DAIDS
Bethesda, MD USA

POLICY

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

Approval Date: 11 AUG 2014 No.: DWD-POL-PH-002.04
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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 good clinical practice will be followed for the management of study products and that study products are only used for participants enrolled in a National Institute of Allergy and Infectious Diseases (NIAID) Division of Acquired Immunodeficiency Syndrome (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 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 Investigator of Record (IoR) is responsible for ensuring that the study products needed for the research activities are available for the duration of the study and that the pharmacy has the equipment and ancillary supplies needed to

perform the pharmacy activities for the conduct of the clinical trial at the clinical research site.

The IoR is responsible for identifying authorized prescribers.

The IoR is responsible for ensuring that the study products are used in accordance with the approved protocol.

The Site Pharmacist is responsible for executing the required pharmacy activities.

It is the responsibility of the IoR and the Site Pharmacist to be knowledgeable of all applicable laws and regulations.

The IoR is responsible for establishing a communication system for study staff so that the protocol and all protocol related information is provided to the Site Pharmacist systematically and in a timely fashion.

The Site Pharmacist is responsible for establishing a system for reporting and documenting discrepancies with regards to study product dispensing or management.

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 DAIDS standards for pharmacy activities to ensure the proper conduct of the trial.

6.0 POLICY

6.1 The pharmacy must have written Policies and Procedures that govern the receipt, storage, inventory process, accountability, record keeping, preparation, distribution, labeling, handling, dispensing and final disposition of study products in accordance with applicable regulations.

6.2 Medication orders or prescriptions and administration of study products must be guided by Policies and Procedures.

6.3 Authorized prescribers must be identified through the use of either the Form FDA 1572 or DAIDS Investigator of Record Agreement.

6.4 The Site Pharmacist must maintain readily accessible files containing communications with clinical research site staff and others (e.g. DAIDS staff).

6.5 Study product accountability records must be available for expedient retrieval, inspection and photocopying by a properly authorized DAIDS Monitor, an FDA employee or representative or if requested by DAIDS Pharmaceutical Affairs Branch.

6.6 The Site Pharmacist must organize and maintain study documents to ensure accurate recording, verification and retrieval of information.

6.7 The study product(s) must be stored as indicated in the label or other product information in a limited access area separate from other primary care medication and other non-study medications and must be inventoried on a monthly basis.

6.8 The Site Pharmacist must maintain the scientific integrity of studies by managing access to treatment-assignment records and study products in blinded studies and by ensuring that the correct study product was dispensed. The Site Pharmacist, PI, IoR, and sponsor must agree on a procedure for unblinding treatment assignment in emergencies.

6.9 The Site Pharmacist must ensure that the study participant is dispensed the correct dose of the proper drug, biologic, vaccine or radiopharmaceutical as defined by the protocol through the implementation of a quality management program.

6.10 The Site Pharmacist must have a system in place that ensures that a participant on a study has signed an informed consent for the most current version of the protocol before dispensing any protocol related study product(s). Study products must be dispensed only to participants who have signed an informed consent for the study.

6.11 The pharmacy must have a study product recall system for identifying retrieving, and returning study products that:
(a) are recalled by manufacturer or supplier
(b) are known to be expired or outdated
(c) have been dispensed to study participants

6.12 There must be a system in place to ensure that all study products dispensed to study participants will not have gone beyond the expiration date at the end of the treatment period for the prescription.

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 in this policy.

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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