Division of Microbiology and Infectious Diseases (DMID)

**Quality Assurance Review Checklist**

**The Quality Assurance (QA) Review Checklist may be used by clinical sites to facilitate focused QA review. This document provides instructions for completing the QA review checklist.**

* Complete the header by inserting the site name where highlighted.
* Complete the following sections within the checklist as applicable to the study:
	+ Informed consent documentation/consent process
	+ Participant eligibility
	+ Safety reporting
	+ Source documentation and Data entry, or Direct Data Entry (DDE).
	+ Study product management
	+ Specimen management
	+ Regulatory file review.

* Ensure all study documentation is Attributable, Legible, Contemporaneous, Original, Accurate and Complete.
* Ensure all fields within the checklist should be completed, as applicable.
* Ensure the findings detected during quality reviews have corrective actions and the completion dates.
* Ensure that the checklist is signed and dated.

**DMID Protocol Title: XXXXXXXXXXXXXXXX**

**QA Summary review covered the following date range**: <*insert dd/MMM/yyyy*> to <*insert dd/MMM/yyyy*>

Please provide signature(s) and date(s) following completion and review of this checklist:

|  |  |
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| **Quality Manager or designee completing this QA review\***  | Date Review Completed: dd/MMM/yyyy |
| **Principal Investigator Signature confirming QA review completed**  | Date Review Completed: dd/MMM/yyyy |

\* Should align with Site Study Personnel Signature/Responsibility List

**DMID Protocol Title**: **XXXXXXXXXXXXX**

**QA review covered the following date range**: <*insert dd/MMM/yyyy*> to <*insert dd/MMM/yyyy*>

When completing the QA Checklist for Column (Yes/No/not applicable), please write **No** if any PID reviewed during this time is identified as having a finding and list applicable PID in the Participant PID column.

| Document Type or Quality review activity | Yes/No/NA | Initials of QA reviewer | Participant(s) PID with identified finding | Findings detected during this review | Corrective Action(s) | Date findings corrected (format dd/MMM/yyyy)/Initials of Corrector |
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| *Example:**Did the ICF/have all required fields completed?* | *No* | *CB* | PID9999 | *Participant did not select option for future use of specimens* | *Consent form presented to participant at the next visit for initials and date to future use option. Progress note written to explain the late selection.*  | *20DEC2021/DA* |

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| **CLINICAL – INFORMED CONSENT (ICF)- Perform 100% Level of Review** |
| List Participant PID number(s)/PID range for Consent Forms reviewed during this reporting period: |

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| **ICF Document**: Was the current IRB approved version of ICF used to consent the participant? Were all pages of the ICF included? If applicable, was the ICF provided in participant’s preferred language? | Choose an item. |  |  |  |  |  |
| **ICF Signatures:** Was the ICF signed and dated in ink and all fields/options listed, initialed by the participant? Did the person obtaining consent, sign? Did the witness sign, if applicable? Was participant given a signed copy? | Choose an item. |  |  |  |  |  |
| **ICF Process:** Was consent obtained before any study procedures were performed? Was the informed consent process with the participant documented in the source? Was the method of consent performed per IRB approval? If non-English speaking, was a translator/witness used and documented? | Choose an item. |  |  |  |  |  |
| **Re-Consent Process:** As per IRB-requirements and approved processes, was a re-consent obtained at next visit before any study procedures were performed, or timely if required before next visit? Was the re-consent process documented in the source? Was the most recent IRB-approved ICF form signed properly? Was participant given a signed copy?  | Choose an item. |  |  |  |  |  |
| **Assent Process:** Has an assent consent form been signed on file with each parent consent form, if any? | Choose an item. |  |  |  |  |  |
| Was an impartial witness present during the parental or assent consent process? | Choose an item. |  |  |  |  |  |
| **Other Language Consent:** Has the participant signed an IRB-approved language consent? | Choose an item. |  |  |  |  |  |
| Has the consenting process been performed by delegated staff listed on the delegation log following the accurate process or procedure required per protocol or site SOP? | Choose an item. |  |  |  |  |  |
| **Secondary Use/ Genetic Testing:** Have any participants updated their consent for secondary/genetic research? Is it documented appropriately, and the database updated? | Choose an item. |  |  |  |  |  |

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| **CLINICAL – ELIGIBILITY AND DOCUMENTATION Perform 100% Level of Review** |
| List Participant PID number(s)/PID range for clinical eligibility reviewed, including eligibility source document review during this reporting period: |

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| Was documentation of participant eligibility completed by PI or designee as listed on the Delegation Log?  | Choose an item. |  |  |  |  |  |
| Does the eligibility sign-off date match the enrollment date? Was eligibility time before registration and study product administration time? | Choose an item. |  |  |  |  |  |
| Does the participant meet inclusion/exclusion criteria per the study protocol? | Choose an item. |  |  |  |  |  |

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| **CHART and eCRF REVIEW AND PROTOCOL DEVIATION REPORTING** |
| List Participant PID number(s) and Visit # for chart and eCRF review with protocol deviation review during this reporting period: |

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| Were any new protocol deviations identified through this quality (QA) review? | Choose an item. |  |  |  |  |  |
| Were all identified deviations/non-compliances documented and entered in the database appropriately to include clarity, conciseness, and consistency? | Choose an item. |  |  |  |  |  |
| Were all identified deviation/non-compliance documents pertaining to participant visits, filed in the participant chart? | Choose an item. |  |  |  |  |  |
| Were protocol deviations/non-compliances/unanticipated problems (UPs) reported to the IRB, as required per reporting requirements outlined in the IRB policies(\*This is to be updated per IRB of record\*?  | Choose an item. |  |  |  |  |  |

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| **SAFETY/ENDPOINTS** |
| List Participant PID number(s) and Visit # range for safety/endpoint review during this reporting period:  |

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| Were all AEs identified, assessed for severity, and relatedness by the PI or delegated Sub-I, and documented for the following:* **Dose 1**: Dose 1 through Day ## (solicited) and Day ## [e.g. 29] (unsolicited)?
 | Choose an item. |  |  |  |  |  |
| Were all SAEs, AESIs, NOCMC, and MAAEs from Day 1 through Day ## recorded in the source documents and database?  | Choose an item. |  |  |  |  |  |
| Were all SAE(s) and SUSARs reported to the Sponsor/DMID within 24 hours of site awareness? If not, was a deviation filed? | Choose an item. |  |  |  |  |  |
| Were all protocol defined AE(s) and SAE(s) and/or unanticipated problems (UPs) reported to Advarra IRB, per the Advarra Handbook? | Choose an item. |  |  |  |  |  |
| Are all serious adverse events followed and documented? Are SAE reports consistent with the participant’s chart? | Choose an item. |  |  |  |  |  |

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| **SPECIMEN COLLECTION** |
| List Participant PID number and Visit # range for specimen collection review during this reporting period: |

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| Were laboratory specimens collected per protocol and documented in the source and eCRF? | Choose an item. |  |  |  |  |  |
| Were all stored vials/tubes labeled only with the global trace (GT) identifiers?  | Choose an item. |  |  |  |  |  |
| Were all specimens entered into the GT specimen tracking system and documented appropriately?  | Choose an item. |  |  |  |  |  |
| Are all shipping records available for samples shipped? | Choose an item. |  |  |  |  |  |
| Was there any temperature excursion and documented appropriately? Was deviation filed with the sponsor?  | Choose an item. |  |  |  |  |  |

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| **REGULATORY (Reviewed in the first month of site activation then quarterly unless there is a protocol amendment/major change)** |
| **Please mark appropriate box: □ A Regulatory Review occurred during this reporting period**  **□ A Regulatory Review did not occur during this reporting period**  |

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| Are all IRB-approved protocol and amendments stored together and accessible? | Choose an item.  |  |  |  |  |  |
| Is the FDA Form 1572/IoR up-to-date and signed and dated by the PI? | Choose an item. |  |  |  |  |  |
| Are all IRB-approved consent forms on file? | Choose an item. |  |  |  |  |  |
| Are all IRB approval/ acknowledgment (e.g. reportable events) letters on file? | Choose an item. |  |  |  |  |  |
| Confirmation of the site’s active FWA number available with expiration date and matches OHRP website?  | Choose an item. |  |  |  |  |  |
| Is DMID required training documented, current and complete for all delegated staff? Required trainings include HSP, GCP, and protocol training. Was IATA or equivalent biohazardous materials training current and documented for staff who are delegated preparation for shipping or shipping? | Choose an item. |  |  |  |  |  |
| Are medical licenses and CVs, Financial Disclosure Forms (FDF) current and on file for the PI and all Sub-I listed on the FDA Form 1572/IoR and submitted to DMID? | Choose an item. |  |  |  |  |  |
| Are monitoring reports and follow-up letters present in the regulatory file? | Choose an item. |  |  |  |  |  |
| Are all study clinicians who sign-off for eligibility and AE/SAE relatedness and severity (and make medical decisions) assigned on the Delegation log and listed on the 1572? | Choose an item. |  |  |  |  |  |
| Are lab normal ranges and lab accreditation present in the regulatory file?  | Choose an item. |  |  |  |  |  |

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| **PHARMACY REVIEW by the Pharmacy Staff** |
| List Participant PID number(s) for pharmacy review during this reporting period (d*o not include unblinding information if the study is blinded)*: |

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| Document Type or Quality review activity | Yes/No/NA | Initials of QA reviewer | Participant(s) PID with identified finding | Findings detected during this review | Corrective Action(s) | Date findings corrected (format dd/MMM/yyyy) |
| Was a quality review for study product storage, preparation, dispensing, accountability log, and cold-chain compliance, conducted since the last QA report?  | Choose an item.  |  |  |  |  |  |
| If yes above, were there findings for documentation or issues noted? Was PI informed immediately of identified issues? Has pharmacy documented any action taken?  | Choose an item. |  |  |  |  |  |
| Is blinded study? Is the blinded staff clearly indicated on the delegation log? | Choose an item. |  |  |  |  |  |
| Was the sponsor notified about identified deviation/non-compliance upon awareness, if needed? | Choose an item. |  |  |  |  |  |
| Is there documentation that the sponsor was notified of findings (CPM, ClinOps, and DMID Product Support Team) and resolution?  | Choose an item. |  |  |  |  |  |

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| **Pharmacist or designee completing this QA review\***Date Review Completed: dd/MMM/yyyy |

\* Should align with Site Study Personnel Signature/Responsibility list

**DDE Studies:** *Include this chart only for DDE studies. Ensure that QC is documented in addition to QA activities.*

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| **Document Type or Quality Review Activity** | **Yes/No/NA** | **Initials of QA Reviewer** | **Participants PID with identified finding** | **Findings detected during this review** | **Corrective Actions** | **Date findings corrected (format dd/MMM/yyyy)** |
| Is the source data consistent with the chart in the MOP? E.g. pregnancy log, point-of-care test results, demographic information, Clinical lab test results, stool logs, electronic medical record, data on any eCRF that supports a question on another eCRF etc.  | Choose an item. |  |  |  |  |  |
| Cross-check: Is data (e.g. eligibility, follow-up assessments) consistent with data in DDE-eCRF when indicated, e.g. lab test results, con-meds, medical history, adverse events?  | Choose an item. |  |  |  |  |  |
| Is source data outside of the eCRF consistent with data in the eCRF?  | Choose an item. |  |  |  |  |  |
| Does the audit trail time indicate any procedures conducted out of the sequence needed for the study, e.g. test results/eligibility are reviewed prior to study product administration? Are staff entering the data in real time? Are staff who entered the data assigned to conducting the procedure per the delegation log?  | Choose an item. |  |  |  |  |  |
| Is the content of the data consistent with the circumstances of the participant (e.g., visit schedule, AEs/SAEs, medications, demographics)? | Choose an item. |  |  |  |  |  |
| Was data for the protocol deviation(s) consistent with the data in the eCRF? | Choose an item. |  |  |  |  |  |
| Are all open queries closed in a timely manner? | Choose an item. |  |  |  |  |  |