DAIDS
Bethesda, MD USA

POLICY

Requirements for Pharmacy Personnel at DAIDS Supported Clinical Research Sites Conducting Trials Outside of the HIV/AIDS Clinical Trials Networks

Approval Date 11 AUG 2014 No.: DWD-POL-PH-003.04
Effective Date: 22 SEP 2014

CHANGE SUMMARY NOTE: This policy has been reviewed for accuracy and updated to meet 508 compliance guidelines. Notable modifications include the change of Pharmacist of Record to Site Pharmacist and a waiver to this policy under exceptional circumstances. This version supersedes version 3.0 dated 01 MAY 09.

1.0 PURPOSE

This policy is designed to ensure that the Principal Investigator (PI) and Investigator of Record (IoR) has an adequate number of qualified pharmacy staff to conduct any National Institute of Allergy and Infectious Diseases (NIAID) Division of AIDS (DAIDS) -supported and/or -sponsored clinical trial.

2.0 SCOPE

This document represents the minimum acceptable standards for pharmacies at clinical research sites utilizing study product(s), and conducting NIAID (DAIDS)-supported and/or -sponsored clinical trials outside of the HIV/AIDS Clinical Trials Networks.

Additional requirements are likely to pertain at sites participating in multi-center clinical trials, such as those performed through the NIAID (DAIDS)-sponsored HIV/AIDS Clinical Trials Networks and/or clinical trials evaluating investigational agents.

3.0 BACKGROUND

Within DAIDS, the Pharmaceutical Affairs Branch (PAB) establishes and oversees policies for clinical research site pharmacies conducting NIAID (DAIDS)-supported and/or -sponsored domestic and international clinical trials. These policies include the development of standard operating procedures, quality assurance measures and accountability processes, prepared by the Site Pharmacist, for the management of study products.

4.0 DEFINITIONS

For definitions see DAIDS glossary.

5.0 RESPONSIBILITIES

The PI and IoR are responsible for ensuring that there is a Site Pharmacist at the site who is qualified by education, training and experience to conduct the trial.

The Site Pharmacist is responsible for meeting the educational requirements needed to maintain licensure/registration.

The PI and IoR are responsible for ensuring that all clinical research site personnel involved in the conduct of any DAIDS-supported and/or -sponsored clinical trial are knowledgeable of the DAIDS standards for pharmacy personnel to ensure the proper conduct of the trial.

6.0 POLICY

6.1 The Site Pharmacist must perform the day to day pharmacy activities and study product management including but not limited to the procurement, storage, inventory, preparation, dispensing, accountability, record keeping, labeling, handling and final disposition of study products for the trial.

6.1.1 Pharmacy staff can assist the Site Pharmacist under his/her direct supervision.

6.1.2 The pharmacy staff must be qualified by pharmacy education, pharmacy training and pharmacy experience to perform his or her respective task(s).

6.2 The Site Pharmacist must be available during clinic hours when study products may need to be dispensed to study participants. 6.2.1 When the Site Pharmacist is absent a designated licensed/registered pharmacist must be present during the clinic hours when study products may need to be dispensed to study participants.

6.2.2 The designated licensed/registered pharmacist(s) must be trained in the conduct of the trial by the Site Pharmacist to perform the activities of the

Site Pharmacist.

6.3 The Pharmacist(s) must comply with all applicable laws and regulations. This includes but is not limited to regulations concerning the import or export of study product.

Note: In exceptional circumstances, the IoR may request a waiver from the OPCRO Director (or designee) to dispense study drug or product by trained personnel other than that described.

7.0 REFERENCES

International Conference on Harmonisation, Guidance for Industry, E6 Good Clinical Practice: Consolidated Guidelines

U.S. Code of Federal Regulations, Title 21, Part 312

Joint Commission International Accreditation Standards for Hospitals, by the Joint Commission on Accreditation of Healthcare Organizations

8.0 INQUIRIES

Questions and comments regarding this policy may be directed to the OPCRO Policy Group

9.0 AVAILABILITY

This policy is available electronically on the Division of AIDS (DAIDS) Clinical Research Policies and Standard Procedures webpage.

10.0 APPENDICIES

None

11.0 APPROVAL

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