SUMMARY GUIDANCE: CREATING AND MANAGING TISSUE BANKS FOR RESEARCH

This document is a summary of the IRB's full policy available at: http://irb.utah.edu/guidelines/tissue-bank.php

Key Information

- ➔ Creating and managing a tissue bank requires IRB approval, because this activity meets the federal definition of "human subject research."
- ➔ Tissue banks created and managed by the University of Utah and its affiliates, Primary Children's Medical Center, and the Salt Lake City Veterans Affairs Heath Care System must submit a Tissue Banking Management Plan as part of the IRB application.
- ➔ Consent and authorization forms must clearly describe the tissue bank's plan for storage and use of the tissues and data.

Key Definitions

What is a Tissue Bank?

Tissue banks collect, store, and distribute human biological specimens for research purposes. In the research domain, tissue banks can be created to store large numbers of samples for analysis in future research projects. When a tissue bank is established for future human research purposes, IRB approval for the functions of the tissue bank is required.

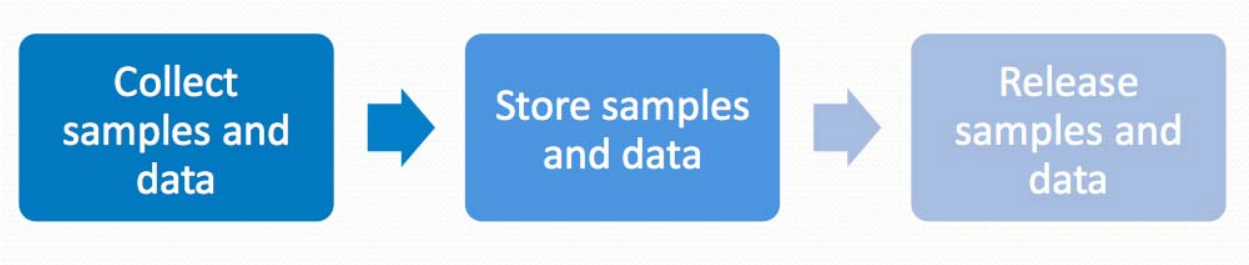
What is Human Tissue?

Any human biological specimen 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.

What does 'De-identified' mean?

De-Identified means that a dataset does not include any of the 18 HIPAA identifiers (see: http://irb.utah.edu/_pdf/IGS%20-%20The%2018%20Protected%20Health%20Information%20PHI%20HIPAA%20Identifiers%20C2013.pdf). It also means that a code number assigned to each individual in the dataset cannot be used to re-identify the individuals. The IRB uses the HIPAA standards of de-identification as described in this definition, even when a study does not involve the use of protected health information (PHI).

Basic Tissue Banking Model



Management Plan

In addition to the usual information contained in a human research protocol and an IRB application, the IRB expects the investigator to maintain a written plan for operating and managing the tissue bank. For a full list of all points to address in the tissue banking management plan, use the IRB guide available online at: http://irb.utah.edu/_doc/TissueBankManagementPlanTemplate.doc

A summary of the points to address is as follows:

Collection of Samples and Data

1. Purpose of the tissue bank
2. Type(s) of samples collected
3. Data points to be collected and linked to the samples
4. Process for obtaining consent and authorization

Storage of Samples and Data

1. Who manages the tissue bank and where will the samples and data be kept
2. Procedures for protecting privacy and confidentiality while samples and data are stored in the tissue bank
3. Procedures for a participant to withdraw samples and data from the tissue bank
4. Process for transfer or destruction of samples and data if the tissue bank closes or the principal investigator leaves the managing institution

Release of Samples and Data for Future Research

1. Description of the governance and oversight for determining if and when samples may be released to investigators for future research
2. Procedures for an investigator to request access to samples and data for use in future research
3. Procedures to ensure approval from the governance/oversight body of the tissue bank prior to sample release
4. Procedure to ensure accompanying data are appropriately prepared (identifiable or de-identified) prior to sample release
5. Process for returning future research results to participants, if applicable

Informed Consent and Authorization

Informed consent must be obtained from participants prior to including individual human samples in a tissue bank for future research, unless a waiver of informed consent is justified. Authorization for use of

protected health information (PHI) must also be obtained if PHI accompanies the sample, unless a waiver of authorization is justified.

For a full list of all points to address in the informed consent and authorization document, use the IRB Tissue Banking Consent Language available online at:
http://irb.utah.edu/_doc/Tissue%20Banking%20Consent%20Language%20091513.docx

A summary of the points to be addressed is as follows:

1. Purpose of the tissue bank
2. Type(s) of samples collected
3. Who manages the tissue bank and where will the samples and data be kept
4. Whether participation in the bank is required or optional in order to be in a specific research project
5. Types of data to be used with the samples, including identifiable information if applicable, and who will have access to the data via the tissue bank and the future research
6. Procedures participants should follow if they want to withdrawn their samples from the tissue bank
7. Commercialization language (verbatim language provided by the IRB)
8. Whether future results or findings will be given back to the participant