sIRB- Reliance on Another IRB
Independent IRB

Boston Children's Hospital

Reliance on Independent IRB

- Boston Children's has a master services agreement with Advarra and WCG, where the Independent IRB can serve as the IRB of record for:
  - Industry funded and initiated multisite human research studies.
  - Federally-funded, cooperative (i.e., "multi-site") human research studies required to utilize a single IRB-of-Record (sIRB).
  - All other requests to rely on an Independent IRB considered on case-by-case basis.

Collect information from the Industry Sponsor

- Determine the proposed Independent IRB.
- Use of independent IRBs other than Advarra and WCG will require a protocol-specific reliance agreement. Contact reliance@childrens.harvard.edu to determine appropriate reliance agreement.
- Collect the Independent IRB initial and most recent continuing review approval documents (if available), approved protocol, informed consent, informational/verbal scripts (as applicable) and recruitment material.

Submit CHeRP Reliance on Another IRB

- Create new protocol 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.
- Studies that involve investigational drugs or medical devise will need to provide relevant information within the drug/device smartform (for example: Investigator Brochure).

BCH will conduct Institutional & Ancillary Review

- BCH IRB will review the Reliance on Another IRB to conduct an institutional review for local context.
- BCH IRB will edit consent form for required local language such as HIPAA authorization and subject injury.
- Your CHeRP submission will trigger all required ancillary reviews (e.g. pharmacy, CTBO).
- Any questions on the submission will be promptly directed back to the study team in CHeRP. Study teams' timely responses to questions and request for information will streamline this process and avoid delays.
- Once the institutional and ancillary reviews are complete, the submission will be returned to the research team with edited consent forms and recruitment material (if applicable).
- BCH IRB will reach out to the Independent IRB to document protocol specific reliance under the master service agreement.

Submit to the Independent IRB

- The BCH research team must follow the sponsor instructions for submitting the edited BCH consent form, recruitment material and any other required documentation to the Independent IRB to receive approval for BCH to be added as a site to the protocol.

Receive Independent IRB Approval

- Once the Independent IRB approves BCH, the research team must resubmit in CHeRP the Reliance on Another IRB with the final, stamped and approved BCH consent forms.

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!