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|  | **JHSPH IRB UPDATE REPORT FORM**  **For IRB Reliance Agreement/sIRB**  *Use to update JHSPH IRB on study activities under*  *review by an external IRB.*  **INSTUCTIONS FOR CHECK BOXES:** **DOUBLE LEFT [CLICK] TO ENTER A CHECK MARK** | |
| JHSPH Principal Investigator: |  | |
| IRB No.: |  | |
| External IRB: |  |  |
| Study Title: |  | |
| 1. Is the study complete and no longer active or under IRB oversight?   Yes  No  ***If yes, please provide the most recent continuing review/progress report letter issued by the reviewing external IRB, and if you are still enrolling at a JHSPH site, a redacted version of a recently used consent form*.**   1. Has your (and the JHSPH) role in the project changed since the initial agreement was signed?   Yes  No   1. Have any changes been approved by the reviewing external IRB since your last approval? If yes, please check off the appropriate box(es) below:   Changes to the recruitment plan for participants at the JHSPH site.  Changes to the process for obtaining informed consent, including identifying the study staff who will obtain informed consent.  Changes to the data security plan  Changes to the data and/or biospecimen sharing plan, including proposals about future use of data/specimens collected at the JHSPH site.  Changes 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.).  Changes that relate to institutional policies or local site legal/regulatory requirements.  Changes to your research activities, funding, or anything else that could affect the JHSPH IRB’s responsibility for oversight of activities associated with JHSPH investigators.  Changes to the JHSPH study team members/co-investigators who will be “engaged” in human subjects research activities.  ***If checked, please submit an administrative amendment to add/remove JHSPH personnel from the study***.  Please explain the changes that you have checked off above in the space below.     1. Has the PI at the external institution reported problem events (unanticipated problems posing risks to subjects or others and incidents of non-compliance), and any suspensions or terminations of this study? If yes, please explain. | | |