 NIAID Bethesda, MD USA	**Document Type** **Policy**	Version No.: 2.0 Date: 1/27/2010
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	Effective Date: 01/27/2010 Release Date: 01/27/2010	
Title: Good Clinical Practice Training for NIAID and Awardee Clinical Research Staff		

APPROVAL

	Approving Entity	**Date**
Approval Mechanism:	***NIAID Clinical Research Subcommittee (NCRS)***	***1/27/2010***

PURPOSE

The purpose of this policy is to identify training requirements and guidelines regarding good clinical practice (GCP), for NIAID and awardee clinical research staff. This policy serves as a harmonized approach for all NIAID Divisions to meet the NIAID Clinical Research Standard regarding GCP training.

SCOPE

This policy applies to individuals involved in the conduct or oversight of research under the auspices of the NIAID (including NIAID staff, contractors, and awardees).

BACKGROUND & RELATED REQUIREMENTS

In January 2007, the NIAID Clinical Research Standards were approved by the NIAID Executive Committee. The Standards were developed to define requirements that maximize the quality of NIAID clinical research. Standard 3.1 states that;

> *Each Division will establish minimal standards for training Division staff and clinical site staff in Good Clinical Practice (GCP), Human Subjects Protection (HSP), Good Laboratory Practice (GLP) and relevant Institute and Division policies.*

A review of related policies was performed by all NIAID divisions beginning June 2007. Below are the related policies and guidance that specifically address GCP:

- HSP training via a specific computer-based training is required for all researchers newly-employed by the NIH, contract staff who work within NIH intramural laboratories, and any other NIH staff who conducts or supports clinical research. (http://www1.od.nih.gov/oma/manualchapters/intramural/3014/main.html).
- Principal Investigators on Clinical Center protocols must complete the Clinical Center's Clinical Research Training Course titled "Protecting Human Subjects" http://www.nihtraining.com/crtpub_508/index.html and pass the multiple-choice exam. No new protocols are approved without certification that PIs have completed these requirements.
- Most NIH staff, including federal officials and contract personnel, are required to take annual ethics training which covers issues regarding conflicts of interest. In addition, newly hired NIH scientific staff are required to take a computer-based course titled "Introduction to Responsible Conduct of Research."
- For grant and contract recipients, documentation that the awardee and all study staff responsible for the design or conduct of the research have received training in the protection of human subjects is required (http://www.niaid.nih.gov/ncn/pdf/clinterm.pdf).

- Michael Gottesman, Deputy Director for Intramural Research, NIH, has signed the NIH's FWA certifying:

> I understand that the Assurance Training Modules on the OHRP website describe the responsibilities of the Signatory Official, the IRB Chair(s), and the Human Protections Administrator under this Assurance. Additionally, I recognize that providing research investigators, IRB members and staff, and other relevant personnel with appropriate initial and continuing education about human subject protections will help ensure that the requirements of this Assurance are satisfied.

The Secretary's Advisory Committee in Human Research Protections (SACHRP) strongly recommended to HHS Secretary, Michael Leavitt, that institutions ensure initial and continuing training for investigators and other members of the research team with responsibility for conducting human subjects research. It was recommended that such training should include ethical principles and their historic foundation, federal regulations, state and local laws, professional standards and institutional policies relevant to the protection of human subjects. http://www.hhs.gov/ohrp/sachrp/documents/20070615SecretarialAdvisoryLetter.pdf

DEFINITIONS

4.1. Good Clinical Practice (GCP): A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.[7.4] GCP standards are comprised from regulations, guidelines, and policies. GCP standards span a broad range of topics including, but not limited to;

- Informed consent
- Maintaining confidentiality
- Specimen handling and use of stored samples
- Ethics committee composition, functions, responsibilities and procedures
- Investigator qualifications, recourses, and responsibilities
- Sponsor responsibilities
- Study design
- Safety reporting and monitoring
- Study documentation
- Quality assurance
- Trial integrity
- Data handling
- Investigational agent handling

- Publication policies
- Human subjects protections
- Research ethics
- Conflict of interest
- 45 CFR 46, including subparts A,B,C, and D
- ICH E6
- 21CFR 11, 21 CFR 312, 21 CFR 50, 21 CFR 54, 21 CFR 56

4.2. Human Subjects Protection (HSP): HSP refers to the established responsibilities and procedures for protecting the rights and safeguarding the welfare of human subjects who participate in research.[7.3] As noted above, HSP is one topic of GCP.

4.3. Clinical Research - Research conducted on human subjects or on material of human origin identifiable with the source person. This shall be considered synonymous with the term human subjects research as defined by the terms human subject and research in the Code of Federal Regulation Title 45, Part 46.102.[7.6]

> (d) *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.[7.5]
>
> (f) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information. [7.5]

Clinical research includes large and small-scale exploratory, interventional and observational studies. There are many types, including; patient oriented research, epidemiological and behavioral studies, outcomes and health services research, clinical studies and clinical trials.

4.4 Clinical Research Staff: Staff who are involved with the conduct or oversight of clinical research. Staff become "involved" in human subjects research when they (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes [45 CFR 46.102(d),(f)]. These staff include, but are not limited to, those who oversee clinical research and staff listed on an FDA form 1572, investigator agreement or protocol cover sheet. .

4.4.1 NIAID Clinical Research Staff: NIAID employees and NIAID contractors who serve as NIAID delegates who function as Clinical Research Staff.

4.4.2 Awardee Clinical Research Staff: Individuals who conduct or oversee clinical research in the performance of their work that is funded by NIAID through a grant or

contract award.

5. RESPONSIBILITIES

5.1 For Awardee Clinical Research Staff: The Principal Investigator (PI) / Project Director (PD) as listed on the grant or contract award is responsible for making decisions regarding relevance (for which personnel is the training applicable), content, frequency, and documentation (how to verify and record that training has occurred) and to assure that their staff maintain compliance with the training requirements and guidelines set forth in this policy.

5.2 For NIAID Clinical Research Staff: Principal Investigators, Branch Chiefs, Lab Chiefs, and Office Directors are responsible for making decisions regarding training relevance. The direct supervisor determines 1) which staff are required to take training and 2) the content, frequency, and documentation procedures (how to verify and record that training has occurred), and their Division Directors assure that their staff maintain compliance with the training requirements and guidelines set forth in this policy.

6. POLICY: GCP TRAINING GUIDELINES

6.1 All clinical research staff should demonstrate a basic knowledge in GCP prior independence in performing their clinical research job functions/oversight.

6.1.1 Basic knowledge may be demonstrated by any of the following documents:

6.1.2 Certification from a recognized clinical research professional organization such as ACRP, SOCRA in which basic GCP knowledge is required in order to attain certification.

6.1.3 A transcript reflecting a passing grade(s) from an accredited institution in a course or program in which basic GCP knowledge is required in order to earn a passing grade

6.1.4 A certification of completion for a course in which basic GCP knowledge is demonstrated in order to receive the certificate. An example of an acceptable course can be found at the NIAID GCP Learning Center website. (http://gcplearningcenter.niaid.nih.gov)
A CV demonstrating extensive knowledge of all aspects of GCP (reflecting certification or coursework as described above).

6.2 Basic knowledge of GCP should include topics as per section 4.1 of this policy.

6.3 For Awardee Clinical Research Staff: The PI / PD should maintain training records and make them available to NIAID Division Clinical Research Staff (or designee) upon request. Documentation of training should include a listing of trainee name(s), date of

training, name/affiliation of trainer, and course title. Course outline /syllabus might also be included.

6.4 For NIAID Clinical Research Staff: NIAID staff should maintain training records and make them available to supervisors upon request. Documentation of training should include a listing of trainee name(s), date of training, name/affiliation of trainer, and course title. Course outline /syllabus might also be included.

6.5 Good Clinical Practice guidance and regulations are frequently revised and updated. Therefore, it is recommended that GCP training repeated / updated at least every 3 years.

7. REFERENCES

7.1 NIAID GCP Learning Center:
http://gcplearningcenter.niaid.nih.gov

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

7.3 NIH Policy Manual:
http://www1.od.nih.gov/oma/manualchapters/intramural/3014/main.html

7.4 ICH Harmonized Tripartite Guideline For Good Clinical Practice,
http://www.ich.org/cache/compo/276-254-1.html

7.5 45 Title 45—Public Welfare and Human Services Part 46—Protection of Human Subjects
http://www.access.gpo.gov/nara/cfr/waisidx_00/45cfr46_00.html

7.6 NIAID Glossary of Funding and Policy Terms and Acronyms
http://www.niaid.nih.gov/ncn/glossary/

8. INQUIRIES

Questions and comments regarding this policy may be directed to the NCRS Executive Secretary at NCRSexecsec@niaid.nih.gov.

9. AVAILABILITY

9.1 This policy is available electronically at the following URL:
http://inside.niaid.nih.gov/organization/DCR/Documents/NIAIDGCPTrainingPolicy.pdf

9.2 Hard copy documents are filed in the DCR office.

10. CHANGE SUMMARY

10.1 This policy will be reviewed every two years. Interim revisions will be made as needed to comply with NIH or other federal regulatory changes and/or at the request of the DCR Director.

10.2 The change summary table below will be updated when the document is reviewed or revised

Version #	Date	Replaces	Date of Review/Revision	Rationale for Review/Revision/Retirement
2.0	01/04/2010	1.0	01/27/2010	The policy must be reviewed every two years instead of every 6 months.