

External IRB Submission Checklist – Investigators

NCI CIRB Studies

When JHM agrees to rely on an external IRB, you are required to submit a local context application [external IRB application] via eIRB. The purpose of this external IRB application is to facilitate all local ancillary reviews that may be required for your study at JHM and to allow JHM to perform a local context review, which is required for all studies where JHM relies on an external IRB.

Please use the following checklist as a guide in completing your external IRB application:

- In “General Information”, item 7, select “Expedited” as the review type.
- In “General Information”, item 8, select “Yes” to indicate that an external IRB will act as the IRB of record for this study and select “NCI CIRB” as the external IRB.
- In “Study Team Compliance Training”, item 2, upload a copy of the PI’s “[Understanding Reliance: Roles and Responsibilities when Relying on an External IRB](#)” training certificate.
- In “Protocol Information”, upload the external IRB’s approved multisite protocol in item 2.
- In “Recruitment Information”, item 11 [*if applicable*], upload a HIPAA Form 4. NCI CIRB **WILL NOT** serve as the Privacy Board and make HIPAA waiver determinations for Johns Hopkins.
- In “Written Consent”, item 3.0, please upload a copy of the JH consent form. In item 4.0, please upload the NCI CIRB consent form. A copy of the [NCI CIRB HIPAA Authorization](#) does not require uploading, as it is available on the JHMIRB website under “Forms” → “NCI CIRB Forms”.
- In “Supplemental Study Documents”, item 2, upload A signed copy of the [Statement of PI Responsibilities when Relying on an External IRB](#) form.
- In “Approval Documents”, item 1.0, upload a copy of the external IRB’s initial approval letter for the study. If the study has received a recently annual approval, in item 2, also upload a copy of the most recent annual approval letter for the study. Upload a copy of the CIRB application in item 3.0.