Touro University Nevada

Touro University Nevada Institutional Review Board (IRB)

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**Addendum 9: Blood, Tissue, Bodily Fluids, or Other Biological Specimens or Samples**

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| --- | --- |
| **Principal Investigator:** |  |
| **Study Title:** |  |

**This addendum is designed for researchers who plan to use specimens/samples from human participants such as blood, other tissues, bodily fluids, or other biological material in their research. Such research qualifies as human subjects’ research, and as such requires review by the Institutional Review Board (IRB). Please complete the addendum form along with the main application form and return it to the IRB.**

**Procedures and Description of the Specimens/Samples**

1. Which of the following describes your role in handling the specimens/samples involved?

a. Collecting YES  NO

b. Receiving YES  NO

c. Sending YES  NO

d. Other (i.e., already under possession of specimens/samples) YES  NO

If you checked ‘YES’, describe your role:

1. Do the specimens/samples:
2. Already exist (previously collected for a different purpose)? YES  NO

**Or**

b. Are being collected for the express purpose of this study? YES  NO

1. Check the type(s) of the specimens/samples.
2. Commercially Available Cell-Lines/cell cultures
3. Vendor Name, City, State, and Country:
4. Non-commercial cell-lines/cell cultures
5. Name and affiliation of source: 
   1. Did the source have IRB approval when the specimens/samples were originally collected, and you can document the approval? YES  NO

**If yes,** include with this application the documentation in the form of an IRB approval form for the collection(s).

1. Specimens/samples removed during medical treatment (surgical samples, biopsies, etc) for purposes **other** than for your research

Name and affiliation of source:

Reason for removal (e.g., breast tissue removed during mastectomy):

1. Autopsy material
2. Repository
3. Pathological waste
4. Publicly available source

**If checked**, describe the source.

1. Specimens/samples removed/collected from participant primarily for your research  
    (e.g., because things like urine, buccal swabs, etc aren’t really “removed”)

**If checked,** contact the IRB for more information.

1. OTHER: Please specify type of specimens/samples  and source:
2. Specimen/sample Information:
3. Population source for specimens/samples (check all that apply):

i.  Healthy adults

ii.  Pregnant women

1. Children
2. Other, please specify

b. Describe the specimens/samples you will be obtaining (e.g., mammary gland tissue).

c. If they are cell lines, describe the tissue type(s) in the culture (e.g., epithelial cell lines).

d. Will blood be drawn from participants for your research? YES  NO

**If yes**, answer the following:

1. Amount of blood:

1. Number of blood draws:

1. Collection method (finger stick, heel stick, ear stick or venipuncture):
2. Are the specimens/samples fixed and, if so, with what fixative? (will represent a trivial risk level if for example, these are paraffin-embedded path specimens/samples)

1. If these blood and other tissue samples are from any source OTHER THAN a commercial vendor, describe the participants in as much detail as you know (age range, sex, pre-existing condition [e.g., Type II diabetes], nationality, where they reside, etc.).

1. If human participants are located at a site other than TUN, will anyone on the **research team** have **direct contact or intervention** with them? (Examples: participant's physician, obtaining specimens/samples directly from the participant, interviewing the participant) YES  NO
2. If you are receiving specimens/samples from outside sources, please check all that apply to the Specimens/samples:
3. Specimens/samples will be anonymized/unlinked. (The Specimens/samples cannot be linked to individual subjects by you or your collaborators, even if the collaborators are at other sites.)
4. Specimens/samples will be coded; however that code cannot be used by either the sender or the receiver to identify specific individuals.
5. Specimens/samples will be coded so that the provider of the Specimens/samples can link them to specific individuals but the receiver will not be able to do so.
6. Specimens/samples will be coded, and the master list will be retained by the receiver, separate from the specimens/samples, but can be used to link the specimens/samples to specific individuals.
7. Specimens/samples will be labeled with identifying information.
8. If the Specimens/samples were received from a source outside of TUN, will you send results back to the provider(s) identified earlier in this form?
9. **No,** I will not send results back to the provider(s).
10. **Yes,** I will send aggregate results to the provider(s).
11. **Yes**, I will send results to the provider(s) that are linked to identifiable individuals.

**If yes,** does the provider intend to link your data to identifiable individuals?

YES  NO

1. Please explain what will happen to the samples once the research is completed.