**Statement of PI Responsibilities when Relying on an External IRB**

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*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 of the study. An External IRB is solely responsible for reviewing the study materials to determine if the study as proposed meets the criteria for approval under the federal human subjects protections regulations. The relying organization [in this case Johns Hopkins University] retains responsibility for ensuring all local ancillary reviews required to conduct the research at this site are completed and for ensuring that any local requirements are communicated to the IRB of Record. In order to facilitate this, each PI, seeking to rely on an External IRB, is responsible for the following:*

1. Complete an online training course: [Understanding Reliance: Roles and Responsibilities when Relying on an External IRB](https://lms14.learnshare.com/l.aspx?Z=ynJHcbGOOibThI1pVOmK6blqBNoqIEIJkvfLjTCdgiM%3d&CID=89). The training will review the initial steps to request reliance on an external IRB, outline how to submit an external IRB application to the JHM IRB and review the roles and responsibilities of local site PIs and study teams when relying on an external IRB;
2. Provide an application to the JHM IRB which contains the submission materials initially approved by the External IRB, including the approved template consent;
3. Engage any research support offices/centers at JHM with oversight responsibility for the research and provide any additional materials needed to those entities in order to grant approval;
4. Monitor and maintain training records to assure that the local study team is in compliance with JHM IRB training requirements;
5. Report to the IRB of record any revisions necessary to the approved documents based on the JHM IRB’s local context review and the review of any JHM ancillary committees in order for the research to be conducted at this site;
6. Once approved as a site by the External IRB provide the initial approval letter to the JHM IRB in order to allow research activities to commence at the JHM site;
7. Maintain an active record of all submissions to the IRB of record and inform any research support office/center of any proposed modifications that may impact the support provided;
8. Submit any modifications to the JHM IRB that require local review. Examples of such changes include:
   1. Protocol changes
   2. Major study-related changes [i.e., study arm closures related to safety or futility, suspension of study activities]
   3. Personnel/PI changes
   4. Changes in funding [e.g., the planned federal funding source changes and the study will be industry-sponsored]
   5. Changes in conflicts of interest
   6. Changes for which there is a specific institutional policy/state law requirement
   7. Changes that impact procedures that have a billable code in EPIC (for which a change in the PRA would be required)
   8. Changes to the Investigator Drug Brochure [IB], drug dispensation, dosing or the targeted population [e.g. changes to the inclusion/exclusion criteria for studies involving an investigational or approved drug used for research purposes]
   9. Changes to plans for research radiation exposure [including a change to the number of subjects exposed or the inclusion of a new population, e.g. minors]
9. Proceed with implementation of any of the above changes only after receiving acknowledgement from the JHM IRB office.
10. For all other changes approved by the reviewing IRB, proceed with using study documents [protocol, site-specific consent form] upon receipt of those IRB-approved documents.
11. Provide the annual re-approval letter to the JHM IRB (prior to expiration of the protocol in the JHM IRB database) in order to maintain an active record (this record will align with the current approval as assigned by the IRB of record);
12. Supply a report of any protocol event or deviation reports that could qualify as a) unanticipated problems posing risks to subjects or others, b) incidents of serious noncompliance or c) continuing noncompliance. Please consult JHM IRB if you are uncertain whether your event requires dual reporting to the External IRB and JHM IRB. JHM reporting timelines should be followed for reporting of these events to the JHM IRB. The reviewing IRB may have different reporting timelines and investigators must adhere to those timelines for reports submitted to the External IRB.
13. Promptly report to the JHM IRB any notifications of suspension or termination that you receive for the applicable study from the External IRB;

**Signature of Principal Investigator:**

*By signing below, you attest that you have reviewed the responsibilities as outlined above and agree to comply with these responsibilities.*

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PI Name Date

**Print Full Name:**

**Address:**

**Email:**

**Phone number:**

**JHM IRB Protocol Number:**

**Study Title:**