****

 **BSPH IRB RELIANCE REQUEST FORM: NON-HOPKINS EXTERNAL IRB**

*See:* <https://www.jhsph.edu/offices-and-services/institutional-review-board/reliance-agreements-and-single-irb/>.

**BSPH IRB will not sign a reliance agreement with an external institution’s IRB if:**

* The external institution’s IRB does not have a Federal Wide Assurance (FWA)
* The external institution is outside the United States
* The research meets criteria for Exemption from IRB review (email bsph.irboffice@jhu.edu

|  |  |
| --- | --- |
| BSPH PI Name:       | BSPH IRB No.:       |
| Study Title:       |

**External IRB Site Information [to be completed by BSPH PI]**

|  |  |
| --- | --- |
| **Please describe the research activity and how it involves human subjects (i.e., research use of their personally identifiable private information or identifiable biospecimens.)** |       |
| **Is BSPH the primary grant recipient?** | YES [ ]  NO [ ]  ***If yes,*** please provide the funder’s name:       and Grant Number (if any):     ***If no*,** for grant review purposes, please provide the IRB registration number for the external reviewing IRB panel (consult with reviewing IRB for information).       |
| 1. **Please describe the research activities that the BSPH study team will conduct. We are trying to assess the level of involvement and control our investigators have over the conduct of this study.**
 |       |
| 1. **Name of Proposed External Institution with IRB oversight:**
 |       |
| 1. **Has the external institution’s IRB approved the study?**
 | YES [ ]  NO [ ]  UNDER REVIEW [ ]  |
| 1. **Name of Reviewing Site PI:**
 |       |
| 1. **Reviewing Site PI Phone #:**
 |       |
| 1. **Reviewing Site PI Email:**
 |       |
| 1. **Name and Title of Reviewing Site IRB Point of Contact:**
 |       |
| 1. **Reviewing Site IRB Point of Contact Phone #:**
 |       |
| 1. **Reviewing Site IRB Point of Contact Email:**
 |       |
| 1. **Name and title of Institutional Official (e.g., Joe Doe, MD, Medical Director):**
 |       |
| 1. **Active FWA # for external IRB (**See: <https://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc>)
 |       |
| 1. **Will the external IRB serve as the HIPAA Privacy Board for this study?**
 | YES [ ]  NO [ ]  N/A [ ]   |
| **Are all investigators and study team members from BSPH credentialed and/or appropriately qualified and meet BSPH’s standards for eligibility to conduct the research as described in the approved protocol?** | YES [ ]  NO [ ]  ***If no,*** please provide details:       |
| **Are all BSPH investigators and study team members listed on this PHIRST application?** | YES [ ]  NO [ ] ***If no,*** please ensure that each person is registered in PHIRST and selected for participation on the study team for this application.***If yes***, please explain each BSPH study team member’s role in the research application:       |
| **Have all members of the BSPH research team completed required ethics, HIPAA, GCP and/or sIRB training?** | YES [ ]  NO [ ]  ***If no,*** *please provide details:*       |
| **Did BSPH determine there is a relevant individual or institutional financial COI for this protocol?** | YES [ ]  NO [ ]  ***If yes****,* provide a summary of the conflict and management plan or attach documentation:       |
| **Does the external IRB REQUIRE use of its own Reliance Agreement template to be signed by BSPH IRB?** | YES [ ]  NO [ ] ***If yes,*** please upload to Question 13.2. in your PHIRST application. |
| **Please provide a rationale as to why the named external IRB has been selected to serve as the IRB for this study.** |       |
| **Please describe the recruitment plan for participants at the research site where BSPH investigators will be working.** | N/A [ ] Describe:       |
| **Please describe the process for obtaining informed consent, including identifying the BSPH study staff, if any, who will obtain informed consent.** | N/A [ ] Describe:       |
| **Please describe the data security plan for data from participants for which BSPH investigators are responsible.** | N/A [ ] Describe:       |
| **Please describe the data and/or biospecimen sharing plan, including proposals about future use of data/specimens collected from participants for which BSPH investigators are responsible.** | N/A [ ] Describe:       |