

## **IMPLEMENTATION PLAN FOR THE PROTOCOL REGISTRATION POLICY AND MANUAL**

The DAIDS Protocol Registration manual and policy will go into effect on May 3, 2010.

On April 26, 2010, the manual, policy, final implementation plan, and other supporting documents will be distributed and posted on the NIAID and RCC web sites.

Beginning November 1, 2010 all sites must meet all the requirements of the new policy and manual. This means that any registration submissions made by sites on or after November 1, 2010 must include the new documentation outlined in the new policy and manual.

### **1. Implementing the new protocol registration language in protocols**

- a. Starting the week of April 12, 2010, the DAIDS Protocol Registration Team (DAIDS PRT) will begin providing a determination regarding protocol registration requirements at the time of DAIDS SRC for new protocols in development. Teams should include the appropriate protocol registration language in the protocol based on that determination.
- b. Starting the week of April 12, 2010, protocol teams will be required to include the new protocol registration language in any full version amendments and letters of amendment (LoAs) in development.
- c. Any new protocols, full version amendments or LoAs that completed final DAIDS sign-off before April 12, 2010 will NOT be required to change any protocol registration language. These protocols will continue under the current protocol registration system until all sites complete registration for that version. Any future full version amendments or LoAs must include the new protocol registration language.

### **2. Training**

- a. Protocol Registration policy/manual/DAIDS Protocol Registration System (DPRS) training will be available for network meetings upon network request. Sessions are currently confirmed for the upcoming ACTG and HPTN Network Meetings. The DAIDS training group is working with other networks to schedule trainings.
- b. Webinars may be provided for non-network/network groups who are unable to schedule or attend face-to-face trainings. An announcement will be sent to non-network/network groups when webinar scheduling is available.
- c. Protocol Registration training will be provided at the DAIDS Regional Training Event (DRTE) in Lusaka, Zambia (August 2010). Additional trainings may be scheduled at future DRTEs based on training resources as needed.
- d. An electronic-learning/computer-based learning tool is in development and will be available in early 2011.

### **3. What can sites expect**

- a. Beginning April 26, 2010 the DAIDS Protocol Registration Office (DAIDS PRO) will implement new procedures to be in compliance with the new policy and manual and to meet the needs of the DAIDS Adverse Experiences Reporting System (DAERS). Site can expect the following changes:
  - i. sites will begin receiving Registration Notifications in place of Approval Notices and Acknowledgment of Materials Received Notices.
  - ii. sites will begin receiving Confirmation of Submission notices instead of Receipt of Submission notices

NOTE: The PRO will not hold up any registrations when sites submit registration packets that do not include the new documents specified in the new policy and manual until November 1, 2010.