1. PURPOSE

1.1 This policy describes the requirement for clinical site quality management for research funded 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 all clinical studies supported by DMID.

3. DEFINITIONS

3.1 Quality Assurance (QA): All those planned and systematic actions that are established to ensure that the trial is performed, and the data are generated, documented (recorded), and reported in compliance with Good Clinical Practice (GCP) and the applicable regulatory requirement(s).

3.2 Quality Control (QC): The operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of the trial-related activities have been fulfilled.

3.3 Clinical Quality Management Plan (CQMP): A written description of the quality control (QC) and quality assurance (QA) procedures, roles and responsibilities, scope, sample size, and frequency of these activities to ensure a level of quality in clinical research activities. Synonymous terms found in funding agreements may include 'quality assurance and quality control procedures' or 'quality management plan'.

For additional definitions, see DMID glossary.

4. RESPONSIBILITIES

4.1 Program Officer (PO) is responsible for oversight of a scientific program and research grants portfolio and ensures that grantees establish a plan for clinical site quality management.

4.2 Contracting Officer's Representative (COR) is responsible for oversight of the DMID contract after an award is made and ensures that a Clinical Quality Management Plan (CQMP) is established as necessary.

4.3 Recipient/ Awardee/ Contractor receives financial support from DMID to conduct research as outlined in their respective agreement and is responsible for ensuring that processes are in place to establish an acceptable level of quality in accordance with all applicable regulations and NIH policies and guidelines.

5. POLICY

5.1 All sites conducting clinical research and trials supported by DMID must have processes in place to ensure the safety and well-being of participants, produce data that is accurate and credible, while being compliant with local and national regulations, ICH/GCP Guidelines, and NIH policies and guidelines.

5.2 The requirements for quality management at clinical research sites depend on the type of trial and funding mechanism.

5.2.1 Activities 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).

5.2.2 Activities that are funded by contracts must comply with the contract Statement of Work (SOW) and any other conditions specified in the award/contract.

5.2.3 All activities supported by NIH require compliance with NIH policies.

5.2.4 In the event this policy contradicts the terms of the grant or contract, the grant or contract will take precedence.

5.3 For a clinical study or a non-IND clinical trial funded by grant or cooperative agreement, site quality management is the responsibility of the grantee.

5.3.1 No routine reporting to DMID is required.

5.3.2 Upon request (if communicated by the DMID PO), the site is expected to describe site processes to accomplish the goals in Section 5.1.

5.4 For a clinical study funded by contract, site quality management is the responsibility of the contractor.

5.4.1 No routine reporting to DMID is required.

5.4.2 Upon request (if communicated by the DMID COR), the site is expected to describe site processes to accomplish the goals in Section 5.1.

5.5 For non-IND/IDE clinical trials and clinical research funded by cooperative agreement or contract, the need and process for clinical site quality management should be determined by the risk of the trial. DMID PO/COR may determine if a written CQMP is required (or if site quality management is the responsibility of the grantee/contractor without a formal CQMP).

5.5.1 Clinical trials with a high-risk intervention (e.g., drug/vaccine used outside the label dose, indication, population, or IND-exempt), comparative efficacy trials, or studies that could alter clinical practice, must have a structured quality management plan.

5.5.2 For non-IND/IDE clinical research cooperative agreements, the PO determines the need and process for clinical site quality management.

5.5.3 For non-IND/IDE clinical research contracts, the COR determines the need and process for clinical site quality management.

5.6 For IND/IDE trials (or equivalent regulatory mechanism in other countries) where DMID is not the regulatory sponsor, regardless of funding mechanism, the sponsor is responsible for ensuring quality processes and procedures are in place.

5.6.1 For IND/IDE trials (or equivalent regulatory mechanism in other countries) where DMID is not the regulatory sponsor, funded under contract, DMID may (if communicated by the DMID COR) ask the sponsor for documentation of site quality processes and procedures.

5.7 For all IND/IDE trials where DMID is the regulatory sponsor, regardless of funding mechanism, clinical sites must establish and implement a DMID accepted clinical quality management plan as an on-site management tool to describe and document quality control (QC) and quality assurance (QA) procedures.

6. REFERENCES

6.1 ICH GCP E6 (R2): E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) | FDA

6.2 NIAID Clinical Research Standards

7. APPENDICES

7.1 NA

8. REVISION HISTORY

8.1 DMID-SM-POL-00005 Clinical Quality Management in Clinical Research is the original version of this procedure within the eQMS.

9. ADDITIONAL INFORMATION

9.1 Document Lead: Office of Clinical Research Affairs (OCRA)

9.2 Posting externally: Yes