IRB Appendix C - Data Repositories

Rev. August 2016

Complete this form to request approval to obtain and store participants' data for future, as yet unspecified, research. Do not complete this form for short-term, study-specific data collection and analysis (limited to the current research study) or if the research solely involves use of previously existing data. The consent process should address possible future uses.

Coded - *Direct personal identifiers have been removed (e.g., from data or specimens) and replaced with words, letters, figures, symbols, or a combination of these for purposes of protecting the identity of the source, but the original identifiers are retained in such a way that they can still be traced back to the source. Note: A code is sometimes also referred to as a "key," "link," or "map."*

De-identified - *All direct personal identifiers are permanently removed from the data, no code or key exists to link the data to the original source or to the individual, and the remaining information cannot be used to reasonably identify the individual.*

Principal Investigator:

Project Short Title:

1. Describe the type(s) of data to be collected and stored. ***Upload a copy of the data collection form(s) to IRBNet.***

2. Indicate the format of the data (check all that apply): ☐ Electronic (including video, digital, etc.) ☐ Hard Copy

3. Indicate whether the data to be stored will be (check one): ☐ Coded ☐ De - Identified

4. Describe the process to de-identify the data, if applicable:

5. If the data is **coded**, will the information include individually identifiable protected health information (PHI)? ◯ Yes ◯ No
HIPAA Authorization is required for storage of data that includes PHI.

6. Describe the source(s) and circumstances of the data collection. Explain whether data will be obtained directly from participants or from a secondary source.

7. Describe the purpose of collecting and storing the data.

8. Will there be limits on the data's intended future use (e.g., for cancer research only)?

Yes
No

Explain why or why not:

9. Specify the procedures by which participants can withdraw their data from storage for future research.

10. Will data be released to other investigators?

Yes
No

If **Yes,** complete the following:

a. List those with whom data may be shared, including whether or not this could include non-URI researchers.

b. Indicate whether the data to be released will be (check one):

- ☐ **Aggregate data only** (no individual data elements)
- ☐ De - Identified
- ☐ Coded

c. Describe the process for requesting and releasing data. State the individual(s) responsible for verifying IRB approval (or exemption) before data release and his/her qualifications or training. ***Upload copies of all applicable forms/agreements that will be used to request and release data to IRBNet.***

11. Describe the physical location/equipment where data will be stored.

12. Describe the procedures for securing data (e.g., locked file cabinet, secure network, password access, and encryption) including devices for temporary transport of data.

13. Explain who will manage the stored data.

14. Indicate how long the data will be stored:

- ☐ Indefinitely
- ☐ Other - Specify:

15. Describe the process for destruction or de-identification of identified/coded data at the end of the retention period (as applicable) or if the PI leaves the university.