Boston Children's Hospital

Understanding Local Context When Using Single IRB Review

What is a local context review and why is it required?

The review of a protocol by a single IRB applies to all relying sites. However there may be some local regulations, policies and consent language which will need to be considered and addressed for each local site. These issues need to be considered during the review process and are referred to as **local context.** A local context review needs to occur at the local site and information is then provided to the reviewing IRB. This includes verification that the site-specific information is incorporated appropriately in applicable study documents. It also is the process through which the local site verifies it has performed its relying site responsibilities as outlined in the reliance agreement.

This generally includes study-specific confirmation of:

- COI
- training/qualifications of local research staff
- ancillary reviews
- application of local laws and policies

Relying sites are required to confirm that their local context review is complete before they can begin the research.

How does local context apply when BCH is the reviewing IRB?

The BCH IRB will review and approve the Master protocol and finalize all study documents (e.g. consent/assent forms, recruitment materials). The BCH research team will then provide each site a "reliance packet" including the approved protocol and editable template consent/assent forms and recruitment materials (created by the BCH IRB reliance specialist), as applicable. Relying sites will be asked to provide, and sign off on, local context information via an *Application for Relying on Boston Children's Hospital's IRB,* also to be included in the "reliance packet". During the reliance review process, the BCH IRB office will make sure that any different requirements for the local site are considered and reviewed as appropriate. In addition, the consent/assent forms and recruitment materials will be finalized for each relying site that include limited local context information.

How does Local context apply when BCH investigators are relying on another, external IRB?

While the IRB review will not occur at BCH, the investigator will be asked to provide the reviewing IRB local context information and assurance that required ancillary reviews have been completed. The BCH IRB office will be asked to provide local context information and consent wording required for BCH. This is why you are asked to fill out a reliance protocol in

CHeRP. While the BCH IRB will not review the protocol, information provided about the protocol will trigger necessary BCH ancillary reviews so we can assure the reviewing IRB they have been completed. No research at the BCH site can begin until a local consent has been finalized by the reviewing IRB and you are notified in CHeRP that the review is complete.

What information does an IRB collect from participating sites as part of the local context review process?

1. Basic institutional information [site contacts, FWA #].
2. Confirmation of completed local training; appropriate credentialing and qualifications to perform the research and confirmation as to whether any study team members have identified a conflict of interest.
3. A description of any local requirements and associated required consent form language [as applicable]. Local requirements may stem from local state laws or institutional policy.
4. Confirmation that all relevant locally-required ancillary reviews have been completed and the outcome of these reviews, as applicable.
5. Any unique local considerations [e.g. concerns relevant to your local community].
6. Information about individual site addressing select study-specific items [e.g. whether a procedure being performed through the study is standard of care at the site], etc.

What tools do IRBs use to collect local context information from site?

Local Context Questionnaire : The questionnaire that helps a reviewing IRB collect information about relying sites' requirements including any state or local laws, regulations, institutional policies, standards or other local factors relevant to the research being conducted at each site. Completion of the questionnaire is a collaborative effort between the local PI/study team and their site's HRPP/Research/IRB Office. At BCH, this is the *Application for Relying on Boston Children's Hospital IRB (FULL and Protocol-Specific versions)*.

Site-Specific Consent Information: Consents approved for each site are modified to include some information that is specific to the local study. In general, this will involve the local site providing institutionally-required consent form language [e.g., research injury language, HIPAA language, cost information, signature lines]. A site-specific consent form will be finalized by the BCH IRB using a reliance template of the approved master consent that has been edited to include any institutional language provided by the local site.

How do relying site investigators prepare for the local context process at their site?

Each investigator that relies on another external IRB must first understand how "local context review" is operationalized at their institution. They need to contact their local IRB office or

their SMART IRB Point of Contact (see https://smartirb.org/participating-institutions) to understand local site requirements. Important questions to ask include:

- Who has the authority at the institution to review and "sign-off" on the local context review?
- Is a formal submission to their local IRB required?
- What study-specific documents must be submitted locally to have the review completed?

What do investigators need to do to request and know if the local context process is complete?

A local context form is usually completed by the local site PI and the institutional representative designated to verify local laws, policies, etc. Lead PIs are usually responsible for distributing this form to the relying site PIs/teams and then receiving it back for their IRB's internal review. At BCH if a PI is serving as the Lead PI for all sites, the completed forms are included as part of the reliance request ("Add Reliance on BCH") submitted in CHeRP for each site. If there are any pending local ancillary reviews or if study team member training has not been completed, local context review is not complete. Generally, the reliance review process cannot proceed until all local context review issues have been resolved.

If BCH serves as the single IRB is there anything else the relying site PI needs to do before research can begin?

Relying PIs/teams need to check with their local IRB/research office to determine what information may be required BEFORE their site can be activated locally. For example, their IRB/research office may require receipt of the BCH-approved consent form for local use and acceptance letter noting the site has received final approval by the BCH IRB.

Once a local site has been activated, do the relying site investigators need to continue to communicate with their local IRB?

Relying site investigators should check with their IRB/organization about the types of items that will require local "review" during the life of the study. Even when relying on an external IRB many organizations require that select submissions be reported locally throughout the study. Examples may include a) changes that may trigger a local ancillary review, b) study team changes, c) complaints from subjects enrolled at the site, etc.