

prefers to amend the existing agreement.

**Q.** Can I charge a fee for providing human samples that I have banked/collected over time?

**A.** You may be reimbursed solely for expenses you will incur in preparing and shipping the human samples.

**Q.** I've been approached by a Company to collect human specimens from a specific population of patients for the Company's research purposes in which I will be participating. Is this considered sponsored research or should I transfer the specimens under a Human Tissue Transfer Agreement and just charge a flat fee?

**A.** This would be considered sponsored research and not a service to the Company. 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 content on the part of the Stanford faculty.

**Q.** A Company has asked me to collect human specimens for the Company's research purposes. I will collect the samples but will not participate in the research. Should I transfer the specimens under a Human Tissue Transfer Agreement and just charge a flat fee?

**A.** No. Unless there is an approved scientific justification for Stanford researchers, the transfer of human tissue/blood to a for-profit company for its research purposes, with or without a fee, is not allowed.

For questions about this process, please contact ICO at 650-723-0651 or [ico@otlmail.stanford.edu](mailto:ico@otlmail.stanford.edu). We look forward to working with you!



6/07

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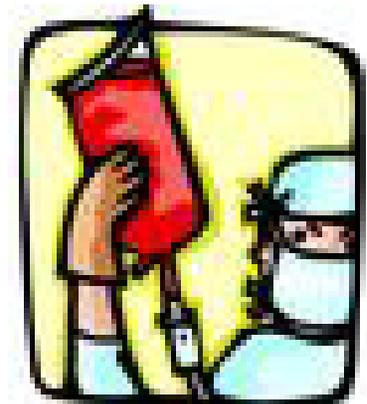
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**Stanford University  
Industrial Contracts Office**

# Human Tissue Transfer Agreement Guidelines



<http://www.stanford.edu/group/ICO/>

## Outgoing Human Tissue Transfers: Governing Principles and Guidelines

Stanford researchers wishing to send 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: tissue, blood products, serum, DNA and other biological materials or specimens 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 who 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 to third parties of human tissue 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 approved protocol
3. Current IRB approval/exemption letter
4. Brief research description

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

### 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; i.e., identifying the entity(ies) to which the samples will be transferred, the Principal Investigator will have to amend/revise the protocol to address the specific 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

## FREQUENTLY ASKED QUESTIONS

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

**A.** A Human Tissue Transfer Agreement is not required when the transfer involves only unidentified data.

**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 a part of clinical care.

**Q.** What if I'm providing human specimens to a colleague(s) for patient diagnosis/clinical purposes?

**A.** A Human Tissue Transfer Agreement is not required.

**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 clinical research/trial sponsor?

**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 Recipient