

ARCHIVED PROCEDURE

Procedure for the Destruction of Clinical Trial Specimens owned by NIAID

Approval Date: 19 MAR 2010

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## 1.0 PURPOSE

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

## 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. This procedure is applicable to the following laboratories and repositories: AIDS Vaccine Evaluation Group (AVEG) laboratories, HIV Network for Prevention Trials (HIVNET) Laboratories, and the DAIDS repository contractor SeraCare BioServices, Gaithersburg, MD. 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<sup>1</sup>. This procedure does not apply to specimens that are property of awardee institutions from research supported through grants and cooperative agreements.

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 trials 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 IRB/EC or as dictated by institutional policies. In cases where NIAID owns the research samples, a DAIDS Project Officer (PO) determines which specimens the laboratory or repository can either destroy or maintain in storage based on relevant regulations, the informed consent, and participant decisions regarding the storage of the specimens. This determination is made in conjunction with the protocol chair and/or co-chair and with DAIDS Branch Chief and Program director authorization.

<sup>1</sup> <http://www3.niaid.nih.gov/LabsAndResources/resources/reposit/guidance.htm>

This procedure describes steps DAIDS considers adequate for determining which NIAID-owned laboratory samples are eligible for destruction.

#### 4.0 DEFINITIONS

For definitions, see DAIDS glossary:

<http://www3.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Glossary.htm>

#### 5.0 RESPONSIBILITIES

##### DAIDS

*DAIDS* is responsible for making decisions about the storage, future use and destruction for DAIDS clinical trial specimens owned by NIAID, consistent with the protocol, informed consent document, IRB/EC determination, and relevant regulations, and for notifying the investigator/ laboratory of its decisions.

##### DAIDS Program Officer (PO)

The *DAIDS PO* is responsible for ensuring that the study Chair, and/or co-chair /PI is aware of and is in agreement with DAIDS decision

##### Laboratory staff

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

##### Principal Investigator

The *Principal Investigator* is responsible for ensuring lab specimens from NIAID (DAIDS) -supported and/or -sponsored clinical trials are stored and ultimately

destroyed in accordance with this procedure, institutional policies, and any applicable local or country laws in a GCLP compliant manner.

## 6.0 POLICY

### 6.1 Notification

- 6.1.1 The Principal Investigator/ laboratory staff will be notified by DAIDS PO if specimens from NIAID (DAIDS)-supported and/or -sponsored clinical trials owned by NIAID need to be destroyed. 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.
- 6.1.2 DAIDS will provide the laboratory 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.

### 6.2 Verification

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

### 6.3 Documentation

- 6.3.1 DAIDS would find it acceptable if laboratory staff provided the following information when identifying which samples will be destroyed: protocol number, notifying authority, type and number of specimens destroyed, date & time of destruction, laboratory staff member's signature & date and the Laboratory Director or designee's signature & date.
- 6.3.2 In accordance with DAIDS GCLP Standards, a list of samples from DAIDS –supported and/or -sponsored clinical trials destined for

destruction should be maintained at the site<sup>2</sup> and contain the information set forth in 6.3.1.

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

6.3.3.1 Comments should be made in the specimen management section about the destruction of the samples along with the sample destruction date.

6.3.3.2 Copies of the storage reports will be kept by the laboratory.

#### 6.4 Discarding of samples

6.4.1 No specimens should be discarded unless all of the following criteria has been met:

1. All protocol defined analyses have been performed; or a determination has been made that analyses cannot reliably be performed.
2. Abstracts, manuscripts, or primary publications already exists, are currently under review; or there is a valid reason for their absence.
3. Protocol chair and/or co-chair are supportive of specimen destruction
4. DAIDS Branch Chief and Program director authorization.

6.4.2 All applicable institutional policies, local or national regulations, and IRB/EC determinations are to be followed when handling or discarding specimens.

#### 6.5 Confirmation

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

<sup>2</sup> <http://www3.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/PDF/GCLP.htm>

## **7.0 REFERENCES**

HPTN/MTN Laboratory manual (Version 1.0, 15 November 2006): Sample Destruction

<http://www.hptn.org/web%20documents/Centrallab/HPTN-MTNLABMANUALVersion1.0.pdf>

## **8.0 INQUIRIES**

Questions and comments regarding this policy may be directed to the OPCRO Policy Group at: [NIAIDOPCROPOLICYGROUP@mail.nih.gov](mailto:NIAIDOPCROPOLICYGROUP@mail.nih.gov)

## **9.0 AVAILABILITY**

This policy is available electronically at the following URL:

<http://www.niaid.nih.gov/labsandresources/resources/daidsclinrsrch/Pages/Default.aspx>

## **10.0 CHANGE SUMMARY**

This procedure is the first version. It does not supersede any other version.

## **11.0 APPENDICES**

None

## **12.0 APPROVAL**

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