JEFFERSON—Office of Human Research

### HUMAN BIOLOGICAL SPECIMEN, TISSUE AND/OR GENETIC RESEARCH

**Version Date – FOR OHR USE: 11/1/18**

Use of identified human tissue and biological specimens collected for research purposes is subject to IRB review. This includes discarded/previously stored surgically removed tissue, tumors, blood, urine, etc. Please provide a written protocol with OHR-15. Form must be typed.

Study Title:

Principal Investigator:

Department: Division:

Contact Person:

Email address: Phone:

PART A - SUMMARY OF RESEARCH

1. Is your laboratory certified as a BL 2 facility?  Yes  No

*If No, contact the Institutional Research Biosafety Officer at 215-503-7422 to arrange an inspection for certification.*

1. If the protocol involves sending tissue to a commercial entity, please certify that the following criteria are met (*see TJU policy #110.17, “Collection, storage, use and distribution of tissue for research purposes”).*

The PI certifies that s/he (*check applicable statements)*:

Will have significant input into the study design and/or conduct of the study.

Will receive experimental data and participate in data analysis.

Has established the right to be a co-author on any publications related to this protocol

Certifies that Jefferson ORA is negotiating a sponsored research agreement, to be signed prior to work commencing.

1. Type Of Specimen(s) Requested:

Blood  Urine  Sputum  Other (specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Tissue (specify type) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Tumor (specify type) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Tissue/tumor specifications:  Fresh Sterile  Forman-fixed  Other: \_\_\_\_\_\_\_\_\_

1. Number Of Specimens Desired: \_\_\_\_\_\_\_\_\_\_\_.
2. Specimens allocated for research purposes may reduce the amount of material available for clinical analysis, future storage or testing. Please justify why the amount of tissue you need is the minimal amount necessary.
3. Where will specimens be obtained? *(provide department, location, and supervisor of lab or storage facility*)
4. Who has authorized your collection of specimens, if they are not from your lab? Please provide name and contact information for this person.
5. If specimens are not currently stored in your lab, provide a detailed explanation of how they will be obtained.

How will confidentiality of subject data be protected?

1. This request is for:

Specimens that already exist/are currently stored (retrospective)

Specimens to be obtained in the future (prospective)

1. Purpose Of Specimen Collection (Describe succinctly): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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1. Please list names of all individuals involved with study/project.

|  |  |
| --- | --- |
| **Name** | **Precise Role/Duties in Study** |
|  |  |
|  |  |
|  |  |

1. If tissue is to be coded and identifiers will be maintained in a separate file or location, please describe the coding mechanism.
2. Will Biological Specimens be released outside of the site?  YES  NO

If yes, please specify who will receive the specimen, for what purpose, and whether identifying information will be released. (Informed consent is required to release specimens with identifiers outside of the site). If biological materials are to be sent outside of the site, contact Innovation Office Management as a Material Transfer Agreement may be necessary.

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1. Will the specimens be stored/banked for future use?  YES  NO

If yes, where will the tissue be stored? What future types of research would you anticipate?

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1. HIPAA (Health Insurance Portability & Accountability Act) Privacy Rule Protections:

The following items are categorized as identifiers under the Privacy Rule regulations. Please check off which of the following will be obtained:

Patient/Subject Name

Address street location

Address town or city\*

Address state\*

Address zip code\*

Elements of Dates (except year) related to an individual. For example, date of birth, admission or discharge dates, date of death\*

Telephone number

Fax Number

Electronic mail (email) address

Social security number

Medical record numbers

Health plan beneficiary numbers

Account numbers

Certificate/license numbers

Vehicle identification numbers and serial numbers including license plates

Medical device identifiers and serial numbers

Web URLs

Internet protocol (IP) address

Biometric identifiers (finger and voice prints)

Full face photographic images

Any unique identifying number, characteristic code

Link to identifier (code)

If any of these items are checked off, the data cannot be considered de-identified and authorization from the subject or a waiver of authorization (OHR-3) from the IRB is required.

\*Use of these items alone falls under provisions of a “limited data set”, which requires the signing of a data use agreement (OHR-6) by Principal Investigator. Please complete and attach, if applicable.

**PART B - TISSUE STORAGE FOR FUTURE RESEARCH**

1. Will collected biological specimens be stored for future research, maintained in a repository, or be used to establish a DNA bank?  YES  NO

If NO, please delete the rest of this section. If YES, please address the following:

Where will the tissue be stored? Specify the location within or outside of Jefferson.

What is the purpose of storing the tissue?

Will identifying information (or links to identifiers) be maintained with the tissue?

YES  NO (If YES complete an OHR-3).

Who will have control for distributing the tissue?

Would a subject be re-contacted and given information derived from the banked specimens?  YES  NO

If YES, under what circumstances?

Would a subject be re-contacted and asked for additional information related to his/her disease or condition?  YES  NO

If YES, under what circumstances? (NOTE – may require submission of a new project for IRB review and approval. Please contact OHR for assistance.)

Are subjects able to withdraw tissue or ask that identifying information be removed?

YES  NO

1. Please describe what types of research you would anticipate using this specimen for in the future.

**PART C - GENETIC RESEARCH**

Does this study involve genetic research?  YES  NO

If NO, please delete the rest of this section. If YES, please address the following:

1. Briefly describe the genetic research:
2. Will the analysis uncover any gene listed as a “clinically actionable gene” according to the list curated by the American College of Medical Genetics and Genomics? If YES, please list and explain a plan of management of secondary findings.
3. Will results of tests be given to subjects?  YES  NO
4. Are subject’s family members going to be studied?  YES  NO
5. Will results of tests be given to subject’s family members?  YES  NO

If YES to question 3 or 4, please explain your plans for disclosure of information.

1. Will subjects or family members be given the option to not receive information about themselves?  YES  NO

If NO, how will information be disclosed to them?

1. If there is the possibility that incidental findings may be made (i.e., paternity, diseases or conditions other than the one under study), explain your plan for disclosure to subject.

YES  NO

1. What support services are available to the subject/family member after s/he receives information (e.g., genetic counseling)?
2. Will research findings be disclosed to the subjects’ physicians for clinical use?

YES  NO

1. Are there psychological and/or social risks associated with the research and the results obtained?  YES  NO

If YES, what are they and what steps will be taken to minimize or eliminate these risks?