**Boston Children’s Hospital (BCH) Process for Use of Western IRB/Copernicus IRB**

**Review Process**

1. Contact the BCH IRB Reliance Specialist to discuss the proposal to use WIRB/Copernicus as the reviewing IRB.  

   *(There are situations when we need to work with WIRB and others directly when a consortium or other group has already contracted with WIRB and BCH needs to be added onto an existing agreement. Both require approval and support from the IRB reliance specialist.)*

2. The IRB reliance specialist will confirm that it is appropriate to agree to the use of WIRB for the study and provide additional instructions.

3. If the Overall PI provides a specific WIRB contact we will communicate with that individual to initiate signature of an agreement to use a Harvard Catalyst master reliance agreement, to which both entities are signatories. If there is no specific WIRB contact for the study, the Reliance Specialist will reach out to an institutional WIRB contact to start this process.  WIRB will be asked to provide the first signature on the designation agreement for the specific study under consideration. The designation agreement will not be signed and finalized by BCH until the steps listed below are complete. A copy of the fully-executed designation agreement will be provided to the PI to be sent back to WIRB, along with any other forms PIs have been asked to complete.

   *(Please note WIRB requires that investigators themselves submit information directly into their electronic system to allow the BCH investigator to conduct research under the auspices of the WIRB IRB. DO NOT complete this WIRB requirement until the BCH IRB has advised you, which will be after steps 3-6 are complete.)*

4. The next step is for the BCH PI to submit a reliance request in CHeRP to use WIRB as the reviewing IRB. Please complete the SmartForms and upload the following documents into the CHeRP submission:

   a. WIRB-approved Study Protocol and any associated approved documents (recruitment materials, surveys, etc.)
   b. WIRB-approved Consent/Assent form(s)  *(Note the consent will need to be adapted in several places to contain the BCH local context information. A Word version of the consent document or template for collecting our local information should be provided accordingly.)*
   c. The original WIRB protocol approval letter and most recent continuing review approval, if applicable.
   d. Any other forms that WIRB requires our local IRB to complete.

5. Once received in our office the CHeRP forms will be reviewed and you will be ask for any clarifications. In addition, CHeRP triggers any necessary ancillary reviews at BCH. Remember that only the IRB review will be ceded to WIRB, not the other institutional sign-off components. You may be contacted as
necessitated by ancillary reviewers such as the Pharmacy, CTBO, Nursing, Research Computing, etc. Any local context issues such as COI disclosures will be reviewed and managed by BCH and information may be passed onto WIRB as necessary.

6. The WIRB-approved consent will be modified with local BCH context and required statements. WIRB expects this. Modifications include BCH HIPAA language as well as payment for injury and any other pertinent local context issue. A copy of the consent with our local context will be provided to the PI/research team so it may be submitted to WIRB for final approval.

7. Once the CHeRP reliance process is complete you then may need to enter information in the WIRB electronic system. The PI is required to do this, not the IRB office. **DO NOT ENTER ANY INFORMATION INTO THE WIRB Electronic SYSTEM until you have been advised by the IRB reliance specialist that you may begin this process.** WIRB may require that local PIs set up accounts and enter information about our site in the system. Our office has no ability to do that. We do not have access to that system. You can call us anytime there are questions.

8. Once WIRB approves the involvement of BCH investigators and approves a version of the consent form for BCH, you need to provide the BCH IRB reliance specialist with a copy of the BCH-specific, WIRB approval letter and BCH-specific approved consent. These should be uploaded directly to the CHeRP request.

9. After all approvals have been obtained and uploaded, then reliance on the external IRB is finalized / accepted by the IRB reliance specialist and you may begin the research at BCH.

**After Initial Review:**

1. WIRB is the IRB of record for all future IRB-associated activities.

2. During the study, the BCH PI and research team are responsible for filing a study amendment in CHeRP if there are changes that could impact the local context review. These may include:
   
   a. New principal investigator
   b. Changes to financial relationships that could create a conflict of interest for the study.
   c. Contractual changes related to payment for study-related injury
   d. Changes impacting HIPAA privacy or data security
   e. Changes impacting costs to participants
   f. Major changes in the protocol or consent
   g. Changes that the pharmacy and other service providers may need to know.

3. To change the PI or other reliance personnel with associated COIs, the BCH PI/research team should create an amendment within the CHeRP request. For reliance support staff changes without COIs, the BCH PI / research team should instead utilize the “Manage BCH Research Team” activity in CHeRP. Note that new personnel must be current on human subjects training and conflict of interest disclosures when submitting the amendment or using the “Manage BCH Research Team” activity in CHeRP. Any PI/personnel changes should then be communicated offline to the lead PI/research team.
4. BCH unanticipated problems that may cause risk or a potential issues of serious or continuing non-compliance must be reported in CHeRP through an unanticipated problem report in addition to reporting it to the WIRB IRB. While WIRB remains responsible for oversight and final determinations, the BCH IRB will likely still have an obligation to investigate and propose corrective actions and communicate this to WIRB.

5. PIs are also responsible to report to BCH any other changes that would impact the need to modify an ancillary reviews or when BCH local HRPP policies need to be reconsidered.

6. CHeRP will send a request for a simplified annual administrative update so that we can continue to track the protocol and know when the research has ended. This does not replace your obligations to provide continuing review information to WIRB.

For any questions please contact IRB reliance specialist, Robleinscky Dominguez at Robleinscky.Dominguez@childrens.harvard.edu or 617-355-5935 (55935).