

MEMORANDUM

Date: March 15, 2012
To: HPTN 067 Protocol Team, HPTN067 Sites
From: HPTN067 SCHARP Team
RE: **HPTN067 Enrollment/Randomization and Retention Reports**

The **Enrollment/Randomization and Retention Reports** for HPTN067 are updated nightly and are based on cumulative data received at SCHARP through the previous week. The reports are meant for use by the protocol team to monitor study progress. These reports contain information for sites that have been activated and include the following information:

1. Enrollment/Randomization Report

- Summary table showing the number of participants enrolled each week (by site and cumulatively)
- Summary table showing the number of participants randomized each week (by site and cumulatively)
- Graph showing randomizations for all sites combined
- Graphs showing randomizations and expected number of randomizations for each active site

2. Retention Report

- Summary table showing the number of participants retained at each DOT visit (by site and cumulatively)
- Summary table showing the number of participants retained at each post-randomization visit (by site and cumulatively)

Please contact the HPTN067 Project Manager at SCHARP, Laura McKinstry (lamckins@scharp.org), with any questions you may have regarding these reports.

Thank you.

Definitions of terms used in the Enrollment and Randomization Report

Enrollment Table:

- **First Enrollment Date** – Enrollment date of the first enrolled participant.
- **Total Weeks** – Total number of weeks since the first participant enrolled.
- **Total Enrollment** – Total number of participants enrolled in the study.
- **Average Per Week** – Average number of participants enrolled each week.

$$\text{Average Per Week} = \text{Total Enrollment} / \text{Total Weeks}$$

Randomization Table:

- **First Randomization Date** – Randomization date of the first randomized participant.
- **Total Weeks** – Total number of weeks since the first participant randomized.
- **Total Randomized** – Total number of participants randomized.
- **Average Per Week** – Average number of participants randomized each week.

$$\text{Average Per Week} = \text{Total Randomized} / \text{Total Weeks}$$

- **Site Target** – Target number of randomized participants for this site, as specified in the protocol.
- **Randomizations Needed** – Total number of randomizations still needed for this site.

$$\text{Randomizations Needed} = \text{Site Target} - \text{Total Randomized}$$

Definitions of terms used in the Retention Report

- Participants are not considered **Expected** for a visit until the target window for the visit has closed.
- If an expected participant has completed the visit before the allowable window closes, the participant is considered as **Retained** at that visit.
- Expected participants who did not complete the visit are categorized as **Not done**.
- **Lost to follow-up** is defined as those participants who are terminated early from the study.