



HUMAN TISSUE TRANSFER GUIDELINES

Definitions

Human Tissues means any biological product or byproduct obtained from a living or deceased individual that is sufficient in type and quantity to permit an analysis of its physical or biochemical properties. This definition includes solid tissues, cells, cell cultures, molecules derived from tissues (DNA, RNA, proteins, etc.) and body fluids, and associated data and information.

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Description

These guidelines apply to *Human Tissues* (as defined above) used in the conduct of research by third party non-profit research institutions. In general, all tissues and data obtained or maintained under the auspices of the University of Utah are assumed to be the property of the University of Utah unless a formal agreement with the University designates otherwise.

Principles Guiding the Transfer of Research Assets

- The University of Utah will comply with all legal and regulatory obligations.
- The University of Utah will protect the welfare of participants in research and honor their expectations with respect to the use of their *Human Tissues*.
- The University of Utah will protect the value to investigators and their use of *Human Tissues* for the conduct of research.
- The University of Utah will protect the value to the University of Utah of *Human Tissues* as property and resources of the University of Utah, and for the development of intellectual property.

Material Transfer Agreement (MTA)

If your research involves the collection and use of *Human Tissues* and you intend to transfer these samples to a location outside of the University of Utah, a Materials Transfer Agreement (MTA) may be required from Technology & Venture Commercialization Office (TVC). The MTA must be signed and approved by TVC before the IRB will give final approval for a study.

Required for:

- All transfers that involve *Human Tissues*; or
- All transfers that involve *Human Tissues* that may result in the limitation of access to these research resources by investigators at the University of Utah.

Required unless:

- The Technology & Venture Commercialization Office (TVC) has approved the tissue transfer through a contract or grant agreement that adequately specifies the management of tissues and associated data; or
- A service agreement has been approved with a provision that tissue samples and data will not be retained or used for research purposes other than for the purposes stated in the service agreement.

Investigator's Responsibilities

The use of *Human Tissues* may only be done as specified in the patient consent forms. The investigator is responsible for reviewing the original consent forms to confirm the appropriate use of the samples that you wish to transfer. Investigators should understand that there are some cases in which the University of Utah cannot permit transfer of samples to another

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.



entity. Investigators must complete the appropriate form found on the TVC website. The TVC will negotiate the MTA and will seek approvals from the department chair, the Vice President for Research, and the IRB prior to finalizing the MTA.

Transfers of Human Tissues for Research Purposes from the University of Utah

Request for approval of a transfer is made by either the Principal Investigator or the third party recipient through completion of the questionnaire available on the TVC website. The notice is shared with the IRB and OSP.

1. TVC reviews request and where appropriate negotiates an MTA.
2. IRB reviews the proposed transfer to ensure the following:
 - The intended use is consistent with the consent given by participants under the original collection protocol(s).
 - The intended use will not conflict with any pre-existing obligations attached to the samples.
 - The intended use is consistent with the University of Utah’s obligations under federal and state laws, regulations, and guidelines, including HIPPA.

Transfers of Tissue Collections

When an investigator or research program seeks to transfer *Human Tissue* set(s) from the University of Utah, TVC will need to prepare an MTA. This may occur with the departure of an investigator who wishes to transfer *Human Tissues* to his or her new institution or in other collaborations involving the transfer of large or significant *Human Tissue* set(s). A key consideration is whether the transfer of such research resources will deny access to the resources by other investigators or programs at the University of Utah.

Points to Address

Application:	<p>1. Study Information page, Procedures: Describe the transfer and the intended use of the samples. <u>The description should include where and to whom samples may be shared or sent to, for what purpose, and what information will be sent with the samples.</u></p> <p>2. HIPAA and the Covered Entity page: Depending upon the information being shared with the samples, it may be appropriate to complete the <u>Safe Harbor (De-Identification) page or Limited Data Set page.</u> Either page may be selected in question 1 of the <u>HIPAA and the Covered Entity page.</u></p> <p>3. Resources and Responsibilities page, question 3: State that no data or material will be transferred to outside institutions or investigators until any and all agreements and contracts are in place with TVC.</p> <p>Documents and Attachments: The signed copy of the MTA must be scanned and attached to the Documents and Attachments page.</p>
Consent Document:	1. The consent must be consistent with the intended use of the samples.

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References & Links

Technology Commercialization Office <http://www.tvc.utah.edu/>

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