Tips - Submitting Amendments in Buck-IRB

Additional guidelines regarding amendment submissions can be found on the ORRP website here.

Personnel Change Request:

- When adding personnel, select activities that each individual will actually perform and is authorized to complete based on study approvals (e.g. written authorization, partial waiver, full waiver). Note: Do not select activities for a study team member when those activities are not included in the research. For example, "process samples" should not be selected when no sample collection is included in the research.
- Personnel change requests are reserved for adding current Ohio State students, staff, and faculty when document updates are not required and removing all personnel.
- Personnel change requests cannot be used to make principal investigator changes or changes in external collaborators.

Standard amendment:

- **General Tips:**
  - Answer all Buck-IRB application questions to reflect the entire study and not just the amendment; the application should be updated as the study evolves.
  - Answer all application questions thoroughly and thoughtfully, provide adequate details to answer application questions, but avoid providing unnecessary information and copying and pasting from study documents.
  - Reference the study application to identify all sections that may require revision with the amendment. A copy of the most recently modified study application can be viewed or downloaded from the "Print/View Study" page of the Buck-IRB application. For example, when the study population is changing, the obvious section to revise would be "Participant Population," however, the study population may have also been referenced in additional application sections such as "Summary, Background, and Objectives," "Number of Participants," etc.
  - When making revisions to the application, consider whether any documents also need to be updated. For instance, when updating the "Number of Participants" page, other study documents (e.g., research protocol, consent form) may need to be updated for consistency with that change.

- **Supplemental questions page:**
  - Describe in summary form the changes/updates requested via the amendment and the documents that will be revised as a result of the change/update. (E.g. the protocol will be revised to provide eligibility clarifications; the protocol, consent form and recruitment flyers will be revised to list updated incentive).
  - Be sure to provide a description and rationale for the proposed change. This section must be completed, even in cases when the study sponsor provides a separate "Summary of Changes" document.

- **Document Tips:**
  - Minimize using staff names on IRB approved documents:
    - Remove staff names from protocol documents when possible. This will prevent the need for document revisions when study staff change.
    - When creating/editing recruitment documents and scripts, instead of listing specific staff names, provide a space where study contact name and contact number can be inserted (i.e., [study contact name] [Study contact e-mail and phone number]) to reduce the need for amendments to update documents with study staff changes.
  - When revising study documents, include both a "tracked" (changes tracked) and a "clean" (changes incorporated) version of documents being revised. Be sure to use the currently approved version of documents when creating the tracked and clean copies.
  - If changes to an instrument are extensive, consider uploading it as a new document rather than tracking extensive changes on a previously approved document. Place a note in the Buck-IRB application stating that the instrument is a new document and the previous version should be removed.
  - If a "new" document (not previously approved by the OSU IRB) is being submitted, include a suffix of "new" in the document title so that it is clearly identifiable.