



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.** But you only need to inform the BCH IRB if the amendment involves any of the changes listed below. Please note appropriate ancillary review(s) will be required when applicable.

- Changing the BCH Principal Investigator (PI)
- Changing the sIRB (i.e. the Reviewing IRB)
- 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
- Funding (e.g., planned federal funding source, industry-sponsorship)
- Conflicts of Interest of the PI and/or BCH staff working on the protocol
 - Changes to Financial Disclosure SmartForm
- Use of BCH Pharmacy that requires change to Investigational drug or supportive medication in any of the following:
 - Dosing, frequency or route of administration
 - Administration guidelines
 - Dispensing workflow
 - Extension of study drug treatment
 - Investigator Brochure (IB)
 - Pharmacy Manual
 - Changes that affect medication orders in any way
- Adding a new collection of tissue removed for clinical purposes that would routinely go to pathology or obtained directly from the operating room
- Modifying or altering any study product under the jurisdiction of the Biosafety Committee with regards to how it's prepared or administered to study participant.
- Modifying or adding plans for research radiation exposure, including a change to the number of subjects exposed or the inclusion of a new population (e.g. minors)
- Adding MRI scans or significant changes in the types of MRI scans and/or ancillary equipment involved with MRI equipment
- Adding a NEW device that emits laser radiation
- Adding or modifying plans for use of non-secure emails or non-secure texts with study participants
- Including additional data sources, devices, drug technologies, or any change to data storage plans



- Adding tests, assessments or other clinical patient care charges that would pose a revision to the billing grid and/or budget

How do I submit an Amendment to BCH IRB?

Create and submit an Amendment to BCH IRB

1. Create an amendment within the pertinent CHERP reliance protocol.
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. Scroll down the left side of the page to find all protocol sections/SmartForms(s).
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. Scroll down the left side of the page to find to find the pertinent SmartForm page(s)
8. Next to the document title, click "..." then "UPLOAD REVISION".
9. For 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 any issues have been addressed, the BCH IRB will administratively approve the Amendment.