IRB Appendix H - Storage of Biological Materials

Rev. June 2015

Complete this form to request approval to collect and store blood, tissue, or other human biological materials for future, as yet unspecified, research. Do not complete this form for short-term, study-specific collection and analysis (limited to the current research study) or if the research solely involves use of previously existing stored specimens. 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/specimen, no code or key exists to link the data/specimen to the original source or to the individual, and the remaining information cannot be used to reasonably identify the individual.*

Principal Investigator: _____ IBC Approval #: _____

Protocol Short Title: _____

IBC approval is required for biological materials

1. Describe the type(s) of specimens to be collected and stored.

2. Indicate whether the specimens to be stored will be: ☐ Coded ☐ De-Identified

3. Describe the process to de-identify the specimens, if applicable:

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

5. If specimens are coded, will the information include individually identifiable protected health information (PHI)? ***HIPAA Authorization is required for storage of data that includes PHI.***

6. Describe the purpose of collecting and storing the specimens:

7. Will there be limits on the specimen's intended future use (e.g., for cancer research only)? ◯ Yes ◯ No

Explain why or why not:

8. Specify the procedures by which participants can withdraw their specimens from storage for future research.

9. Will samples be released to other investigators? ◯ Yes ◯ No

If Yes, complete the following:

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

b. Indicate whether samples to be released will be (check one): ☐ Coded ☐ De-Identified

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

10. Describe the physical location/equipment and security provisions where the specimens will be stored.

11. Explain who will manage the stored specimens.

12. Indicate how long the specimens will be stored:

☐ Indefinitely

☐ Other - Specify:

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