**Site Clinical Quality Management Plan: *Protocol-Specific***

**Site Name:**

**DMID Protocol Number: ##-####**

**Protocol Title:**

**CQMP Version#:**  **Version Date:**

1. **Purpose**

The purpose of the Clinical Quality Management Plan (CQMP) is to describe the components of Quality Management (QM) that will be implemented by the research site. Quality Management is a system of oversight to document, track, internally evaluate, and improve performance. Quality Management includes planning and associated real-time Quality Control (QC) and periodic Quality Assurance (QA) activities. These activities facilitate effective protocol implementation and compliance with DMID guidelines and Good Clinical Practice (GCP) requirements, verify the accuracy of data, and identify process areas in need of corrective action.

This CQMP provides a description of QC and QA activities, focusing on key areas of study implementation. It may be revised to include additional *critical* protocol processes that are specific to the study (e.g., clinical, specimens/laboratory, regulatory file). Other DMID accepted quality plans may be used with the approval of the DMID CPM.

Clinical Quality Management (CQM) tools, including DMID-prepared checklists and summary review tools, are available for use on the CROMS Website (<https://www.dmidcroms.com/CRS/QM/SitePages/Qualitymanagement.aspx>).

1. **Quality Management Concepts**

* Quality Management is a shared responsibility between the sponsor and the clinical site. Site level quality management is a distinct activity from the Sponsor obligation of Monitoring.
* Quality Control (QC) entails the timely review of up to 100% of study data. The purpose of QC is to ensure source data is attributable, legible, contemporaneous, original, accurate, and complete. QC data checks are effective when performed as close to data capture (documentation) as possible and are critical to early detection of deviations, omissions, erroneous data, as well as identifying gaps in study implementation and site training. The issues identified through the QC process are corrected upon identification or as soon as possible.
* Quality Assurance is a retrospective examination of processes (i.e., key quality indicators such as informed consent, study product management, SAE reporting, etc.), that must be documented. QA reviews take a broader assessment of study activities to determine compliance with the IRB-approved protocol, Manual of Procedures (MOP), DMID Standard Operating Procedures (SOPs), and other DMID guidance, as well as site compliance with local site SOPs and policies. QA reviews present opportunities to identify, address, and improve site process inefficiencies, and develop new processes.
* During QA Audits, the findings and other quality checks will be summarized and analyzed for trends impacting data integrity. Areas where processes should be developed or enhanced to increase quality will be identified.
* Staff meetings will be scheduled to provide opportunities for summary report review and discussion of QM findings, corrective actions, staff training, and process improvement.

1. **Responsibilities**

Sites are responsible for quality management. The Principal Investigator (PI) is responsible for maintaining quality oversight. Site staff are required to perform and document QC checks and QA reviews to ensure detection of errors, implementation of corrective and/ or preventive actions, reporting of deviations and notification of appropriate parties in a timely fashion (e.g. IRB/Ethics Committee (EC) – as appropriate).

* QC checks should be completed promptly with some checks prioritized (e.g., consent reviews may need to be conducted more quickly than sample QC checks)
* **Staff performing QA reviews should be independent from QC.** Staff should be familiar with the IRB/EC of record reporting guidelines to ensure the IRB/EC is notified of any reportable items appropriately.
* Documentation of the QA reviews will be available for review upon request by DMID or designee.

1. **QA Review Frequency**

* Initiate the first QA Review within **[*72 hours*]**of enrollment [***of the 3rd participant at the site*]**.
* Conduct a QA Chart Review of ***[percentage should be proportionate to study enrollment from 30-50% minimally]*** of enrollments since the last QA review. See Quality Indicators below.
  + It is recommended that the study activities conducted by new staff are included in this review, as new staff are added to the protocol.
* Review all visits (from screening through study completion) for participants selected for QA review for protocol processes.
* Continue QA reviews monthly while participant visits are less than a month apart, then reviews can occur bimonthly thereafter until study closure.
* Specimen Management: At least monthly review until last specimen is shipped.
* Study Product: Conduct study product accountability monthly and document reviews. *[As applicable]*
* Regulatory File Review: Complete a review according to the checklist within the first month of site activation. Thereafter, regulatory QA reviews according to the checklist should occur at least quarterly ***[ within 1 week following a protocol amendment and/or major changes for example change in PI, new consent, or change in study staff*, *or prior to monitoring visits, as applicable].***

1. **Focus for QA Reviews**

* Informed Consent- *[****100%]*** review of Informed Consent Process documentation and signed Consent Forms (including screen failures).
* Re-Consent – ***[100%]*** review of signed Consent Forms, and process documentation for participants designated by IRB-required re-consent.
* Chart Review – Minimum of **[*30% to 50%]*** of dosed subjects will have 100% chart review of Source Documentation and eCRF.
* If trends or issues are identified, it is the site’s responsibility to modify the percentage of participant records selected for review and/or increase the frequency of review. E.g.:
  + If study product administration deviation is submitted for wrong product or dose administered, increase the review percentage to 100% of study product administration source documents (e.g., product order, study product logs, and administration records)
  + If issues are identified with adverse event reporting, then increase the review of the percentage of source documents for participants.
* If trends or issues are identified, develop, and implement strategies to prevent trends and inefficiencies from continuing. The proposed remedy should include processes to track improvement and resolution.

***[The following areas of focus may be adjusted based on protocol]***

* ***Specimen Management Review:***
* Initiate the first QA Review within 72 hours of the first 3 participants enrolled at the site and continue to review through the shipment of the final specimen.
* ***Study Product Management Review****:*
* If the study is blinded, please remember that an unblinded review can only be conducted by a pharmacist or designated unblinded staff.
* Review a minimum of 30% of participant, when vaccinations have occurred in the previous month.

1. **Communication and Documentation**
   * QA reviews are documented on the QA tool utilized as specified in the Appendix 1 attestation.
   * Discrepancies and issues identified during the QA review should be discussed with the PI and study team upon the completion of the review.
2. **CQMP Submission**

* PI signature and date for this CQMP will be submitted prior to activation to the Clinical Project Manager (CPM) and the CROMS Clinical Quality Management Team [cqmp@dmidcroms.com](mailto:cqmp@dmidcroms.com)

For questions or assistance with this form, please contact the CQMP Team at [CQMP@dmidcroms.com](mailto:CQMP@dmidcroms.com)

**The CQMP will be reviewed internally by the site at least annually. Changes to the CQMP will be submitted to DMID.**

Quality Management Designee Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_

**Appendix 1**

**Protocol Checklist Principal Investigator Attestation**

**Please submit the PI attestation prior to enrolling your first participant.**

I acknowledge that Quality Assurance activities are required for the \_\_\_\_\_\_\_\_\_ Protocol to ensure the safety and protection of human participants and reliability of data.

Please mark what your site intends to use to document QA Activities:

\_\_\_\_\_\_\_ I confirm that this protocol Specific QA Checklist Version \_\_\_\_\_ will be completed at the level of review (e.g. Quality Indicators and frequency) and requested intervals stated in this document. Using the tools provided.

\_\_\_\_\_\_\_\_\_I confirm that QA activities will be documented at the level of review and at intervals requested in the Quality Assurance (QA) Checklist, but my site will be documenting this on an existing DMID-approved clinical quality management tool that is utilized at my site (please name the tool here): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Principal Investigator Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date\_\_\_\_\_\_\_\_\_\_\_

Site Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_