External IRB Submission Checklist – Investigators

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 or provide the name of 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],* 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.
- ☐ *For studies that will be enrolling at a JHM site via a process that includes consent,* the external IRB may either a) build your site-specific consent based on information you provide ***or*** b) request that relying site investigators build their own site-specific consent using the external IRB's approved consent form template. **The Johns Hopkins Consent Form Template should not be used for external IRB studies.** 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:
    - ☐ ***If the external IRB will build your site-specific consent,*** please provide them with our **JHM Consent Language** guidance, which outlines mandatory and recommended language to include in the site-specific consent form. The external IRB should incorporate our mandatory consent language into their approved master template consent. Our consent form specialist will review the site-specific consent and provide a summary of any changes needed to meet our institutional consent language requirements.
    - ☐ ***If the external IRB will provide a master consent template only,*** 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 **JHM Consent Language** to assist with including the JHM required language]. Our consent form specialist will revise the site-specific consent to include changes needed to meet our institutional consent language requirements.
- ☐ In "Supplemental Study Documents", item 2, upload the following:

- ☐ A separate document outlining how JHM is engaged in the research [e.g., JHM investigators are consenting/enrolling; performing data analysis only]
- ☐ Any local context forms that required completion by the JHM IRB staff
- ☐ A signed copy of the **Statement of PI Responsibilities when Relying on an External IRB** form.

☐ In "Approval Documents", item 1, upload a copy of the external IRB's initial approval letter for the study. Please ensure the letter includes [at a minimum]: the study expiration date, overall risk determination [e.g., minimal risk/expedited review] and any regulatory determinations [i.e., pediatric risk category]. 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.