Research Data Repository

Continuing Review Annual Update Form

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| --- | --- |
| **Principal Investigator:**  |  |
| **Repository Protocol Title:**  |  |
| **eIRB #:** |  |
| **SOP Version Date(s):** |  |

|  |  |
| --- | --- |
| **Repository Administrator:** |  |

Please answer the following:

1. Was all data contributed to your repository during this cycle collected under IRB approval with either informed consent or an appropriate waiver of consent?

[ ]  Yes [ ]  No [ ]  N/A- no samples/data have been collected to date

1. How many subjects’ data have been contributed to your repository since it was opened?
2. Was any data distributed from your repository since your last annual report (during this Continuing Review cycle)? [ ] \*Yes [ ] No

\*If Yes, list below the eIRB #s for the studies that received the data, and/or please attach a list of all studies that **received** data from this repository.

 eIRB#:

4. What type of data was distributed? (select one):

[ ]  De-identified (do not contain ANY of the 18 HIPAA Identifiers)

[ ]  Identifiable

[ ]  N/A-no data was distributed

5. How was data distributed? (select all that apply):

[ ]  Electronic

[ ]  Hard copy

[ ]  N/A- please explain why:

6. Has there been any change to the SOP regarding storage location?

[ ] \*Yes [ ] No

\*If Yes, please explain:

7. Have any deviations, reportable events and/or any other problems occurred in the last Continuing Review period, especially Privacy or Information Security Incidents? [ ] \*Yes [ ] No

\*If Yes, please explain:

8. Do all security safeguards listed in the SOPs remain in place? [ ] Yes [ ] \*No

\*If No, please explain:

My signature below indicates that I have reviewed for accuracy and completeness all information submitted in and with this form and have read and agree to the above assurances:

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Principal Investigator Date

**Upload this form under Question 6.0 of your Continuing Review in eIRB. You must name this document “IRB #XXXXXX RDR Annual Report 20yy-20yy” (updating the time period covered by the report accordingly) when uploading it in eIRB.**

 **Maintain a copy of this completed, signed form in your records.**