DAIDS
Bethesda, MD
USA

Requirements for Human Subjects Protection (HSP) and Good Clinical Practice (GCP) Training for Clinical Research Site Personnel

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Replaces: V 1.0

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) funded and/or sponsored clinical research.

2.0 SCOPE

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

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

Key personnel - Individuals who are involved in the design and conduct of NIH-funded human subjects' clinical research. (NIH)

This includes all individuals named on the Form FDA 1572 or DAIDS Investigator of Record Agreement and any clinical research site personnel who have more than minimal involvement with the conduct of the research (performing study evaluations or procedures or providing intervention) or more than minimal study conduct-related contact with study subjects or confidential study data, records, or specimens.

All other personnel with minimal involvement in the conduct of the research or minimal study conduct-related contact with the participants (e.g., drivers, couriers. clerical and administrative staff etc.), should receive training emphasizing the protection of participant privacy and confidentiality.

Clinical research - Research conducted on human subjects or on material of human origin identifiable with the source person.

Clinical research includes large and small-scale, exploratory, and observational studies. There are three types:

1. Patient-oriented research.
2. Epidemiologic and behavioral studies.
3. Outcomes and health services research.

Clinical trial - A prospective study of human subjects designed to answer questions about biomedical or behavioral interventions, e.g., drugs, treatments, devices, or new ways of using known treatments to determine whether they are safe and effective. (NIH)

Good Clinical Practice (Consolidated Guidance, ICH E6) - An international ethical and scientific quality standard for designing, conducting, recording, and reporting of trials that involve the participation of human subjects. (ICH)

ICH E6 is not a regulation, but the guidance presented represents the FDA's current thinking on good clinical practice.

For additional definitions, see the DAIDS Glossary.

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5.0 RESPONSIBILITIES

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.

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 Neonates Involved in Research

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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. Expedited Adverse Event Reporting

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6.1.2.5.2. Protocol Registration (and the DAIDS Investigator of Record Form)

6.1.2.5.3. 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.

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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, 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

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7.0 REFERENCES

Frequently asked Questions for the Requirement for Education on the Protection of Human Subjects, NIH, Office of Extramural Research
http://grants.nih.gov/grants/policy/hs_educ_faq.htm

U.S. Code of Federal Regulations, Title 45, Part 46 and Subparts http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm
International Conference on Harmonisation, Guidance for Industry, E6 Good Clinical Practice: Consolidated Guideline
http://www.fda.gov/oc/gcp/guidance.html

U.S. Code of Federal Regulations, Title 21, Parts 11, 50, 54, 56, and 312 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
The Belmont Report
http://www.fda.gov/oc/ohrt/irbs/belmont.html

NIH Required Education in the Protection of Human Research Participants Policy http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html

Office for Human Research Protections http://www.hhs.gov/ohrp/

The Declaration of Helsinki
http://www.wma.net/e/policy/b3.htm

The Nuremberg Code
http://www1.ushmm.org/research/doctors/codeptx.htm

8.0 INQUIRIES

Questions and comments regarding this policy may be directed to the OPCRO Policy Group at:
NIAIDOPCROPOLICYGROUP@mail.nih.gov

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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 JUL 06	N/A	N/A	N/A

11.0 APPENDICES

None.

12.0 APPROVAL

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

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