

## How to Request BSPH Reliance on an External IRB

*Note: All PIs who want JHU to serve as the Single IRB (sIRB) for an NIH funded study for U.S. based sites must submit the application to the SOM IRB's sIRB system.*

### Initial Application in PHIRST

A BSPH PI who wishes to have BSPH rely on an external institution's IRB, must send an email to the BSPH IRB Office at [BSPH.irboffice@jhu.edu](mailto:BSPH.irboffice@jhu.edu) to request a reliance submission. The IRB Director will help determine if a reliance agreement is possible and what kind of Reliance Agreement is required for the particular study. **The PHIRST system has an sIRB application (see Question 13 on the first page)** that the PI must complete whether the proposal is at the grant submission stage or already funded. The PI must complete this application and upload all requested documents.

- The PI must identify all the study team members who will be engaged in human research at the BSPH site, and must ensure that they are all registered in the PHIRST system and have completed necessary training. The BSPH IRB is responsible for verifying the qualifications and training of the local study staff.
- For studies that have been funded, the PI must upload the protocol, consent documents, and other recruitment materials proposed for use at the BSPH site, the sIRB approval letter, and the Reliance Agreement signed by both institutions.

The BSPH IRB will review the submitted materials. If the project is at the grant proposal stage, the IRB will upload a "Letter of Support" that the PI may provide to the Lead Site. If the project is funded, the IRB will assist with obtaining a Reliance Agreement between the BSPH and the external IRB. It will perform the local context review, which includes reviewing the submitted protocol and consent documents as well as obtaining any approvals required from ancillary reviewers (HIPAA, COI, KKI, Biosafety, P&T, etc.). Once the local context review is complete, the BSPH IRB will upload a Local Context Approval letter into PHIRST and will return it to the BSPH PI. **No research may start without completion of this process; the provision of the Local Context Approval Letter is notice that the PI may begin.**

### Continuing Review

The BSPH PI is required to report to the BSPH IRB:

- any revisions to the approved study documents that could affect the local site review, including changes that could require re-review by our ancillary reviewers (P&T, COI, HIPAA, etc.),
- personnel changes,
- data security changes,
- changes that relate to institutional policies or local legal/regulatory requirements,
- the annual re-approval letter produced by the external IRB, and
- the report of any protocol events (unanticipated problems posing risk to subjects or others and incidents of non-compliance), and any suspensions or terminations of the study.