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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 the following minimum requirements prior to receiving Division of AIDS Site Approval (see Office of Clinical Site Oversight (OCSO) SOP entitled Clinical Research Site Approval Process for Network Sites). This approval is different from study specific site activation approval. As such, 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) and DAIDS staff to ensure Network and protocol-specific requirements are met. The OCSO Program Officer (PO) will: (1) communicate site approval requirements to the site; (2) identify issues; (3) facilitate issue resolution in order to efficiently complete the site approval process.

Requirements and SOPs are reviewed and verified by OCSO (see the OCSO SOP on Activation and OCSO requirements).

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 and United States Food and Drug Administration (US FDA) 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 policy: Requirements for Manual of Operational Procedures).

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.