

DAIDS
Bethesda, MD USA

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

Approval Date: 11 AUG 2014

No.: DWD-SOP-LB-012.02

Effective Date: 01 OCT 2014

CHANGE SUMMARY NOTE: Policy has been reviewed for accuracy and updated to meet 508 compliance guidelines. This version supersedes version 1.0 dated 23 SEP 10.

1.0 PURPOSE

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

The WITS specimens are no longer available. Data from the study are still publicly available through the [National Technical Information Service \(NTIS\)/WITS](#).

2.0 SCOPE

This procedure applies only to archived 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.

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

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4.0 DEFINITIONS

For definitions see, [DAIDS glossary](#).

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 data;
2. provide advice about appropriateness of WITS data for proposed research.

6.0 POLICY

6.1 Access to Archived WITS DATA

Investigators wishing to access archived WITS data will:

Obtain the WITS Public Use Datasets CD-ROM which are publicly available through the [National Technical Information Service \(NTIS\)/WITS](#)

7.0 REFERENCES

[Women and Infant Transmission Study \(WITS\) Public Datasets NTIS Website](#)

8.0 INQUIRIES

General questions regarding the WITS and scientific areas of inquiry should be directed to [Dr. Carolyn Williams](#) or 301-402-2305.

Questions regarding access or quality of data should be directed to the [NIAID WITS Access](#) email group.

Questions and comments regarding this DAIDS procedure 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](#) webpage.

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10.0 APPENDICES

None

11.0 APPROVAL

Emily Erbelding, MD