

Q. Can I charge a fee for providing human samples?

A. If you would like to charge for your time and effort in collecting or preparing the samples, please use the following guidelines:

(1) If you are providing human samples that you have banked or collected over time for another purpose (e.g. from a clinical trial), you may charge for the expenses you incur in preparing and shipping the samples. This fee is paid directly to your department. You may add the University's 8% infrastructure cost to your total fee, but this is not mandatory.

(2) If you are obtaining human samples for the other party's research purposes and you are also participating in the research, this is considered sponsored research. Please work with your RPM in RMG to create a budget, which includes Stanford's full indirect cost rate for research on campus. ***Note that Stanford does not enter into fee-for-service agreements where the fee is the purchase of human specimens and the service is the procurement and sale of human specimens, and there is no research on part of Stanford faculty.***

Q. I am unsure whether my samples are considered human tissue and require IRB review. What should I do?

A. Submit your protocol to the IRB, which will determine whether transfer of your samples is approved or exempt, or will make a non human subjects (NHS) determination. Regardless of the IRB's decision, transfer of your samples may still require a Human Tissue Transfer Agreement.

Further information about the IRB process and human subjects may be found at the Human Subjects Research website (<http://humansubjects@stanford.edu>).

For questions about this process, please contact ICO at (650) 723-0651 or ico@stanford.edu. You may check the status of your HTA on the web through our Researcher Portal on our website (<http://otlportal.stanford.edu/>). Please contact us if you would like access.

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Human Tissue Transfer Agreement Guidelines



**Stanford Industrial
Contracts Office**
<http://www.stanford.edu/group/ICO>

Outgoing Human Tissue Transfers: Governing Principles and Guidelines

Stanford researchers sending human tissue samples to researchers at other entities for research purposes need to be aware of important IRB and Stanford guidelines governing such transfers.

What is considered human tissue?

Human tissue is specimen, blood products, serum, DNA and other biological materials that are obtained from: (1) patients as part of their regular clinical care, but that are excess and would otherwise be discarded or archived; or (2) individuals who are participating in clinical research and have agreed to donate their specimens for research or for deposit in tissue repositories.

Underlying principles: Dean Pizzo posted the following announcement in the School of Medicine's Dean's Newsletter (December 16, 2002, <http://deansnewsletter.stanford.edu/>):

"Effective immediately, all Stanford personnel who wish to share human tissue or blood products with an individual or organization outside of the university must do so using a Material Transfer Agreement (MTA). There should be a brief scientific justification for the sharing of material provided with the MTA. Exchange of tissue or blood products for remuneration is not a sufficient justification."

Transfer of human tissue to outside parties must be done as part of an activity that is consistent with the instructional, scholarship, and research objectives of Stanford. The transfer must be done in a manner that is consistent with applicable law, including those laws and regulations governing patients' privacy, informed consent, and other rights.

Procedure for outgoing human tissue transfer agreements:

Principal Investigators should submit the following documents to ICO:

1. Completed Human Tissue Transfer Routing Form
2. IRB protocol number or current IRB approval/exemption letter
3. SRC and/or SCRO approval, if applicable
4. Brief research description
5. Scientific justification and value to your research

Once these documents are received and reviewed, ICO will send the receiving entity a copy of Stanford's template Human Tissue Transfer Agreement. ICO and the receiving entity will negotiate the Agreement, if necessary. Once the terms have been agreed on, ICO will send the Agreement to the Principal Investigator for signature. ICO will then sign and obtain the Recipient's signature. Once a fully executed Agreement is in place, the Principal Investigator can send the human tissue to the receiving entity.

IRB approval:

ICO will contact the Stanford IRB to ensure that appropriate protocols are in place before the Agreement is signed. Please note that if the approved protocol does not include a specific reference to

the tissue transfer; that is, identify the entity(ies) where the samples will be transferred, the Principal Investigator may have to amend or revise the protocol to address this transfer. The amended protocol must be reviewed and approved by the IRB before ICO can sign the Agreement. We recommend that you submit or amend/revise your IRB protocol as soon as you know that you will be providing human tissues to a third party.

FAQs

Q. I'm sending patient data - do I need a Human Tissue Transfer Agreement?

A. A Human Tissue Transfer Agreement is not required when the transfer involves only data. However, a data use agreement may be required. Please contact ICO.

Q. What if I'm providing human specimens to a colleague(s) for a second opinion or to share a unique case?

A. A Human Tissue Transfer Agreement is not required - this is considered clinical care.

Q. I'm paying a third party to analyze some samples as a service and not for the third party's research purposes. Do I need a Human Tissue Transfer Agreement?

A. No.

Q. What if I will be providing human tissues to the sponsor of clinical research or a clinical trial?

A. A Human Tissue Transfer Agreement is not required if the transfer is clearly addressed in the clinical research/trial agreement. If the transfer is not addressed in the existing agreement, a Human Tissue Transfer Agreement is needed, unless the receiving entity prefers to amend the existing agreement.