

Division of AIDS (DAIDS) Site Clinical Operations and Research Essentials (SCORE) Manual: DAIDS Protocol Registration and Institutional Review Board/Ethics Committee Communications

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DAIDS Protocol Registration Process and Institutional Review Board/Ethics Committee Communications

Ethical and regulatory approvals ensure protection of participants' rights and well-being, study data integrity, and adherence to applicable regulations.

The Principal Investigator (PI)/Investigator of Record (IoR) must obtain all necessary ethical and regulatory approvals before enrolling participants in DAIDS clinical trials, and report any updates to the clinical trial, e.g., protocol amendments, serious adverse events (SAEs), etc. to the ethical and regulatory bodies.

The Office for Policy in Clinical Research Operations (OPCRO) [Protocol Registration Manual](#) defines mandatory Clinical Research Site (CRS) processes for registering protocols according to DAIDS Clinical Research Policies and requirements (as applicable), in addition to all applicable regulations for human subjects protection and the use of study products, biologics, and/or devices.

CRSs will complete the protocol registration process for all applicable DAIDS clinical trials.

Communicating with the Institutional Review Board /Ethics Committee

CRSs must have an Institutional Review Boards (IRBs)/Ethics Committees (ECs) that adheres to International Council for Harmonisation (ICH) Good Clinical Practices (GCP), also referred to as ICH E6, and applicable local laws and regulations. IRB/EC must have an active Federal Wide Assurance (FWA) (or equivalent) as well as a statement of compliance as per applicable regulations.

CRSs must submit to their IRB/EC and other applicable Regulatory Entities (REs)/Regulatory Authorities (RAs) for review and approval the initial version and all subsequent versions of: protocol; letters of amendment (LoA); CRS-specific Informed Consent Forms (ICFs); Investigator's Brochure (IB); participant recruitment advertisements; and any other documentation (participant diaries, parent/caregiver dose preparation instructions, self-nasal swab collection instructions, etc.) that they plan to give participants.

Before implementing the protocol and enrolling participants, CRSs must receive approval from their IRB/EC and other applicable REs/RAs, as well as successfully complete DAIDS protocol registration.

During the study, CRSs must submit all documents to their IRB/EC and applicable REs/RAs, as required. These documents may include annual or semi-annual reports; continuing approvals; protocol deviation(s); adverse events (AEs); severe adverse events (SAEs); notifications of premature clinical trial termination or suspension.

Some IRBs/ECs and REs/RAs may have stricter reporting requirements for SAEs than DAIDS, in which case the CRS must follow those requirements.

Upon study completion, the CRS should provide the IRB/EC and applicable REs/RAs with a summary of its clinical trial-related activities and any known clinical trial outcome(s). CRSs must adhere to their IRB's/EC's and/or RE's/RA's additional reporting requirements, as per local laws and regulations.

Communicating with the DAIDS Protocol Registration Office

Before beginning the DAIDS protocol registration process, CRSs must:

- Receive final DAIDS approval for the protocol.
- Complete all Office of Clinical Site Oversight (OCSO) Site Activation requirements that can be found in the section [Site Activation Process](#) of this manual.
- Train delegated CRS staff on DAIDS Protocol Registration System (DPRS).
- Receive IRB/EC approval of the protocol, ICF, and other protocol-related documents.

DAIDS protocol registration process verifies that:

- CRSs received the necessary IRB/EC, RE/RA, and Institutional Biosafety Committee (IBC) approvals as applicable.
- CRSs provided all the pertinent qualification and requirements documentation that DAIDS, ICH E6, United States (U.S.) federal regulations, and National Institutes of Health (NIH) require.
- CRS-specific ICFs contain the ICH E6's and U.S. federal regulations' compliance information, including the required ICF elements, per 45 Code of Federal Regulations (CFR) part 46.116 and 21 CFR part 50.25.

CRSs can begin by submitting protocol registration documents via the DPRS, track and monitor progress of submissions, provide corrections or updates, respond to reminders and notifications from the system, and view registration reports. For more information about the DPRS, see the [Introduction to DAIDS Systems](#) section of this manual.

The Regulatory Support Center of the Protocol Registration Office (PRO) will provide CRS staff initial registration notification as one of the requirements for Network Protocol Activation. Screening and enrollment can only begin once OCSO Site Activation and Network Protocol Activation approvals are obtained.

Each CRS will submit to the PRO all subsequent IRB/EC approvals (protocol amendments, revised consent forms, etc.) that were received during the study.

The *Protocol Registration Manual* details clinical trial-wide submission requirements for each PRO-required document and process.

References

1. [Protocol Registration Manual](#)