

*Purpose of form: To review the BCH Principal Investigator's responsibilities when conducting a study under the oversight of an IRB external to Boston Children's Hospital.*

## Relying Investigator Responsibilities and Guidance

As a BCH Principal Investigator relying on another Institution's IRB review (External IRB) you should be aware of the process to make this decision and your responsibilities if this arrangement is approved.

### **1. You should contact the BCH Reliance specialist to:**

- Discuss whether ceding IRB oversight to an External IRB is appropriate.
- Determine the appropriate reliance agreement to be utilized.
- Provide copies of the study wide protocol and template consent documents(s), which will help facilitate the discussion.

### **2. If BCH agrees to cede review to an external IRB, you will be asked to:**

- Create a protocol application in CHERP. When asked for 'Type of Submission', selecting "Reliance on Another IRB" will generate forms for the reliance request. Please note this will not be reviewed by the BCH IRB but will be used to assure review by other necessary components of the BCH human research protection program (e.g. Pharmacy, CTBO, COI). You will need to upload documents such as the initial protocol approval letter from the external reviewing IRB and the approved protocol and consent. You may not begin any work until you have been notified via CHERP that the reliance on an external IRB has been accepted at BCH.
- Work with the BCH IRB reliance specialist to incorporate locally-required language into the consent template to be used at BCH. For example, while the consent will include text approved by the external IRB, there are some BCH institutional-specific requirements such as local study team and IRB contact information, compensation for injury language, and BCH HIPPA language that must be added as well.
- Ensure that any other necessary data use agreements and material transfer agreements are completed as well as any departmental reviews.
- Become familiar with how you access updated documents from the external IRB on an ongoing basis. This includes access to amendments, continuing review and revised protocols. As an investigator you are still responsible for accessing all research protocol documents. However, updated documents will not be stored in CHERP so you will need access to them through the PI at the reviewing site.

- Become familiar with the external IRB's reportable event policies to ensure that you appropriately report protocol deviations, noncompliance, significant subject complaints, subject injuries, unanticipated problems, or other events required by the external IRB to be reported and within the specified timeframe. Once your protocol is approved for reliance on External IRB you are required to:
- Follow all determinations of the External IRB and conduct the research in accordance with the approved protocol.
- Notify the Lead PI of the External IRB:
  - Any reportable events that occur locally, according to regulations and the External IRB's policy.
  - Any changes (including those related to funding and personnel) in accordance with the External IRB's policies and procedures for timing and content of such submissions.
  - Any management plans, including any updates to these plans, as relevant to the study.
  - Any applicable information for continuing review progress reports in accordance with the External IRB's policies and procedures for timing and content of such submissions.
- Only implement changes of protocol, including local variations, after the External IRB has approved them, except in cases where a change is required to avoid an apparent immediate hazard to participants.
- Provide, upon request, access to study records for audit by the local institution, the External IRB's institution, and other regulatory or monitoring entities.

**3. Once your protocol is approved for reliance on External IRB you are required to make the following submissions/ updates to your approved BCH 'Reliance on Another IRB' application:**

- Submit an amendment through CHERP for any changes to the protocol that include:
  1. PI changes or changes in conflicts of interest of BCH staff working on the protocol.
  2. Changes in funding [e.g., the planned federal funding source changes and the study will be industry-sponsored]
  3. Changes for which there is a specific institutional policy/state law requirement this could include:
    - 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
  4. Changes to the Investigator Drug Brochure [IB], drug dispensation, dosing or the targeted population.
  5. Changes to plans for research radiation exposure [including a change to the number of subjects exposed or the inclusion of a new population, e.g. minors].

- Submit a Reportable Event at BCH for any Unanticipated Problems that have the potential to cause risk, serious or continuing noncompliance. Note this is required in addition to reporting to the lead PI.
  
- Utilize “Manage BCH research team” to add/remove BCH personnel from research protocols in CHeRP.