**RELIANCE INVESTIGATOR’S ASSURANCE FORM**

**Statement of BSPH PI Responsibilities when Relying on a NON-HOPKINS External IRB**

*Under a reliance agreement with an External sIRB, BSPH retains responsibility for completing all site-specific ancillary reviews required to conduct the research and for ensuring that any site specific requirements are communicated to the External sIRB. It is also responsible for retaining a local file of the currently approved study documents and for monitoring reportable events that occur at the BSPH site. An External sIRB 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 BSPH PI seeking to rely on an External sIRB is responsible for the following****:*

1. Submitting an application to the BSPH IRB’s PHIRST system which includes the submission materials initially approved by the external sIRB, including the approved template consent;
2. Engaging as needed the research support offices/centers at JHU with oversight responsibility for the research and provide any additional materials needed to those entities in order to grant approval;
3. Adding all co-investigators and student investigators to the PHIRST application, and monitor and maintain training records to ensure they comply with BSPH IRB training requirements;
4. Reporting to the IRB of record any revisions necessary to the approved documents based on the BSPH IRB’s site specific review (including the review of any JHU ancillary committees) in order for the research to be conducted at this site;
5. Once approved as a site by the external IRB, uploading the initial approval letter in the PHIRST system in order for research activities to commence at the BSPH site;
6. Maintaining an active record of all submissions to the external sIRB and inform any research support office/center of any proposed modifications that may impact the support provided;
7. Submitting any modifications to the BSPH IRB that require site specific review. Examples of such changes include:
	1. BSPH personnel/PI changes
	2. Changes in funding [e.g., the planned federal funding source changes and the study will be industry-sponsored]
	3. Changes in conflicts of interest
	4. Change to data security procedures
	5. Changes for which there is a specific institutional policy/state law requirement
	6. For studies occurring at JHH/affiliates, changes that impact procedures that have a billable code in EPIC (for which a change in the PRA would be required)
	7. Changes to study procedures such as drug dispensation or 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]
	8. 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]
8. Proceed with implementation of any of the above changes only after receiving acknowledgement from the BSPH IRB office.
9. 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.
10. Uploading the annual re-approval letter to the PHIRST system (prior to expiration of the study approval) in order to maintain an active record (this record will align with the current approval as assigned by the external sIRB);
11. Supplying in a timely fashion reports of protocol events that could qualify as a) unanticipated problems posing risks to subjects or others, b) incidents of serious noncompliance or c) continuing noncompliance. Please consult BSPH IRB if you are uncertain whether your event requires dual reporting to the external sIRB and BSPH IRB.
12. Promptly reporting to the BSPH IRB any notifications of suspension or termination that you receive for the applicable study from the external IRB;

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

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

BSPH PI signature Date

**Print Full Name:**

BSPH IRB Protocol Number:

Study Title: