

ARCHIVED PROCEDURE

Access to Archived Specimens and Data from Completed Study:
Women and Infants Transmission Study (WITS)

Approval Date: 23 AUG 2010
Effective Date: 23 SEP 2010

No.: DWD-SOP-LB-012.01

1.0 PURPOSE

The purpose of this procedure is to define criteria for investigator access to archived specimens and datasets, from a completed National Institute of Allergy and Infectious Diseases (NIAID) Division of AIDS (DAIDS) co-sponsored study.

2.0 SCOPE

This procedure applies only to archived specimens and datasets from the Women and Infants Transmission Study (WITS). It does not pertain to the Pediatric HIV/AIDS Cohort Study (PHACS).

Note: Investigators needing data and/or specimens from PHACS participants should follow procedures available on the PHACS website (<https://phacs.nichdclinicalstudies.org/overview.asp>).

3.0 BACKGROUND

The WITS was a prospective cohort study of HIV-infected pregnant women and their infants living in cities across the United States. The study was active from 1990 – 2007, and was primarily funded by the NIAID, with co-funding from the Eunice Kennedy Shriver National Institute on Child Health and Human Development (NICHD) and National Institute on Drug Abuse (NIDA). The initial goal of the WITS was to understand the natural history of HIV-1 infection in pregnant women and their infants, children and adolescents. With the advent of potent HIV therapy, WITS research was expanded to study antiretroviral therapy (ART) efficacy and safety.

WITS findings and publications include examination of the clinical and immunologic characteristics associated with HIV disease in mothers and their infants, the impact of maternal plasma HIV-1 RNA levels on perinatal HIV transmission, HIV-1 genotypic zidovudine drug resistance and the risk of maternal to infant transmission, and the role of viral co-infections on mother-to-child HIV transmission.

4.0 DEFINITIONS

See DAIDS Glossary at:

<http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Pages/Glossary.aspx>

5.0 RESPONSIBILITIES

Chief of Epidemiology or designated staff member

The *Chief of Epidemiology or designated staff member* in NIAID, DAIDS will: 1) respond to all general and scientific inquiries regarding access to the archived WITS specimens; 2) provide advice about appropriateness of WITS data and availability of specimens for proposed research; 3) facilitate receipt and review of all specimen requests related to WITS.

Investigators

Investigators wishing to access archived WITS specimens will:

- 1) Meet eligibility requirements for receipt of WITS specimens;
- 2) Obtain the WITS Public Use Datasets CD-ROM for accessing the necessary clinical and laboratory data, as well as the specimen inventory, needed to identify and request specimens;
- 3) Provide to DAIDS Staff accurate information needed to outline the specimen request and transfer of materials;
- 4) Be responsible for all shipping costs associated with receiving sample shipments from the DAIDS HIV/AIDS Specimen Repository.

DAIDS Repository Staff

Under guidance of the NIAID/DAIDS Project Officer, *DAIDS HIV/AIDS Specimen Repository staff* will prepare and ensure timely sample shipments, including appropriate billing of shipping costs, to investigators who receive written DAIDS approval to receive WITS specimens.

WITS Specimen Access Committee (WSAC)

The *WSAC* will collectively review each written request on a semi-monthly basis.

6.0 PROCEDURE

6.1 Access to Archived WITS Specimens

6.1.1. Eligibility to Receive WITS Specimens

Investigators, outside of the US Government, interested in accessing WITS specimens must be affiliated with an entity that has an assigned Data Universal Number System (DUNS). A DUNS can be obtained via the appropriate registration process on the eRA Commons and/or grants.gov websites. There are *no exceptions* to the DUNS requirement for non-federal investigators.

6.1.2. Specimen Request Submission to DAIDS

To request access to WITS specimens, interested investigators must complete and submit a WITS Material Transfer Agreement (MTA). Signed PDF forms are acceptable. If the proposed research is part of a grant application, the applicant should specify the date a decision is needed. Incomplete requests will not be considered.

6.1.2.1. Linkage to WITS Clinical and Laboratory Data

Each specimen is labeled with a unique identifier. Applicants will need to identify specimens by the participant ID number [IDNUM] and the unique specimen ID number [SPECINUM] using an EXCEL spreadsheet format. The spreadsheet must be sent to DAIDS, who will then facilitate the request with the DAIDS HIV/AIDS Specimen Repository.

Specimen requests are reviewed by DAIDS in the order they were received. A specific vial may no longer be available at the time of an applicant's request. Before completing a spreadsheet, investigators are encouraged to ask for the current list of samples which are no longer available (niaidwitsaccess@mail.nih.gov).

6.1.3. Review of Specimen Requests by WSAC

A written decision will be rendered and forwarded to the applicant investigator within six weeks of receiving the specimen request. DAIDS staff will also verify the availability of requested specimens in the WITS inventory during this review process.

6.1.4. Outcomes of Review

The WSAC review will be based on the information provided. The sole consideration by the WSAC will be to determine the appropriateness of using the WITS specimens for the proposed scientific inquiries. The decision of the WSAC may be to approve the request as written, approve with suggested comments, or disapprove the request.

6.1.4.1. Appeals

The applicant investigator may appeal the WSAC decision at any time but must do so formally in writing and address the documented comments that prevented approval of the initial specimen request.

6.2. Logistics for Specimen Shipment and Receipt

6.2.1. If approved, the MTA will be signed by DAIDS and a PDF file will be returned to the applicant's institution.

6.2.2. Shipment and receipt of samples

To ensure efficient use of the DAIDS HIV/AIDS Specimen Repository, shipments for approved specimen requests will be staged according to the chronological order of approved requests, and the number of vials to be pulled from inventory. Samples will be processed according to the following:

- 1) The entire volume of a requested specimen vial will be shipped by the DAIDS Repository to the recipient laboratory (there will be no thawing and aliquotting of specimens).
- 2) Only specimen type and specimen ID will be verified for accuracy, the applicant investigator is responsible for any other discrepancies related to the requested specimens.

Specimens later found to be misidentified by an applicant cannot be returned to the DAIDS Repository, and should be destroyed by the applicant investigator or his/her designated recipient laboratory.

Repository shipping containers, complete with pre-filled return address labels, will be used. The receiving laboratory must return these containers to the DAIDS Repository within five business days.

6.2.3. Cost of shipping samples

There are *no costs to applicants for specimen handling*. However, applicant investigators must provide to the DAIDS Repository staff the appropriate billing number for overnight shipping before shipment of an approved specimen request.

7.0 REFERENCES

Electronic Research Administration (eRA)

http://era.nih.gov/electronicReceipt/preparing_grantsgov_reg.htm#2/

eRA Commons

<http://commons.era.nih.gov/commons/>

Grants.gov

http://www.grants.gov/applicants/get_registered.jsp

Women and Infant Transmission Study (WITS) Public Datasets NTIS Website

<http://www.ntis.gov/search/product.aspx?ABBR=PB2009500037>

8.0 INQUIRIES

General questions regarding the WITS and scientific areas of inquiry should be directed to Dr. Carolyn Williams (cw237k@nih.gov, or 301-402-2305).

Questions regarding access to specimens and/or data should be directed to the email group, NIAIDWITSAccess@niaid.nih.gov

Questions and comments regarding this DAIDS procedure may be directed to the OPCRO Policy Group at: 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/Laboratories.aspx>

10.0 CHANGE SUMMARY

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

11.0 APPENDICES

None

12.0 APPROVAL

/ Scott Proestel, M.D. /
Scott Proestel