Thinking Ahead: A Reference Guide to Planning Your Buck-IRB Amendment

Below is a list of common types of Buck-IRB amendments with a list of sections in the Buck-IRB application and study documents that may require corresponding revision.

There are many types of changes that can be made to approved research studies, so this is not an exhaustive list. It is, however, a useful guide to thinking about the kinds of changes that you may need to make to the Buck-IRB application and other study documents when submitting amendments.

For more help in planning your amendment, you may consult this printable Buck-IRB application for amendments that includes all the form questions and conditional logic: http://orrp.osu.edu/files/2019/03/IRB-Amendment-Submission.pdf.

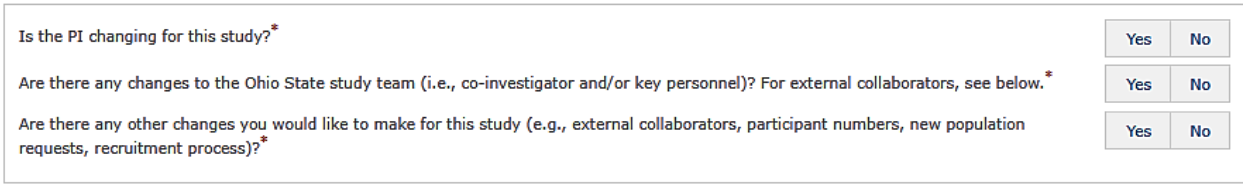
For further information, contact the Office of Responsible Research Practices (https://orrp.osu.edu/contact/).

Table of Contents

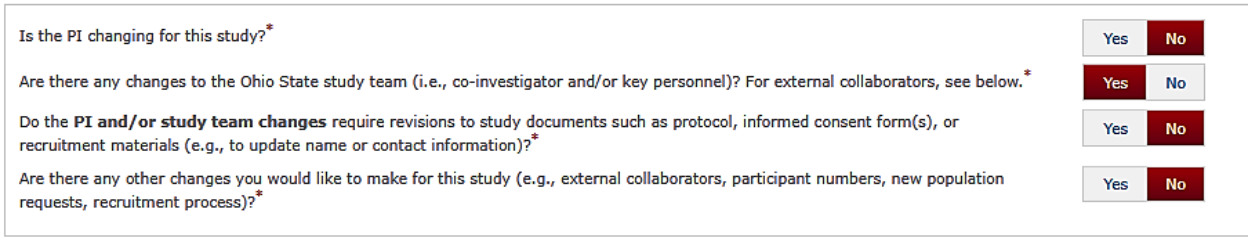
(Click on any item to jump to that section)

Reference 1 (Personnel Changes)

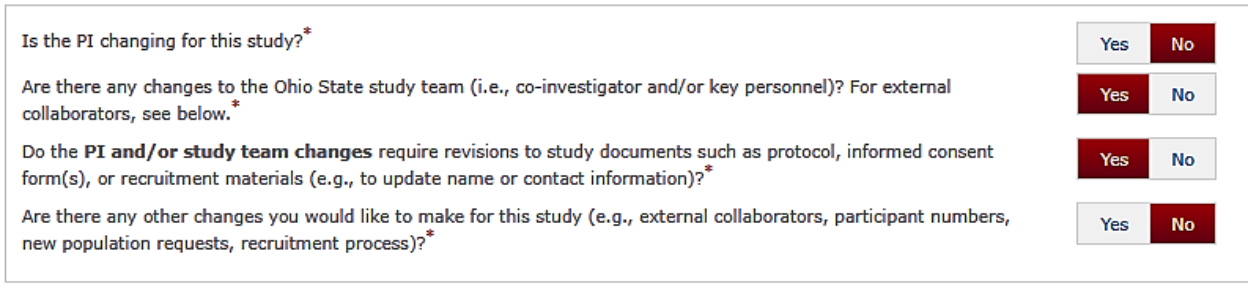
When starting an amendment, Buck-IRB will first prompt you to identify what kind of amendment you are requesting:



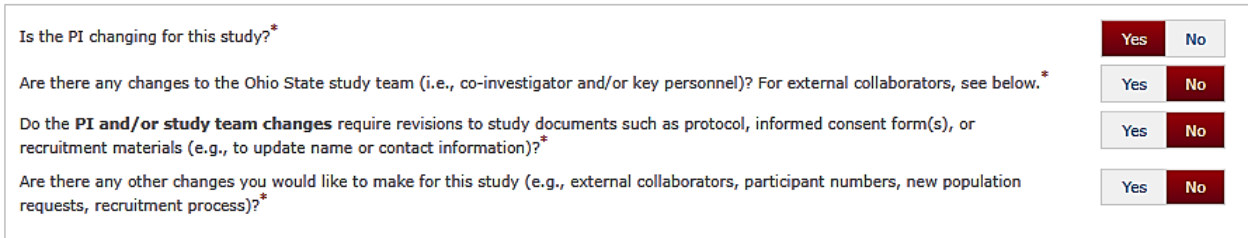
If you are only making a personnel change and that change does not require revisions to documents, indicate that as such:



If the personnel change does require document revisions, indicate that as such:



If you are making a change in Principal Investigator, indicate that as such:



See below for more detail on how to make PI and other personnel changes in Buck-IRB.

IF YOU ARE CHANGING: *YOU MAY NEED TO REVISE:*

PERSONNEL CHANGES

- Adding or removing **Additional Contacts**

Note: An additional contact only receives study correspondence and should not be engaged in any research activities.

An amendment is not required to add or remove Additional Contacts. This can be done at any time in Buck-IRB:

PERSONNEL CHANGES

- Adding or removing current Ohio State students or staff members <u>when document changes are not required</u>
- Removing external collaborators <u>when document changes are not required</u>

Submit a Personnel Change Request:

Personnel Change amendments are usually processed within a few days.

PERSONNEL CHANGES

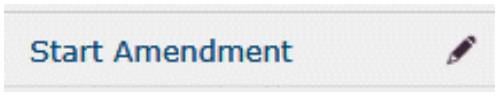
Any personnel changes that do not qualify for a Personnel Change Request, including:

- Changing the Principal Investigator
- Personnel changes that require document revision (e.g., updating the protocol)

  [NOTE: Whenever it is feasible, avoid putting personnel names on study documents, particularly names of key personnel, to avoid having to potentially revise the names on those documents].

- Adding external personnel (including OSU Physicians, Inc.)

Submit a standard amendment:



Buck-IRB application	• *Scope of changes at time of amendment* Indicate whether the PI and/or other study personnel are changing • *Proposed Changes* If external collaborators are changing, select "External Collaborators" and revise accordingly. • *Proposed Changes* Other sections of the application might require revision if they list personnel.
Documents (submit "clean" and "tracked" versions of any documents that are revised)	• Research protocol Protocols often include a cover page with a list of investigators that may need to be updated, or you may wish to remove the collaborators from the protocol document. • Consent form If changing PI and the study is still enrolling, then revise PI name and contact info. • HIPAA research authorization If changing PI and the study is still enrolling, then the PI name and contact info will need to be updated.

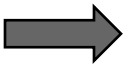
Reference 2 (Non-personnel Changes)

For non-personnel changes, Buck-IRB will prompt you to select which sections of the application require revision, as shown below:

Selected sections of the application will open up for edits.

The following pages provide guidance on which sections of the application and what study documents might require revision for selected types of amendments. It is best practice to review the entire application ahead of time to see which sections may require editing with the requested amendment. This could help circumvent an incomplete notice from ORRP.

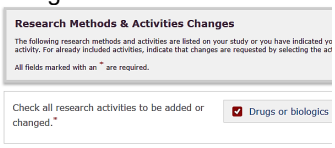
IF YOU ARE CHANGING:	*YOU MAY NEED TO REVISE:*	
FUNDING Adding or removing a funding source.	**Buck-IRB application**	• *Proposed Changes* Click on each section that will require revision. • *Supplemental Questions* Describe all funding changes and the rationale each change here. • *Funding and Financial Conflicts* When adding or removing funding, this section will require revision. Also upload a copy of all new funding documents. • *Financial Conflict of Interest* Note whether anyone on the study has a financial conflict of interest with a study sponsor.
	Documents (submit "clean" and "tracked" versions of any documents that are revised)	• Research protocol The study protocol may specify the sponsor(s). This may require revision. • Consent-HIPAA form The first page of the form lists a "Sponsor," which may need to be updated. Other sections of the form (e.g., Confidentiality, HIPAA Authorization) may also specify sponsors and require revisions.
RESEARCH LOCATIONS Adding or removing a research location (an Ohio State site, a domestic non-Ohio State site, or an international site).	**Buck-IRB application**	• *Proposed Changes* Click on each section that will require revision. (NOTE: Various section of the application might reference research locations, so review the full application ahead of time to determine which sections require revision). • *Supplemental Questions* Describe all additions or removals of research locations, as well as the rationale for the change(s), here. • *Location of Research* This section will need to be updated to add or remove any Ohio State locations, domestic non-Ohio State locations, or international research sites. (If a site is being added and Ohio State's IRB needs to review a copy of the new site's IRB approval, submit a copy of that approval). You may also be required to upload a Letter of Support for certain sites.
	Documents (submit "clean" and "tracked" versions of any documents that are revised)	Review all approved documents (e.g., protocol, recruitment materials, consent forms) to see if revisions are required to update research location.

IF YOU ARE CHANGING:	*YOU MAY NEED TO REVISE:*	
PARTICIPANT NUMBERS Increasing or decreasing the number of participants to be enrolled in the research		**Buck-IRB application** **Documents** (submit "clean" and "tracked" versions of any documents that are revised)	• *Proposed Changes* Click on each section that will require revision. This varies depending on the nature of the amendment. • *Supplemental Questions* Describe the change in participant numbers and the rationale for that change here. • *Summary, Background, and Objectives* Check to see if the description of the research includes participant numbers that need to be revised. • *Research Methods & Activities* Check to see if the description of the research activities includes participant numbers that need to be revised. • *Number of Participants* Make sure this section is updated with the new accrual goal and the number's derivation response is revised as needed. • *Participant Population* Check to see if the description of the participant populations includes participant numbers that need to be revised. • Research protocol Protocols often include a "Sample" or "Participants" section that specifies the number of participants to be enrolled. • Consent form Section 2 of the consent form usually specifies the number of participants to be enrolled.

IF YOU ARE CHANGING:	*YOU MAY NEED TO REVISE:*	
PARTICIPANT POPULATIONS Adding or removing cohorts; revising existing participant populations		**Buck-IRB application**
		• *Proposed Changes* Click on each section that will require revision. This varies depending on the nature of the amendment. • *Supplemental Questions* Describe the change in participant population and the rationale for that change. • *Summary, Background, and Objectives* Check to see if the description of the research includes participant information that may need to be revised. • *Research Methods & Activities* Check to see if the description of the research activities includes participant information that needs to be revised. • *Participant Population* Update the description of the populations. NOTE: To revise information on specific populations approved for the research, select that population on the "Participant Population Changes" page:  The supplemental questions in the application pertaining to that population will then appear for editing. • *Participant Identification, Recruitment and Selection* There are sections here where the responses might require revision with a change in study populations. • *Informed Consent Process* Be sure the response in this section are still all accurate and that a consent process is detailed for each study population.
		Documents (submit "clean" and "tracked" versions of any documents that are revised)
		• Research protocol Revise the description of the study populations, if needed. • Consent form Ensure that the consent form has been appropriately revised. If a new consent form is needed for a different population (e.g., adding healthy controls to a study) then make sure that is included). • Recruitment materials Review all recruitment materials (flyers, brochures, emails, etc.) and make any necessary changes to update the study population(s).

IF YOU ARE CHANGING:	*YOU MAY NEED TO REVISE:*	
RECRUITMENT Changing the recruitment methodology.	**Buck-IRB application**	• *Proposed Changes* Click on each section that will require revision. This varies depending on the nature of the amendment. • *Supplemental Questions* Describe the change in recruitment methodology and the rationale for that change here. • *Summary, Background, and Objectives* Check to see if there is any description of the recruitment process that requires revision. • *Research Methods & Activities* Check to see if there is any description of the recruitment process that requires revision. • *Participant Identification, Recruitment and Selection* Revise the description(s) of the eligibility criteria and the recruitment process as needed.
	Documents (submit "clean" and "tracked" versions of any documents that are revised)	• Research protocol Protocols often include a description of the recruitment strategy, which may require revision. • Recruitment materials (flyers, brochures, recruitment scripts, etc.) If there are study-specific recruitment materials, review them to see if any revisions are required.
INCENTIVES Changing the incentive plan or structure.	**Buck-IRB application**	• *Proposed Changes* Click on each section that will require revision. • *Supplemental Questions* Describe the change in the incentive(s) and the rationale for that change here. • *Children* If the study involves children, then the "Children" section of the application may require revision to the description of the incentives provided. • *Incentives to Participate* This section will likely need revision.
	Documents (submit "clean" and "tracked" versions of any documents that are revised)	• Research protocol Check to see if the incentive structure is described in the protocol. • Consent form Check the section headed "Will I be paid for taking part in this study?" to see if revisions are required.

IF YOU ARE CHANGING:	*YOU MAY NEED TO REVISE:*	
ADDING, REMOVING, or REVISING INSTRUMENTS Any revisions to study instruments (e.g., data collection forms, surveys, questionnaires); adding or removing instruments.	→	**Buck-IRB application**	• *Proposed Changes* Click on each section that will require revision. This varies depending on the nature of the amendment. • *Document Changes* Revise the following sections to add or remove documents, as needed: ▪ Data collection forms and/or other instruments ▪ Subject information (e.g., newsletters, instruction sheets, and appointment reminder cards) ▪ Surveys and/or questionnaires • *Supplemental Questions* Describe the change in instruments and the rationale for that change here. • *Summary, Background, and Objectives* Check to see if this section identifies the instruments used in the research and revise if needed. • *Research Methods & Activities* Check to see if this section identifies the instruments used in the research and revise if needed. • Duration If adding or removing study instruments changes the expected time commitment for participants, then revise this section accordingly.
		Documents (submit "clean" and "tracked" versions of any documents that are revised)	• Research protocol Review the protocol to see if any descriptions or lists of instruments used in the research require revision. • Consent form If the expected duration is changing, then section 2 ("How long will I be in the study?") should be revised. Also, if the consent includes a list or descriptions of the study instruments revision may be required.

IF YOU ARE CHANGING:	*YOU MAY NEED TO REVISE:*	
INVESTIGATOR'S BROCHURE (IB) UPDATES Providing updated Investigator's Brochures for study drugs for IRB review. NOTE: The IRB only needs to review an updated IB if the changes affect the risk information.	→	**Buck-IRB application** • *Proposed Changes* Click on each section that will require revision. • *Research Methods and Activities* In order to submit a new IB: 1. Select "Research Methods and Activities." 2. On the "Research Methods & Activities Changes" page select "Drugs."  3. Edit the specific drug page to add the IB, and if needed update the side effects. • *Risks, Harms, and Discomforts* If the risk information requires revision, then update this section. • *Assessment of Risks and Benefits* If the risk/benefit information requires revision, then update this section. • *Monitoring* If the risk or safety information is increasing the risk level or changing the monitoring activities, then this section may require revision.
		Documents (submit "clean" and "tracked" versions of any documents that are revised) • Research protocol If the risk information for a drug(s) requires updating, then revise the protocol accordingly. • Consent form If the risk information for a drug(s) requires updating, then revise the consent form accordingly
PROTOCOL LETTERS OF AMENDMENT Providing letters from the sponsor(s) indicating changes to the protocol and study materials without providing a revised protocol document.	→	**Buck-IRB application** • *Proposed Changes* Click on each section that will require revision. A letter of amendment can pertain to any number of changes within the Buck-IRB application, so review the full application and make any necessary changes.
		Documents (submit "clean" and "tracked" versions of any documents that are revised) • Research protocol Upload a copy of the Letter of Amendment. NOTE: The letter will be saved as an approved document in Buck-IRB along with the protocol until a new version of the protocol is submitted for review and approval. • Consent form Make any necessary changes to the consent form. • Instruments/data collection forms/subject information materials

IF YOU ARE CHANGING:	*YOU MAY NEED TO REVISE:*
	Make any necessary changes to study instruments, data collection forms, or subject information materials. • Recruitment materials Make any necessary changes to the recruitment materials.