

DAIDS
Bethesda, MD USA

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

Approval Date 11 AUG 2014
Effective Date: 20 OCT 2014

No.: DWD-POL-PH-004.04

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 there are acceptable facilities meeting uniform standards for the storage, preparation, dispensing, quarantine and disposition of study products for National Institute of Allergy and Infectious Diseases (NIAID) Division of Acquired Immunodeficiency (DAIDS)-supported 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 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 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-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 Principal Investigator (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

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the clinical research site.

The PI and Investigator of Record (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 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.

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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.

Note: In exceptional circumstances, the IoR may request a waiver from the OCSO Director (or designee) to dispense study drug or product from a location that does not meet the standards 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.

11.0 APPENDICES

None

12.0 APPROVAL

Emily Erbelding, MD