16 NEW SITE REQUIREMENTS

16.1 Site-specific Requirements

All new HPTN Clinical Research Sites (CRSs) or other established site at the discretion of the Division of AIDS (DAIDS) must meet certain requirements prior to receiving DAIDS Site Activation. This approval is different from study-specific site activation. Office of Clinical Site Oversight (OCSO) site approval does not indicate that a CRS may begin conducting a study. CRS staff must work with the Leadership and Operations Center (LOC), Laboratory Center (LC), Statistical and Data Management Center (SDMC) and DAIDS staff to ensure Network and protocol-specific requirements are met. The OCSO Program Officer (PO) will: (1) communicate site activation requirements to the site; (2) identify issues; (3) facilitate issue resolution to efficiently complete the site activation process.

Requirements and SOPs are reviewed and verified by OCSO.

Before site activation by OCSO, a CRS must have a PAB-approved pharmacy. The Pharmacist of Record (PoR) must complete a PAB Pharmacy Establishment Plan (PEP) and any applicable associated PEP Modules for each pharmacy associated with a CRS and submit these documents to PAB for review and approval

16.2 Site SOPs

HPTN CRSs are expected to have written SOPs for site operations and study operations to ensure compliance with HPTN and DAIDS procedures, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) E6 Guidelines (use drop down menu in the webpage) and United States Food and Drug Administration (US FDA) regulations and any other regulations, where applicable. CRSs will develop certain site-specific SOPs that describe the procedures for general site operations – i.e., those that are applicable across all studies performed at that site. Existing site SOPs may be used to satisfy these requirements.

Sites must follow the policies and template outlined in the DAIDS SCORE Manual for development of SOPs: https://www.niaid.nih.gov/sites/default/files/score-quality-management.pdf

16.3 Clinical Site Monitor Special Assignment Initiation Visit

The OCSO PO may choose to have the Laboratory or Clinical Site Monitor conduct an initiation visit before the initiation of a new HPTN site. The purpose of this visit is to ensure that both the facility and staff can carry out the DAIDS research.

16.4 CRS Relocation to a New Site

Although not technically a new site, an established CRS may transfer mid-study to a new clinical research location. This is expected to be rare, but the steps needed for a successful transfer are outlined below. The lists may not be exhaustive. The initial declaration of intent to move should be made simultaneously to the CRS's OCSO Program Officer and to the HPTN Central Resources (LOC, LC, and SDMC).

16.4.1 DAIDS OCSO Responsibilities

DAIDS OCSO, including PAB (if applicable), will ensure the CRS completes the following after giving approval to complete the transfer (discussion of any HPTN Pharmacist responsibilities are considered in Section 23):

- The new CRS needs to be registered and updated in the NIAID CRMS
- After new registration is confirmed, the old CRS needs to be de-registered

- If there is a change in pharmacy location associated with the new clinical research location, the PoR must complete a new PAB Pharmacy Establishment Plan (PEP) and applicable PEP Modules and submit these documents to PAB for review and approval
- Notification must be made to the RSC safety teams so important information goes to the new site location
- OCSO decides if the participant charts can simply be transferred from the old site to the new or if certified copies need to be made and transferred

16.4.2 LOC, LC and SDMC Responsibilities

The LOC, LC and SDMC will ensure that the CRS completes the following for the new site transfer:

- Registration will signal the participants' data transfer, which will be managed by the SDMC
- The LOC will confirm if the CRS is still enrolling or not
- The LOC will ensure the creation of alias lists for the new site location
- The LC will provide their approval after laboratory requirements for the new CRS are met (e.g., new protocol analyte list (PAL), chain of custody, etc.)
- The LOC will discuss with OCSO the need for study-specific re-activation and the need for participant re-consent. Re-consenting decisions may be left to the discretion of the responsible IRB/EC