

SPECIMEN STORAGE AND DISPOSAL POLICY AND PROCEDURES – THE STRONG HEART STUDY

Background

In addition to the objectives listed below, this policy is predicated upon two distinct factors. First, the Study's tribal partners possess an inherent sovereignty, in many respects on a par with that possessed by state and national governments. Second, the Tribes often assert a proprietary interest in biological specimens obtained from their respective members. These factors preclude unilateral decisions regarding the uses, handling and ultimate disposition of biological specimens obtained during the Study.

Objectives

Penn Medical Laboratory (PML) in MedStar Health Research Institute is the custodian for plasma, serum, urine and DNA samples of participants in the Strong Heart Study (SHS), and plasma, serum and urine samples of participants of the Strong Heart Family Study (SHFS). The Genetics Core Laboratory at the Texas Biomedical Research Institute (TBRI) is the custodian for nucleic acid samples from the SHFS. PML and TBRI are charged with inventory and safe storage of these samples under optimal conditions to insure stability of analytes. PML and TBRI cannot release these samples unless directed by the study Steering Committee and under current guidelines of the Indian Health Service, National Heart Lung and Blood Institute and all relevant Institutional Review Boards (Human Use). Samples can be released to foster specific meritorious and ethical research of cardiovascular disease and their risk factors as outlined in the study consent forms. The specific use is subject to scientific review by the study Steering Committee and the NHLBI. Released samples can only be used for the approved measurements by the designated investigator, and unused samples are to be returned in good condition to the PML and TBRI with documented history of the uses of each sample including a log of freeze thaw cycles. Consistent with the consent forms, the samples will not be used for profit, patenting and/or commercial purposes, and cells will not be kept growing and will not be cloned.

I. Policies and procedures described in this document are designed to:

- Release authorized samples only after appropriate review as laid out in Section 4 of this document.
- Release samples after receipt of the signed *Sample Use Agreement* (Appendix 1 of this policy and available through the website following the *Request SHS Study Samples* link).
- Insure sample integrity by keeping the samples in appropriate storage conditions and documenting the history of those storage conditions.
- Insure that the samples are secure and safe from unauthorized use.
- Insure confidentiality of the sample donor in accordance with study guidelines.
- Maintain records of samples stored, removal, freeze thaw cycles, and their placement to insure efficient retrieval.
- Follow procedures to insure that samples are released appropriately and transferred under conditions that insure sample integrity.
- Maintain records indicating where, when and why samples were released.
- Insure that disposal or destruction of samples is done in accordance with both good laboratory practice and the guidelines of the participants.

II. Sample Storage Conditions:

Penn Medical Laboratory

A. Plasma, urine, and serum and DNA

Samples are stored in airtight, gasketed vials at -70 to -80° C. Vials are filled leaving at least 0.5 cc airspace at the top of each vial. Vials are marked in indelible ink on freezer-safe labels with participant number, date of collection and PML acquisition number. The freezers are locked and the key is the responsibility of the laboratory supervisor.

B. Database, sample inventory

The laboratory maintains a computerized database containing the following data on each stored sample: date of receipt, condition on receipt, number of vials, approximate volumes of each sample, freezer location, sample type (serum, plasma, urine, etc.), release date, release destination, release purpose, return date, return volume, freeze thaw cycles logged. PML will maintain records of freezer temperatures. Temperatures are manually logged on all workdays by the technical staff and reviewed for drift. Periodic maintenance records as recommended by the freezer manufacturer will be kept available for inspection. Records of freezer malfunction and maintenance will also be made available.

C. Damaged storage samples

PML will notify the Steering Committee of sample damage evidenced by thawing or breakage of samples. Computerized and paper logs of samples will include such events.

Genetics Core Laboratory at TBRI

A. Buffy coat, DNA and RNA

Buffy coat and RNA samples are stored in airtight, gasketed vials at -70 to -80° C. Vials are marked in indelible ink on freezer-safe labels with an anonymous sample ID (which maps to a SHFS participant ID). Each vial is stored in a cardboard freezer box which is housed in freezer racks. To the extent possible, samples from any one individual are split between different freezers. The freezers are locked, and the key remains in the possession of the sample manager. Freezers are plugged into power outlets that are served by emergency generators in case of building-wide power outages. Each freezer is connected to two alarm systems; one maintained by the Genetics Core Lab and the other by TBRI, and both of which alert designated individuals of freezer failure and/or power failure by directly dialing out continually to programmed individuals until a required confirmation code has been entered to assure contact has been established. Each -80° C freezer is also equipped with a CO₂ injection system which is set to automatically inject coolant into the freezer when the temperature exceeds a predetermined set point.

DNA samples are stored in airtight, gasketed vials, matrix tubes or sealed 96- or 384-well plates in -20° C, non-frost-free freezers. Vials and tubes are marked in indelible ink on freezer-safe labels with an anonymous sample ID (which maps to a SHFS participant ID). Plates are labeled and sample IDs are given in plate layouts present in the SHFS sample database. The freezers are locked and the key remains in the possession of the sample manager. Each -20° C freezer is equipped with an external thermometer which displays its internal temperature.

All freezers are monitored daily with temperatures logged at least weekly to monitor drift. The -80° C freezers are contracted to receive semi-annual maintenance.

B. Database, sample inventory

The Genetics Core Laboratory maintains a computerized database containing the following data on each stored sample: date of receipt, condition on receipt, sample type, date on tube (if available), SHS number, DNA sample number, concentration, amount, aliquots made and updated amounts, sample release date, destination and purpose, return date and volume, and last condition of sample. The sample database is automatically backed-up to a TBRI Genetics Department server, and periodic archived copies are stored in a safe in the office of the Director of the Genetics Core lab.

C. Damaged storage samples

TBRI will notify the Steering Committee of sample damage evidenced by thawing or breakage of samples. Computerized and paper logs of samples will include such events.

III. Disposal of Samples

Samples will be disposed of at the direction of the Steering Committee by routine laboratory methods. Prior to this, a request will be made to appropriate Tribes regarding culturally correct methods of disposal of damaged or non-usable samples and the laboratory will make every effort to cooperate with those requests. Any procedures used for disposal of samples must be consistent with Good Laboratory Practice, and minimize biohazard contamination.

IV. Release of samples

Administrative pathway for release of samples:

Requests are presented in writing to the Steering Committee. Requests are judged by their scientific merit, potential benefit to the Indian Communities, and consistency with human use guidelines (as outlined in the signed consent) specific to the SHS. Requests for samples must be specific. The samples must not be used for additional measurements unless additional written approval is received from the Steering Committee. All uses must be consistent with the participant consent of the study.

Request for samples should justify the volume/amount of sample requested and whether previously unused (never thawed) samples are necessary. Requests should be brief and generally follow guidelines used in scientific proposals of rationale, hypotheses, specific aims, background, methods and planned analyses.

Study participants and participating Tribes will be notified by the newsletter when new tests are done using stored specimens. The investigators will write articles in the newsletter describing what tests are being done and how they will increase understanding of CVD in American Indians. Scientific articles resulting from the laboratory studies of the stored specimens will be reviewed and approved by the publications committee, all participating Tribes, and by NHLBI prior to publication.

This policy will not preclude obtaining explicit tribal and/or IRB approvals in the event that ancillary studies are proposed which would require re-contact of participants or other issues that would suggest consultation with appropriate IRBs or tribal governments.

B. Release instructions:

Written requests to release samples *Request to Release Samples* (Appendix 2 of this policy and available through the website following the *Request SHS Study Samples* link) will be made by the Steering Committee after review of scientific merit and ethical considerations. The written request must confirm that scientific merit will include the originality of the research, value to the tribal communities and participants, and quality of the measurements proposed.

Samples to be released must be identified by date, volume/amount or number of vials to be released, shipping destination and contact person, and study IDs.

PML and TBRI will maintain records of requests for a period of 15 years. These records will be made available to the sponsor and tribal governments upon request.

C. Technical procedure for releasing samples:

Samples are removed from storage only by PML and/or TBRI employees who are trained in safe sample handling. Written logs of the samples requested are used to locate and remove samples. Each sample found is logged onto the table and these data are promptly transferred into the relevant computer database. The removed samples and the list are reviewed by a technical supervisor. Discrepancies are logged and resolved. Samples requested which are not found are logged and investigated to insure consistency between the data base and sample inventory. See *PML Sample Request Log* (Appendix 3 of this policy.)

The sample shipment is coordinated with the receiving laboratory to insure safe receipt of the requested samples. The requesting laboratory must acknowledge the receipt and condition of the samples upon arrival. **Any discrepancies between the number and amount of samples approved for use by the requested laboratory, and those received, must be reported by the requesting laboratory within one month of receipt of the samples.**

Recipients of released samples are instructed to either return or destroy any unused portion after their study is complete, and to supply copy of the data derived from the samples to the CC or TBRI as appropriate.

Specimen Storage Policy Appendix 1

Sample Use Agreement

The Strong Heart Study release tracking number _____

The release of the Strong Heart Study samples is subject to the following policies and procedures. No samples will be released until the investigator agrees to the following policies and procedures approved by the Steering Committee:

1. Samples can be released to foster specific meritorious and ethical research as outlined in the consent forms. The specific use is subject to prior approved scientific review of the Steering Committee and the NHLBI. The laboratory releases samples only after written instructions are received from the Steering Committee.
2. Released samples can only be used for the approved measurements in the specified laboratory and unused samples are to be returned in good condition to PML and/or TBRI with documented history of the uses of each sample including a log of freeze thaw cycles. The investigator must supply PML and/or TBRI with the name, phone number, E-mail address and shipping address of the person responsible for receiving the samples.
3. The samples will be released for a period of ___ days ending on (dd/mm/yyyy). At the termination of this period, the investigator must either return the samples to PML and/or TBRI, or request and receive permission from the Steering Committee for a specified extension to complete the analyses.
4. Samples must be returned to the PML and/or TBRI with any remaining material at the completion of the approved use period as described above. Samples should be returned in their original containers with the original label. Samples are to be shipped under conditions specified by the Medical or Technical Director of the PML and/or Director of the Genetics Core Lab at TBRI. Unused samples must not be discarded.
5. Data derived from the use of these samples are the joint property of the Steering Committee and the investigator. Publication of the results of these investigations is subject to the policies and prior approval of the Publications Committee, the NHLBI and the appropriate tribal councils.
6. The investigator acknowledges and abides by the informed consent document limiting use of these specimens for the study of cardiovascular disease and its risk factors and specimens will only be used for those purposes. The samples will not be used for profit, patenting and or commercial purposes, and cells will not be kept growing and will not be cloned.

I have read the sample storage policies and understand that the samples must be used only for uses approved in writing by the Steering Committee. I agree to abide by the limitations set forth in these policies.

Printed name: _____

Date: _____

Signature: _____

Address, city, state, zip, phone number, e-mail address

Specimen Storage Policy Appendix 2

Request to Release Samples

Date:

A request to the Penn Medical Laboratory (PML) and/or Texas Biomedical Research Institute (TBRI) is made to release the following samples (attach list or table if necessary):

Type of sample: plasma serum urine DNA other:

Strong Heart Study or Strong Heart Family Study Phase: _____

Minimum volume (or weight for DNA) needed for each sample: _____ uL (or ng).

OK to use previously thawed samples? Yes No

To: (name of investigator)

Shipping address:

Phone contact:

E-mail address:

Purpose of the Request:

Signature: _____ Date: _____

When will the samples be returned to the PML or TBRI?

Date:

For PML lab use (attach log of sample request vs. those actually sent):

Samples pulled and shipped on: ____-____-____ (mm/dd/yyyy)

Technician name (print)_____

Technician signature _____ Date:_____

Supervisor name _____

Supervisor signature_____ Date:_____

