

SOP 504	RESEARCH INVOLVING TISSUE USE AND BANKING
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Approved by IRB Executive Committee: February 11, 2009
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DEFINITIONS

- a) Human Tissue** 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.
- b) Tissue Repository (Tissue Bank)** Tissue repositories collect, store, and distribute human biological specimens over time. The creation of a tissue repository may be for diagnostic, clinical, or research purposes; although, repositories can be used for multiple purposes. Tissue repository activities involve three components: (a) the collection of samples and data; (b) the storage and data management center; and (c) the re-disclosure of tissues.

POLICY

It is the responsibility of the University of Utah IRB to review and approve research that involves the collection, use, storage, and re-use of all human tissue that is generated within, transferred to, or transferred from the University of Utah and its covered entity.

The University of Utah IRB follows federal regulations governing research involving human subjects, University policy, and IRB tissue use and banking guidelines when reviewing research involving human tissues. All guidance is posted on the IRB website.

All research involving human tissues must be reviewed by the IRB. This includes research involving the following types of samples:

- Samples collected for research purposes
- Samples originally collected for non-research purposes
- Autopsy samples
- Publicly available samples

The use of samples and associated individual data from research tissue banks is governed under the agreement made in the signed informed consent document or the IRB approved protocol for the tissue bank.

1. Samples cannot be used for research outside the scope stated in the informed consent document or the protocol.
2. Individual data cannot be associated with the sample other than as specified in the informed consent document or the protocol.
3. In order to use samples and associated individual data outside of the agreements in the informed consent document or protocol, additional informed consent must be obtained from the participant or the use must be approvable under a waiver of consent (and authorization if applicable).

Samples and associated individual data that are transferred to or from the University of Utah is governed by signed agreements between the University of Utah and the sending/receiving institution, entity, or investigator. Agreements are made through a contract or a Materials Transfer Agreement (see IRB guidance regarding Materials Transfer Agreements on the RB website).

Research that involves veterans or research conducted at the VASLCHCS and which involves tissue use, tissue banking, or development of a commercial product is subject to VA policy as well as IRB policy. The VA designates human subject research to include both living and deceased individuals. Therefore, research involving human tissues from an autopsy or postmortem sampling requires full IRB approval as well as a signed informed consent document by a responsible family member that meets VA requirements.

Human biological specimens, as well as the linked clinical data collected as part of research projects conducted by VA investigators in VA facilities or approved off-site locations, must be maintained at VA-approved tissue banks.

PROCEDURE

1. Procedure for Review of Research Involving Human Tissues

- 1.1. Investigators must submit all information and documents required by the IRB for human tissue use and banking in a new study application.
 - 1.1.1. For research involving tissue banking, consent documents must include the University of Utah IRB tissue banking language. The language is available on the IRB website.
- 1.2. The IRB reviews the plan for using tissues and if applicable, tissue banking. The IRB will approve such research proposals in accordance with the applicable guidelines and regulations.