

ARCHIVED POLICY

Requirements for Pharmacy Facilities 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

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**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 there are acceptable facilities meeting uniform standards for the storage, preparation, dispensing, quarantine and disposition of study products for Division of the Acquired Immunodeficiency Syndrome (DAIDS) funded and/or sponsored clinical trials.

## 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 research trial(s) must be identified as the Pharmacist of Record.

**Pharmacy Equipment:** Apparatus (device or machinery) that is utilized to ensure the physical and scientific integrity of the study product during shipment, storage, handling, and preparation. Examples of pharmacy equipment are: biological safety cabinets, refrigerators, -20 C freezers, -70 C freezers, air conditioners, dehumidifiers, thermometers, vortex machines, temperature alarm systems, limited access/security systems (e.g., alarms, key lock) in study product and pharmacy regulatory file storage areas, locking file and storage cabinets, shelving, counting trays for tablets and capsules, graduated cylinders, spatulas, study product containers, fax machines, computers, and printers.

**Pharmacy Ancillary Supplies:** Any materials or tools that may be used in a pharmacy to perform and support the day to day activities and functions of the pharmacist, such as needles and syringes, oral syringes, prescription vials and lids, gowns, masks, IV solutions, diluents.

For additional definitions see DAIDS glossary.

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

## 5.0 RESPONSIBILITIES

The *PI* is responsible for ensuring that there is a pharmacy that meets the DAIDS requirements for pharmacy facilities and that the pharmacy has equipment and

ancillary supplies required for the conduct of the clinical trial at the clinical research site.

The *PI and IoR* are responsible for ensuring that all site personnel involved in the conduct of any DAIDS funded and/or sponsored clinical trial are knowledgeable of the DAIDS policy for pharmacy facilities to ensure the proper conduct of the clinical trial.

## **6.0 POLICY**

- 6.1 There must be a pharmacy. The pharmacy (pharmaceutical service) must have the capacity to initiate, conduct, participate in and support the DAIDS funded and/or sponsored research trials to be conducted at the clinical research site. The pharmacy must be of sufficient size with adequate equipment and supplies to provide the range of activities required.
- 6.2 Access to the pharmacy must be limited to pharmacy staff and the pharmacy must be locked when pharmacy staff is not present. Access to study products and study product records must be limited to authorized pharmacy staff only.
- 6.3 Electrical power must be available in the pharmacy 24 hours a day, 7 days a week, 365 days a year, through regular or alternate sources to ensure a suitable work environment for the day to day pharmacy operations.
- 6.4 Controlled room temperature storage conditions must be maintained 24 hours a day, 7 days a week, 365 days a year, using heating and air conditioning equipment as required.
- 6.5 Study products must be prepared and dispensed in a clean, secure, and safe environment that complies with local laws, regulations, and professional practice standards. Study products must be clearly labeled, properly stored, adequately segregated from other products, and protected from vermin and extreme humidity, heat/cold, and light.
- 6.6 The site must have plans for implementing a program for inspecting, testing, and maintaining pharmacy equipment and documenting the results.
- 6.7 The pharmacy must have an emergency procedure in place to protect study products stored at room temperature as well as in cold storage, in the event of water or electrical system disruption or failure.

- 6.8 There must be proper equipment and facilities to ensure the safety of any person storing, preparing, administering, packaging, destroying or otherwise coming into contact with the study product(s) that may pose a chemical, physical, mutagenic, carcinogenic or other potential hazard.
- 6.9 Clean water and facilities for washing hands, equipment and other supplies must be available.

## **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](mailto: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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