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| **PROTOCOL-SPECIFIC CLINICAL QUALITY MANAGEMENT PLAN (CQMP)**  <insert Site Name>  <insert DMID Protocol Number: ##-####/protocol title >  *<insert version #/ date, dd/mmm/yyyy, for this protocol-specific clinical quality management plan>* |

**Background**: This protocol-specific CQMP Instructional Template reflects the basic attributes outlined in the current DMID CQMP Policy. It is available for discretionary use by clinical sites conducting DMID-supported clinical studies/trials. The CQMP processes described in this plan should align with the protocol, the International Council for Harmonisation (ICH) Good Clinical Practice E6(R2) Guidelines, and site best practices for ensuring protections for human subjects are in place, and study data is attributable, legible, contemporaneous, original, accurate, and complete.

**Purpose**: The purpose of this protocol-specific CQMP is to identify the protocol, clinical sites where protocol procedures are conducted, and protocol-driven processes for which quality control and quality assurance reviews are independently conducted and documented by delegated study staff. Implementation of a single CQMP by multiple sites can ensure consistent implementation of quality measurements. A protocol-specific CQMP may be used as a stand-alone CQMP for use by multiple sites conducting a single protocol, or as part of site-specific CQMPs defining its use.

**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 protocol-specific CQMP Instructional Template in Microsoft Word allows for modification by the site, as needed.

1. **Complete all fields/sections**: Refer to the ‘<instructions>’ provided in red font in each field throughout the template. For emphasis,
   1. List all sites**:**
      1. *Lead site*: List the administrative/award site and respective location.
      2. *Clinical sites*: For multiple sites conducting a single protocol, ensure all clinical sites and respective locations are listed where study participants are enrolled, receiving study product/intervention, and are followed for safety.
2. Apply Version Control: When adopting and modifying this template for discretionary use, correct the header/footer to reflect version control. The template date is fixed. Please refer to the DMID Information Sheet; Document Version Control Guidelines.
   1. Ensure header/footer contain appropriate version/date and pagination for the site’s CQMP and associated tools/documents.
3. Apply consistent date formats: e.g., DD/MMM/YYYY
4. Sign and Date: Provide appropriate signatures and dates.
5. File and Maintain: Include this protocol-specific CQMP along with the site CQMP (if part of a site CQMP) and associated tools when submitting to DMID for review/approval. Quality review documentation should be maintained in a designated file at the site.
6. Updating/Revising the CQMP: Quality management processes may be revised for continuous improvement (e.g., specific procedures, increase or decrease in QA frequency and sample size) based upon its implementation effectiveness, quality review findings, and changes to the protocol design/procedures.

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| **PROTOCOL INFORMATION** |

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| DMID PROTOCOL NUMBER AND TITLE | *<Insert protocol number (##-####)>: <insert full protocol title>* |
| LEAD/ADMINISTRATIVE SITE(S) NAME(S) AND ADDRESS/CITY/STATE/COUNTRY | *<insert full site name, address, city, state, country for administrative/award site* |
| CLINICAL SITE(S) NAME(S) AND ADDRESS/CITY/STATE/COUNTRY | *<insert full site name, address, city, state, country for clinical site(s) conducting protocol-driven procedures in the field, pharmacy, and laboratory>* |
| INSTITUTION/IRB NUMBER | *<insert corresponding reference numbers>* |
| SITE PRINCIPAL AND SUB-INVESTIGATOR NAMES | *<insert full name and credentials of site investigator. Ensure the information matches the information provided on the Form FDA 1572, and/or DMID Form Investigator of Record (IoR)>* |
| PROJECTED ACCRUAL/ ENROLLMENT | *<insert this figure from the approved protocol>* |
| INITIAL ESSENTIAL REGULATORY DOCUMENT REVIEW DATE | *<insert the date of the initial regulatory file review, prior to study/site initiation. Refer to section* **QUALITY REVIEW OF SITE ESSENTIAL REGULATORY DOCUMENTS (SERD***) in this document.* |
| INTERIM ESSENTIAL REGULATORY DOCUMENT REVIEW | *<insert the date of the most recent interim regulatory file review to ensure the regulatory file is complete and current (e.g., current IRB approvals, changes to Form FDA 1572 or DMID Form IoR.>* |
| ENROLLMENT START DATE | *<insert the date of first subject consented following approval of protocol and site activation. Use date format dd/mmm/yyyy >* |
| RECORD REVIEW SAMPLE SIZE | * Quality Control 100% * Quality Assurance sample size: *<insert range of % based upon enrollment rates>* |
| FREQUENCY OF QUALITY REVIEW | * Quality Control (daily/real time) * Quality Assurance: *<e.g., weekly, monthly, quarterly; consider time management, enrollment/accrual rate, timely reporting, source document verification error trends>* |
| PROJECTED CQMP REVIEW | *<insert date (format dd/mmm/yyyy)>; Recommended once during the protocol period (e.g., Phase 1 trials) or annually. More frequent reviews may be necessary as determined by error rates, changes in personnel, adverse findings effecting protocol conduct, key subject safety and/or data integrity>* |
| FREQUENCY OF SUMMARY REPORTING and site review. | *<insert the frequency of site and/or protocol team meetings, teleconferences, completion/submission of quality reports, progress reports. Frequency should support sponsor reporting requirements, effectiveness of corrective actions. Where applicable, DMID-designated clinical site monitors will record the signatory/date of the most recent QM report>* |

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| **CLINICAL RESEARCH STUDY STAFF AND DELEGATED TASKS**  *Complete fields / rows consistent with the Study Personnel Signature-Responsibility List* |

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| TITLE *<amend to reflect site study staff roles>* | ROLE | NAME | Site/Location |
| STUDY PHYSICIAN / NP / PA |  |  |  |
| CLINICAL RESEARCH / STUDY COORDINATOR / STUDY NURSE / RESEARCH NURSE / SUB-INVESTIGATOR |  |  |  |
| REGULATORY SPECIALIST |  |  |  |
| PHARMACIST |  |  |  |
| BIOSTATISTICIAN |  |  |  |
| CLINICAL QUALITY MANAGEMENT DESIGNEE |  |  |  |
| Study Staff, Study Worker(s) / Field Staff |  |  |  |
| LABORATORY PERSONNEL <include designated IATA-trained staff responsible for shipping specimens> |  |  |  |
| OTHER *<add Title. Add additional rows as needed>* |  |  |  |

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| **SOURCE DATA / SOURCE DOCUMENTATION OF HUMAN SUBJECT STUDY PROCEDURES** |
| **Case Report Forms:** <*Describe the quality checks in place to ensure complete and accurate data is recorded, reported and reconciled. Refer to the approved protocol, the applicable data coordinating center data collection forms; and, where provided, the Manual of Procedures for additional instructions>.* |
| **Laboratory procedures**: *<Describe the quality checks in place to ensure laboratory procedures are conducted as per protocol. List the protocol-specific laboratory tests for which quality checks will be implemented and documented. Refer to the approved protocol and, where applicable, Manual of Procedures. Examples include,*   * Specimens type, mode of collection *<i.e., nasal swab, naso-pharyngeal swab, stool, blood via venipuncture/finger stick>* * Documentation *<case report forms, documentation of consent to storage of specimens for future use>* * Storage *<protocol-defined location(s)>* * Shipping *<protocol-defined and according to IATA Dangerous Goods declaration>* |
| **Accountability of Investigational/Licensed Study Product:** *<Describe the quality checks in place to ensure complete and accurate management of study product from receipt through disposition, protecting the mask / blind, and communications across the study team to ensure timely coordination with study visits, inventory / re-ordering and reporting. Describe the chain of custody and control for shipments and transfer, as applicable. Include locations where study product is stored, maintained and administered.>* |
| **Safety Reporting:** *<Describe the quality checks in place to ensure: timely reporting of Serious Adverse Events (SAEs), necessary for the protection of clinical trial subjects and for rapid dissemination of significant new findings related to the safety of investigational drugs; accuracy of documented human subject safety events; compliance with the protocol and required timelines for safetyreporting; and follow up of affected study subjects.>* |

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| **QUALITY REVIEW OF SITE ESSENTIAL REGULATORY DOCUMENTS (SERD)**  *<Describe the quality checks in place to ensure SERD are complete and accurate prior to submission to the sponsor. If SERD are coordinated through the NIAID Clinical Research Management System, refer to N-CRMS,* [*https://ncrms.niaid.nih.gov*](https://ncrms.niaid.nih.gov) *. Log on credentials are required. Submission of SERD apply to pre-activation, protocol amendment, continuing review, other updates, and close-out. Refer to SERD Training Materials for Sites, and CQMP tools (referenced in this CQMP) for documenting quality review of the site Regulatory File for this protocol.* |

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| **TRAINING**  *List each applicable training; check with the DMID CPM for guidance on sponsor-required training. Training should be consistent with roles of clinical site/key personnel performing procedures per the approved protocol.* |

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| **NIH/DMID-REQUIRED TRAINING (Titles)** | **TRAINING FREQUENCY** |
| *Protecting Human Subjects (45 CFR 46)-* ***required*** | *Example:* *Initially prior to study initiation for all staff* |
| International Council for Harmonization (ICH) Good Clinical Practice (GCP) E6(R2) | *Example: at least every three years, per* [*NIH Policy*](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html) |
| Protocol specific training |  |
| IATA/Dangerous Goods Regulations | *Example: every two years* |
| Investigator Responsibilities |  |
| Clinical Quality Management |  |
| DMID Regulatory File Document Guidelines |  |
| DMID Source Documentation Standards |  |
| Study Product Management |  |
| Additional training | *Add rows as needed* |

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| **QUALITY MANAGEMENT PROCESS**  *<Describe the quality control, quality assurance checks in place including workflow/process to ensure human subjects protections are in place and study data is attributable, legible, contemporaneous, original, accurate and complete (ALCOAC) reliable and verifiable. Include the process for summarizing quality review findings and informing Corrective Action(s)Planning and, where applicable, changes to the CQMP> (ICH GCP E6, section 4.9.0 Records)* |

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| **QUALITY MANAGEMENT TOOLS**  *<List quality Tools/Forms used to document Quality Control and Quality Assurance review /findings: List tools/forms by title. Ensure each tool describes instructions for use; reflects applicable protocol /site identification, procedures and applicable regulatory documents; applies version control; and is maintained with this CQMP.>* |

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| **QUALITY CONTROL – Real time** | **QUALITY ASSURANCE - Retrospective** | **Summary Report(s)** |
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| * *<add rows as needed>* | * *<add rows as needed>* | * *<add rows as needed>* |

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| **CORRECTIVE ACTION(S) PLANNING**  *<Describe the corrective action process for identifying and communicating results/recommendations, and corrective action timelines for implementation and evaluation of implemented corrective and preventive actions. Ensure concordance with the site CQMP, where applicable.>* |

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| **REVIEW OF QUALITY MANAGEMENT PLAN**  *<Describe the process and timeline/frequency for integrating necessary process improvements into the CQMP. Following the initial submission of the protocol-specific CQMP for DMID approval, a revised CQMP should be submitted for review and approval to DMID.>* |

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| **SIGNATURES**  **Signatures:** *<Provide names of the Principal Investigator and**Site**Quality Management Designee responsible for overseeing the development and implementation of the quality management plan at the clinical site(s).>* |

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Print Name of Site Quality Management Designee

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Signature of Site Quality Management Designee Date

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Print Name of Site Principal Investigator

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Signature of Site Principal Investigator Date