

Statement of Homewood PI Responsibilities when Relying on an External sIRB

Under a reliance agreement with an External sIRB, Homewood IRB 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 Homewood 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 Homewood PI seeking to rely on an external sIRB is responsible for the following:

1. Submitting an application to the Homewood IRB's eHIRB 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 eHIRB application, and ensuring they comply with Homewood IRB training requirements;
4. Reporting to the IRB of record any revisions necessary to the approved documents based on the Homewood 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 eHIRB system in order for research activities to commence at the Homewood 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 Homewood IRB that require site specific review. Examples of such changes include:
 - a. Homewood personnel changes
 - b. Changes in conflicts of interest
 - c. Change to data security procedures
 - d. Changes for which there is a specific institutional policy/state law requirement
 - e. Changes to study procedures
8. Uploading the annual re-approval letter to the eHIRB 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);
9. 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 the Homewood IRB if you are uncertain whether your event requires dual reporting to the external sIRB and the Homewood IRB.
10. Promptly reporting to the Homewood 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.

Homewood PI signature

Date

Print Full Name:

Address:

Email:

Phone number: