**FORM: Annual Activity Report for Continuing Review**

Specimen or Data Banking

This form is for use with projects submitted via RUTH that include banking specimens or data for future uses beyond the original study. Reporting should be limited to the data and specimens that are stored at ISMMS and/or are under the control of the study’s PI.

**RUTH Study Number:** Click or tap here to enter text.

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| --- | --- |
| 1. **GENERAL** | |
| [Total consented to future use] | How many individual subjects have consented to future use of their specimens and/or data? |
| Yes  No | Have any specimens or data been used or shared with other researchers?  *If yes, provide project title, PI, location and date.*  Click or tap here to enter text. |
| Yes  No | Have any stored specimens or data been shared with other researchers, other than the original collaborators, for the purpose of this project?  *If yes, provide project title, PI, location, number of specimens or data and date of transfer*  Click or tap here to enter text. |
| Yes  No | Has the study team used any stored specimens or data for purposes other than conducting the approved research in this protocol?  *If yes, provide project title, numbers of specimens or data used to date*  Click or tap here to enter text. |
| Yes  No | Have any stored specimens or data been withdrawn for any reason?  *If yes, please explain how many and why?*  Click or tap here to enter text. |
| **2. RE-CONSENT**  **The following questions are specific to living individuals with stored specimens or data who have turned 18 and/ or regained capacity since their data/specimens were collected and stored for future research.**  **If all participants have always been 18 years or older and have capacity, check here and skip this section** | |
| Yes  No | Have any living individuals turned 18 and/or regained capacity since the specimens or data were stored?  *If yes, provide a breakdown of the number reconsented, the number yet to be reconsented, and the number that refused reconsent.*  Click or tap here to enter text. |
| Yes  No | For those who have not been reconsented or who refused reconsent, has they been withdrawn from the study and have future use of their data been restricted?  *If no, provide a narrative explaining the reason. Use HRP-095 – SOP- Obtaining Informed Consent When Minor Turns 18 as a guide in providing your explanation.*  Click or tap here to enter text. |