Section 11. Reporting Plan

11.1 Purpose of Reporting Plan

During the study, the Statistical and Data Management Center (SDMC) for HPTN74 (SCHARP) will: 1) review all study data on CRFs, checking for completeness and accuracy; 2) monitor data collection, data quality, and study conduct; 3) monitor adherence to key protocol requirements; and 4) produce reports.

The purpose of this reporting plan is 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.
- ensure the Protocol Team approves the plan prior to study initiation.

The reporting plan is prepared by the HPTN074 SDMC Project Manager at SCHARP in conjunction with SDMC HPTN074 statisticians and programmers.

11.2 Reports

The table below lists the distribution frequency and distribution list for the reports that will be produced for HPTN074. 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 Name	Purpose	Components	Distribution Frequency	Responsibility for Preparation	Distribution Platform	Distribution List
Enrollment and Randomization	Monitors participant enrollment and randomization as reflected by case report form data received and entered into DataFax	Enrollment and retention data are presented for all sites individually and across all study sites. Includes the number of participants randomized and enrolled each week (compared with weekly enrollment targets)	Daily	SDMC Protocol Programmer	Atlas	Anyone
Retention	Monitors participant retention as reflected by case report form data received and entered into DataFax	Retention data are presented for all sites individually and across all study sites. Includes the total number participants randomized and 1) retained 2) visit not done, and 3) lost to follow-up Total retention is the number of participants randomized who completed follow-up visits divided by the total number of participants expected for a visit	Daily	SDMC Protocol Programmer	Atlas	Anyone
Data Quality Control (QC)	Identifies missing and/or inconsistent data	Lists missing pages, overdue visits, missing data, and questions about inconsistent or unclear data	Every 2 weeks	SDMC Data Coordinator	E-mail	Site Study Coordinator, Site Data Manager, Other site staff as requested, SDMC Project Manager

Site Data Management Quality	Summarizes site performance in data management and quality	Cumulative and previous-month statistics including: • 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 CRFs to SCHARP DataFax • Mean number of days for sites to fax AE CRF to SCHARP DataFax	Monthly	SDMC Project Manager	Atlas	Anyone
Site-Specific Specimen Monitoring	Compares the storage of specimens in LDMS to those indicated as "stored" on case report forms	Site-specific listings of all discrepancies between the case report form and data entered into LDMS as well as LDMS data entry errors	Bi-monthly	SDMC Lab Data Operations Programmer	E-mail	Site Study Coordinator, Other site staff as requested, Laboratory Center Representative, SDMC Project Manager
Study Monitoring Committee (SMC)	Monitors the overall progress of the study and study conduct at each site	Summary by site, and overall: • Trial design and SMC history • Accrual • Baseline characteristics of participants	Will occur after ~ 4 months of enrollment and every 6 months thereafter	SDMC Statistical Research Associates, with assistance from SCHARP study team	E-mail	SMC (open/closed), Protocol Chairs (open), Selected members of HPTN Core, SDMC,

		• Enrollment, randomization and retention of participants • Adverse event data • Termination Other study conduct information, as required by the SMC				Network Lab and DAIDS (open)