

DAIDS
Bethesda, MD USA

POLICY

Requirements for DAIDS Funded and /or Sponsored Laboratories in Clinical Trials

Approval Date: 9 DEC 13
Effective Date: 12 DEC 13

No.: DWD-POL-LB-005.04

NOTE: This Policy has been reviewed for accuracy and updated to meet 508 compliance guidelines. Key changes include the removal of Comprehensive Laboratory Plan listed in section 6.4. This version supersedes version 3.0 dated 15 APR 09.

1.0 PURPOSE

The National Institute of Allergy and Infectious Diseases (NIAID), Division of Acquired Immunodeficiency Syndrome (DAIDS), has established specific requirements for laboratories processing and testing biologic samples from participants enrolled in clinical trials supported and/or -sponsored by the NIAID (DAIDS). These requirements relate to general laboratory operations, quality assurance and control procedures, management of specimens, and management of laboratory data. The purpose of this policy is to safeguard participants enrolled in clinical trials and individuals who perform laboratory testing, and to ensure the reliability and validity of all laboratory measurements taken to determine eligibility, identify and manage adverse events, and assess outcomes during the course of the clinical trial.

2.0 SCOPE

This policy applies to laboratories performing testing in support of clinical trials supported and/or sponsored by the NIAID (DAIDS).

3.0 BACKGROUND

This policy identifies requirements regarding laboratory operations in order to ensure compliance of laboratories with the Code of Federal Regulations (CFR) and the DAIDS Guidelines for Good Clinical Laboratory Practice (GCLP) Standards. The GCLP concept possesses a unique quality, as it embraces both the research/pre-clinical and clinical aspects of Good Laboratory Practice (GLP). GCLP standards encompass applicable portions of 21 CFR part 58 or GLP, and 42 CFR part 493, or Clinical Laboratory Improvement Amendment (CLIA), and they are enhanced by standards from accrediting bodies such as the College of American Pathologists (CAP) and South African National Accreditation System. The purpose of these regulations and standards are to promote good laboratory practices and to assure reliable and reproducible laboratory results and documentation/records.

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4.0 DEFINITIONS

For additional definitions see DAIDS glossary.

<http://www.niaid.nih.gov/labsandresources/resources/daidsclinrsrch/Pages/Glossary.aspx>

5.0 RESPONSIBILITIES

This policy, and the associated specific requirements for U.S. and non-U.S. laboratories (Appendices 1 and 2), have been created by DAIDS Clinical Laboratory Oversight Team (DCLOT) whose responsibility is to oversee the laboratory component of NIAID (DAIDS) supported and/or sponsored clinical trials. DCLOT will be responsible for updating this policy and supporting appendices in response to changes in federal regulations and based on continued experience in the conduct of clinical trials. DCLOT will be responsive to queries by investigators who need assistance with understanding this policy and with implementing the specific requirements for U.S. and non-U.S. laboratories. DCLOT will be responsible for working in partnership with the Network/non-Network staff to determine if laboratories have acceptable performance. The Grant Principal Investigator is responsible for ensuring that laboratories processing and testing biologic samples from participants enrolled in clinical trials adhere to the laboratory requirements identified in this policy as well as following specific guidance described in individual protocols.

6.0 POLICY

- 6.1. NIAID (DAIDS) supported and/or sponsored clinical trials involving human subjects must ensure compliance with federal regulations including procedures to protect the safety of all participants. These studies must be conducted in a manner to assure the sponsor and regulatory agencies that all data submitted are a true reflection of the results obtained during a study and that this data can be relied upon when making risk and/or safety assessments of study products. DAIDS has determined that GCLP standards are the minimal requirements that clinical research laboratories should follow (see Appendix 3).
- 6.2. In addition to maintaining operations in compliance with GCLP standards, DAIDS has established and maintains specific requirements for laboratory performance in five areas.

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6.2.1. Laboratory Safety, Diagnosis and Food and Drug Administration (FDA) approved Primary Endpoints Tests

Tests that are used for diagnosis, determining eligibility, endpoints, monitoring the safety of the intervention and making patient management decisions should be performed in laboratories that conduct operations in accordance with GCLP standards. These tests should be quality assured by external proficiency testing surveys. When not available, alternative external quality assurance measures should be devised. U.S. laboratories must be CLIA-certified or waived for certain testing.

6.2.2. Non-FDA Approved End Point Tests

This section covers research tests not yet approved by the US FDA nor validated by International Conference on Harmonisation (ICH) or US Pharmacopeia. Generally, the endpoint tests should be performed in laboratories that conduct operations in accordance with GCLP. External quality assurance should be applied to Research Use Only tests if they are used for primary study endpoints. If existing external quality assurance (EQA) surveys are not available, a suitable form of alternative proficiency assessments should be devised and proposed to DAIDS for approval.

6.2.3. Study Specimen Management

Procedures for the management of trial specimens must be documented and followed to ensure the integrity of specimens and their timely testing. Procedures must address specimen acquisition, receipt, processing, testing, storage and shipping according to regulations (e.g. International Air Transport Association (IATA)) and under conditions that preserve specimen integrity (e.g. maintaining the cold chain), and tracking as applicable.

6.2.4. Study Laboratory Data Management

Procedures for the management of laboratory data must be documented and followed to ensure data integrity and timely

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reporting of results and are required to include appropriate procedures for data quality assurance (QA) and corrective actions. Procedures should address data acquisition, recording/entry, data modification, signatures, export, archiving and security, as well as integration of the laboratory data with the main study database. Computerized laboratory systems should be validated and compliant with 21 CFR Part 11 for Investigational New Drug (IND)-enabling studies. For non-IND studies, computerized laboratory systems should be validated, taking into account the elements of 21 CFR Part 11.

6.2.5. Laboratory Quality Management Plan

Laboratories must have a documented Quality Management Plan (QMP) that describes the overall quality management program of the laboratory. For additional information please refer to Appendix 3 - DAIDS Guidelines for GCLP Standards. DAIDS recommends labs designate a senior staff member to be responsible for executing the lab QMP.

These laboratory requirements may be reviewed periodically and updated as necessary to maintain currency with accepted practices and technological innovation. For the convenience of current and potential investigators and collaborating laboratories, separate documents with specific requirements are provided for U.S. based laboratories (Appendix 1) and non-U.S. laboratories (Appendix 2). Differences in these documents pertain largely to laboratory accreditation bodies and procedures within and outside of the United States.

6.3. Laboratory Oversight

DAIDS and/or its contractors may conduct laboratory-specific audit visits to determine GCLP standards compliance. Performance in external proficiency testing surveys for DAIDS studies will be monitored by DAIDS and/or its contractors.

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7.0 REFERENCES

U.S. Code of Federal Regulations, Title 21, Parts 11 and 58

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

U.S. Code of Federal Regulations, Title 42 CFR Part 493

<http://www.gpo.gov/fdsys/granule/CFR-2011-title42-vol5/CFR-2011-title42-vol5-part493/content-detail.html>

CLIA Program – Clinical Laboratory Improvement

Amendments <http://www.cms.hhs.gov/clia/>

International Air Transport Association (IATA) Dangerous Goods Shipping

Regulations <http://www.iata.org/>

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://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Documents/laboratorypolicyI.pdf>

10.0 CHANGE SUMMARY

This policy supersedes version 3.0 dated 15 May 09.

11.0 APPENDICIES

Appendix 1 - DAIDS Requirements for U.S. Laboratories [LB.401]

Appendix 2 - DAIDS Requirements for non-U.S. Laboratories
[LB.402]

Appendix 3 - DAIDS Guidelines for Good Clinical Laboratory Practice Standards
[LB.403]

12.0 APPROVAL

Emily Erbelding, MD