1. PURPOSE

1.1 The purpose of this Policy is to establish the standards for Good Clinical Practice (GCP) training in trials funded and sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), Division of Microbiology and Infectious Diseases (DMID).

2. SCOPE

2.1 This Policy applies to awardees for all clinical trials funded by and/or supported by DMID, including investigators and clinical research staff at research sites conducting, managing, and/or overseeing trials (e.g., coordinating centers).

2.2 GCP requirements for DMID staff are covered under a separate policy (DMID-QM-POL-00005).

2.3 GCP requirements for vendors are covered under a separate policy.

3. DEFINITIONS

3.1 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.

3.2 Clinical Trials – NIH's Definition of a 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. https://grants.nih.gov/policy/clinical-trials/definition.htm

3.3 Coordinating Center- Awardee/recipient of funding that is responsible for overseeing or managing the clinical research sites conducting research supported by DMID as part of a network or collaborative group (e.g., IDCRC, ARLG, CIVICS).

For additional definitions, see DMID glossary.
https://www.niaid.nih.gov/research/dmids-clinical-research-glossary

4. RESPONSIBILITIES

4.1 As defined under Policy.

5. POLICY

5.1 Decision making authority:

5.1.1 Activities outside of DMID that are funded by grants including cooperative agreements must comply with the NIH Grants Policy Statement (NIHGPS) and any terms and conditions in the Notice of Award (NoA).

5.1.2 Activities outside of DMID that are funded by contracts must comply with the contract statement of work (SOW) and any other conditions specified in the award/contract.

5.1.3 All funding from the NIH require compliance with NIH policies including the NIH GCP policy.

5.1.4 The DMID policy (below) is written to align with NIH GCP policy. In the event the policy below contradicts the terms of the grant or contract, the grant or contract will take precedence.

5.2 NIH Policy states that "all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonisation (ICH) E6 (R2)."

5.3 NIAID Policy states that "all awardee 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."

5.4 The requirements for HSP training depend on the type of trial and funding mechanism.

IND/IDE Clinical Trials

Type of Trial	Grant	Cooperative Agreement	Contract
IND/IDE held by DMID	See 5.5.1	See 5.5.1	See 5.5.1
IND/IDE held by another entity	See 5.5.2	See 5.5.2	See 5.5.2

Non-IND/IDE Clinical Trials and Clinical Studies

Type of Trial/Study	Grant	Cooperative Agreement	Contract
Clinical Trial: High Resource	See 5.5.3	See 5.5.3	See 5.5.1
Clinical Trial: Low Resource	See 5.5.3	See 5.5.3	See 5.5.1
Clinical Study (not a trial): Higher Risk Procedure	See 5.5.5	See 5.5.5	See 5.5.5
Clinical Study (not a trial): Not High Risk	See 5.5.5	See 5.5.5	See 5.5.5

5.5 DMID policy on GCP training:

5.5.1 For DMID sponsored IND trials:

- All staff who are involved in the design, conduct, oversight, or management of clinical trials should have documented training in GCP prior to performing their clinical research job functions/oversight. At a minimum, this includes:
  - The Principal Investigator (PI) / Project Director (PD) as listed on the grant or contract award.
  - The PI of the clinical trial (if different than above).
  - Any sub-investigators listed on the Form FDA 1572.
  - Any sub-investigators or associate investigators listed on the IRB application.
  - Any staff on a delegation log in a role that interacts directly with trial participants.
  - Any staff performing recruitment (discussing details of the trial), consent, and evaluation of inclusion/exclusion criteria.

- Any staff who are responsible for study coordination, data collection, and data management.
- For other staff involved with the trial that obtain information or specimens for the purpose of research, the site PI / PD should consider local and institutional policies and whether GCP training would be helpful in ensuring the integrity of the data/samples, accuracy of the study, and in protecting the rights of trials participants. The site PI / PD is responsible for identifying other staff that need GCP training.

5.5.2 For non-DMID sponsored IND trials, the IND sponsor has the responsibility of determining which clinical staff need documented GCP training.

5.5.3 For non-IND trials funded by grant or cooperative agreement:
- the PI / PD as listed on the grant or cooperative agreement must have GCP training.
- the PI / PD is responsible for determining which additional staff need GCP training.

5.5.4 For non-IND trials funded by contract, GCP training requirements will follow those specified for DMID sponsored IND trials above. (5.5.1)

5.5.5 GCP training is not required for clinical studies that are not clinical trials.

5.6 GCP training should occur at least every three years in order to remain current with regulations, standards, and guidelines.

5.7 Recipients of GCP training are expected to retain documentation of their training, refresher training, and make this documentation of training accessible to supervisors and compliance auditors/monitors upon request.

5.8 Acceptable GCP trainings:

5.8.1 For DMID sponsored IND trials and non-IND trials funded by contract, acceptable GCP trainings include:
- Collaborative Institutional Training Initiative (CITI)
- NIDA GCP
- NIAID GCP Learning Center (no longer available for new training)
- GCP trainings from universities, institutions, or companies accredited for higher education or continuing education and training (regardless if credits are claimed).
- Other GCP trainings may be acceptable. The OCRA director or deputy director will make the determination about other acceptable trainings. A list of trainings that have been determined to be acceptable will be maintained for reference.

5.8.2 For all other trials, the person designated in section 5.5.2 or 5.5.3 will determine acceptable GCP training.

6. REFERENCES

6.1 Guideline for Good Clinical Practice E6 (R2)

6.2 NIH GCP policy

6.3 NIAID Clinical Research Standards

6.4 NIAID HSP and GCP Policy

6.5 NIH's Definition of a Clinical Trial

7. APPENDICES

Not applicable

8. REVISION HISTORY

- Revision 1, effective 8 January 2024, was rewritten from the prior policy DMID Policy-017 NCRS-3.1 v 3, and was the original version in the eQMS.
- Revision 2 – The table in 5.4 was reformatted for Section 508 compliance.

9. ADDITIONAL INFORMATION

9.1 Document Lead: Associate Director for Clinical Research

9.2 Posting externally: Yes