DAIDS Pharmaceutical Affairs Branch (PAB)

The Division of AIDS (DAIDS) requires the Clinical Research Site (CRS) Leader to delegate the responsibility for study product management at the CRS to a licensed/registered pharmacist. This pharmacist is the Pharmacist of Record (PoR).

The CRS leader is responsible for ensuring that there is a pharmacy that meets the DAIDS requirements for pharmacy personnel (PoR and Associate Pharmacist), pharmacy facilities, and pharmacy equipment as well as all ancillary supplies required for the conduct of DAIDS sponsored and/or supported clinical trials which involve study product(s) at the CRS.

A PAB-approved DAIDS PAB Pharmacy Establishment Plan (PEP) is required for each pharmacy affiliated with a CRS. The CRS PoR should request the DAIDS PAB PEP Template and any applicable PAB PEP Modules from PAB. For pharmacies known to DAIDS (including protocol specific sites) and new to DAIDS, the PEP template and modules are to be completed by the CRS PoR and submitted to DAIDS PAB within 6 weeks of receipt of the CTU Transition Packet for PAB review and approval. PAB will review the submitted documents to determine that the required personnel, facilities, and equipment are available for the conduct of studies requiring product storage under controlled room temperature, as well as any other applicable capabilities. PAB will inform the CRS leader and PoR whether the site pharmacy's storage, equipment, and transportation capabilities meet PAB requirements or if there are any issues regarding the personnel, facilities, or equipment. Once those issues are resolved, the PoR will need to submit an updated PEP, as well as any other applicable modules, for review. The PEP will be approved when all required personnel, facilities, and equipment are in place and operational.

Pharmacies known to DAIDS

- Pharmacies currently operating under a PAB-approved PEP for an existing CRS aligned with a specific DAIDS Network (including protocol specific sites) may continue operating under this plan.
- Pharmacies that will be undertaking additional work because an existing CRS is affiliated with a new Network will be required to submit a new PEP that includes information that reflects the updated Network(s) affiliation within 6 weeks of receipt of the CTU Transition Packet. Approval of the new PEP will be required prior to initiating clinical trials work with the new Network.

Pharmacies new to DAIDS

Pharmacies new to the DAIDS HIV/AIDS Clinical Trials Network will be required to submit a DAIDS PAB PEP Template for approval prior to clinical trial initiation. A pharmacy assessment visit may be conducted by a DAIDS contracted representative prior to approval as feasible.

DAIDS PAB *continued*

Pharmacies at Phase Out CRS

Pharmacies at CRS funded by DAIDS in the previous grant cycle (either fully funded or PS), where a proposed network affiliation(s) was not selected for re-funding in the next grant cycle will continue operating under a PAB-approved PEP until the CRS completes all network protocol activities by the end of year 15 (2021) based on DAIDS and Network Guidance.

Pharmacist of Record (PoR)

The PoR is the primary individual whose responsibilities include:

- Performing the day-to-day dispensing and accountability activities
- Establishing internal policies and procedures that includes the pharmacy Quality Management Plan
- Developing and maintaining a study product management system

Refer to the DAIDS PAB *Pharmacy Guidelines and Instructions for DAIDS Clinical Trials Networks* (https://www.niaid.nih.gov/research/daids-clinical-research-pharmacy-and-study-products-management) for a complete description of PoR's responsibilities.

The PoR and all other site pharmacists must be licensed and/or registered to practice pharmacy in the jurisdiction in which they are working.

Ensuring quality work requires that the PoR commit the necessary and appropriate amount of time to meet the pharmaceutical needs and requirements of the DAIDS Clinical Trials.

DAIDS PAB Pharmacy Establishment Plan and Modules

The CTU should provide the PAB section of the DAIDS CTU Transition Packet to the PoR at each CRS within the CTU. Each CRS PoR must complete and submit a DAIDS PAB PEP Template and optional Modules to PAB for review and approval.

The DAIDS PAB PEP Template must be completed for each pharmacy that is associated with a DAIDS CRS. Each DAIDS PAB PEP Template must be completed by the PoR for that pharmacy.

The PoR should email DAIDS PAB PEP at DAIDSPABPEP@niaid.nih.gov to obtain an electronic copy of the following documents:

- DAIDS PAB PEP Template
- DAIDS PAB Modules (if applicable): Refrigerated Storage, -20°C Freezer Storage, -70°C Freezer Storage, Biosafety Cabinet/Isolator, Additional Storage Area, and Transportation/Chain of Custody
- DAIDS PAB Pharmacist of Record Information Sheet (if applicable)
- DAIDS PAB Associate Pharmacist Information Sheet (if applicable)

The PoR must include the affiliated CRS name and number, as well as the CTU name when requesting the above document(s) from PAB.

Click here to see more information about PAB and related trainings for the site pharmacist on the DAIDS Learning Portal.