

POLICY

Human Subjects Protection (HSP) and Good Clinical Practice (GCP) Training Requirements

Approval Date: 16 FEB 2015
Effective Date: 16 MAR 2015

No.: DWD-POL-CL-03.03

CHANGE SUMMARY NOTE: This policy has been reviewed for accuracy and updated to meet 508 compliance guidelines. An addition of the reference to the NIAID GCP Learning Center website has been added. This version supersedes version 2.0 dated 05 FEB 07.

1.0 PURPOSE

The purpose of this policy is to identify the training requirements and the means by which the requirements can be met for human subjects' protection (HSP), Good Clinical Practice (GCP), and Food and Drug Administration (FDA) regulations for personnel at clinical research sites conducting Division of Acquired Immunodeficiency Syndrome (DAIDS)-supported and/or sponsored clinical research.

2.0 SCOPE

This policy applies to personnel involved in clinical research (HSP training) and clinical trials (GCP training, and for IND trials, FDA regulations training) at DAIDS funded and/or supported clinical research sites.

3.0 BACKGROUND

National Institutes of Health (NIH) policy requires that all key personnel involved in the design or conduct of clinical research must receive education on HSP before NIH funds are awarded. HSP training involves education on the requirements of the U.S. federal regulations at 45 CFR 46, Protection of Human Subjects. Individuals who become involved in the project after the initial award must also receive this training.

In addition to HSP training, for those individuals conducting clinical trials, training on GCP is also required. Specifically, DAIDS-required GCP training involves education for clinical research site personnel on the conduct of research including data and document management that are found in the International Conference on Harmonisation (ICH) GCP guidelines (ICH E6). In some cases, these guidelines provide details in these areas of research conduct not found at 45 CFR 46.

Finally, individuals conducting clinical trials under the jurisdiction of the FDA, including all trials conducted under an Investigational New Drug Application (IND), must receive training on the applicable regulations found in CFR Title 21 in addition to HSP and GCP training.

All applicable U.S. regulations are statutory requirements that must be met for all studies.

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4.0 DEFINITIONS

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

5.0 RESPONSIBILITIES

DAIDS staff – DAIDS staff whose responsibilities involve clinical research site oversight are responsible for ensuring HSP training has occurred before a grant award can be made. In addition, these staff members are also responsible for ensuring that training in GCP and applicable FDA regulations are conducted in accordance with this policy.

Principal Investigator (PI) – The PI is responsible for ensuring that all personnel receive the appropriate HSP and, if indicated, training in GCP and the applicable FDA regulations. The PI is also responsible for ensuring that new staff (added after the initial award) receives this training during orientation and that new personnel are adequately supervised during the period prior to formal training.

Note: The PI should communicate with DAIDS staff to determine appropriate training to meet the requirements of this policy.

6.0 POLICY

6.1 Training Requirements for all Key Personnel

6.1.1 HSP Training Requirements for personnel involved with the conduct of any clinical research.

Prior to awards being made for clinical research and on a recurring basis as specified by this policy, all key personnel must receive HSP training that includes the following:

6.1.1.1 U.S. Code of Federal Regulations 45 CFR 46 Protection of Human Subjects - required for all NIH-funded clinical research

6.1.1.1.1 Subpart A – Basic HHS Policy for Protection of Human Research Subjects

6.1.1.1.2 Subpart B – Additional Protections for Pregnant Women, Human Fetuses and

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- 6.1.1.1.3 Subpart C – Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as subjects
- 6.1.1.1.4 Subpart D – Additional Protections for Children Involved as Subjects in Research
- 6.1.1.2 The Belmont Report
- 6.1.1.3 The Declaration of Helsinki (strongly encouraged)
- 6.1.1.4 The Nuremberg Code (strongly encouraged)
- 6.1.2 GCP training requirements for personnel involved in all clinical trials, in addition to HSP training (section 6.1) Prior to the initiation (that is, before screening or enrollment of the first subject) of a DAIDS funded and/or sponsored study/trial, and on a recurring basis as specified by this policy, all key personnel must receive training that includes the following:
 - 6.1.2.1 Investigator Roles and Responsibilities (ICH E6, section 4)
 - 6.1.2.2 Relevant topics in Sponsor responsibilities (ICH E6, section 5), including Investigator Selection, Confirmation of Review by IRB/EC, Data Handling and Recordkeeping, Quality Assurance and Quality Control (QA/QC), and DAIDS related policies
 - 6.1.2.3 Essential documents (ICH E6, section 8) and DAIDS related policies
 - 6.1.2.4 Source Documents (ICH E6, section 8) and DAIDS related policies
 - 6.1.2.5 Additional DAIDS specific policies:
 - 6.1.2.5.1.1 Expedited Adverse Event Reporting
 - 6.1.2.5.1.2 Protocol Registration (and the DAIDS

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Investigator of Record Form)
6.1.2.5.1.3 Manual of Operations

Note: While acceptable HSP/GCP/FDA training may be obtained from many sources, additional training on relevant DAIDS policies must also be obtained to fulfill the requirements of this policy.

6.1.3 FDA training requirements for personnel involved in clinical trials subject to FDA regulations in addition to HSP training (section 6.1) and GCP training (section 6.2) Prior to the initiation (that is, before screening or enrollment of the first subject) of a DAIDS funded and/or sponsored study/trial and on a recurring basis as specified by this policy, all key personnel must receive training that includes relevant aspects from the following:

- 6.1.3.1 21 CFR Part 11 Electronic Records and Signature
- 6.1.3.2 21 CFR Part 312 Investigational New Drug Application with particular attention to Sections 312.53 (FDA Form 1572) and 312.60-70 (Investigator's Responsibilities)
- 6.1.3.3 21 CFR Part 50 Protection of Human Subjects
- 6.1.3.4 21 CFR Part 54 Financial Disclosure by Clinical Investigators
- 6.1.3.5 21 CFR Part 56 Institutional Review Boards

6.1.4 Other Training Requirements and Documentation

6.1.4.1 Timing and Frequency of Training

The types of training required for clinical research site personnel by this policy must be received within the previous 3 years before the time required by this policy and repeated within every 3 years thereafter. However, more frequent training is encouraged.

New clinical research site personnel (hired after study/trial initiation) shall receive HSP and/or GCP training within 90 days of assignment to the project and prior to their functioning without direct supervision,

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unless it was received within the past 3 years and documentation is available.

6.1.5 Documentation of Training

6.1.5.1 The PI will maintain complete training records and make them available to DAIDS staff, study monitors, or others as designated during site visits. Documentation of training shall consist of a listing of: trainee name(s), date of training, name/affiliation of trainer, title of course, and the primary contents covered in the training.

6.1.5.2 The PI will provide documentation of the training to the Program Officer and/or other designated DAIDS staff upon request.

6.1.5.3 Proof of training for new personnel will be maintained onsite and will be forwarded to the Program Officer as part of the non-competing Progress Report (Type 5).

6.1.6 Training Delivery Methods

6.1.6.1 Training may be delivered by a number of methods. The following represents examples of training delivery methods, however, others may be considered acceptable.

6.1.6.1.1 DAIDS-sponsored HSP/GCP/FDA training sessions

6.1.6.1.2 Commercial training programs

6.1.6.1.3 CD-based modules

6.1.6.1.4 Online training programs such as National Cancer Institute online training for HSP or university-based online modules may meet HSP/GCP/FDA requirements

7.0 REFERENCES

[Frequently asked Questions for the Requirement for Education on the Protection of Human Subjects, NIH, Office of Extramural Research](#)

[U.S. Code of Federal Regulations, Title 45, Part 46 and Subparts](#)

DAIDS
Bethesda, MD USA

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[International Conference on Harmonisation, Guidance for Industry, E6 Good Clinical Practice: Consolidated Guideline](#)

[NIAID GCP Learning Center, \(Satisfies both HSP and GCP training\)](#)

[U.S. Code of Federal Regulations, Title 21, Parts 11, 50, 54, 56, and 312](#)

[The Belmont Report](#)

[NIH Required Education in the Protection of Human Research Participants Policy](#)

[Office for Human Research Protections](#)

[The Declaration of Helsinki](#)

[The Nuremberg Code](#)

8.0 INQUIRIES

Questions and comments regarding this SOP 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 Documents](#) webpage.

10.0 APPENDICIES

None

11.0 APPROVAL

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