sIRB- Reliance on Another IRB
Independent IRB

Boston Children's Hospital

Instructions for Independent IRB

- 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 involves 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"
- Complete SmartForms
- Attach:
  - IRB approvals (initial & continuing)
  - Approved protocol
  - Approved Consent Template (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 additional reliance-related documents the BCH IRB needs to complete.
- For investigational drugs/devices → complete relevant SmartForm

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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
- Document protocol-specific reliance under master agreement
- Note BCH has master service agreements with Advarra and WCG. Use of other Independent IRB will require legal review for reliance agreement.

Step 4: Submit to the Independent IRB

Research team must follow sponsor instructions to submit:

- Edited BCH consent forms
- Recruitment materials
- Any other required documentation

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 Independent IRB Approval

Once Independent IRB approves BCH:

- Research team resubmits in CHeRP
- Include final stamped & approved BCH consent forms

Step 6: BCH IRB Approves Reliance on Another IRB

- BCH IRB will provide the fully executed protocol specific reliance documentation to the research team.
- Research activities may begin at BCH!