

Instructions- Reliance on Academic/Hospital sIRB

- Federally funded multisite research under sIRB regulatory mandate → proceed to Step 2
- All other multisite research → proceed to Step 1

Step 1: Does this protocol require BCH IRB Chair/Vice Chair Review before CHERP submission?

Non-federally funded studies involving vulnerable population (children, decisionally impaired adults) must be reviewed by the BCH IRB Chair/Vice Chair *if* they involve:

- Placebo-controlled-studies that pose greater than minimal risk to participants assigned to the placebo arm (e.g., lumbar puncture, PIC line)
- Genetic manipulation interventions (gene therapy, editing, CRISPR, ASO)
- First-in-Human Trials (Phase 1)
- Fetal therapies - studies that involve surgical and non-surgical methods to treat diseases or abnormalities in the fetus, and range from fetal surgery to medications administered directly to the fetus or to the pregnant person that directly treat the fetus

→ If research does NOT involve categories above → proceed to Step 2.

→ If research does involve categories above, **before submission in CHERP**, please email name of proposed IRB, protocol & consent to reliance@childrens.harvard.edu.

- Decision of whether research may be reviewed by an Independent IRB will be provided within 1 week.
- Investigators told they may proceed with reliance on Independent IRB → proceed to Step 2.
- Investigator told them must submit to BCH IRB → create new protocol select submission type New Research Application. Research will be reviewed by the BCH IRB.



Step 2: Submit CHERP Reliance on Another IRB

- Create new protocol in CHERP
- Select Submission Type: "Reliance on Another IRB"
- Identify reliance agreement and upload the reliance agreement documentation in Reliance Information smartform. **Note: BCH prefers to use the SMART IRB Master Agreement ([check institutions [here](#)].** BCH recommends reliance be documented via SMART acknowledgement letter or Flexibility Agreement rather than SMART online request system.
- Attach:
 - IRB approvals (initial & continuing)
 - Approved protocol
 - Consent (Add BCH PI and payment information only. BCH IRB will revise further on research team behalf. See Step 3)
 - Recruitment materials (Modified for use at BCH: logo/ PI contact information)
 - Any reliance-related documents (e.g., flexibility agreement, local context questionnaire)





Step 3: BCH Institutional & Ancillary Review

BCH IRB will:

- Review for local context
- Edit consent for required local language (HIPAA, subject injury)
- Trigger ancillary reviews (pharmacy, CTBO, etc.)
- Return edited consent, recruitment materials and local context survey
- Document protocol-specific reliance – SMART IRB flexibility agreement



Step 4: Submit to the Lead PI/sIRB

Research team must follow Lead PI/sIRB instructions to submit:

- Edited BCH consent forms
- Recruitment materials
- Any other required documentation e.g., flexibility agreement, reliance letter, local context questionnaire)
- Note** If the sponsor or sIRB requests revisions to the BCH edited consent forms, please resubmit the proposed revisions showing tracked changes, in CHERP. Our IRB office will review the proposed changes prior to final approval by the sIRB.



Step 5: Receive sIRB Approval

Once sIRB approves BCH as site:

- Research team resubmits in CHERP
- Upload final stamped & approved BCH consent forms



Step 6: BCH IRB Approves Reliance on Another IRB

- BCH IRB will ensure reliance agreement is fully executed and finalize administrative approval.