

Section 10. Reporting Plan

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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 HPTN061 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
13.3.1	Enrollment/Retention	Updated daily and posted on SCHARP Web Portal	NA
13.3.2	Data Quality Control (QC)	Bi-monthly	Site Study Coordinator Site Data Manager Other site staff by request
13.3.3	Data Management Quality	Monthly	Protocol Teams, OCSO
13.3.4	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 HPTN061 Protocol and Reporting Programmers
Frequency	Updated daily
Distribution List	NA - posted on SCHARP Web Portal (ATLAS)
Components	By site, weekly and cumulative: <ul style="list-style-type: none">• Enrollment: For all sites individually and combined, the number of participants enrolled each week, and a comparison with the weekly enrollment targets.• Retention: For all sites individually and combined by visit. 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 HPTN061 Data Coordinator
Frequency	Bi-Monthly
Distribution List	Site Study Coordinator Site Data Manager Other site staff by request, such as QA/QC coordinator
Components	<ul style="list-style-type: none">• 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 site performance regarding data quality
Responsibility for Preparation	SCHARP HPTN061 Project Manager
Frequency	Monthly
Distribution List	Protocol Team, OCSO
Components	Cummulative and past-month statistics: <ul style="list-style-type: none">• 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 sites to fax forms to DataFax.

10.3.4 Study Monitoring Committee (SMC) Report

Purpose	To monitor the progress of the study and study conduct at each site.
Responsibility for Preparation	SCHARP HPTN061 Statistical Research Associates, with assistance from SCHARP study team
Frequency	After about 4 months of enrollment and every 6 months thereafter, or as determined by the SMC.
Distribution List	SMC Protocol Chairs Observers from HPTN Core, SDMC, NL, DAIDS
Components	Summary by site, and overall: <ul style="list-style-type: none">• Summary of trial design and SMC history• Accrual of participants• Baseline characteristics• Retention• Termination• Other study conduct information, as required by the SMC