

Investigator Guidance Series

University of Utah Institutional Review Board

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)

For studies that involve the transfer of *Human Tissues* outside of the University of Utah, a Materials Transfer Agreement (MTA) may be required from Technology Commercialization Office (TCO). The MTA must be signed and approved by TCO 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.

** In all cases, no personally identifiable information relevant to the health or medical condition of the tissue source(s) are transferred with the *Human Tissues*

Required unless:

- The Technology Commercialization Office (TCO) 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.

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

Investigator Guidance Series

University of Utah Institutional Review Board

Routine 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, and notice is received by TCO, IRB or the Office of Sponsored Projects (OSP). The notice is shared inter-office with the IRB, TCO and OSP.

1. TCO reviews request and where appropriate negotiates an MTA to ensure:
 - The transfer will not conflict with any pre-existing obligations attached to the *Human Tissues*.
 - The transfer will not substantially affect the University of Utah's right and ability to use the *Human Tissues* for other purposes.
 - The transfer will benefit the University of Utah by requiring a re-deposition of the data created by the third party.
 - The transfer will benefit the University of Utah through a requirement that the third party grant the University a right to use intellectual property developed using the *Human Tissues* for its own non-commercial research purposes.
 - The transfer will benefit the University of Utah by requiring the third party to share any financial benefit derived from the transfer commensurate with the impact of the contribution the transferred *Human Tissues* have made.
 - The use of the *Human Tissues* is appropriately limited in purpose and time.
 - The *Human Tissues* will be returned or destroyed at the termination of the project and MTA.
2. IRB reviews the proposed transfer to ensure the following:
 - The intended use is consistent with the consents 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

The following guidelines apply when an investigator or research program seeks to transfer *Human Tissue* set(s) from the University of Utah. 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.

1. TCO reviews the proposed transfer as outlined above for routine transfers.
2. IRB review the proposed transfer as outlined above for routine transfers.
3. Approval of the faculty member's Chair and the University Administration is required for transfers of *Human Tissue* collections. The key question is whether a transfer will inappropriately limit the ability of the University of Utah to pursue research activities.

At the request of a faculty member, a Department Chair, the TCO, or University of Utah Administration, the Tissue Advisory Committee (TAC) will acquire the relevant information and prepare a recommendation for the University of Utah administration regarding the transfer of sample sets or datasets. The TAC will collaborate with the IRB and TCO in preparing its

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

Investigator Guidance Series

University of Utah Institutional Review Board

recommendations.

- a. The TAC will discuss the potential transfer with other key investigators as listed on IRB documents to determine whether the transfer will negatively impact research at the University of Utah.
- b. The TAC, in consultation with the TCO, will determine if the following signatures are appropriate prior to transfer.
 - i. Chair of the Department—The MTA and the recommendations of the TAC are submitted to the Chair of the applicable department for signature approval.
 - ii. The Dean of the relevant school or college—The MTA and the recommendations of the TAC are submitted to the Dean of the applicable school or college for signature approval.
 - iii. Vice President for Research—The MTA and the recommendations of the TAC are submitted to the Vice President for Research for signature approval.

Points to Address

Protocol Summary:	1. Study Procedures: Describe the transfer and the intended use of the samples.
Consent Document:	1. The consent must be consistent with the intended use of the samples.
Documents and Attachments:	1. Completed MTA: The signed copy of the MTA must be scanned and attached to the Documents and Attachments page.

References & Links

Technology
Commercialization
Office

<http://www.tco.utah.edu/>

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