Table of Contents

1.0 PURPOSE

1.1 This procedure describes steps for the destruction of laboratory specimens from National Institute of Allergy and Infectious Diseases (NIAID) Division of AIDS (DAIDS)-supported and/or -sponsored clinical research that are owned by NIAID in the custody of DAIDS-supported laboratories or repositories.

2.0 SCOPE

2.1 This procedure applies to specimens obtained from NIAID (DAIDS)-supported and/or -sponsored clinical research that are: 1) the property of NIAID and 2) stored at DAIDS-supported and/or -sponsored laboratories or repositories. For example, currently this procedure is applicable to many specimens in the following laboratories and repositories: laboratories that were formerly part of the AIDS Vaccine Evaluation Group (AVEG) and HIV Network for Prevention Trials (HIVNET), and the NIAID Specimen Repository contractor. Unless otherwise stated, specimens collected by contractors are the property of the NIAID; specimens collected by grantees (including cooperative agreements) are the property of the awardee institution, not NIAID, hence not covered by this SOP.

Note: For studies that are co-supported by DAIDS and other federal and non-federal partners, a mutual agreement among all parties is needed regarding the application of the procedure and/or process to be followed for stored specimens.

3.0 DEFINITIONS

3.1 For definitions, see DAIDS glossary.

4.0 RESPONSIBILITIES

4.1 NIAID DAIDS

4.1.1 DAIDS is responsible for making decisions about the storage, future use and destruction for DAIDS clinical research specimens owned by NIAID, consistent with the protocol, informed consent and relevant regulations, and for notifying the investigator/laboratory/repository of its decisions.

4.2 Laboratory or repository staff

4.2.1 Laboratory or repository staff are responsible for ensuring that the specimens from NIAID (DAIDS)-supported and/or -sponsored clinical research are stored according to protocol requirements in a current Good Clinical Laboratory Practice (GCLP)-compliant manner. Once DAIDS notifies the laboratory or repository to destroy specimens, laboratory or repository staff are responsible for implementing this DAIDS procedure and following instructions for specimen destruction.

4.3 Principal Investigator (PI) of the laboratory or repository

4.3.1 The Principal Investigator of the laboratory or repository is responsible for ensuring laboratory specimens from NIAID (DAIDS)-supported and/or -sponsored clinical research are stored and ultimately destroyed in accordance with this procedure, institutional policies, and any applicable local or country laws in a GCLP-compliant manner.

4.4 PI for the contract for the clinical research that collected the specimens

4.4.1 The PI for the contract for the clinical research under which specimens are generated and sent to the repository is responsible for assisting NIAID/DAIDS in determining which specimens owned by NIAID that may be destroyed, in compliance with the requirements in the protocol, the informed consent and relevant regulations.

5.0 PROCEDURE

5.1 The DAIDS-supported and/or -sponsored laboratories and repositories receive and store samples from NIAID (DAIDS)-supported and/or -sponsored clinical research conducted both domestically and internationally. If a clinical research participant does not provide consent for the samples to be retained, all laboratory specimens provided by the participant are to be destroyed as indicated by the Institutional Review Board (IRB)/ Ethics Committee (EC) or as dictated by institutional policies. In cases where NIAID owns the research samples, the appropriate DAIDS Contracting Officer Representative (COR) knowledgeable about the contract that supported the clinical research determines which specimens the laboratory or repository can either destroy or maintain in storage. This procedure describes steps DAIDS considers adequate for determining which NIAID-owned laboratory samples are eligible for destruction and the process for their destruction.

5.2 Determination of specimens for destruction

5.2.1 DAIDS COR will determine which specimens may be destroyed in consultation with the PI for the clinical research that collected the specimens, Study Chairs and or co-chairs, as applicable, and relevant DAIDS staff. Any decision must be consistent with the requirements in the protocol, the informed consent, and any relevant regulations. The IND status (or equivalent for studies under a non-FDA regulatory authority such as European Medicines Agency) where applicable, of each protocol is to be closed, terminated or withdrawn before any decision is made about destroying specimens. The DAIDS COR confirms that protocol-defined analyses have been performed (or determines that they cannot reliably be performed). The DAIDS COR is to also ensure abstracts and manuscripts or primary publications exist or are under review or a reason not to publish exists.

5.2.2 If it may no longer be possible to contact PI for the clinical research that collected the specimens, Study Chairs and or co-chairs, COR may seek advice from NIAID leadership for final determination of the disposition of these samples, as applicable.

5.2.3 In the rare circumstances, stored samples from specific participants (e.g., who received a specific investigational agent and reported an unusual Serious Adverse Events (SAE) may be quarantined, and retained for an indefinite period, even after IND or equivalent is closed/withdrawn.

5.3 Notification

5.3.1 The Principal Investigator/laboratory staff will be notified by the DAIDS COR knowledgeable about the NIAID (DAIDS)-supported and/or -sponsored clinical research that collected the specimens if specimens owned by NIAID need to be destroyed due to participant's wishes, applicable regulations, protocol and/or specimen storage space and budget constraints. NIAID Specimen Repository PI/staff will be notified by the NIAID Specimen Repository COR. Because research may be conducted in a variety of U.S. domestic and international settings and across diverse populations, investigators are advised to contact their local IRB/EC or legal counsel at their institution for guidance about any additional requirements, local regulations, laws, and institutional policies related to specimen destruction.

5.3.2 DAIDS will provide the laboratory or repository with a list of protocols/specimens and a date by which the specimens are to be destroyed. This notification may also include special requirements for destruction and documentation.

5.4 Verification

5.4.1 Laboratory/repository staff will check specimen inventories to ensure the specimens are stored in the facility. Laboratory/repository staff will note and resolve any discrepancies such as specimen type, numbers, source protocol, etc., before destruction.

5.5 Documentation

5.5.1 Laboratory/repository staff provide the following information using the format outlined on the "List of Samples from DAIDS-supported and/or -sponsored clinical research destined for destruction" Table (see Appendix 1): protocol number, notifying authority, type and number of specimens destroyed, date and time of destruction, Laboratory/repository staff member's signature and date and the Laboratory/repository Director or designee's signature and date.

5.5.2 A list of samples from DAIDS-supported and/or -sponsored clinical research destined for destruction (see Appendix 1 List of Samples from DAIDS-supported and/or -sponsored clinical research destined for destruction) is maintained at the site in accordance with the Storage and Retention of Clinical Research Records Policy.

5.5.3 If the laboratory/repository uses the Laboratory Data Management System (LDMS), specimens will be removed from the specimen storage section of the LDMS.

5.5.3.1 Comments are made in the specimen management section of the LDMS about the destruction of the samples along with the sample destruction date and identification of responsible staff.

5.5.3.2 Copies of the storage reports will be kept by the laboratory/repository.

5.5.4 Chain of custody is required to be maintained throughout the specimen destruction process.

5.6 Destroying samples

5.6.1 All applicable institutional policies, and local or national regulations are to be followed when handling or destroying specimens.

5.7 Confirmation

5.7.1 Confirmation of destruction is sent out to DAIDS according to DAIDS instructions with relevant documentation.

6.0 REFERENCES

6.1 HPTN/MTN Laboratory manual: Section 13 Laboratory Component (Sample Destruction)

7.0 APPENDICIES

7.1 Appendix 1 List of Sample from DAIDS Research destined for destruction

List of Samples from DAIDS funded and/or sponsored clinical trials destined for destruction

Laboratory staff should provide the following information using the format outlined below: protocol number, notifying authority, type and number of specimens destroyed, date and time of destruction, Laboratory staff member's signature and date and the Laboratory Director or designee's signature and date.

Protocol number	**Specimens destroyed**	**Specimen destruction notifying authority (DAIDS, other, please specify)**	**Date & Time of specimen destruction**	**Laboratory staff ID**

8.0 REVISION SUMMARY

8.1 DAIDS-OD-A-SOP-00008 rev 01 is the first version of this procedure within the Quality Management System. The previous document number was DWD-SOP-LB-010.02