External Reliance FAQ

What if I want to use an external IRB to be the IRB of record?

Request for external IRB reliance must be reviewed and approved by the CHS IRB

What do I have to submit to the IRB 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 application is abbreviated in comparison to our full board and expedited applications and is typically reviewed during an expedited review session. The CHS IRB will administratively acknowledge/approve the application, if it is allowing the use of the external IRB reliance.

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

The IRB charges review fees for commercially funded studies with financial support. This includes a local context review fee when CHS relies on an External IRB [e.g., CHS is not the IRB of Record].

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 CHS 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 upload to IRBManager. This will notify our office to update the expiration date based on the external IRB approval letter and ensure we are aware that your study remains active.

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. Failure to provide copies of continuing review or progress report request will result in the CHS termination of the study, meaning no research-related activity may continue by CHS faculty/staff.

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 CHS investigators to submit on-going Progress Reports at intervals suitable for the research protocol or research study activities.

My external IRB application is "Administratively Acknowledged" or "Administratively Approved". Does this mean "IRB Approved" to begin research?

External IRB applications are Administratively Acknowledged or Administratively Approved by CHS rather than [IRB] approved. The external IRB approves the research study. As a relying site, we are acknowledging or approving that our local context review is complete, and research can begin with IRB of record approval.

The external IRB approved a revised protocol, other modifications or updates. Do I need to submit these to CHS IRB?

When relying on an external IRB, it is important for CHS investigators to recognize that the CHS IRB and the institution still retain important responsibilities for the oversight and ongoing local conduct of the study. You should submit any modifications, in addition to any other updates to the study (e.g. recruitment material, letters to patients, updated IB, DSMB reports) along with the IRB of record review and approval, to the CHS IRB that will do an administrative local review. Failure to provide copies of revisions to the protocol, other modifications or updates will result in the CHS termination of the study, meaning no research-related activity may continue by CHS faculty/staff.

Does CHS IRB stamp documents from the external IRB?

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

What are my obligations when an external IRB is responsible for reviewing my research study?

The responsibilities of the research team remain largely the same, and include:

- Submitting and obtaining acknowledgement of a "Review by non-CHS" IRB application which is used to track reliance relationships with external IRBs
- Obtaining initial approval from the Reviewing IRB as a participating study site
- Complying with the Reviewing IRB's policies (e.g., reporting noncompliance, unanticipated problems, and subject complaints)
- Complying with the determinations of the Reviewing IRB
- Using the most current IRB-approved documents, including the protocol, consent forms, and recruitment documents
- Complying with applicable policies from CHS (e.g., conflict of interest, training and education, research subject compensation processes)
- The CHS IRB requires that CHS researchers will comply with the determinations of the reviewing IRB regarding initial review, continuing review, review of revisions, reportable events, as well as DSMB and device reports for studies covered under the reliance agreement. Documentation of these determinations must be provided **within 10 business days** of the reviewing IRB's determination by the CHS principal investigator to the CHS IRB via IRBManager.
- Researchers and research staff at the local site must meet CHS IRB requirement for training in ethics and regulations of human subjects research