



My protocol is approved for **Reliance on Another IRB.**

Q. Do I need to inform the BCH IRB of amendments approved by the sIRB?

A. **YES.** You need to inform the BCH IRB if the amendment involves any of the following changes:

- Conflicts of interest of the PI and/or BCH staff working on the protocol.
- Funding (e.g., planned federal funding source, industry-sponsorship)
- sIRB (i.e. the Reviewing IRB)
- Investigator Drug Brochure [IB], drug dispensation, dosing or the targeted population.
- Plans for research radiation exposure, including a change to the number of subjects exposed or the inclusion of a new population (e.g. minors)
- Changes for which there is a specific institutional policy/state law requirement, such as:
  - Changes in recruitment of research subjects which are not consistent with BCH policy
  - Changes in the informed consent process which are not consistent with BCH policy

**How do I submit an Amendment to BCH IRB?**

**Create and submit an Amendment to BCH IRB**

1. Create an amendment within the reliance protocol in CHERP.
2. Complete the amendment form summarizing changes, noting the sIRB has approved the amendment.
3. If the proposed changes require revisions to the protocol SmartForms, click "SmartForm" link to the right of "Link to Protocol Copy" field in the amendment dashboard.
4. Click on the appropriate section of the application/smartform.
5. Complete the pertinent SmartForm(s).
6. If you are proposing changes to a previously reviewed document, go into the SmartForm page where the original document resides by clicking the "SmartForm" link to the right of "Link to Protocol Copy" field in the amendment dashboard.
7. Click on the appropriate section of the application/smartform.
8. Click on the three dots next to the document and select "UPLOAD REVISION" button to update a document previously submitted.
9. For a new documents upload the documents using the "+ADD" function.
10. Save changes and submit Amendment.

**BCH IRB review and determination**

1. Once received, the IRB will administratively review the Amendment submission and trigger any applicable ancillary reviews.
2. If the IRB has any questions or concerns, the submission will be returned with Sticky Notes. The PI/research team should promptly respond to each Sticky Note and resubmit.
3. Once all ancillaries are complete and all issues have been addressed, the BCH IRB will administratively approve the Amendment.