**INSTRUCTIONS FOR DEVELOPING A CLINICAL QUALITY MANAGEMENT PLAN**

**USING THE**

**DMID SAMPLE CLINICAL QUALITY MANAGEMENT PLAN (CQMP)**

**(INSTRUCTIONAL TEMPLATE)**

**Background**: This CQMP Instructional Template reflects the basic attributes outlined in the current [DMID CQMP Policy](https://www.niaid.nih.gov/sites/default/files/qualitymgmtplan.pdf). It is available for discretionary use by clinical sites conducting DMID-funded clinical studies/trials.

**Purpose**: The purpose of this template is to serve as a guide for measuring quality of protocol-directed records collected and maintained during the lifecycle of the protocol; for ensuring quality management principles are in place; the quality of the conduct of the protocol through implementation and adherence to Good Clinical Practices and applicable federal/local regulations; timely review of source data and source documentation; human subject protections are in place; and optimizing the reliability and integrity of the data collected to answer the study objectives.

**DMID-CROMS CQMP review service:** This service is requested at the discretion of DMID/DMID Clinical Project Manager (CPM). This request applies to initial and revised CQMPs. Documentation of the review of a site CQMP is communicated to the contractor/site and DMID. Please note, 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.

**How to use this template:** This Clinical Quality Management Plan (CQMP) Instructional Template in Microsoft Word allows for modification by the site, as needed, to develop a site CQMP. Please check with the DMID Clinical Project Manager (CPM), and refer to the [DMID Information Sheet for the Clinical Quality Management Plan](https://www.dmidcroms.com/Shared%20Documents/Clinical%20Quality%20Management%20Plan%20Info%20Sheet.pdf) for guidance, and [DMID Document Version Control guidelines](https://www.dmidcroms.com/Shared%20Documents/Document%20Version%20Control%20Guidelines%20Info%20Sheet.pdf#search=DMID%20version%20control%20guidelines).

1. **Complete**: Begin using this tool by completing the header information (name of the Institution/Site, version number and date of the CQMP).
	1. Detailed ‘<instructions>’ in red font are provided throughout the template, and in each section, 1-10
	2. The instruction page may be modified to suit the needs of the site.
	3. Address each section of the CQMP instructional template, modifying as necessary.
	The following tools/associated documents are available for discretionary use to complement the CQMP development:
		1. DMID Sample Chart Audit Tool
		2. DMID Sample Regulatory File Review Tool
		3. DMID Sample Quality Management Summary Report Tool
		4. Protocol-specific Instructional Template (if indicated).
	4. Remove ‘DMID Sample’ and replace with Institution/clinical site name.
2. **Apply Version Control**: When adopting and modifying this template for discretionary use, correct the header/footer to reflect version control. Please refer to the [DMID Information Sheet; Document Version Control Guidelines](https://www.dmidcroms.com/Shared%20Documents/Document%20Version%20Control%20Guidelines%20Info%20Sheet.pdf#search=DMID%20version%20control%20guidelines).
	1. Ensure header/footer contain appropriate version/date *and* pagination for the site’s CQMP and associated tools/documents.
	2. **Remove template instructions**: These should be removed from the CQMP once developed and/or submitted to DMID.
3. **Sign and Date**: Provide appropriate signatures and dates, as per Section 10 of this template.
4. **File and Maintain**: File the all versions of the site’s CQMP and associated documents/tools in the site’s Quality Management file.

**Resources:**

* DMID CROMS (Clinical Research Operations and Management Support): [https://www.dmidcroms.com/\_layouts/DMID\_CROMS/DMIDHome.aspx](https://www.dmidcroms.com/_layouts/15/DMID_CROMS/DMIDHome.aspx)
	+ Resources and Tools
	+ Clinical Research Support
	+ Training
* U.S. Food and Drug Administration E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) Guidance for Industry

<https://www.fda.gov/downloads/Drugs/Guidances/UCM464506.pdf>

* U.S. Food and Drug Administration Bioresearch Monitoring, Clinical Investigators, Inspectional <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/fda-bioresearch-monitoring-information/bioresearch-monitoring-program-information>
* U.S. Food and Drug Administration Guidance for Industry, Electronic Source Data in Clinical Investigations <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm328691.pdf>
* U.S. Food and Drug Administration Guidance for Industry Use of Electronic Health Record Data in Clinical Investigations <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM501068.pdf>
* International Council for Harmonisation (ICH) Good Clinical Practice E6(R2) <https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf>
* NIAID Clinical Research Management System (N-CRMS) Site Essential Regulatory Documents (SERD):
* login page <https://ncrms.niaid.nih.gov/>

***DMID SAMPLE* CLINICAL QUALITY MANAGEMENT PLAN**

**(INSTRUCTIONAL TEMPLATE)**

<*Replace DMID SAMPLE with Institution/Site Name*>

<*Insert Version # and Date of CQMP*>

# PROTOCOL and/or SITE IDENTIFICATION

* 1. Site Identification *<insert full name and location for the clinical site where protocol activities and clinical quality management activities are conducted. For multiple sites conducting a protocol, refer to the Protocol-specific CQMP, section 3.0, if applicable>*

# RESPONSIBILITY

<*Insert Title of Quality Management Designee*> <*Name*> is designated by the Principal Investigator *<insert PI name>* to develop, implement, and oversee all functions of this quality management plan.

<*Insert additional functional roles of site staff associated with the Quality Management Process. Ensure delegated staff and respective functions are documented on the Study Personnel /Site Responsibility-Signature Log or equivalent Delegation of Responsibility log*>

# CLINICAL QUALITY MANAGEMENT PROCESS DESCRIPTION

* 1. Quality Control (QC) Activities: <*Describe the ongoing, real-time, day-to-day activities conducted at the site as part of the QC proces*s. *Source documentation/data review should consider A.L.C.O.A.C principles (attributable, legible, contemporaneous, original, accurate, and complete). Reference applicable site Standard Operating Procedures by title/identifier. Ensure objective review of source documentation.*>
		1. Roles/Responsibilities: <specific to QC>
		2. Record Selection: <*Describe the key quality indicator, frequency and sample size (typically 100%) of records selected for internal real-time review (i.e., eligibility, informed consent, study procedure, study product management, study product administration, safety assessment/reporting).>*
		3. Quality Control Tools
			1. Internal (site) Sources: < *i.e., study visit schedule/procedures, eligibility checklist, informed consent document>*
			2. External Sources: *<Data Entry, Query/Error, or Transmission Reports from the Data Management Center >*
	2. Quality Assurance (QA) Activities: <*Describe the retrospective/periodic review and frequency of quality review activities (routine and targeted reviews) conducted at the site as part of the QA process. Review of systems and processes used to optimize data integrity and ensure human subject protections (e.g., informed consent, eligibility, laboratory processes, recordkeeping, protocol conduct/compliance, Good clinical Practice). Reference applicable site Standard Operating Procedures by title/identifier*>
		1. Roles/Responsibilities *<specific to QA>*
		2. Record Selection: *<insert the minimum percentage and/or a range of percentage of records selected for quality assurance review.*
		3. Quality Assurance Tools
			1. Internal (site) Sources: *<Chart Review checklists / Worksheets, Summary Reports from Internal QA/QC Findings, Regulatory File Review Tool>*
			2. External Sources: *<Clinical Site Monitoring Reports, Data Entry, Query/Error, or Transmission Reports from the Data Management Center>*
	3. Protocol – specific CQMP: *<If applicable, describe the use and process for implementing quality reviews. Recommended for sites conducting multiple protocols across multiple institutions, global and domestic locations. A DMID template is available on the DMID CROMS website and can be attached to the site CQMP. The template can be modified to define and provide data in fields specifying protocol-driven parameters for QC and QA recording and reporting.>*
	4. Oversight of Subcontractor site(s): *<Where applicable under certain DMID agreements, describe subcontractor requirements and timelines for implementing quality management methods consistent with contractual obligations>.*

# KEY QUALITY INDICATORS

*<*List the Key Quality Indicators that will be reviewed as applicable to processes defined in section 3.0, and for each subject and/or records selected for internal quality review *(routine and/or targeted review)*. Describe the quality checks in place for each indicator>

* 1. Informed Consent Form and Process
	2. Eligibility Criteria
	3. Study Product Management: Receipt, Storage, Preparation, Transport, Administration, and Accountability (if applicable) *<Describe the following applicable components: >*
		1. Review and comparison of the study product accountability logs, shipping records, and the study product inventory
		2. Randomization code list and decoding procedures
		3. Study product storage, handling, and labeling procedures
		4. Vaccine or other study product/challenge preparation procedures
		5. Study product administration processes
	4. AE/SAE Identification and Reporting
	5. Protocol Visits *<evaluate for missed visits, out of window visits, lost to follow-up, etc.>*
	6. Protocol-specific Procedures (all inclusive)
	7. Intervention/Study Discontinuation
	8. Reactogenicity (if applicable)
	9. Specimens *<Describe quality checks in place for the following components: >*
		1. Processing
		2. Storage
		3. Documentation
	10. *<Add additional protocol-specific indicators, as applicable>*

# REGULATORY FILE REVIEW

*<Describe the QA activities conducted on the Regulatory File, ensuring the file is complete and current>*

* 1. Frequency of Review: *<Insert how often the Regulatory File will be reviewed considering prior to enrollment/site activation, during the study and/or when revised protocol, informed consent are IRB-approved, at the close of the study>*
	2. Regulatory File Review Tool: *<Insert name and location of tool to be used for regulatory review>*
	3. *<Add additional regulatory QA activities, where applicable>*

# TOOLS and CHECKLISTS

*<Describe the tools, checklists, and reminders that will be used in the CQMP process. Examples include, but are not limited to the following: >*

* 1. Internal (site) Sources: *<e.g., study visit checklists, Standard Operating Procedures>*
	2. External Sources: *<Data Entry, Query/Error, or Transmission Reports from the Data Management Center, Clinical Site Monitoring Reports>*
	3. *<Add additional tools/forms, as applicable>*
1. **STAFF TRAINING / QUALIFICATIONS** *<Contact the DMID CPM to confirm DMID training requirements>*

*<Describe the site processes for ensuring and documenting qualified staff and competency>*

* 1. Institution-specific Training: <*List specific trainings, i.e., Human Subjects Protection, Phlebotomy, Dangerous Goods Regulations, research staff training, applicable site policies/procedures, etc.*>
	2. Protocol-specific Training: <*List specific trainings, i.e., specimen handling/processing, study product, data management, etc.*>
	3. DMID-specific Training: *<List specific trainings, i.e., Human Subjects Protection, Good Clinical Practice, DMID Regulatory File Document Guidelines, DMID Source Documentation Guidelines>*
	4. <Add any additional training>

# CLINICAL QUALITY MANAGEMENT REPORTING

*<Describe how the results of the internal assessments will be summarized, analyzed, and communicated to the staff and informing decisional strategy. Reference applicable SOPs by title/number.>*

* 1. Tools/forms used to document / summarize quality reviews: *<List tools/forms used for documenting quality review summaries. Ensure titles/dates listed here are concordant with title on tool/form. >*
	2. Identification of Problem Areas: *<Identify key quality indicators where problems are occurring>*
	3. Trend Analysis: *<Describe the process for analyzing findings for trends impacting study conduct, human subject protections and integrity of study data; determining needed improvements in key quality indicators>*
	4. Corrective Action Plan(s): *< Describe the plan and timeline implemented for corrective action(s). >*
	5. Revision to the CQMP: *<Describe the process for determining needed revisions to the CQMP, informing evaluation of the CQMP for effectiveness>*

# SITE EVALUATION OF THE CLINICAL QUALITY MANAGEMENT PLAN

*<Describe the process/method for the site’s periodic review of the CQMP for effectiveness. Define the frequency; a minimum of once during the protocol period (i.e., Phase I clinical trials), or annually is recommended; however, results of the site’s quality reviews may necessitate increased frequency reviews. Include applicable SOP title/number. >*

* 1. CQMP Review: <*Insert time frame for CQMP review>*
1. **SIGNATURES/DATES** <*insert printed names, signatures and date of signature of the Principal Investigator and personnel designated responsibility for overseeing the development and implementation of the protocol-specific CQMP, concordant with responsibilities described in the site’s CQMP and Study Personnel /Site Responsibility-Signature Log or equivalent Delegation of Responsibility log. Ensure distribution to multiple sites listed where protocol-driven activities and quality reviews are conducted.*>

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Signature of CQMP Designee *<insert title/role>* Date

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Signature of Principal Investigator Date

*<add additional signatures as applicable>*