**Understanding Site Onboarding: What Happens Before/After the Local Context Review Process**

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

A local context review is a study-specific review that needs to occur at the local site. This includes verification that the site-specific information is incorporated appropriately for the site in applicable study documents. It also is the process through which the relying 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

Sites are required to confirm that their site’s local context review is complete before onboarding can begin.

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

1. Basic institutional information [site contacts, FWA #]
2. Information about the relying site study team including 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 requirements
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 how your site addresses select study-specific items [e.g. whether a procedure being performed through the study is standard of care at your site], etc.

***What tools does the JHM IRB to collect local context information from my site?***

Local Context Questionnaire [LCQ]: The LCQ is a questionnaire that helps the JHM IRB collect information about your site’s requirements including any state or local laws, regulations, institutional policies, standards or other local factors relevant to the research being conducted at your site. Completion of the LCQ should be a collaborative effort between the local PI/study team and your site’s HRPP/Research Office/IRB.

Site-Specific Consent Information [SSCI] Template: JHM IRB uses a two-part consent form process. The first part of the consent form [Master] includes information that applies to all study sites. The second part of the consent form [SSCI] includes information specific to the study site. The master template consent is being provided to facilitate your local context review only and is not approved for use to enroll subjects. The SSCI allows your site to provide institutionally-required consent form language [e.g., research injury language, HIPAA language, cost information, signature lines]. A site-specific consent form will be created by the JHM IRB using the approved master template consent form and the completed site-specific consent template your site provides.

***How do I prepare for the local context process at my site?***

You must first understand how “local context review” is operationalized at your institution. We recommend that you first contact your IRB office or your SMART IRB Point of Contact [<https://smartirb.org/participating-institutions/>] to understand your 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 your local IRB required?
* What study-specific documents must be submitted locally to have the review completed?

***There are questions on the local context forms that I do not know how to answer. Who should I contact?***

Completion of the LCQ should be a collaborative effort between the local PI/study team and your site’s HRPP/Research Office/IRB. In addition to your site’s HRPP/Research Office/IRB, you can contact your coordinating center team or the JHM IRB reliance team [JHMIRBReliance@jhmi.edu].

***How do I know if my local context process is complete?***

The LCQ must be signed by local site PI AND the institutional representative designated to verify local laws, policies, etc. The LCQ must be complete and signed before submission to JHM IRB for review. If there are any pending ancillary reviews or if study team member training has not been completed, local context review is not complete. Please be as careful as possible in completing this questionnaire so that the document does not need to be re-signed.

***I’ve received my site approval documents from the JHM IRB. Is there anything else I need to do before research can begin?***

You should check with your local IRB/research office to determine what information may require receipt BEFORE your site can be activated locally. For example, your site may require receipt of the JHM IRB stamped consent form for use at your site and approval letter noting your site has been formally approved as a site.

***Once my site has been activated, do I have to continue to communicate with my local IRB?***

Participating sites 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. Investigators relying on the JHM IRB are expected to be knowledgeable about their local site requirements.

***What JHM IRB policies should my site review and follow in supporting the ongoing local context process?***

JHM IRB policies can be found here: <https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/organization_policies/index.html>

Key JHM IRB policies, such as the [Organizational Policy on Prompt Reporting of Reportable Events](https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/organization_policies/prompt_reporting_policy.html), must be followed by participating sites. In this example, JHM reporting timelines should be followed for reporting of these events to the JHM IRB in addition to any local reporting requirement that differ from JHM IRB reporting timelines.

Participating site investigators are still responsible for adhering to institutional and state law requirements for their own site.

***Can I access my study documents in the eIRB system?***

The JH PI/Overall PI/coordinating center is primarily responsible for providing study and site approval documentation to participating sites; however, the participating site PI, site lead study contact and up to three additional site contacts may opt to have access to study approval and local context documents via the JHM electronic IRB system or an alternate electronic IRB reliance system. This is achieved by use of federated authentication or account provisioning. Please contact the JH PI/Overall PI/coordinating center to determine whether access can or should be granted.

***How do I contact the JHM IRB reliance team?***

Please contact the JHM IRB Reliance Team at JHMIRBReliance@jhmi.edu with any questions.