

# DMID INFORMATION SHEET

## Clinical Quality Management Plan

The DMID Clinical Quality Management policy applies to sites conducting DMID-funded Human Subjects research. A Clinical Quality Management Plan (CQMP) serves as an on-site management tool, describing quality control (QC) and quality assurance (QA) processes to be implemented by the clinical site for internal evaluation and documentation of site performance of protocol procedures; identifying and resolving problems at the earliest stages.

The site CQMP prompts site staff to:

- ❖ Verify compliance with the protocol,
- ❖ Ensure data accuracy and completeness of data capture in a timely manner,
- ❖ Protect human subjects' rights and welfare, and
- ❖ Ensure Good Clinical Practice (GCP) standards and regulatory requirements are met.

### Responsibilities

#### PI or designated Site Quality Management Staff

- ❖ Develops, implements, and evaluates the CQMP
- ❖ Provides an initial and revised CQMP to the DMID COR
- ❖ Conducts internal quality management activities, reports, periodic review of the plan as prescribed in the CQMP
- ❖ As applicable, communicates QC and QA findings to appropriate study teams and DMID

#### DMID COR, as applicable

- ❖ Facilitates review and approval of a CQMP, as applicable under terms of funding

#### DMID CQMP Liaison

- ❖ DMID point of contact for Site CQMP development, ongoing evaluation and consultation.

- ❖ As indicated, DMID CQMP Liaison will correspond with COR, protocol Clinical Project Manager and Site Staff. During development may recommend CQMP modifications, and post implementation may recommend changes based on analysis of performance indicators.

#### DMID Clinical Research Operations and Management Support (CROMS) CQMP Team

- ❖ Provide consultative clinical quality management document review and guidance during the development and review process.
- ❖ Document and communicate review outcome to the clinical site Staff and DMID.
- ❖ CQMP review status is made available to the CROMS Clinical Site Monitoring team for verification of CQMP implementation.

### Implementation

#### CQMP Development:

- ❖ DMID Clinical Quality Management Plan guidance, sample templates and tools are located on the DMID-CROMS website and available for discretionary use by contractor/clinical sites developing a CQMP.

#### Information Disclaimer

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### **CQMP Submission for Review and Approval:**

- ❖ The DMID-CROMS CQMP review service is requested at the discretion of DMID. This request applies to initial and revised CQMPs. Documentation of the review process is communicated to the contractor/site and DMID.
- ❖ Where the CQMP is a deliverable stipulated in a DMID funding agreement (i.e., contract, Statement of Work) it is subject to approval by DMID

### **Additional Information**

- ❖ During DMID Clinical Site Monitoring visits, a member of the monitoring team will verify the current CQMP implemented at the site, and request the most recent quality management report signatory and date. Should there be questions raised by the monitoring team, DMID may be contacted for further information.
- ❖ Visit the DMID-CROMS Clinical Quality Management web page at <https://www.dmidcroms.com/CRS/QM/SitePages/Qualitymanagement.aspx> for detailed guidance, templates and tools.

### **Definitions**

**Clinical Quality Management (CQM):** Quality management is the overall system that includes all activities involved in Quality Assurance and Quality Control, including the assignment of roles and responsibilities, the reporting of results, and the resolution of issues identified during the review.

**Clinical Quality Management Plan (CQMP):** A written document that encompasses both Quality Assurance and Quality Control procedures and details the responsibility, scope, and frequency of these activities.

**Contracting Officer Representative (COR):** Government representative responsible for technical management of the contract.

**Clinical Project Manager (CPM):** DMID Branch-specific representative who is the primary DMID point of contact communicating scientific and operative issues related to the development and implementation of the protocol.

**Quality Assurance (QA):** The periodic, systematic, objective, and comprehensive examination of the total work effort to determine the level of compliance with Good Clinical Practice (GCP) standards.

**Quality Control (QC):** The real time (“day to day”) observation and documentation of the sites work processes to ensure that accepted procedures are followed.

### **Questions**

Contact your DMID protocol-specific Point of Contact or email the [DMID Office of Clinical Research Affairs, OCRA Help](#)

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