

**To:** MTN 009 Protocol Team  
**From:** MTN 009 SCHARP Team  
**RE:** MTN 009 Procedure Completion Report

## Description of Data Used in this Report

This report includes data received at SCHARP prior to the production of the report, relevant to visits conducted through the final day of the month prior to the production of the report. The report is updated and posted on ATLAS on approximately the 10th of each month and includes visits through the end of the preceding month.

## Description of Procedure Completion Data

The purpose of this report is to summarize site performance regarding study endpoint data collection. The completion of the following procedures is summarized overall and by site:

1. Demographic form administration
2. ACASI questionnaire administration
3. HIV testing
4. Plasma specimen storage

### *Demographic Forms*

Demographic forms are expected for all participants enrolled in MTN 009. Demographics forms are counted as completed when the forms are present in the SCHARP database.

### *ACASI Questionnaires*

ACASI questionnaires are expected for all participants enrolled in MTN 009. These questionnaires are counted as completed when the Demographics forms are present in the SCHARP database, and these forms have a response of yes for question 19, "Did the participant complete the ACASI Questionnaire at this visit?"

### *HIV Testing*

HIV testing is expected for all participants enrolled in MTN 009. HIV testing is counted as completed when the Screening and Enrollment HIV Test Results (SEH) form is present in the SCHARP database with item 2 (Final HIV status) marked as negative, positive, or other.

### *Plasma Specimen Storage*

Plasma specimen storage is expected for all HIV-positive participants enrolled in MTN 009. Plasma specimens are counted as stored when item 2 on the SEH (Final HIV status) is positive AND a Laboratory Test Results (LTR) form is present in the SCHARP database with item 3 (Specimen Storage: Plasma) marked as stored.

Please contact the MTN 009 Project Manager at SCHARP, Karen Patterson ([karen@scharp.org](mailto:karen@scharp.org)), with any questions you may have regarding this report.