

Protocol for Tissue Procurement Services and Cell/Tissue/DNA Repositories

For assistance, contact the IRB at 214-648-3060.

Title page

- Complete title
- Sections and page numbers
- Date of the protocol (printed on each page); date of amendment if the protocol is ever modified
- Investigators responsible for the policies and management of the tissue procurement service/repository
- Investigators' addresses and telephone, fax, and electronic mail numbers

Objective(s)

- Purpose of the service/repository (e.g., to support the laboratory research in cardiovascular disease conducted in the Division of Cardiology at UT Southwestern)

Background

- Rationale for maintaining a repository of samples to be used in a particular area of scientific investigation (e.g. cardiovascular disease)

Eligibility criteria

- Health status (e.g. healthy volunteer, patient with borderline hypertension, diabetes, etc.)
- Age
- Gender
- Race/ethnic background
- Relationship to proband (if applicable)
- Availability for follow-up/future contact
- Ability to speak and read English
- Ability to give informed consent

Recruitment

- All methods used to recruit subjects
- Identity of all persons who recruit/interact with subjects
- Identity of all persons who can learn/discover the names of donor-subjects

Training in the policies protecting the rights and welfare of human subjects in research

- Assurance that all persons who recruit/interact with subjects or who can learn/discover the names of donor-subjects have had approved training:

See <http://www2.utsouthwestern.edu/utswirbt/human/>

- Such persons must provide written assurance of compliance with the statements in the Belmont Report, 45 CFR 46, and Multiple Project Assurance M-1304.

Research information to be collected

(1) Samples

- Source (e.g. finger stick, venous blood, surgical waste, etc.)
- Schedule of collection (timing of each collection)
- Explain whether samples are obtained as part of standard medical/surgical care or solely for research.
- If collected solely for research, identify the amount of the sample (e.g., 5 mL of blood obtained by venipuncture).
- Identity and qualifications of personnel responsible for sample collection

(2) Other data used in the research

- Information collected from interviews with subjects
- Written questionnaires
- Review of donor-subject's medical records
- Use of information about the donor-subject's family that does not require consent of the family member

- Use of information about the donor-subject's family requiring the consent of the family member

Policies of the Repository

(1) Collection of samples

- How the donor-subject will be identified on the collection container (name, initials, diagnosis, medical record number, birth date, Social Security number, surgical-pathology number, medical account number, sponsor's identifier code, etc.)
- If anonymous samples are collected, explain who knows the identity of donor-subjects, and describe any written records of a donor-subject's identity that will be kept (such as a surgical-pathology log).

(2) Storage of Samples

- Name of institution
- Building and room number
- Primary contact (name, telephone number, electronic mail address)
- Duration of storage at this site
- Use of personal identifiers on storage containers that could be traced—in any way—to the donor-subject

(3) Linkage of sample to the donor-subject

- If a sample is traceable to a donor-subject, specify how the linkage is maintained throughout sample processing.
- If a sample is not traceable, specify at what point the link between the donor-subject and the sample is permanently broken.

(4) Use of samples

- Intended use of sample (e.g. study of cardiovascular disease, diabetes mellitus, dementia, etc.) by investigators at UT Southwestern (including Children's Medical Center of Dallas, Dallas Veterans Affairs Medical Center, Parkland Health & Hospital System, Presbyterian Hospital of Dallas, Retina Foundation of the Southwest, Texas Scottish Rite Hospital for Children, Zale Lipshy University Hospital)
- Development of cell lines/DNA libraries
- Intended use of sample by investigators not affiliated with UT Southwestern

- Identify the specimens and other data which may be obtained from the repository.

(5) Use of samples by investigators not affiliated with UT Southwestern

- Maintain a current record of the Multiple Project Assurance for an IRB at another medical center if (a) data and specimens are sent from that medical center to human cell banks at UT Southwestern and/or (b) data and specimens are sent from human cell banks at UT Southwestern to another medical center.

- Distribute the sample collection protocol and informed consent document approved by the IRB at UT Southwestern to collector-investigators (and their local IRB's) if sample and data collection occur at other medical centers and are sent to UT Southwestern.

- Maintain documentation providing assurance that collector-investigators at another medical center are prohibited from providing the cell bank at UT Southwestern with access to the identities of donor-subjects or to information through which the identities of donor-subjects may readily be ascertained.

- If an investigator at another medical center receives data and specimens from investigators at UT Southwestern, maintain documentation that (a) the recipient of samples from a UT Southwestern cell bank acknowledges that the conditions for use of the research material are governed by the IRB at UT Southwestern in accordance with 45 CFR 46, (b) the recipient agrees to comply fully with all such conditions and to report promptly to the cell repository at UT Southwestern any proposed changes in the research project and any unanticipated problems involving risks to subjects or others, (c) the recipient remains subject to applicable State or local laws or regulations and institutional policies which provide additional protections for human subjects, and (d) the research material may be utilized only in accordance with the conditions stipulated by the IRB at UT Southwestern. Any additional use of this material requires prior review and approval by the IRB at UT Southwestern and, where appropriate, by an IRB at the recipient site, which must be convened under an applicable OHRP-approved Assurance.

(6) Approval of sample use

- Identity of person, committee, etc. responsible for determining how samples will be used and by whom

- Required assurance: "All research utilizing subjects' samples must be approved by the IRB at UT Southwestern."

(7) Computer security

- Required assurance: "The computer storing the donor-subject's identity is not linked to the Internet."

(8) Reports of DNA Test Results

Identity of recipients of DNA test results

- Donor-subject
- Donor-subject's legally responsible representative
- Donor-subject's private physician
- Donor-subject's family member(s)
- Donor-subject's medical insurance provider
- Donor-subject's life insurance provider
- Donor-subject's employer

A donor-subject must give explicit, properly-informed, written consent for release of the results of DNA tests to anyone, including the donor-subject.

Requirements of the IRB at UT Southwestern if results of DNA tests are given to subjects

- Labeling of samples must maintain the identity of the donor-subject throughout processing.
- Genetic (and possibly psychiatric) counseling must be available for any donor-subject.
- The laboratory conducting DNA tests must comply with all State and local regulations and maintain current licensure as a clinical laboratory.
- Donor-subjects must be properly informed of the possible psychological, social, economic, and legal risks related to the results of DNA tests.
- Donor-subject must be properly informed of the possibility of unforeseen risks (e.g., identification of a medical risk, risk of being a carrier, or risk to a subject's offspring).
- Clear mechanism for reporting the results of DNA tests to a donor-subject
- Only scientifically-valid, confirmed information may be given to a donor-subject. The information must have significant implications for a subject's health

concerns. A course of action to ameliorate or treat these concerns must be readily available.

- A subject has the choice to receive DNA test results or not unless not having the information could be harmful to the subject.

(9) Publication of private information

- Intent to publish a donor-subject's family tree
- Intent to publish any information which could be linked to the donor-subject

(10) Certificate of Confidentiality

- Intent to obtain a Certificate of Confidentiality

(1) Obtain final, written approval of the consent form from the IRB at UT Southwestern.

(2) Contact Olga Boikess for a Certificate of Confidentiality (301-443-3877).

(3) Submit a photocopy of the Certificate of Confidentiality to the IRB (attached to IRB Form MOD).

(11) Release of a donor-subject's sample to a third party for purposes other than research

- Conditions when a sample clearly labeled with a donor-subject's name could be released to the donor-subject, family member, physician, medical/life insurance provider, employer, etc. (e.g. clinical use)

(12) Future contact with donor-subjects

- Reasons for contacting donor-subjects (e.g. to invite donor-subjects to participate in future research, to provide reports about the results of DNA tests, to invite a donor-subject's family members to participate in research, to obtain health information, etc.)

Removal from study

- Conditions when a donor-subject's sample and other related data may be removed from the database
- Effect on cell lines or libraries

Possible risks to donor-subjects

- Pain or discomfort
- Psychological, social, economic, or legal risks related to participation in genetic research, particularly unwanted release of private information to a third party
- Measures available to reduce or eliminate risks

Adverse events

- Identity of person(s) responsible for reporting adverse events to investigators, IRB, and sponsor (as applicable)

Possible benefits

- To donor-subject
- To donor-subject's family members
- To others in society
- To the University/investigators

Costs to subjects

- Study procedures
- Travel
- Parking
- Lost wages
- Child-care expenses

Biostatistics

- Identity of the biostatistician assigned to the service