


Title: Requirements for Human Subjects Protection (HSP) and Good Clinical Practice (GCP) Training for NIAID and Awardee Clinical Research Staff	
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Title: Requirements for Human Subjects Protection (HSP) and Good Clinical Practice (GCP) Training for NIAID and Awardee Clinical Research Staff

APPROVAL

Approving Entity

Date

Approval Mechanism:

NIAID Clinical Research Subcommittee (NCRS)

1. PURPOSE

1.1. The purpose of this policy is to identify training requirements and guidelines regarding human subjects protections (HSP) and Good Clinical Practice (GCP), for NIAID and awardee staff. This policy serves as a harmonized approach for all NIAID Divisions to meet the NIAID Clinical Research Standard regarding HSP and GCP training and aligns with NIH training policies.

2. POLICY

2.1. All staff who are involved in the conduct, oversight, or management of clinical research should demonstrate a basic knowledge in HSP, prior to performing their clinical research job functions/oversight.

2.2. All staff who are involved in the conduct, oversight, or management of clinical trials should demonstrate a basic knowledge in GCP, prior to performing their clinical research job functions/oversight.

3. SCOPE

3.1. This policy applies to individuals involved in the conduct, management, or oversight of clinical research and clinical trials under the auspices of the NIAID (including NIAID staff, contractors, and awardee staffs).

4. RESPONSIBILITIES

4.1. **For Awardee 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 key personnel the training is 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.

4.2. **For NIAID Staff:** Division Directors or their designee (Principal Investigators, Branch Chiefs, Lab Chiefs, Office of Clinical Research, as examples) are responsible for making decisions regarding relevance (for which personnel the training is 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. NIAID's SOP for Good Clinical Practice (GCP) Training for Key NIH Extramural Staff Involved in NIH-Funded Clinical Trials may be referenced at <http://inside.niaid.nih.gov/topic/funding/sop/Pages/gcp-training-staff.aspx#>

5. DEFINITIONS

5.1. **Good Clinical Practice (GCP):** *GCP principles constitute an international ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials. GCP describes the responsibilities of investigators, sponsors, monitors, and institutional review boards in the conduct of clinical trials.*

<http://inside.niaid.nih.gov/topic/funding/sop/Pages/gcp-training-staff.aspx#>

5.2. **Clinical Research**¹-

Research with human subjects that is:

1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. It includes: (a) mechanisms of human disease, (b), therapeutic interventions, (c) clinical trials, or (d) development of new technologies.

2) Epidemiological and behavioral studies.

3) Outcomes research and health services research

Studies falling under 45 CFR 46.101(b) (4) (Exemption 4) are not considered clinical research by this definition.

5.3. **Clinical Trial** - A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.²

6. BACKGROUND & RELATED REQUIREMENTS

6.1. The 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.*

<https://www.niaid.nih.gov/research/niaid-clinical-research-standards>

6.2. NIH related policies and guidance that specifically address GCP:

6.2.1. Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-funded Clinical Trials

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html>

¹ <https://nih-extramural-intranet.od.nih.gov/nih/glossary.htm#C>

² <https://grants.nih.gov/grants/glossary.htm>

- 6.2.2. Frequently Asked Questions: NIH Policy on Good Clinical Practice (GCP) Training for NIH Awardees Involved in NIH-Funded Clinical Trials
http://osp.od.nih.gov/sites/default/files/FAQs_on_NIH_GCP_Policy.pdf
- 6.2.3. NIH SOP Number 25: Training Requirements for the NIH Human Research Protection Program (HRPP)
https://ohsr.od.nih.gov/public/SOP_25_v4_2-29-16_508.pdf
- 6.2.4. Policy on Good Clinical Practice Training for NIH Staff Involved in the Conduct, Management, and Oversight of Clinical Trials
https://nih-extramural-intranet.od.nih.gov/d/nih/policies/OER_announce_2016-02.htm
- 6.2.5. NIAID's SOP for Good Clinical Practice (GCP) Training for Key NIH Extramural Staff Involved in NIH-Funded Clinical Trials
<http://inside.niaid.nih.gov/topic/funding/sop/Pages/gcp-training-staff.aspx#>
- 6.2.6. NIAID Clinical Terms of Award
<http://www.niaid.nih.gov/ncn/pdf/clinterm.pdf>
- 6.2.7. Required Education In The Protection Of Human Research Participants
<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>

7. DOCUMENTATION

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

- 7.1.1. Certification from a recognized clinical research professional organization such as the Association of Clinical Research Professionals (ACRP), or the Society of Clinical Research Associates (SOCRA) for which basic HSP / GCP knowledge is required in order to attain certification.
- 7.1.2. A transcript reflecting a passing grade(s) from an accredited institution in a course or program in which basic HSP / GCP knowledge is required in order to earn a passing grade.
- 7.1.3. A certification of completion for a course in which basic HSP / 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>).
- 7.1.4. A Curriculum Vitae (CV) demonstrating extensive knowledge of all aspects of HSP / GCP (reflecting certification or coursework as described above).

7.2. Maintenance of training records

- 7.2.1. **For Awardee 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.
- 7.2.2. **For NIAID Staff:** NIAID staff should maintain training records and make them available to supervisors (or their 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 or content might also be included.

7.3. HSP and GCP guidance and regulations are frequently revised and updated. Therefore, GCP training must be refreshed at least every three (3) years in order to remain current with regulations, standards and guidelines. Recipients of HSP and/or GCP training are expected to retain documentation of their training.

8. INQUIRIES

- 8.1. 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 three 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.
2.0	01/27/2010	N/A	03/26/2012	The policy was renewed without any changes, except for broken <i>url</i> links that needed to be fixed.
3.0	4/19/2017	2.0		The policy was revised to align with the new NIH GCP training policy