External IRB Submission Checklist – Investigators

If JHM IRB is being asked to rely on an external IRB, a local application must be submitted in eIRB. The purpose of this application is to facilitate all local ancillary reviews that may be required for your study at JHM and to allow the JHM IRB to perform a local context review, which is required for all studies where JHM IRB relies on an external IRB.

Please ensure the following information is included in the eIRB application:

- In “General Information”, Question 6 (or ‘Summary of Changes’ for change in research applications), please state that the application includes a reliance request.
- In “General Information”, Question 7, select “Expedited” as the review type.
- In “General Information”, Question 8, select “Yes” to indicate that an external IRB will act as the IRB of record for this study and select or provide the name of the External IRB.
- In “Study Team Compliance Training”, Question 2, upload a copy of the PI’s external IRB training certificate.
- In “Recruitment Information”, Question 11 [if applicable], do NOT upload a HIPAA Form 4 if the external IRB WILL serve as the Privacy Board and make HIPAA waiver determinations for Johns Hopkins as a relying site.

For studies that will be enrolling at a JHM site via a process that includes consent, the External IRB may either a) build the site-specific consent based on information JH supplies or b) request that relying sites build their own site-specific consent. It is important to confirm with the external IRB which process they follow before beginning your external IRB application. Please follow the appropriate instructions below:

a. If the External IRB will build the site-specific consent, please upload a copy of the External IRB’s approved master template consent. Please note the JHM IRB would expect that this template consent make clear which sections of the consent document are customizable. Appropriate site-specific consent language will be provided via a JHM IRB letter.

b. If the External IRB has requested that relying sites build their own site-specific consent, please upload a copy of the External IRB’s approved master template consent AND a tailored version of the External IRB’s approved master template consent that includes JHM-required consent language. Please refer to the following guidance on required JHM template language when using an external IRB to assist with building the site-specific consent form.

- In “Supplemental Study Documents”, Question 2, upload the following:
  a. A separate document* outlining how JHM is engaged in the research and a description of why the non-JH site is best suited to provide IRB review for this study.
    i. Please specify whether the non-JH IRB is AAHRPP-accredited.

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ii. The description of how JHM is engaged in research should specify what types of activities JHM investigators will be involved in [e.g. JHM will be an enrolling site or JHM investigators will only be involved in data analysis].

iii. *For studies that will be enrolling at a JHM site via a process that includes consent*, please specify whether a) the External IRB will create the consent and has requested only site-specific language (or b) the External IRB has requested that JHM create their own tailored consent and one has been uploaded in the “Written Consent” section.

b. Any materials supplied by the planned External IRB
c. A draft reliance agreement [if applicable]
d. Any documentation* provided by the reviewing IRB that the JHM IRB is required to complete as part of its local review [often referred to as “local context forms”]
e. A signed copy of the Statement of PI Responsibilities when Relying on an External IRB form.

☐ In “Approval Documents”, Question 1, upload a copy of the reviewing IRB initial approval letter for the study. If the study has received re-approval by the reviewing IRB, in Question 2, upload a copy of the most recent annual approval letter for the study.

☐ In the “Submit” activity textbox, please include the following language: “This application includes a reliance request.”

*Please include the term “Reliance Request” in the naming conventions used for your documents.