

DAIDS
Bethesda, MD USA

POLICY
Protocol Documents

Approval Date: 30 SEP 2014
Effective Date: 30 OCT 2014

No.: DWD-POL-CL-01.02

CHANGE SUMMARY: This Policy has been reviewed for accuracy and updated to meet 508 compliance guidelines. Key changes include mandating that certain information be included in the protocol document and references the non-mandatory use of the DAIDS Protocol Documents Template. Additional modifications include expanding the background section to clarify why certain information needs to be included in a protocol document. This version supersedes version 1.0 dated 20 DEC 06.

1.0 PURPOSE

The purpose of this policy is to describe the elements that will be included in protocol documents for National Institute of Allergy and Infectious Diseases (NIAID) Division of AIDS (DAIDS)-supported and/or -sponsored clinical trials.

2.0 SCOPE

This policy applies to all NIAID (DAIDS)-supported and/or -sponsored clinical trials that are conducted outside of the HIV/AIDS Clinical Trials Networks. This policy does not apply to informed consent (IC) development or DAIDS IC templates. The DAIDS Policy on IC Development provides information on informed consent use and content.

3.0 BACKGROUND

The term "protocol" is defined as a complete written description of, and scientific rationale for, clinical trial activities. Clinical trials must be conducted in accordance with a written protocol, appendices and other relevant documentation.

Protocol documents provide the framework by which the clinical trials will be conducted. Protocol documents provide safeguards for the health and safety of the participants, as well as seek answers to specific research questions. Protocol documents must be approved by all applicable review bodies (e.g., Ethics Committee/Institutional Review Board (EC/IRB) and applicable Regulatory Entity(ies) [RE]) prior to the implementation of research, and throughout the clinical trial, as applicable (e.g., amendments, continuing review).

Protocol documents include, among other information, the study objectives, study design, population to be studied, study product/intervention, study procedures/evaluation, safety assessment, clinical management, statistical considerations, data handling, and informed consent document(s).

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The DAIDS Protocol Documents Policy, [Manual](#) and [Template](#) describe the information that must be included in protocol documents.

4.0 DEFINITIONS

For definitions, see [DAIDS glossary](#).

5.0 RESPONSIBILITIES

Protocol Chair/Co-Chair

The Protocol Chair/Co-Chair is/are responsible for ensuring that the protocol document developed by the team and submitted to DAIDS for review and approval is complete and consistent, methodologically sound, and directs study conduct to be in accord with all applicable regulations, and NIH and DAIDS policy. Protocol documents for clinical trials must also reflect awareness of, and compliance with, local laws and regulations, as applicable.

DAIDS Scientific Review Committees

DAIDS Scientific Review Committees (SRCs) are responsible for the review, comment and approval or disapproval of all clinical trials supported and/or sponsored by the DAIDS before the protocol is submitted for DAIDS-required final reviews/sign-offs (e.g., full regulatory review, Medical Officer, and final DAIDS sign-off) prior to implementation. There are some exceptions to the requirement for SRC review (e.g., low-risk behavioral counseling interventions). DAIDS staff will make this determination and inform the Protocol Chair/Co-Chairs. Exceptions require approval of the DAIDS Program Director.

DAIDS Regulatory Affairs Branch

The DAIDS Regulatory Affairs Branch is responsible for the full regulatory review of the protocol. If the protocol will be registered with the DAIDS Protocol Registration Office, then full regulatory review is required. The DAIDS Regulatory Affairs Branch is responsible for the final DAIDS sign-off of the protocol document.

DAIDS Medical Officer

The DAIDS Medical Officer is responsible for the review and approval of the protocol after SRC and full regulatory review, if applicable. The DAIDS Medical Officer is responsible for providing any comments upon completion of the review.

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The DAIDS Medical Officer comments must be addressed before final DAIDS sign-off.

6.0 POLICY

- 6.1 The clinical trial protocol must contain all essential information required to implement a study and should be organized to allow ready access to relevant information. The clinical trial protocol document must reflect awareness of, and compliance with, the following:
 - 6.1.1 All NIAID (DAIDS)-supported and/or -sponsored clinical trials must be written in compliance with U.S. Code of Federal Regulations at 45 CFR 46 (Subparts A-D) and the International Conference on Harmonisation (ICH), Guidance for Industry, E6 Good Clinical Practice.
 - 6.1.2 Clinical trials subject to the U.S. Food and Drug Administration (FDA) regulations must be written in compliance with the applicable FDA regulations at 21 CFR 50 and 56.
 - 6.1.3 All NIAID (DAIDS)-supported and/or -sponsored clinical trials must also comply with all applicable laws and regulations at each clinical research site.
 - 6.1.4 NIH, NIAID, and DAIDS have specific policies and guidance directing particular aspects of study development, implementation, analysis, and publication, which includes the following DAIDS policies: [Data Management and Statistics](#), [Enrolling Children in Clinical Research: Protocol Document Requirements](#), [Expedited Adverse Event Reporting](#), Identification and Classification of [Critical Events](#): Site Responsibilities, [Informed Consent Development](#), Requirements for [Laboratories in Clinical Trials](#), Requirements for [Pharmacy Facilities at DAIDS Supported Clinical Research Sites Conducting Trials Outside of the HIV/AIDS Clinical Trials Networks](#), [Protocol Registration](#), and [Study Progress and Safety Monitoring](#).
 - 6.1.5 There may be additional requirements specified in the terms of award included in the Notice of Award for grants, Statement of Work in NIAID contracts, or other requirements identified in NIAID Program Announcements, Requests for Applications, or Requests for Proposals.

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6.2 The [DAIDS Protocol Documents Manual](#) identifies the elements (e.g., specific content areas) that must be addressed in clinical trial protocols. The manual also identifies other regulatory and guidance documents that should be consulted during protocol development and specifies the level of detail that must be incorporated in the primary protocol document. The [DAIDS Protocol Documents Template](#) provides a format that may be used during protocol development.

7.0 REFERENCES

[HHS regulations for the Protection of Human Subjects at 45 CFR 46](#)

[FDA regulations for the Protection of Human Subjects at 21 CFR 50](#)

[FDA regulations on Institutional Review Boards at 21 CFR 56](#)

[Guidance for Industry, E6 Good Clinical Practice: Consolidated Guidance](#)

[NIAID Clinical Terms of Award](#)

[Data Management and Statistics](#)

[Enrolling Children in Clinical Research: Protocol Document Requirements](#)

[Expedited Adverse Event Reporting](#)

[Identification and Classification of Critical Events: Site Responsibilities](#)

[Informed Consent Development](#)

[Requirements for Laboratories in Clinical Trials](#)

[Requirements for Pharmacy Facilities at DAIDS Supported Clinical Research Sites
Conducting Trials Outside of the HIV/AIDS Clinical Trials Networks](#)

[Protocol Registration](#)

[Study Progress and Safety Monitoring](#)

8.0 INQUIRIES

Questions and comments regarding this SOP may be directed to the [OPCRO Policy Group](#).

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9.0 AVAILABILITY

This policy is available electronically on the [Division of AIDS \(DAIDS\) Clinical Research Policies and Standard Procedures](#) webpage.

10.0 APPENDICES AND RELATED DOCUMENTS

[DAIDS Protocol Documents Manual](#)

[DAIDS Protocol Documents Template](#)

11.0 APPROVAL

Emily Erbelding, MD