1.0 PURPOSE

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 in the custody of DAIDS-supported laboratories or repositories that are owned by NIAID.

2.0 SCOPE

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 (see Specimen Repository Guidance), not NIAID.

Note: For studies that are co-funded by DAIDS and other parties, a written agreement is needed regarding the application of the procedure and/or process to be followed for stored specimens.

3.0 BACKGROUND

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 should 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.

4.0 DEFINITIONS
For definitions, see DAIDS glossary.

5.0 RESPONSIBILITIES
NIAID DAIDS

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.

Laboratory or repository staff

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 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.

Principal Investigator (PI) of the laboratory or repository

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.

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

The PI for the contract for the clinical research is responsible for assisting NIAID/DAIDS in determining which specimens owned by NIAID may be discarded, in compliance with the requirements in the protocol, the informed consent and relevant regulations.

6.0 POLICY

6.1 Determination of specimens for destruction
DAIDS COR will determine which specimens may be discarded in consultation with the PI for the clinical research that collected the specimens, Study Chairs and or co-chairs, as applicable. Any decision must be consistent with the requirements in the protocol, the informed consent and any relevant regulations. The IND status of each protocol should be closed, terminated or withdrawn before any decision is made about discarding specimens. It should be confirmed that Protocol defined analyses have been performed (or determined that they cannot reliably be performed). DAIDS COR should also ensure abstracts and manuscripts or primary publications exist or are under review or reason not to publish exists.

6.2 Notification

6.2.1 The Principal Investigator/laboratory staff will be notified by 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. 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.

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

6.3 Verification

6.3.1 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.

6.4 Documentation

6.4.1 Laboratory/repository staff should 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.

6.4.2 In accordance with DAIDS GCLP Standards, 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) should be maintained at the site. (DAIDS guidelines for GCLP standards)

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

6.4.3.1 Comments should be made in the specimen management section about the destruction of the samples along with the sample destruction date and identification of responsible staff.

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

6.5 Discarding of samples

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

6.6 Confirmation

6.6.1 Confirmation of destruction will be sent out to DAIDS according to DAIDS instructions.

7.0 REFERENCES

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

Questions and comments regarding this SOP may be directed to the OPCRO Policy Group.

9.0 AVAILABILITY

This policy is available electronically on the Division of AIDS (DAIDS) Clinical Research Policies and Standard Procedures Documents webpage.

10.0 APPENDICIES

Appendix 1 List of Sample from DAIDS Research destined for destruction

11.0 APPROVAL

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Acting Director, Office for Policy in Clinical Research Operations (OPCRO)