

ARCHIVED POLICY

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

Approval Date: 01 APR 09
Effective Date: 01 MAY 09

No.: DWD-POL-PH-003.03

NOTE: This policy has been reviewed for accuracy and updated to meet 508 compliance guidelines. This version supersedes version 2.0 dated 20 DEC 06.

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 Division of Acquired Immunodeficiency (DAIDS) funded 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 DAIDS funded 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 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 DAIDS funded 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 Pharmacist of Record, for the management of study products.

4.0 DEFINITIONS

Division of AIDS (DAIDS) sponsored: DAIDS is responsible for the management (including submission of the Investigational New Drug Application (IND) to FDA and initiation of the study) and oversight for the trial.

Division of AIDS (DAIDS) funded: DAIDS is providing financial support for trial or study.

Investigator of Record (IoR): The person responsible for the conduct of the clinical trial, at a clinical research site. This person is the signatory for the Form FDA 1572 (IND studies), or IoR Agreement (Non-IND studies).

Principal Investigator (PI): The qualified person designated by the applicant institution to direct the research. PIs oversee the scientific and technical aspects of a grant and the day-to-day management of the research.

Pharmacy: Any facility, building, or room used to perform one or more of the following functions: storage, preparation, dispensing, management of study products, (example: dispensary, drug storage unit, drug store).

Study products: Any drug, biologic, vaccine, radiopharmaceutical, item or device that are either provided for the study or identified in the protocol as being a study product.

Pharmacist of Record: A licensed/registered pharmacist who performs the day to day pharmacy activities and study product management including but not limited to the procurement, storage, preparation, dispensing and final disposition of study products for DAIDS funded and/or sponsored clinical trial(s) must be identified as the Pharmacist of Record.

For additional definitions see DAIDS glossary.

<http://www3.niaid.nih.gov/research/resources/DAIDSClinRsrch/Glossary.htm>

5.0 RESPONSIBILITIES

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

The *Pharmacist of Record* 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 funded 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 Pharmacist of Record 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 Pharmacist of Record 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 Pharmacist of Record must be available during clinic hours when study products may need to be dispensed to study participants.
 - 6.2.1 When the Pharmacist of Record 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 Pharmacist of Record to perform the activities of the Pharmacist of Record.
- 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.

7.0 REFERENCES

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

<http://www.fda.gov/oc/gcp/guidance.html>

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

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>

Joint Commission International Accreditation Standards for Hospitals, 2002 by the Joint Commission on Accreditation of Healthcare Organizations

<http://www.jointcommissioninternational.org/international.asp?durki=8086&site=109&return=7659>

8.0 INQUIRIES

Questions and comments regarding this policy may be directed to the OPCRO Policy Group at: NIAIDOPCROPOLICYGROUP@mail.nih.gov

9.0 AVAILABILITY

This policy is available electronically at the following URL:
<http://www3.niaid.nih.gov/research/resources/DAIDSClinRsrch/Default.htm>

10.0 CHANGE SUMMARY

This policy replaces version 2.0 dated 20 DEC 06.

11.0 APPENDICES

None

12.0 APPROVAL

/Richard Hafner, MD/
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