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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 Division of AIDS Site Activation. This approval is different from study specific protocol activation approval. 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 in order to efficiently complete the site activation process.

Requirements and SOPs are reviewed and verified by OCSO.

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 Conference of Harmonisation \(ICH\) Good Clinical Practice 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 also see DAIDS Appendix: [Required Site SOPs](#).

SOPs describe and document a research site's approach to conducting research and serve to ensure standard, uniform performance of site- and study-related tasks. SOPs identify who is responsible for a task and describe actions to be conducted by responsible staff. SOPs also may serve as useful training tools for new staff. The same format should be used for all SOPs at a research site. In general, it is recommended that the SOP format include, at a minimum, the following elements:

- SOP number and title
- Purpose
- Scope (to whom the SOP applies)
- Staff responsibilities/roles
- Procedure listing/description
- Reference to relevant regulations and guidelines
- Version number and approval and effective date
- Revision history (when the SOP was revised and why)
- Approval signature(s)

Additional, optional elements that may be included in site SOPs include responsibilities, materials and equipment, and definitions.

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 are able to carry out the DAIDS research.

Date of Issue: DECEMBER 2018

16.4 CRS Relocation to a New Site

Although not technically a new site, an established CRS may transfer mid-study 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 Operations Groups (LOC, LC, and SDMC). This will allow for the cascade of events relative to the move to happen with the greatest coordination.

16.4.1 DAIDS OCSO and PAB Responsibilities

OCSO and PAB will ensure the CRS completes the following after giving approval to complete the transfer:

- The new CRS needs to be registered and updated in the NCRMS
- After new registration is confirmed, the old CRS needs to be de-registered
- Registration of the new CRS triggers PAB for shipment of study product after completion of required pharmacy documents (chain of custody, temperature transportation logs, etc.) and transportation of equipment (biosafety cabinet, freezers, etc.)
- 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. The SDMC will prepare the new PTIDs and supervise the movement of data which will include the protocol database, enrollment/retention database and the data feed to the NIAID CRMS
- 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 (new PAL, reference ranges, 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 local IRB/EC