

## HPTN062 Data Communiqué #4

25 March 2011

This is official study documentation for the HPTN062 trial. Please print it and circulate among relevant staff for their review, and file it in your HPTN062 SSP Manual behind the “Communiqués” tab. This document is considered part of the SSP manual.

### UPDATES

#### **Back-up Randomization Procedures:**

In circumstances where CTU staff need to randomize a participant, but are unable to access the online randomization system for whatever reason, the site should do one of the following:

- If the technical problems are expected to resolve quickly, determine if the participant is able to wait at the site until another attempt can be made, or
- Arrange for the participant to return within the randomization/enrollment window to be randomized, or
- Contact one of the **SCHARP emergency randomization contacts, or one of the HPTN 062 backup emergency randomization contacts below**. These contacts are each able to randomize participants if the site is unable to do so.
- **You will need to provide the participant ID(s) (PTIDs). If the online system is down, you will also need to provide the number of participants previously enrolled.**

NOTE: Keep in mind there is a 9 or 10 hour time difference between SCHARP and Lilongwe, and a 6 or 7 hour time difference between U.S. east coast contacts and Lilongwe (depending on whether or not the U.S. is on daylight savings time). Leave a message if your call is not answered immediately and you will be contacted as quickly as possible.

**SCHARP Emergency Randomization Contacts:** These contacts are able to randomize participants whether or not the online system is available. NOTE: If the online system is down you will need to provide the number of participants previously enrolled in addition to participant PTID(s); this information will be used to determine the next available randomization assignment on the list of randomization slots/assignments.

Diana Lynn:  
Work: 206-667-4980  
Cell: 425-941-8087 (text messaging accepted)  
Home: 425-820-8547  
Email: dlynn@scharp.org

San-San Ou:  
Work: 206-667-5502  
Cell: 919-599-2159  
Email: sou@scharp.org

**HPTN 062 backup emergency contact below:** These contacts are able to randomize participants if the online system is available, but not if the online system is down.

Amy Corneli:  
Work: 919-544-7040, ext 11248  
Work cell: 919-450-5954  
Home: 919-960-8409  
Personal cell: 919-265-9170  
Email: ACorneli@fhi.org

Audrey Pettifor:  
Cell: 919-260-2394  
Email: apettif@email.unc.edu

REMINDER:

**Randomization System Link:** Authorized staff can access the Randomization System via the HPTN 062 Web page at [http://www.hptn.org/research\\_studies/hptn062.asp](http://www.hptn.org/research_studies/hptn062.asp). Look for the “HPTN 062 Randomization Page” link under “HPTN 062 Quick Links”, pictured here:

