Division of AIDS (DAIDS) Site Clinical Operations and Research Essentials (SCORE) Manual: Pharmacy Requirements

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Pharmacy Requirements

The Division of AIDS (DAIDS) is responsible for complying with regulations and requirements governing the management of study products used in DAIDS clinical trials which include:

- United States (U.S.) Food and Drug Administration (FDA) regulations
- International Council for Harmonisation (ICH) Good Clinical Practice (GCP) requirements (ICH E6)
- Regulations outlined by other international authorities, such as the European Medicines Agency (EMA)

The Principal Investigator (PI)/ Investigator of Record (IoR) at a DAIDS Clinical Research Site (CRS) ensures that a study is conducted in accordance with the protocol, U.S. federal regulations, in-country regulations, provisions imposed by the Institutional Review Board (IRB)/Ethics Committee (EC), and any other applicable regulatory entities. The PI/IoR oversees all clinical trial-related site activities, including day-to-day operations, performance, and compliance.

DAIDS requires that the PI/IoR delegates the responsibility of study product management to a licensed/registered Pharmacist of Record (PoR). The PI/IoR oversees pharmacy-related activities for each clinical trial including but not limited to the following:

- Ensuring the PoR is trained and demonstrates adequate understanding of the clinical trial
- Implementing procedures to ensure the site PoR manages study products in accordance with the protocol
- Ensuring that the PoR has established procedures for the maintenance of study product management records in compliance with protocol and applicable regulations
- Providing adequate supervision for the delegated pharmacy activities to ensure the PoR complies with applicable protocol and regulatory requirements

Pharmacy Guidelines for DAIDS Clinical Trials Networks

The DAIDS Pharmaceutical Affairs Branch (PAB) has established the *Pharmacy Guidelines and Instructions for DAIDS Clinical Trials Networks* which describes the required pharmacy and study product management standards for the conduct of DAIDS clinical trials and includes requirements for personnel, facilities, equipment, and processes. The PoR is expected to comply with these guidelines, in addition to local and in-country regulations for pharmacy practice.

Pharmacist of Record and Associate Pharmacist Responsibilities

The PoR is a licensed/registered pharmacist who performs the day-to-day pharmacy and study product management activities including receiving, storing, preparing, dispensing, and final disposition of study products for DAIDS clinical trials.

The PoR also establishes site pharmacy policies and procedures including a pharmacy quality management plan.

The Associate Pharmacist (AP) is a licensed/registered pharmacist who fulfills the role and responsibilities of the PoR in their absence.

CRS Pharmacy Requirements

- Before site activation by the Office of Clinical Site Oversight (OCSO), a CRS must have a PAB-approved pharmacy. Refer to Site Activation Process section of this manual for additional information regarding Site Activation.

- The 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.

- The PEP Modules include: Refrigerated Storage, -20°C Freezer Storage, -70° C Freezer Storage, Biosafety Cabinet/Isolator, Transportation/Chain of Custody, and Additional Pharmacy Room Temperature Storage Area.

- Approval of the PEP and PEP Modules signifies that the site pharmacy has the required personnel, facilities, and equipment necessary for appropriate conduct of DAIDS clinical trials, as described in the *Pharmacy Guidelines and Instructions for DAIDS Clinical Trials Networks*.

The PoR may send questions regarding PEP submission and approval process to DAIDSPABPEP@niaid.nih.gov.

Clinical Research Products Management Center

The Clinical Research Products Management Center (CRPMC) supports the DAIDS Clinical Trials Networks. As a contractor of DAIDS, the CRPMC centrally manages the receipt, storage, and distribution of study products.

The CRS PoR may order study products through the CRPMC Online Site Management and Ordering System (COSMOS).

For U.S. sites, the CRPMC ships orders Monday through Thursday to arrive the next business day. For non-U.S. sites, the CRPMC coordinates shipments with the CRS PoR and courier service to ensure that study product orders arrive in the shortest amount of time possible, on a day when pharmacy staff are present.

For more information on the CRPMC, refer to the *Pharmacy Guidelines and Instructions for DAIDS Clinical Trials Networks*.

References

1. U.S. Code of Federal Regulations, Title 21, Parts 11, 50, 54, 56, 312, 800 and 892,
2. U.S. Code of Federal Regulations, Title 45, Part 46 and Subparts
3. International Council for Harmonisation Good Clinical Practice (ICH E6)
4. FDA Guidance: Investigator Responsibilities - Protecting the Rights, Safety, and Welfare of Study Subjects [Oct 2009]
5. Office for Human Research Protections
6. Pharmacy Guidelines and Instructions for DAIDS Clinical Trials Networks

Version History

V1.0	1/19/2021	Original Version
V2.0	6/30/2021	Corrected PABPEP email address on pg 3 Added link to the pharmacy guidelines on pg 5