

Frequently Asked Questions (FAQs):
IRB Reliance Agreements at Boston Children's Hospital

Questions

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Answers

1. [What is a Reliance Agreement?](#)
 - A reliance agreement (also called an IRB Authorization Agreement) is a document signed by two or more institutions engaged in human subjects research that permit one or more institutions to cede review to another IRB. The signed agreement permits a single IRB to review human subject research activities for more than one site.
2. [What is the purpose of a Reliance Agreement?](#)
 - A reliance agreement avoids duplicate IRB initial review and continued oversight when multiple IRBs have jurisdiction for the same multi-site research protocol. Once the agreement is executed, it can lessen the administrative burden and regulatory oversight of multiple institutions' IRBs.
3. [Are reliance agreements accepted by all institutions?](#)
 - Institutions vary as to whether they will utilize reliance agreements. Many institutions will decide if they will allow a reliance agreement based on the

research protocol being reviewed. Some institutions have standing arrangements to utilize other IRBs for specific types of research. From a regulatory perspective, federal regulations allow for reliance agreements to be used for multi-site research.

4. Does Boston Children's Hospital utilize reliance agreements?

- Yes, Boston Children's Hospital has both agreed to allow other institutions to cede review to the Boston Children's Hospital IRB and it has also agreed to relinquish review to IRBs at other organizations. However, Boston Children's does not engage in reliance agreements with international IRBs or commercial IRBs.

5. How is a decision made whether a Reliance Agreement should be considered and used?

- Several factors (such as the study protocol, the risk level, the involvement of each institution and its investigators, funding, etc.) are considered when determining whether a reliance agreement should be used or whether each institution should conduct their own IRB review. Boston Children's investigators are encouraged to contact IRB Specialist Daniel Alderson (daniel.alderson@childrens.harvard.edu; 617-919-1918) to assist with such determinations.

6. What is a cede/reliance request?

- A cede/reliance request is when an investigator makes a request to their IRB to utilize a reliance agreement (either as the 'Reviewing Site' or the 'Relying Site'). The mechanism to request a reliance review varies by institution. At Boston Children's Hospital, a submission in CHeRP is required. See "How do I submit a request for another institution to rely on Boston Children's?" and "How do I submit a request for Boston Children's to rely on another institution?" below for details.

7. What is a Harvard Catalyst cede request?

- The Harvard affiliated institutions have joined together to sign one "master reliance agreement" which allows investigators from Harvard affiliated sites to request a single IRB review for research that is performed in more than one institution. A Harvard Catalyst cede request is used when one Harvard Catalyst affiliated institution asks to cede review to another Harvard Catalyst affiliated institution. Investigators still need to request that the cede IRB review arrangement be approved, however an individual reliance agreement does not need to be signed. Harvard Catalyst has created an informatics system in which investigators can submit a request into a central system. Each of the institutions involved will be notified and will review the request and determine if ceding

review/approval/oversight to another is acceptable. More information regarding Harvard Catalyst Cede Requests can be found at the following website: <http://catalyst.harvard.edu/services/irbcede/>

- It should also be noted that the Harvard Catalyst master agreement has also recently been extended to other non-Harvard affiliated institutions. A complete list may also be found at the website.

8. How does Boston Children's IRB decide to accept or decline a reliance request?

- Several factors (such as the study protocol, the risk level, the involvement of each institution and its investigators, funding, etc.) are considered in deciding whether a reliance agreement should be sought or whether each engaged institution should conduct their own IRB review. The decision to accept or decline the use of a reliance agreement is done on a protocol-by-protocol basis.

9. How do I submit a request for another institution to rely on Boston Children's?

- In order to allow another institution to rely on Boston Children's Hospital IRB oversight you must have a protocol (either under IRB review or approved) in CHeRP. To begin this process, submit an 'Add Reliance on BCH' activity in CHeRP. From within the applicable protocol in CHeRP, you are able to select this (as you would to submit an Amendment, Continuing Review, Reportable Event, etc.). 'Add Reliance on BCH' can be requested at any time, even with other activities (such as an Amendment or Continuing Review) currently pending or under review. The request can be approved as long as approval for the main protocol has been obtained. One 'Add Reliance on BCH' must be submitted for each site. However, if you wish for multiple institutions to rely on BCH, CHeRP allows for multiple 'Add Reliance on BCH' requests to be open at the same time.

10. How do I submit a request for Boston Children's to rely on another institution?

- Even when Boston Children's IRB will not review a protocol, it is important that we have record of the research conducted at BCH that is under the jurisdiction of another IRB. Although IRB review will be conducted elsewhere, there are other ancillary reviews that may need to occur at Boston Children's (clinical trials office, pharmacy, radiation safety review, etc.). Entering the protocol in CHeRP will allow these reviews to occur. To begin this process, create a new protocol and select the type 'Reliance on Another IRB'. The smartform will generate questions applicable to your research, depending on the category(ies) you select as your involvement. This type of submission goes through an abbreviated administrative review.

11. Once submitted in CHERP, how are cede requests ('Add Reliance on BCH' or 'Reliance on Another IRB') reviewed?

- Reliance/cede requests are reviewed by a BCH IRB Designee through an administrative process. The Designee will review the submission, obtain any/all additional information from investigators, determine whether the request can be accepted on behalf of BCH IRB, and obtain a determination from the other IRB whether the request can be accepted. Once a determination is made by both IRBs, the request will be approved and any necessary reliance documentation will be executed by both IRBs.

12. When should I submit a request?

- A reliance request can be submitted at any time. However, approval of the reliance will be held until the initial protocol is approved at BCH (if another institution is relying on BCH) or until the initial protocol or amendment to include BCH is approved at the other institution (if BCH is relying on another).

13. If one IRB agrees to rely upon another IRB, is an application still needed with the Relying IRB's system?

- If BCH is relying on another IRB: Yes, a 'Reliance on Another IRB' submission is still needed. This submission is not an IRB review process (since the IRB review will be ceded to another institution) but rather is a means to review/approve the cede request, trigger applicable ancillary reviews, and track research activities occurring at BCH.
- If another institution is relying on BCH IRB: It will depend on the other institution's processes. Researchers may need to submit through their IRB system even if that IRB will rely upon BCH IRB. Further information should be obtained from that institution's IRB office.

14. If another institution relies upon BCH IRB, what responsibilities does the BCH Principal Investigator and research staff have?

- If you agree to be a principal investigator for a protocol that assumes responsibility for IRB review of other sites, your responsibilities increase. Not only are you responsible for the IRB review/oversight/reporting of research activities conducted at Boston Children's, you now become responsible for IRB review and reporting for the sites that are relying on the BCH IRB as part of your protocol. It is important that before you consider assuming this responsibility, you have the resources and infrastructure to do so. This will likely depend on relationships with investigators at the other sites since you will need to depend on

them to provide information about the research activities at their sites. Once a reliance agreement has been executed for other sites to rely upon (cede review to) BCH IRB, the BCH PI is considered the ‘overall PI’ for the multi-site research protocol and obtains overall responsibility for the protection of human subjects for all sites. This includes the collection of all regulatory information needed by BCH IRB and the notification/communication for all IRB-related matters to all sites. For example, if a reportable event occurs at a relying site the PI at that site will need to inform you so you can report that to the BCH IRB. Please see “Responsibilities for PIs engaged in Reliance Agreements” document for a complete list of responsibilities.

15. If Boston Children’s relies upon another IRB, what responsibilities does the BCH Principal Investigator and research staff have?

- Once a reliance agreement has been executed for BCH to rely upon (cede review to) another IRB, the BCH PI is responsible for obtaining all regulatory protocol information (approved protocol, approved consent documents, etc.) from the ‘overall PI’. Any questions or required reporting will need to go through the PI at the reviewing IRB site. You will no longer interact with the Boston Children’s Hospital IRB for protocol issues related to that research. You will be responsible to providing information needed at the time of continuing review or if any unanticipated problems occur. Please see “Responsibilities for PIs engaged in Reliance Agreements” document for a complete list of responsibilities.

16. Continuing Reviews: I am the PI for a protocol and another institution is relying on BCH. What do I need to consider at the time of continuing review?

- As the ‘overall PI’ with another institution relying on BCH, you need to collect all required information needed to complete the continuing review submission form. The continuing review at BCH IRB will be conducted for all sites. Therefore, all information such as enrollment numbers, reportable events, etc. must be collected from all relying sites and included in BCH’s continuing review.

17. Continuing Reviews: I am the PI for a protocol at BCH but we have relied on another IRB review. Do I need to submit continuing reviews at BCH?

- The continuing review that occurs at the ‘providing’ site’s IRB will include BCH’s involvement in the research. Therefore, you will need to provide all necessary information for that IRB’s continuing review to the ‘overall PI’ at the site BCH is relying on. A continuing review at BCH will not occur. However, a notice from CHeRP will be sent annually asking you to indicate whether BCH’s involvement in the research is ongoing or complete.

18. Unanticipated problems: I am the PI for a protocol and another institution is relying on the BCH. If there is an unanticipated problem at another site, do I need to report it to the BCH IRB?

- Yes. All unanticipated problems, deviations, suspensions and terminations, noncompliance, subject complaints, etc. from any relying site should be reported to BCH IRB. BCH IRB review and notify the relying site's IRB of any such issues.

19. Unanticipated problems: I am a PI for a protocol at BCH but we have relied on another IRB review. If an unanticipated problem has occurred with one of my subjects, who do I report it to?

- All unanticipated problems, deviations, suspensions and terminations, noncompliance, subject complaints, etc. should be reported to the 'overall PI' at the Providing Site who will report to the IRB that BCH has relied upon. That Providing/Reviewing IRB will notify BCH IRB of any such issues.

20. Consent forms: I am the PI for a protocol and another institution is relying on the BCH IRB. Do they use a BCH consent?

- The consent forms to be used at a relying site will be reviewed and approved by BCH IRB. However, they should include site-specific information (headers, HIPAA/privacy language, injury language, contact information, etc.). Consent forms used at a relying site can be separate forms or 'hybrid' forms can be created to include both sites' information in the same form.

21. Consent forms: I am the PI for a protocol at BCH but we have relied on another IRB review. Do I still use a BCH consent form?

- The consent forms to be used at BCH will be reviewed and approved by the IRB we rely on. However, they should include BCH-specific information (headers, HIPAA/privacy language, injury language, contact information, etc.). Consent forms used at BCH can be separate BCH-only forms or 'hybrid' forms can be created to include both sites' information in the same form.

22. How can I receive additional information?

- Boston Children's Hospital IRB Specialist Daniel Alderson (617-919-1918; daniel.alderson@childrens.harvard.edu) can provide assistance with any questions regarding reliance agreements.