

# Section 13. Reporting Plan for HPTN057

---

<b>Protocol Statistician:</b>	Elizabeth Brown
<b>Project Manager:</b>	Lynda Emel
<b>Statistical Research Associate:</b>	Fang Gai and Tony Mwatha
<b>SAS Programmers:</b>	Jackie Fitzpatrick
<b>Data Coordinator:</b>	Debbie Lands
<b>Technical Document Specialist:</b>	Stacie Kentop
<b>Clinical Affairs Safety Associate:</b>	Molly Swenson

## 13.1 Purpose of Reporting Plan

This Reporting Plan describes the procedures and reports that SCHARP plans to use to monitor data collection, data quality, participant safety and trial conduct for HPTN057. During the study, SCHARP activities will include: 1) ongoing review of all study data, checking for completeness and accuracy; 2) production of reports for monitoring of study enrollment, retention rates, safety and study results; 3) monitoring adherence to key protocol requirements

The purposes of this plan are:

- to identify the content of each report;
- to identify those responsible for the production, review, and distribution of each report;
- to identify who should receive and review the reports so corrective action (if necessary) is taken; and
- to ensure that the protocol team approves and agrees to both the types of reports to be generated by SCHARP and the schedule for reporting.

## 13.2 Procedures

This reporting plan has been prepared by the Project Manager at SCHARP in conjunction with SCHARP statisticians and programmers. The dates in this monitoring plan are estimates since some analyses are event-driven rather than time-driven. Therefore, this plan will be modified as necessary.

## 13.3 Reports

The schedule table below lists the various reports that SCHARP will produce and the frequency of distribution. Following the table is a description of each report that includes the purpose, who will prepare the report, the distribution frequency, who will receive the report, the method of distribution, and specific components of the report. The day of the week these reports are distributed will be determined once data collection begins. The first Site Data Management Quality Report will be produced once an adequate amount of data is in DataFax. Thereafter, these reports will be produced on a monthly basis based on the date of the first report.

**Table 13-1: Reporting Schedule**

<b>Report</b>	<b>Distribution Frequency</b>	<b>Distribution List</b>
<b>13.3.1 Enrollment/Retention</b>	Updated daily	Posted on Atlas
<b>13.3.2 Data Quality Control (QC)</b>	Bi-monthly, or as needed	- Site Study Coordinators - Site Data Managers - SCHARP Project Manager
<b>13.3.3 Clinical Queries</b>	As needed	Staff designated by site
<b>13.3.4 Site Data Management Quality Report</b>	Monthly, or as needed	Posted on Atlas
<b>13.3.5 Protocol Safety Review Team (PSRT)</b>	Weekly, or as needed	Protocol Safety Review Team: - Protocol Statistician - Protocol Chair - NIAID Medical Officer - NICHD Medical Officer - SCHARP Clinical Staff - SCHARP Project Manager - CORE Clinical Research Manager - Designated Site Clinicians
<b>13.3.6 Study Monitoring Committee (SMC)</b>	As determined by the SMC (no more SMC reviews anticipated)	SMC Protocol Team Others, as needed

In general, routine reports generated from the SCHARP database (e.g., QC Reports, Enrollment/Retention Reports) will include data submitted by sites up to 10 calendar days prior to the date of the report. Other reports, such as SMC Reports, will have a scheduled data submission cut-off date communicated to sites before the report is generated.

---

### 13.3.1 Enrollment and Retention Report

**Purpose:** To monitor participant accrual and retention as reflected by data submitted to SCHARP DataFax.

**Responsibility for Preparation:** SCHARP HPTN057 SAS Programmers

**Responsibility for Distribution:** SCHARP HPTN057 SAS Programmers

**Frequency:** Updated daily

**Distribution List:** Posted to Atlas web portal

**Components:** Enrollment: the number of infants enrolled/randomized.  
Retention: Includes: Total enrolled (broken down by active, inappropriately enrolled, lost to follow-up and deceased status), expected for next visit (including percentage of visits conducted on time and late), not expected for next visit. Percent retained is calculated as the number of participants who are expected and have completed a visit divided by total number of participants expected for a visit.

---

### 13.3.2 Data Quality Control (QC) Report

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

**Responsibility**

**for Preparation:**

- SCHARP HPTN057 Data Coordinator
- SCHARP HPTN057 SAS Programmers
- SCHARP HPTN057 Project Manager

**Responsibility**

**for Distribution:** SCHARP HPTN057 Data Coordinator

**Frequency:** Bi-monthly, or as needed

**Distribution List:** Distributed by e-mail to Site Study Coordinator, Site Data Manager, CORE CRM, and SCHARP Project Manager.

**Components:**

- Fax/Re-fax list (missing pages, overdue visits, missing data, inconsistent data)
- Questions and Answers (more complex problems)

---

### 13.3.3 Clinical Queries Report

**Purpose:** To identify and reconcile clinical and laboratory issues and inconsistencies to study data.

**Responsibility**

**for Preparation:** SCHARP HPTN057 Clinical Affairs Safety Associate

**Responsibility**

**for Distribution:** SCHARP HPTN057 Clinical Affairs Safety Associate

**Frequency:** Weekly or as needed

**Distribution List:** Distributed by e-mail to site clinical staff designated, CORE Clinical Research Manager

**Components:** Two types of clinical queries:

- The first is the Clinical Query and is used by Clinical Affairs Safety Associates (CASA) to acquire additional information on abnormal lab values, physical exam data, clinical adverse events, suspected etiology of the AE, or the site's plan for follow-up.
- The second type of query is the AE Clarification Request. This query is generated by the MedDRA coding staff to clarify AE description or diagnosis on the Adverse Experience Log form.

---

### 13.3.4 Site Data Management Quality Report

**Purpose:** To summarize site performance regarding data management and quality.

**Responsibility**

**for Preparation:** SCHARP HPTN057 Project Manager

**Responsibility**

**for Distribution:** SCHARP HPTN057 Project Manager

**Frequency:** Monthly, or as needed

**Distribution List:** Posted to Atlas web portal

**Components:**

- Total Records: The total number of CRF (DataFax) pages received by site.
- Total QCs: The total number of quality control errors identified on the pages included in Total Records. Data is presented by site.
- QC Rate/100 Pages: The average number of quality control errors identified (per the description of Total QCs above) for every 100 pages of data received by SCHARP. Data is presented by site.

---

### 13.3.5 Protocol Safety Review Team (PSRT) Reports

**Purpose:** To monitor study adverse experiences and laboratory toxicities on a regular basis

**Responsibility**

- for Preparation:**
- SCHARP Reporting Programmers
  - SCHARP HPTN057 Clinical Affairs Safety Associate

**Frequency:** Every week, or as determined by the HPTN057 PSRT

**Distribution List:** Posted to Atlas web portal

**Components:** There are four standard reports;

- Safety Review Report (SRR): By participant listings of demographics, AEs and abnormal lab values.
- Adverse Experience Requiring Review report (AERR): By participant listings of selected AE data.
- Safety Summary: Summary of reactogenicity and adverse experiences by severity, relationship to vaccine and body system.
- Pre-Existing Conditions: By participant listing of all pre-existing conditions.

---

### 13.3.6 Study Monitoring Committee (SMC) Report

**Purpose:** To monitor study progress at each site.

**Responsibility**

**for Preparation:**

- SCHARP HPTN057 Data Coordinators
- SCHARP HPTN057 SAS Programmers
- SCHARP HPTN057 Statistical Research Associates
- SCHARP HPTN057 Project Manager
- SCHARP HPTN057 Technical Document Specialist
- SCHARP HPTN057 Statistician (to review prior to distribution)

**Responsibility**

**for Distribution:**

- SCHARP HPTN057 Technical Document Specialist
- SCHARP HPTN057 Statistical Research Associates

**Frequency:** Every 6 months, or as determined by the HPTN SMC

**Distribution List:** Distributed by e-mail to HPTN SMC members, the Protocol Team, and others as needed.

**Components:** Summary of:

- Trial Design and History
- Accrual
- Retention
- Mother Demographics
- Infant Baseline Characteristics
- Adherence to Study Drug dosing
- Availability of primary and secondary endpoint data
- Termination
- Adherence to visit schedule
- Site Performance
- Other information, as requested by the SMC