



ACTG/IMPAACT LABORATORY STANDARD OPERATING PROCEDURE			
Title:	Discarding and Destroying Locally Stored Specimens		
SOP number:	LTC-SOP-77	Effective:	20Apr2026
Version:	v1.0	Last reviewed:	17Apr2026
Originator:	ACTG/IMPAACT Lab Technologist Committee	Pages:	5

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1. PURPOSE

The purpose of this Standard Operating Procedure is to provide a standardized procedure for discarding and destroying locally stored specimens containing human biological material.

Note: This document is intended to provide guidance for discarding and destroying locally stored ACTG or IMPAACT specimens if local procedures are not in place. Institutional policies and procedures may supersede procedures outlined in this document.

2. BACKGROUND

The Repository Advisory Group (RAG) will determine when study specimens are no longer needed and should be discarded and destroyed. *Note:* Unless otherwise stated in the protocol LPC, remnant specimens that exist in storage after the required protocol-related testing is completed should be destroyed and not used for any other purposes or shipped to the biorepository.

3. SCOPE

This SOP pertains to all human biological specimens located at ACTG/IMPAACT Network laboratories that need to be discarded and destroyed.

4. DEFINITIONS

Term	Definition
ACTG	Advancing Clinical Therapeutics Globally
IMPAACT	International Maternal Pediatric Adolescent AIDS Clinical Trials Group
DMC	Data Management Center
LDMS	Laboratory Data Management System
LTC	ACTG/IMPAACT Laboratory Technologist Committee
PPE	Personal Protective Equipment
RAG	Repository Advisory Group
SOP	Standard Operating Procedure

5. RESPONSIBILITIES

- 5.1. The Network Laboratory Directors (or his/her designee) have the authority to establish, review and update this procedure.
- 5.2. The ACTG/IMPAACT Laboratory Technologist Committee (LTC) is responsible for the maintenance and control of this SOP documentation.
- 5.3. The Laboratory Director is responsible for the implementation of this LTC SOP or laboratory-specific SOP and for ensuring that all appropriate personnel are trained. A laboratory SOP must:
 - 5.3.1. Include, without procedural modification, the portions of the current version of the LTC SOP that are used within the network site-affiliated laboratory.
 - 5.3.2. Reference the current version of the LTC SOP.

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- 5.4. All laboratory technicians are responsible for reading and understanding this SOP prior to performing the procedures described.
- 5.5. The site’s principal investigator and designee are responsible for understanding and adhering to the patient preparation and specimen collection components.

6. EQUIPMENT AND CONSUMABLES

- 6.1. Personal Protective Equipment (PPE, as required by local institutional policies):
 - 6.1.1. Laboratory gown or coat
 - 6.1.2. Gloves
 - 6.1.3. Face shield or mask
- 6.2. Biowaste Containment System, as required by local institutional policies


7. PROCEDURES

The ACTG has a standard process for the archiving of ACTG study specimens (ACTG SOP-145). Per ACTG SOP-147, the ACTG Laboratory Center tracks and stores relevant specimen destruction documentation. The Repository Advisory Group (RAG) reviews and approves the list of protocols identified for specimen destruction, discusses and resolves issues concerning destruction, monitors progress of specimen destruction and communicates decisions concerning specimen destruction with the protocol teams. The Data Management Center serves as a member on the RAG, generates inventory lists to assist in decision making, and prepares and sends specimen destruction requests to ACTG Network Laboratories and the ACTG Biorepository. ACTG Clinical Research Site clinicians or study coordinators must also notify the DMC if a study participant declines or withdraws consent for future use of stored specimens (ACTG SOP-146). Reference to the destruction of IMPAACT specimens may be found in Section 17 of the IMPAACT Manual of Procedures.

- 7.1. The laboratory must receive notification in writing (i.e., by email) when specimens are identified to be destroyed.
 - 7.1.1. Specimens may need to be discarded if specimens were collected in error (e.g., the wrong additive). *Note:* The laboratory should consult the protocol team before discarding.
 - 7.1.2. Specimens may need to be discarded due to withdrawn consent from the study participant.
 - 7.1.3. Specimens may need to be discarded because all protocol-related testing has been completed and the network-owner has deemed them to be no longer needed.
 - 7.1.4. Specimens may need to be discarded if there are locally-stored specimens at a closed Clinical Research Site.
- 7.2. Laboratories may locate the specimens in LDMS storage using:
 - 7.2.1. LDMS Reports Module
 - 7.2.2. LDMS Storage Module
 - 7.2.3. LDMS Specimen Management Module
- 7.3. Laboratories must confirm the specimens in storage match the LDMS storage reports.
 - 7.3.1. Laboratories should physically inspect and verify the specimens in the storage container maintaining appropriate cold chain requirements.
 - 7.3.2. Laboratories may use an LDMS Box Report to confirm specimen locations.

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- 7.4. Once the specimens in the storage container have been verified, laboratories may remove the specimens from storage and place them in a biohazard waste containment system per their institutional policies.
 - 7.4.1. Laboratories may discard the cryovials and reuse the storage containers.
 - 7.4.2. Laboratories may discard the entire storage container with the cryovials.
 - 7.4.3. Biohazard waste must be removed and discarded per local institutional policies.
 - 7.4.4. If possible, a second person should verify that the correct specimens are being discarded.
 - 7.5. Laboratories must update the LDMS to accurately reflect that specimens were destroyed/discarded by using the condition code of DSR (destroyed) for each aliquot.
 - 7.5.1. The condition code for a single specimen may be modified in LDMS Specimen Management Module.
 - 7.5.2. The condition code for entire storage boxes may be modified in the LDMS Storage Module by clicking on the arrow next to the *Edit* button and selecting *Set Condition Code*. Set the condition code to DSR, document the reason for the specimen destruction, and date and initial the change in the comment section.
 - 7.6. Laboratories must share an LDMS report (e.g. specimen log report) showing the destroyed specimens with the respective protocol PIs for archival.
 - 7.7. Contact Frontier Science User Support (716-834-0900, ext. 7311, or support@frontierscience.org) for additional support.
8. REFERENCES
- 8.1. LDMS user manual website <https://www.ldms.org/resources/>
 - 8.2. ACTG SOP-145 Specimen Archiving Process
 - 8.3. ACTG SOP-146 Study Participant Withdrawal of Consent for *Non-Protocol* Specimen Storage and Use.
 - 8.4. ACTG SOP-147 Destruction of Specimens
 - 8.5. ACTG SOP-148 Disposition of Specimens at Closed Clinical Research Sites
 - 8.6. IMPAACT Manual of Procedures
9. INQUIRIES
- 9.1. Contact the ACTG/IMPAACT LTC Leadership at actg.ltcleadership@fstrf.org for questions and comments related to these procedures
10. NETWORK LAB CENTER SOP APPROVAL

NAME AND TITLE	SIGNATURE	DATE OF APPROVAL
Grace Aldrovandi, MD ACTG/IMPAACT Network Laboratory Principal Investigator		17Apr2026

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11. REVISION HISTORY OR RECORD RETIREMENT

VERSION #	EFFECTIVE DATE	REPLACES	DATE OF REVISION	RATIONALE FOR [REVISION/RETIREMENT]
1.0	20Apr2026			Original

12. APPENDICES (Not Applicable)

13. LABORATORY SOP REVIEW

LABORATORY STAFF NAME	DATE OF CONFIRMATION OF UNDERSTANDING