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| DAIDS<br>Bethesda, MD<br>USA | <b>POLICY</b>                                         | No.: DWD-POL-CL-05.00 |
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## 1.0 PURPOSE

The purpose of this policy is to identify the minimal requirements for the Manual of Operational Procedures (MOP) and to provide guidance on the development and maintenance of a MOP for Division of Acquired Immunodeficiency Syndrome (DAIDS) funded and/or supported clinical research sites.

## 2.0 SCOPE

This policy applies to all clinical research sites conducting DAIDS funded and/or sponsored clinical trials.

## 3.0 BACKGROUND

DAIDS funded and/or sponsored clinical trials are conducted in many settings both domestic and international. Depending on the trial type and size and resource availability at the site, operations may vary considerably. The MOP delineates the procedures that must be followed for performing various functions at the clinical research site. Developing and maintaining a MOP is also a means of documenting how a specific clinical research site operates for administrative and management activities as well as activities related to the conduct of clinical trials.

## 4.0 DEFINITIONS

See Glossary of DAIDS Terms.

## 5.0 RESPONSIBILITIES

The Principal Investigator or designee is responsible for ensuring that the MOP is developed in sufficient detail to guide site study activities and is revised as necessary to incorporate changes to procedures and operations. All copies of the MOP must contain the most current information.

Note: DAIDS may at its discretion, review and approve site MOPs.

## 6.0 POLICY

6.1. Each DAIDS funded and/or supported clinical research site will develop and maintain a MOP (or set of documents that together constitute a MOP). The contents of the MOP will include, at a minimum, those documents that describe procedures routinely conducted at the clinical research site and may be documented in the form of a policy or Standard Operating Procedure (SOP). The documents will provide

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details on how the site addresses U. S. regulatory requirements; standards for Good Clinical Practice (GCP); National Institutes of Health, National Institute of Allergy and Infectious Diseases, and DAIDS policies and procedures; and any applicable local laws and regulations or institutional policies and procedures.

- 6.2. For clinical research sites that are participating in a network, the network MOP pertaining to clinic, pharmacy, laboratory, and/or data management may be used as long as it fulfills the requirement of, and is not in conflict with, DAIDS policies. Any necessary study-specific SOPs will also need to be developed and maintained.
- 6.3. The MOP must be reviewed by the clinical research site staff prior to the initiation of DAIDS funded and/or sponsored clinical trials as part of the site establishment and staff orientation process. Clinical research site staff must have ready access to the MOP either in electronic format or hard (paper) copy.
- 6.4. A core set of SOPs must be in place **prior to** the initiation of any DAIDS funded and/or sponsored clinical trials. These required SOPs are listed in Appendix 1. The contents of the resulting MOP may be in any order. DAIDS may, at its discretion, designate that additional SOPs be in place before trial initiation.
- 6.5. Other SOPs should be developed as applicable to specific clinical research projects, but may not be required to be in place at the clinical research site prior to initiation of the project. For an extensive listing of possible SOPs, see Appendix 2.
- 6.6. When procedures change and revisions to the MOP are necessary, a system for version control must be evident and a copy of each non-current version of the MOP must be retained and archived.
- 6.7. The MOP must be available to DAIDS staff or DAIDS designated representatives for inspection upon request. DAIDS may, at its discretion, review and approve the MOP before clinical trial initiation.

## 7.0 REFERENCES

International Conference on Harmonisation, Guidance for Industry, E6 Good Clinical Practice: Consolidated Guideline  
<http://www.fda.gov/oc/gcp/guidance.html>

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## 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>

The signed original is maintained in the OPCRO policy office.

## 10.0 CHANGE SUMMARY


| Version # | Date       | Replaces | Date of Revision | Rationale for Revision/Retirement |
|-----------|------------|----------|------------------|-----------------------------------|
| 2.0       | 20 DEC 06  | V 1.0    | 20 DEC 06        | DAIDS Final Review                |
| 1.0       | 14 JULY 06 | N/A      | N/A              | N/A                               |

## 11.0 APPENDICES

Appendix 1 – Required Site SOPs

Appendix 2 – Manual of Operations (MOP) Sample Table of Contents

## 12.0 APPROVAL

| Signature                                                                                                                                   | Program/Branch                                                  | Date                     |
|---------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|--------------------------|
| Authorized By: <u></u><br>Richard Hafner, MD<br>Director | Office for Policy in<br>Clinical Research<br>Operations (OPCRO) | <u>December 20, 2006</u> |