# 1. Introduction


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## 1.1 Overview of Manual

This study specific procedures (SSP) manual includes specifics on study conduct including the sources of procedural information available to HPTN 083-02 study site staff, the responsibilities of the site Investigators, site activation processes and requirements, data collection, entry, and processing, and reporting of serious adverse events (SAE), social harms and protocol deviations by site staff for HPTN 083-02.

## 1.2 Source of Procedural Information

All study procedures must be conducted in accordance with the study protocol and this SSP manual. Unless instructed by the HPTN Leadership and Operations Center (LOC), if there is inconsistency between this manual and the protocol, the specifications of the protocol take precedence. Please alert the HPTN Leadership and Operations Center (LOC) of any such inconsistencies.

In instances where there is an urgent need for a change to the SSP manual, and when a full revision of the SSP is not imminent, the LOC may distribute an email containing a "Notification of Interim Change" to the current version of the SSP manual. These interim changes will be considered an official part of the SSP manual, and should be considered official by any monitoring agents. Study site staff are encouraged to contact the HPTN LOC Clinical Research Managers (CRM) with all questions related to interpretation and proper implementation of the protocol. Sites Participating in HPTN 083-02

## 1.3 Sites Participating in HPTN 083-02

Clinical Research Sites (CRSs) that will participate in HPTN 083-02 are listed in Table 1.

**Table 1**
**Participating HPTN 083-02 Sites by Region**

| Region | CRS Name | CRS ID | City | State/ Country |
|---|---|---|---|---|
| Africa | Groote Schuur HIV CRS | 31708 | Cape Town | South Africa |
| Asia | Thai Red Cross AIDS Research Centre (TRC-ARC) CRS | 31802 | Bangkok | Thailand |

| | | | | |
|---|---|---|---|---|
| Latin America | Instituto de Pesquisa Clinica Evandro Chagas (IPEC) CRS | 12101 | Rio de Janeiro | Brazil |
| US | Hope Clinic of the Emory Vaccine Center CRS | 31440 | Decatur | Georgia |
| US | Adolescent and Young Adult Research at the CORE Center (AYAR at CORE) | 31958 | Chicago | Illinois |

## 1.4 Investigator Responsibilities

HPTN 083-02 must be conducted in accordance with the US Code of Federal Regulations (CFR) and the International Conference on Harmonization (ICH) Consolidated Guideline for Good Clinical Practice (GCP). Copies of the regulations governing the conduct of this study (45 CFR 46 and 21 CFR 11, 50, 54, 56, and 312) and the ICH guideline can be requested from the HPTN LOC or found online at https://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR and http://www.ich.org/home.html respectively. The DAIDS Policy for Requirements for Essential Documents at Clinical Research Sites Conducting DAIDS Funded and/or Sponsored Clinical Trials (DWD-POL-RA-03.00) and the DAIDS Policy for Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials (DWD-POL-CL-04.00), which are useful for interpreting and operationalizing these regulations and guidelines, can be downloaded from https://www.niaid.nih.gov/research/daids-clinical-site-implementation-operations.

HPTN 083-02 also must be conducted in accordance with all local regulations, policies, and guidelines applicable to human subjects research in general and/or the conduct of study procedures in particular.

The Investigator of Record (IoR) at each site is the person responsible for the conduct of the clinical trial at the clinical research site. This person is the signatory for the FDA Form 1572 which must be signed prior to site activation, to formally indicate his/her agreement to conduct the study in accordance with the protocol; this SSP manual; all applicable US and in country regulations, policies, and guidelines; and HPTN policies.

Investigators may delegate work involved in conducting the study to other study staff members; however, delegation does not relieve the Investigator of his/her ultimate responsibility for all study procedures performed and all study data collected. Additional guidance can be found in the US Food and Drug Administration's Information Sheet Guidance: Information Sheet Guidance for Institutional Review Boards (IRBs), Clinical Investigators, and Sponsors available at https://www.fda.gov/science-research/guidance-documents-including-information-sheets-and-notices/information-sheet-guidance-institutional-review-boards-irbs-clinical-investigators-and-sponsors.