

Section 10. Reporting Plan

10.1 Purpose of Reporting Plan

During the study, SCHARP activities include: 1) ongoing review of all study data on CRFs, checking for completeness and accuracy; 2) monitoring of data collection, data quality, and study conduct; and 3) monitoring adherence to key protocol requirements.

The purposes of this plan are to:

- identify the content of each report;
- identify those responsible for production and distribution of each report;
- identify who should receive and review the reports so corrective action (if necessary) is taken.

10.2 Procedures

The reporting plan will be prepared by the HPTN 062 Project Manager at SCHARP in conjunction with SCHARP statisticians and programmers.

10.3 Reports

The table below lists the distribution frequency and distribution list for the reports described in this document. The exact day of the week these reports are distributed will be determined once data collection begins. The first Data Management Quality report will be produced once an adequate amount of data is in the database. The sections following this table describe each report in detail.

Report		Distribution Frequency	Distribution List
10.3.1	Enrollment/Retention	Updated daily and posted on SCHARP Web Portal	NA
10.3.2	Data Quality Control (QC)	Bi-monthly	Site Study Coordinator Site Data Manager Other site staff by request
10.3.3	Data Management Quality	Monthly	Protocol Teams, OCSO
10.3.4	Study Monitoring Committee (SMC)	After approximately 4 months of enrollment and every 6 months thereafter	SMC Protocol Chairs Observers from HPTN Core, SDMC, NL and DAIDS

10.3.1 Enrollment/Retention Report

Purpose To monitor participant enrollment and retention as reflected by CRF data received and entered by SCHARP.

Responsibility for Preparation: SCHARP HPTN 062 Protocol and Reporting Programmers

Frequency Updated daily

Distribution List: NA - posted on SCHARP Web Portal (ATLAS)

Components; Weekly and cumulative:

- Enrollment: The number of participants enrolled each week, and a comparison with the weekly enrollment targets.
- Retention: Includes total enrolled (broken down by active, inappropriately enrolled and lost to follow-up), expected for visit (including percentage of visits conducted on time and late), not expected for the visit and total retention calculated as the number of participants who have completed study visits divided by total number of participants expected for a visit.

10.3.2 Data Quality Control (QC) Report

Purpose: To identify and correct missing and inconsistent data in the database

Responsibility for Preparation: SCHARP HPTN 062 Data Coordinator

Frequency Bi-Monthly

Distribution List:

- Site Study Coordinator
- Site Data Manager
- Other site staff by request, such as QA/QC coordinator

Components: List of missing pages, overdue visits, missing data, questions about inconsistent or unclear data.

10.3.3 Data Management Quality Report

Purpose To summarize over time the site performance regarding data quality

Responsibility for Preparation: SCHARP HPTN 062 Project Manager

Frequency: Monthly

Distribution List: Protocol Team, OCSO

Components: Cumulative and past-month statistics:

- Total number DataFax form pages received.
- Total number of quality control (QC) errors identified in DataFax and sent to the site.
- Percent QCs Resolved.
- Rate of QCs sent per 100 pages.
- Mean number of days for the site to fax forms to DataFax.