External IRB FAQs

How do I request Johns Hopkins to allow an external IRB to be the sIRB for my study?

All requests for reliance must first be submitted through the reliance request survey that is available on the JHM IRB website at https://www.hopkinsmedicine.org/institutional_review_board/about/agreements/.

What are my responsibilities as a PI when relying on an external IRB?

You, as PI, will need to make sure that all study personnel receive appropriate training and are qualified to perform their duties, and that the study is conducted in accordance with the sIRB approved protocol and IRB policies. These requirements are outlined in the "Statement of PI Responsibilities when Relying on an External IRB", which must be signed and submitted with your reliance request.

What do I have to submit in eIRB2 when relying on an external IRB?

A local context review is still required so that we can address any local concerns, perform ancillary reviews, etc. The eIRB2 application is abbreviated in comparison to our full board and expedited applications and is typically reviewed during an expedited review session.

Are there review fees involved when relying on an external IRB?

JHM IRB charges review fees for commercially funded studies with financial support in excess of $10,000. This includes a local context review fee when JHM relies on an External IRB [e.g., JHM is not the IRB of Record]. Please refer to the Fees for JHM IRB Review guidance for more information.

Do I have to submit a Continuing Review application for my external IRB application?

No. A continuing review application is not required for studies where JHM is not the IRB of record. In cases where the reviewing IRB has determined that continuing review is required and will provide an annual re-approval letter you should use the "**Upload External IRB Approva**l" activity, located on the parent application workspace, to upload the external IRB's annual approval letter under "**Continuing Review Approval Letter**". This will notify our reliance department to update the expiration date based on the external IRB approval letter and ensure we are aware that your study remains active. **Please Note:** If the External IRB issues updated consent forms to reflect a new approval and expiration date, do not upload the consent forms via the "Upload External IRB Approval" activity. Updated study documents should be submitted via Change in Research application.

As our HRPP is responsible for tracking all active research, including research that is reviewed by an external IRB, our HRPP may require a local progress report for external IRB applications, even where no continuing review or progress report has been required by the reviewing IRB. The purpose of this progress report is to provide a local update about the status of the research at our site. Where a continuing review is not required by the reviewing IRB and a progress report has not been required by our HRPP, a three-year expiration will be assigned to the study. Study teams must keep their study's status "active" by submitting an "extend approval" request. Failure to submit an extend approval request will result in the termination of the study, meaning no research-related activity may continue at the JHM site.

Do I need to submit any documentation if the external IRB does not require a continuing review for my study?

Under certain circumstances, a Continuing Review is no longer required under the Revised Common Rule. As a Relying Institution, we reserve the authority to require JHU investigators to submit on-going Progress Reports at intervals suitable for the research protocol or research study activities.

If the External IRB approves a study under the revised common rule and does **not** require continuing review, JHM will apply the following rules:

- If JHM is contributing more than 500 records, a 1-year expiration date will be applied. The PI will be required to submit a Progress Report to JHM in 1 year.

- If JHM is contributing less than 500 records, a 3-year expiration date will be applied. The PI will be required to run an activity to "extend" the acknowledgment period for an additional 3 years if the study is still active.

My external IRB application is "Acknowledged". Does this mean "Approved"?

External IRB applications are acknowledged rather than approved. The external IRB approves the research study. As a relying site, we are acknowledging that our local context review is complete and research can begin.

The external IRB approved a revised protocol. Do I need to submit that in eIRB?

When relying on an external IRB, it is important for JHM investigators to recognize that the JHM IRB and the institution still retain important responsibilities for the oversight and ongoing local conduct of the study. You should submit any modifications to the JHM IRB that require local review. Please refer to the "Statement of PI Responsibilities when Relying on an External IRB" for examples of changes and other information that should be reported to JHM IRB.

Does JHM IRB stamp documents from the external IRB?

Documents approved by the external IRB [including consent forms] are not stamped by JHM IRB. In addition, we do not require the JHM logo to be included on our site-specific documents.

The final version of the site-specific JH consent initially approved by the external IRB will be available in your "Stamped Documents" tab. After initial acknowledgment, the External IRB will serve as the source of record for any updated versions of your site-specific JH consent. Please refer to the "Statement of PI Responsibilities when Relying on an External IRB" for a list of changes that require local review prior to proceeding with implementation of the updated version of the site-specific consent form.

If you submit a revise version of the site-specific JH consent approved by the external IRB, it will be available in your "Stamped Documents" tab upon acknowledgment of the Change in Research. For changes that do not first require local review, you may proceed with using an updated version of your site-specific consent forms upon receipt from the External IRB.

As not every Change in Research requires local IRB review, for external IRB applications eIRB should not be relied upon as the source system for approved versions of the consent form. Final approved versions of any stamped documents must be secured from the reviewing IRB.

Can I add non-Hopkins study team members to my eIRB application?

Non-Hopkins investigators should not be added as "study team members" within the eIRB application, as this implies that JHM IRB covers their research activities and that non-Hopkins investigators are subject to our IRB training requirements. The eIRB application should be limited to Hopkins-affiliated investigators only.

There are special circumstances whereby we would consider granting new/extended access to a non-Hopkins affiliated person. For example, if a non-Hopkins individual will be serving in a coordinating center role or completing eIRB applications on behalf of the Hopkins PI. All exceptions must be reviewed and approved by the Reliance Team. Contact JHMIRBReliance@jhmi.edu for more information.