sIRB- Reliance on Another IRB

Boston Children's Hospital

Determine if the protocol falls under the single IRB requirement

- Federally-funded, cooperative (i.e., "multi-site") human research studies are required per the Common Rule (45 CFR 46.114) to utilize a **single IRB-of-Record (sIRB)**.
- BCH sIRB Policy outlines how BCH will operationalize reliance on external IRB – protocols which do not fall under the sIRB requirement will be considered for reliance on a protocol by protocol basis.
  - BCH does not rely on external IRBs for exempt research.
  - BCH will on rely on an independent IRB (e.g. WCG, Advarra) for federally funded cooperative research.

Collect information from the Lead PI/research team

- Determine what reliance agreement will be used – BCH strongly prefers the SMART IRB Master agreement! Search participating institutions here. Note reliance on an independent IRB (e.g. WCG, Advarra) will require execution of a different agreement, which will be facilitated by the BCH reliance team.
- Collect the initial IRB approval, most recent continuing review approval (if applicable), approved protocol, informed consent for use at BCH, recruitment material for use at BCH and any reliance-related documents

Submit CHeRP Reliance on Another IRB

- Create New Research Application within CHeRP
- Select Type of Submission as "Reliance on Another IRB"
- Complete SmartForms
- Attach initial and continuing review (if applicable) IRB approval; approved protocol, consent form edited for BCH PI name/location/contact information, BCH recruitment material and any additional reliance-related documents.

BCH IRB will conduct Administrative, and trigger Ancillary, Review

- BCH IRB will review the Reliance on Another IRB to ensure proposed research is consistent with BCH policy.
- BCH IRB will edit consent form for use at BCH.
- Submission will trigger all ancillary reviews (e.g. pharmacy, CTBO)
- BCH IRB will add sticky notes for any questions or requested changes and return the submission to research team.
- Research team should promptly respond to all sticky notes and resubmit.
- Once the administrative review and all ancillary reviews are complete, the submission will be returned to the research team with edited consent forms and completed/signed reliance documentation.

Submit Documents to Lead PI/sIRB

- The BCH research team will submit the edited consent forms and completed/signed reliance documentation back to the Lead PI/research team, coordinating center/group, or directly to the sIRB, per instruction from the sIRB/coordinating center/group .

Receive sIRB approval & resubmit Reliance on Another IRB

- BCH research team must resubmit the Reliance on Another IRB with the stamped and approved BCH consent forms.

BCH IRB Approves Reliance on Another IRB

- BCH IRB will ensure reliance agreement is fully executed and finalize administrative approval.
- Research activities may begin at BCH!

Protocols utilizing the IRB Reliance Exchange (IREx) will have a different workflow and instructions will be provided by the lead IREx contact.