1.0 Purpose:

To describe the Division of Microbiology and Infectious Diseases (DMID) policy for clinical sites conducting DMID-funded clinical research to establish Clinical Quality Management Plans (CQMPs).

2.0 Scope:

This policy applies to sites conducting DMID-funded clinical research. All DMID-funded clinical research sites are encouraged to develop and implement a CQMP. All DMID-contract funded sites conducting clinical trials are required to implement a CQMP if a CQMP plan is included in the terms of award.

3.0 Policy:

All DMID-funded clinical sites should develop and implement a CQMP as an on-site management tool to internally evaluate and document the site's performance of the protocol procedures. The plan should encompass quality control (QC) and quality assurance (QA) procedures, detailing the responsibility, scope, and frequency of these activities. Implementing the CQMP process enables site staff to verify data accuracy and completeness of data capture, protect human subjects' rights and welfare, and ensure Good Clinical Practice (GCP) standards and regulatory requirements are met.

4.0 Background:

Quality Management (QM) is an overall system of oversight to document, track, and improve performance. QM planning and associated QC (real-time) and QA (periodic) activities facilitate effective protocol implementation and compliance with DMID and GCP requirements, verify the accuracy of data, and identify process areas in need of corrective action.

DMID staff is responsible for providing direction on criteria for instituting, implementing, and reviewing CQMPs. DMID may request a copy of a site-specific or protocol-specific CQMP for review and acceptance. DMID reserves the right to review site CQMP findings.

DMID Clinical Quality Management guidance, sample tools, and training are available on the DMID Clinical Research Policies, Guidances, and Tools public web site to aid clinical sites in meeting the requirements of this policy. See section 7.0 references.

5.0 Definitions:

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 GCP and the applicable regulatory requirement(s). These are periodic activities.

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. These are real-time activities.

6.0 Responsibilities:

Role	Responsibilities
DMID Programmatic Branches and Contracting Officer's Representative	• Notify Principal Investigators (PI) of their responsibility for CQMP development and implementation
Office of Clinical Research Affairs (OCRA)	• Provide operational support and CQMP guidance, templates, and tools to the sites • Review and accept site/protocol-specific CQMPs, as applicable • Review findings from CQMP activities, as applicable
Clinical Research Site PI or designee	• Develop, implement, and evaluate the CQMP • Provide a written CQMP to DMID upon request and submit revisions as appropriate • Conduct internal QM activities, including corrective and preventive actions • Prepare reports that summarize and analyze findings, as applicable • Communicate findings to appropriate study staff • Submit findings to DMID as requested

7.0 References:

Division of Microbiology and Infectious Disease's public web site- Clinical Quality Management page

International Conference on Harmonization (ICH) E6: Good Clinical Practices

Code of Federal Regulations Title 21, Part 312: Investigational New Drug Application

Code of Federal Regulations Title 21, Part 812: Investigational Device Exemptions

8.0 Inquiries:

Questions or comments regarding this policy may be directed to:

Associate Director for Clinical Research
Division of Microbiology and Infectious Diseases (DMID)
NIH / NIAID
6610 Rockledge Dr.
Bethesda, MD 20892
DMIDPolicyQuery@niaid.nih.gov

9.0 Availability:

This policy is located electronically at:
http://www.niaid.nih.gov/labsandresources/resources/dmidclinrsrch/Pages/clinicalmgmt.aspx

10.0 Change Summary:

Version Number	Date of Revision: DD-MMMYYYY	Replaces	Effective Date: DD-MMM-YYYY	Description of Revision/Retirem ent
1.0	N/A	N/A	14-JAN-2008	N/A
2.0	18-AUG-2008	Version 1.0	01-SEP-2008	Update links, clarify purpose, workflow, administrative
3.0	23-FEB-2009	Version 2.0	01-APR-2009	Add KQI, clarifying language; sample tools revised
4.0	19-MAY-2010	Version 3.0	01-OCT-2010	Annual review; administrative changes; revised DMID URL
5.0	17-JAN-2014	Version 4.0	31-JAN-2014	Revised to new policy format
6.0	17-JUN-2016	Version 5.0	13-JUL-2016	Administrative changes