

APPENDIX D
BROAD GTEx LEGACY SPECIMEN WITHDRAWAL POLICY
14 March 2018

1. PURPOSE

The purpose of this document is to describe the process to be followed when a donor, a donor's legally authorized representative (LAR), a deceased donor's next of kin (NOK), or a Biospecimen Source Site (BSS) withdraws the consent for or recalls the specimens and/or data for a GTEx case that was collected by the National Cancer Institute (NCI) for the Genotype Tissue Expression (GTEx) program, overseen by the NCI Biorepositories and Biospecimen Research Branch (BBRB). This process will also be followed when specimens, slides, aliquots and derivatives, and data are recalled for all reasons and as reviewed and approved by the NIH GTEx program. The GTEx Legacy Collection is held at the Broad Institute of Harvard and MIT, located in Cambridge, MA, 02142.

2. SCOPE

This process is applicable to all case-specific materials from a donor collected for the GTEx program and must be followed by all project staff that are responsible for the performance and management of the project at the Broad Institute. Should a request for withdrawal of biospecimens be made, any remaining specimens and associated data will be destroyed; however, samples and information being used in studies that have already started cannot be withdrawn. In addition, test results from studies that used the donor's samples and information will not be destroyed.

2.1. RESPONSIBILITY

2.1.1. Requester: Responsible for requesting the initiation of a withdrawal or recall request on behalf of the donor, their next of kin, legally-authorized representative (LAR), the BSS or other approved party. Usually, the Requester is the BSS Principal Investigator or designee. They may contact the BSS.

2.1.2. Broad Lead: Responsible for acknowledging a withdrawal/recall request in the GTEx Laboratory, Data Analysis and Coordinating Center (LDACC) and monitoring the process for completion. This includes managing the destruction (or return) of case-specific materials, sequestering of related data, verification of completion, and notification to the appropriate parties when all withdrawal/recall requirements are met. This Lead is a staff member at the Broad.

3. DEFINITIONS

3.1. Case-specific materials: All biospecimens, data, slides, digital images, aliquots, and derivatives currently being stored at the LDACC or an External Collaborating entity that are associated with a specific case. This does not include materials released to the research community under an approved protocol and cannot be withdrawn or recalled, Material Transfer Agreement (MTA), or Data Use Agreement (DUA).

- 3.2. Legally-Authorized Representative (LAR): An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.
- 3.3. Withdrawal of consent: When the donor, Next of Kin, LAR or other approved entity requests the withdrawal of their original consent to participate in GTEx or related projects.

4. PROCEDURE

- 4.1. The Broad Lead will acknowledge the withdrawal/recall to all pertinent parties via email. This may include the BSS, Leidos Biomedical and/or NIH. The Broad lead will verify that all the essential information is provided with the request for processing with associated information detailing case ID, specific materials to be withdrawn to include data, as applicable. If the information is incomplete, the Broad will work with the appropriate parties to request and complete the necessary information to process the withdrawal. The requests will be tracked and the records maintained by LDACC.

A table to track the progress of the withdrawal request and sample termination will be created and maintained on Broad Institute Google Drive. It will be restricted for viewing and editing to the Broad Specimen Access Committee and the Broad personnel responsible for the withdrawal (Broad Specimen Access Committee members is in Appendix A: Committee Member of GTEx Legacy Specimen Access and Distribution Plan, February 14, 2018). The table headers are presented below:

Request Received (date)	Description of the request	Donor ID	Lab notified (date)	Termination verified (date)	External notification sent (date)

- 4.2. The Broad Lead will assign duties to be performed at the Broad by the appropriate Broad staff member for performing the request. This may include destruction of samples and sequestering of data. Once the appropriate actions have been taken, the actions will be recorded and the sample marked as "terminated" in the LDACC Biological Samples LIMS by assigned staff member. This automatically removes the terminated samples from the Portal inventory. This means those samples are no longer available on the portal for research request of specimens.
- 4.3. The Lead will notify external entities (such as the BSS, Leidos Biomedical and NIH) that the request has been completed.

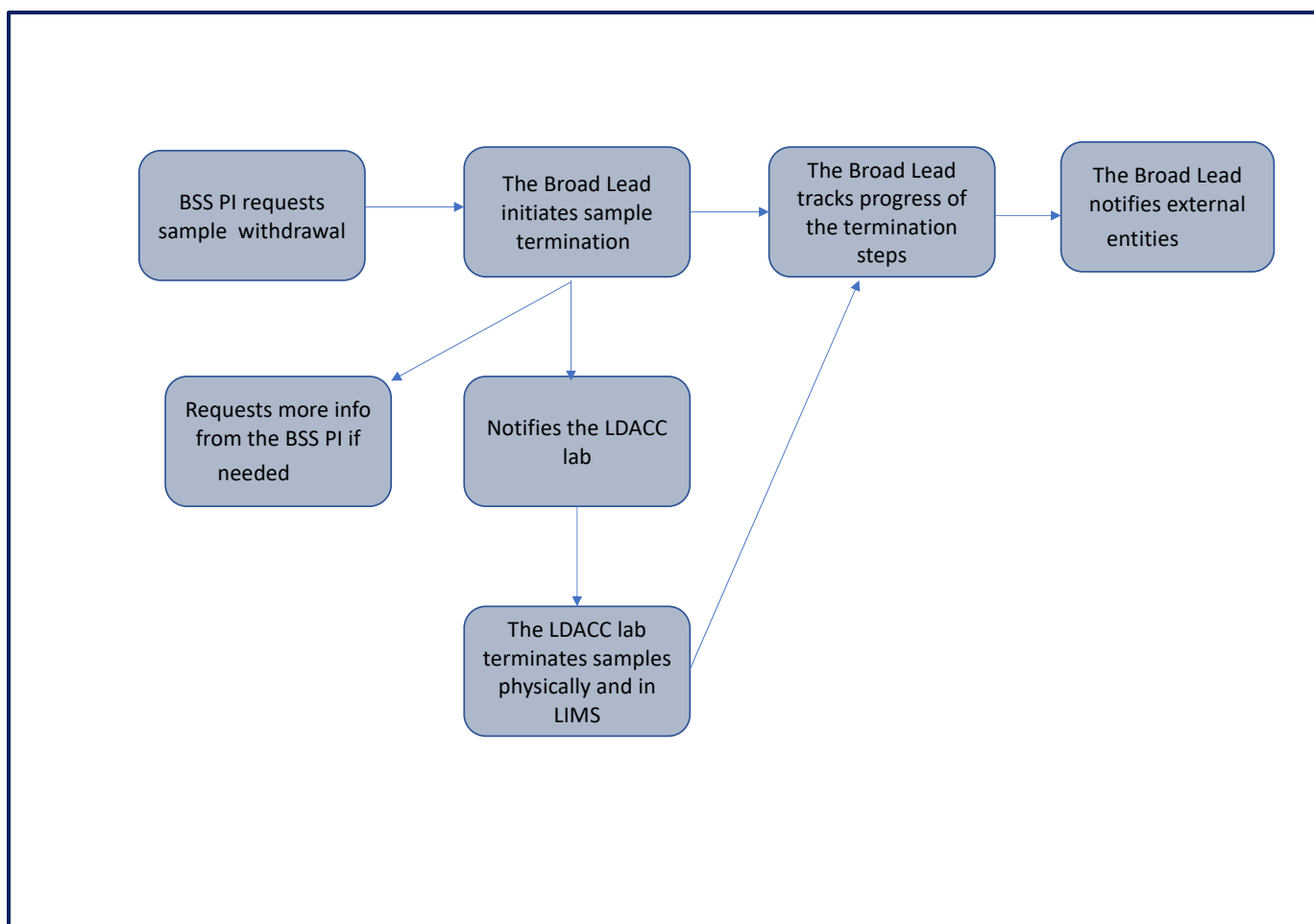


Figure 1: Withdrawal Workflow Procedure

5. REFERENCES

- NCI Best Practices for Biospecimen Resources: <http://biospecimens.cancer.gov/bestpractices>
- HHS Guidance on Withdrawal of Subjects from: Data Retention and Other Related Issues: <http://www.hhs.gov/ohrp/policy/subjectwithdrawal.html>