Annual Status Report if the study meets the requirements and the follow-up procedures are for clinical care only once 'Save & Continue' is selected.

If the study does transition to an Annual Status Report and you indicated there was a PI change and/or Ohio State personnel changes on the Scope of Changes page, those changes will need to be submitted in a separate amendment or personnel change request as they will not carry over to the Annual Status Report.

- 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.”

If participants have completed all research intervention, what is the current status of research?*

☐ Research remains active only for long-term follow-up (or re-contact) and data analysis.

☐ Research remains active only for data analysis.

☒ Research is complete; no further activities, including accessing identifiable/coded data and/or biospecimens, will occur.

The research is marked as complete per the above response, so the Continuing Review application will be deleted and change to a Final Study Report once 'Save & Continue' is selected.

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.

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](#), [eCUI](#), or contact UOHR for more information. All fields marked with an * are required.

New PI name*

Please enter the full name or lastname. If 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

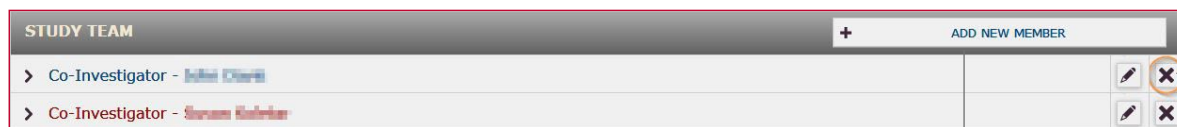
Will the former PI remain on the Ohio State study team?*

☐ Yes ☐ No

NOTE: If the former PI will continue to collaborate after leaving Ohio State, you should answer "no" to this question and submit an amendment to add the former PI as an external collaborator.

Study Personnel:

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



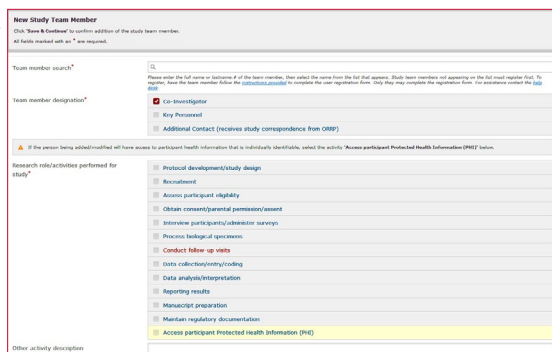
STUDY TEAM

+ ADD NEW MEMBER

> Co-Investigator - John Clark

> Co-Investigator - Susan Kessler

- 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.



New Study Team Member

Click "Save & Continue" to confirm addition of the study team member. All fields marked with an * are required.

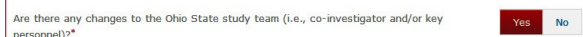
Team member search*

Team member designation*

Research role/activity performed for study*

Other activity description

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.



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

Yes No

Click **Continue** > to proceed.

Click **Save & Continue** > to proceed.

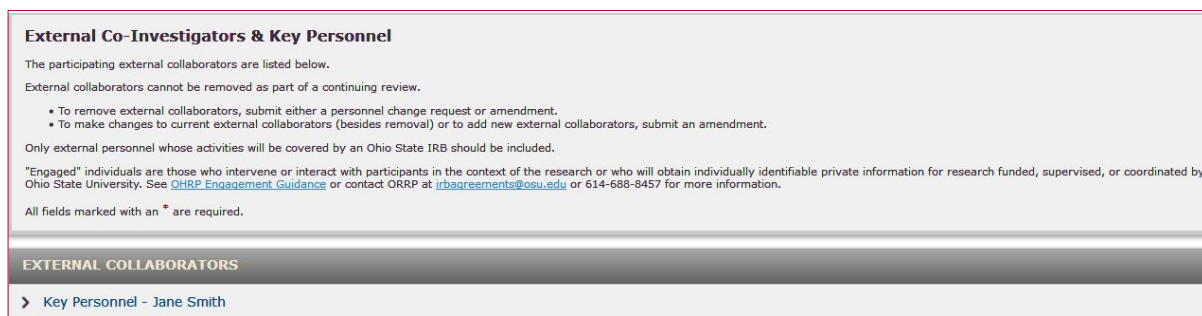
- To remove a study team member, click the "X" next to the person's name.

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.



External Co-Investigators & Key Personnel

The participating external collaborators are listed below.

External collaborators cannot be removed as part of a continuing review.

- To remove external collaborators, submit either a personnel change request or amendment.
- To make changes to current external collaborators (besides removal) or to add new external collaborators, submit an amendment.

Only external personnel whose activities will be covered by an Ohio State IRB should be included.

"Engaged" individuals are those who intervene or interact with participants in the context of the research or who will obtain individually identifiable private information for research funded, supervised, or coordinated by Ohio State University. See [QHRP Engagement Guidance](#) or contact ORRP at irbagreements@osu.edu or 614-688-8457 for more information.

All fields marked with an * are required.

EXTERNAL COLLABORATORS

> Key Personnel - Jane Smith

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.

Funding and Financial Conflicts

If the research is federally funded and involves a subcontract to or from another entity, an IRB Authorization Agreement may be required. [Contact ORRP](#) for more information.

All fields marked with an * are required.

Is the research currently funded?*

☒ Yes
☐ No

Add a sponsor (if not already listed below)*

Lookup a sponsor by name. If a sponsor to be added does not appear in the search, please [contact ORRP](#) to have the sponsor added to the system. Multiple sponsors can be added. For funding sources internal to Ohio State (e.g., departmental funds, start-up funds), select 'internal funds' as the funding source. If Ohio State is the recipient of a sub-award, select both the sponsor and the primary awardee as sponsors.

SPONSORS

X

Is any support other than monetary (e.g., drugs, equipment, etc.) being provided for the study?*

☒ Yes
☐ No

Please specify the support and provider:*

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.

Is there a new, revised, or renewal grant application since the last IRB review?*

☒ Yes ☐ No

Provide a copy of the current grant application with this submission. The university is required to verify that all funding proposals and grants (new or renewals) have been reviewed by the IRB before funds are awarded.*

UPLOADED FILES

No files have been uploaded.

Click Select Files to add files to this form.
For files greater than 20MB, please see [instructions for large files](#).

SELECT FILES

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

Financial Conflict of Interest

All Ohio State investigators and key personnel must have a current COI disclosure (updated as necessary for the proposed research) before IRB review. Examples of financial interests that must be disclosed include (but are not limited to) consulting fees or honoraria; stocks, stock options or other ownership interests; and patents, copyrights and royalties from such rights. For more information, see Office of Research Compliance [COI Overview](#) and [eCOI](#).

Please indicate if any Ohio State University investigator (including principal or co-investigator), key personnel, or their immediate family members has a financial conflict (including salary or other payments for services, equity interests, or intellectual property rights) that would reasonably appear to be affected by the research, or a financial interest in any entity whose financial interest would reasonably appear to be affected by the research. Select 'none' if no financial conflicts exist.*

☒ None

☐ Michael Piro
☐ John Bardo
☐ Steven Rindler
☐ Ben Clark
☐ Houston Harlan
☐ Mark Miller
☐ Kelly Wilson

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:

- 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.

Are you requesting **Expedited Review**?*

☒ Yes ☐ No

- 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.

Category #8
Continuing review of research previously approved by the convened IRB.

☒ Apply for category #8

Please categorize the status of the participant enrollment.*

<input checked="" type="radio"/> Where (i) the research is permanently closed to the enrollment of new participants; (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of participants.
<input type="radio"/> Where no participants have been enrolled and no additional risks have been identified.
<input type="radio"/> Where the remaining research activities are limited to data analysis.

- 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.

Category #8
Continuing review of research previously approved by the convened IRB.

☒ Apply for category #8

Please categorize the status of the participant enrollment.*

<input type="radio"/> Where (i) the research is permanently closed to the enrollment of new participants; (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of participants.
<input checked="" type="radio"/> Where no participants have been enrolled and no additional risks have been identified.
<input type="radio"/> Where the remaining research activities are limited to data analysis.

- 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.

Category #8
Continuing review of research previously approved by the convened IRB.

☒ Apply for category #8

Please categorize the status of the participant enrollment.*

<input type="radio"/> Where (i) the research is permanently closed to the enrollment of new participants; (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of participants.
<input type="radio"/> Where no participants have been enrolled and no additional risks have been identified.
<input checked="" type="radio"/> Where the remaining research activities are limited to data analysis.

- 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.

Category #9
Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.
☒ Apply for category #9

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.

Summary of the Research
All fields marked with an * are required.

Briefly summarize the purpose and procedures of the proposed research using non-technical language that can be readily understood by someone outside the discipline. Use complete sentences.*

You have entered 0 of 5000 characters.

Attach a copy of the current protocol. If personnel and/or participant numbers changes are being requested at the time of the continuing review and the research protocol will be revised, tracked and clean versions of the document should be provided here.*

UPLOADED FILES
No files have been uploaded.

Click Select Files to add files to this form

See [Guidelines for writing a research protocol](#) for more information.

SELECT FILES

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.

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.

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”).

Participant Enrollment	
<small>Do not use numerals other than to describe the total participant numbers in the boxes below. Buck-IRB counts all numerals toward the total enrolled to date or since the last year. Example: 30 children from first grade and 25 from second grade enrolled (instead of 1st grade or 2nd grade).</small>	
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).*	
<input type="text" value="20 students, 10 teachers"/>	
<small>You have entered 24 of 500 characters.</small>	
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 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.

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).*	
<input type="text" value="10 students, 5 teachers"/>	
<small>You have entered 23 of 500 characters.</small>	
Number of participants enrolled since last IRB initial or continuing review (this field is auto-calculated and not editable):*	15
If actual total enrollment to date is significantly different (over or under) from IRB approved number, provide an explanation.	
<input type="text"/>	
<small>You have entered 0 of 3000 characters.</small>	

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?*	<input type="button" value="Yes"/> <input type="button" value="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.

Provide the new **total** number of participants (or number of participant records, specimens, etc.) for your research.*

50

You have entered 2 of 3000 characters.

Increase to maximum number of participants (this field is auto-calculated and not editable):	0
New total requested maximum number of participants (this field is auto-calculated and not editable):	50

Rationale for adding participants*

You have entered 0 of 3000 characters.

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 unanticipated problems involving risks to subjects or others.

Since the last IRB review (initial or continuing), in research at Ohio State or at a site(s) approved by an Ohio State University IRB:

Have there been any unanticipated problems involving risks to subjects or others (including ones as defined above)?*

Yes No

Has there been any serious and/or continuing non-compliance?*

Yes No

Have there been any suspensions or clinical holds? *

Yes No

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.

Provide a summary of the problems/events, particularly focusing on relevant risk information.*

Do NOT include adverse events that occurred at the expected frequency or severity, or those that were expected.
Do NOT include participants' personally identifiable information.
You have entered 0 of 5000 characters.

If applicable, upload any supporting documents about any events and/or problems summarized above (e.g., Annual IND or IDE progress summary reports, audit reports, etc.).

Click Select Files to add files to this form.
For files greater than 20MB, please see [instructions for large files](#).

Do NOT upload individual safety reports (e.g., IND safety reports).
Do NOT upload the investigator brochure.

SELECT FILES

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.

If participants have completed all research intervention, what is the current status of research?*

- ☒ Research remains active only for long-term follow-up (or re-contact) and data analysis.
- ☐ Research remains active only for data analysis.
- ☐ Research is complete; no further activities, including accessing identifiable/coded data and/or biospecimens, will occur.

Follow-up procedures completed for clinical care only.*

Yes No

The Continuing Review application will be deleted and changed to an Annual Status Report if the study meets the requirements and the follow-up procedures are for clinical care only once 'Save & Continue' is selected.
If the study does transition to an Annual Status Report and you indicated there was a PI change and/or Ohio State personnel changes on the Scope of Changes page, those changes will need to be submitted in a separate amendment or personnel change request as they will not carry over to the Annual Status Report.

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.

Was the research subject to a Data and Safety Monitoring Board (DSMB) or other similar committee/group review (e.g., OSUCCC-James DSMC)?*

Yes No

Select one of the below:*

- ☐ The group/DSMB has **never** met, so no report is currently available.
- ☐ The group/DSMB has met at least once since the last IRB review (initial or continuing).
- ☐ The group/DSMB has met once since the last IRB review (initial or continuing). We have not yet received the report.
- ☐ The group/DSMB has not met since the last IRB review (initial or continuing).
- ☐ The group/DSMB is no longer meeting so there is not a new report to provide. The most recent DSMB report was provided to the IRB at a previous continuing review.

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.

Assessment of Risks and Benefits
Since the last IRB review (initial or continuing):
<input type="radio"/> There have been no changes in the assessment of risks and benefits. (If there have been any amendments that involved changes in risks and/or benefits, or any events involving risk, do NOT select this.)
<input type="radio"/> There have been changes in the assessment of risks and benefits.

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 Documents:

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

Other Files/Comments
<p>This page should be used to provide ORRP or the IRB with additional information related to the current submission.</p> <p>The general comments text area can be used to provide clarification to ORRP staff or the IRB members.</p> <p>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.</p> <p>All fields marked with an * are required.</p>
<div><div>UPLOADED FILES</div><div>No files have been uploaded.</div><div>Click Select Files to add files to this form</div><div>SELECT FILES</div></div>
<div><div>Additional comments for this submission.</div><div>You have entered 0 of 3000 characters.</div></div>

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.

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, 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.