**[Study no. or nickname] MONITORING VISIT REPORT**

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| **SITE NUMBER** |  | **VISIT DATE(S)** |  |
| **SITE NAME** |  |
| **MONITOR NAME** |  |

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| **I. SITE PERSONNEL** | **Met with Monitor?** |
| **TITLE** | **NAME** | **YES** | **NO** | **N/A** |
| **Site Investigator/QI** |  | [ ]  | [ ]  | [ ]  |
| **Sub or Co-Investigator(s)** |  | [ ]  | [ ]  | [ ]  |
| **Site Coordinator** |  | [ ]  | [ ]  | [ ]  |
| **Other** |  | [ ]  | [ ]  | [ ]  |
| Changes in personnel since last visit?  | [ ]  | [ ]  | [ ]  |
| Training provided to new personnel? | [ ]  | [ ]  | [ ]  |
| **Comments:** |

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| **II. FACILITY AND OPERATIONS ASSESSMENT** | **YES** | **NO\*** | **N/A** |
| A. Case Report Forms and Site/Regulatory Files are securely stored with limited access. | [ ]  | [ ]  | [ ]  |
| B.Site facilities (clinical space, office space, etc.) are appropriate. | [ ]  | [ ]  | [ ]  |
| C. Site operations/resources (staffing, knowledge base, etc.) adequate. | [ ]  | [ ]  | [ ]  |
| **Comments** *(\*any "no" response requires comment)***:** |
| **III. PROTOCOL/AMENDMENTS** | **YES** | **NO\*** | **N/A** |
| A. Is the current protocol on file? | [ ]  | [ ]  |  |
| B.Have all protocol amendments and amended ICFs been submitted for REB approval? | [ ]  | [ ]  |  |
| C. Are the amendments on file? | [ ]  | [ ]  |  |
| D. Are the following REB approvals on file? Date of ApprovalOriginal Protocol: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Amendment #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Amendment #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Amendment #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Amendment #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Amendment #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Original ICF: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Version #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Version #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Version #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Version #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Version #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]  | [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]  |  |
| **Comments** *(\*any "no" response requires comment)***:** |

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| **IV. SITE / REGULATORY FILE REVIEW** | **YES** | **NO\*** | **N/A** |
| 1. Qualified Investigator Undertaking on file.
 | [ ]  | [ ]  | [ ]  |
| 1. Regulatory Approval (NOL) on file
 | [ ]  | [ ]  | [ ]  |
| 1. Health Authority Approval on file.
 | [ ]  | [ ]  | [ ]  |
| 1. Research Ethics Board Membership Attestation on file.
 | [ ]  | [ ]  | [ ]  |
| 1. All REB approved consents on file.
 | [ ]  | [ ]  | [ ]  |
| 1. All REB approvals/yearly renewals on file.
 | [ ]  | [ ]  | [ ]  |
| 1. Current Laboratory certifications on file.
 | [ ]  | [ ]  | [ ]  |
| 1. Laboratory normal ranges on file.
 | [ ]  | [ ]  | [ ]  |
| 1. Current Curriculum Vitae of Investigators & Sub-Investigators on file.
 | [ ]  | [ ]  | [ ]  |
| 1. All Safety reports on file.
 | [ ]  | [ ]  | [ ]  |
| 1. All versions of the Investigator's Brochures / Product Monographs on file.
 | [ ]  | [ ]  | [ ]  |
| 1. All versions of the Operations Manual on file.
 | [ ]  | [ ]  | [ ]  |
| 1. Screening Log on file, up-to-date & accurate.
 | [ ]  | [ ]  | [ ]  |
| 1. Randomization Log on file, up-to-date & accurate.
 | [ ]  | [ ]  | [ ]  |
| 1. Monitoring Log on file.
 | [ ]  | [ ]  | [ ]  |
| 1. Standard Operating Procedures on file and up-to-date.
 | [ ]  | [ ]  | [ ]  |
| 1. Site Signature/Delegation Log on file and up-to-date.
 | [ ]  | [ ]  | [ ]  |
| 1. Training (e.g. GCP, Food and Drug Regulations Part C, Div 5, study specific), as applicable
 | [ ]  | [ ]  | [ ]  |
| 1. Protocol Deviations and SAEs – logged/reported to Sponsor and REB, as applicable
 | [ ]  | [ ]  | [ ]  |
| **Comments** *(\*any "no" response requires comment)***:**  |

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| **V. LABORATORY/SPECIMEN INFORMATION** | **YES** | **NO\*** | **N/A** |
| 1. All versions of the Lab Manual on file (if applicable).
 | [ ]  | [ ]  | [ ]  |
| 1. Specimen storage log on file and up-to-date
 | [ ]  | [ ]  | [ ]  |
| 1. Specimen shipment completed in a timely fashion.
 | [ ]  | [ ]  | [ ]  |
| 1. Specimen shipment log completed, accurate and up-to-date.
 | [ ]  | [ ]  | [ ]  |
| 1. Were copies of Lab Reports available for review?
 | [ ]  | [ ]  | [ ]  |
| 1. Are the original Lab Reports being reviewed by the Investigator and are clinically significant abnormalities being noted?
 | [ ]  | [ ]  | [ ]  |
| 1. Are Lab Reports reviewed/assessed by the Investigator in a timely fashion?
 | [ ]  | [ ]  | [ ]  |
| **Comments** *(\*any "no" response requires comment)***:** |

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| **VI. STUDY DRUG DISPENSING PERSONNEL** | **Met with Monitor?** |
| TITLE | NAME | **YES** | **NO** | **N/A** |
| **Pharmacist** |  | [ ]  | [ ]  | [ ]  |
| **Research Coordinator** |  | [ ]  | [ ]  | [ ]  |
| **Back-up Personnel** |  | [ ]  | [ ]  | [ ]  |
| **Other** |  | [ ]  | [ ]  | [ ]  |
| Changes in personnel since last visit?  | [ ]  | [ ]  | [ ]  |
| Training provided to new personnel? | [ ]  | [ ]  | [ ]  |
| **Comments**  |

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| **VII. STUDY DRUG DISPENSING / MANAGEMENT PLAN** | **YES** | **NO\*** | **N/A** |
| A. Study medication management plan on file. | [ ]  | [ ]  | [ ]  |
| B. Current Operations Manual on file. | [ ]  | [ ]  | [ ]  |
| C. Current REB approved version of the protocol on file. | [ ]  | [ ]  | [ ]  |
| D. All Investigator’s Brochures/Product monographs on file. | [ ]  | [ ]  | [ ]  |
| E. Correspondence related to study/study medication on file. | [ ]  | [ ]  | [ ]  |
| F. Study medication stored in a locked room or locked refrigerator with limited access. | [ ]  | [ ]  | [ ]  |
| G. Used/Expired study medication physically separated from dispensable study medication. | [ ]  | [ ]  | [ ]  |
| H. Temperature Log (refrigerator/room). | [ ]  | [ ]  | [ ]  |
| I. Site complies with pharmacy section of Operations Manual. | [ ]  | [ ]  | [ ]  |
| **Comments** *(\*any "no" response requires comment)***:**  |

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| **VIII. STUDY DRUG ACCOUNTABILITY & INVENTORY** | **YES** | **NO\*** | **N/A** |
| A. Study medication shipments received accurately recorded. | [ ]  | [ ]  | [ ]  |
| B. Study medication dispensing log on site and up-to-date. | [ ]  | [ ]  | [ ]  |
| C. All study medications dispensed for study participants ONLY. | [ ]  | [ ]  | [ ]  |
| D. Study medication supply within expiration date | [ ]  | [ ]  | [ ]  |
| E. Consistency between record/dispensing log and actual count. | [ ]  | [ ]  | [ ]  |
| **Comments** *(\*any "no" response or inventory discrepancy requires comment)***:**  |

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| **IX. STUDY DRUG BLINDING/UNBLINDING** | **YES** | **NO** | **N/A** |
| A. Emergency Code-breaking Procedures in place? If “no”, please comment. | [ ]  | [ ]  | [ ]  |
| B. Emergency Code-breaking envelopes stored in a secure and accessible location? (If applicable) If “no”, please comment. | [ ]  | [ ]  | [ ]  |
| C. Emergency Code-breaking envelopes intact? (If applicable) If “no”, please comment. | [ ]  | [ ]  | [ ]  |
| D. Has a code been broken? If “yes”, please comment. | [ ]  | [ ]  | [ ]  |
| **Comments**  |

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| **X. CENTRALIZED (REMOTE) MONITORING** |
| [FINDINGS AND OR COMMENTS:]  |

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| **XI. ADDITIONAL COMMENTS SECTION** |
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| **XII. INFORMED CONSENT (ICF)** |
| **Participant ID** | **Date ICF Signed** | **Version Signed** | **Date of Screening** | **Date of Treatment Start** |
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| **XIII. CASE REPORT FORM REVIEW** |
|  | **Targeted Monitoring Summary *(all "Yes" comments require comment)*** |
| **Participant ID** | **From: Visit # and Date** | **To: Visit # and Date** | **Consent Deviations** | **Eligibility Deviations** | **Missed Clinical Endpoints or Death** | **Missed SAEs** | **Protocol Deviations** | **Other (if "yes", specify in space provided):** |
|  |  |  | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** |  |
|  |  |  | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** |  |
|  |  |  | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** |  |
|  |  |  | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** |  |
|  |  |  | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** |  |
|  |  |  | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** |  |
|  |  |  | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** |  |
|  |  |  | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** | [ ]  **Yes**[ ]  **No** |  |

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| **XIV. SUMMARY OF ACTIONS TO BE TAKEN BY SITE (to be followed until listed as resolved)** |
| Date Site Notified(dd-mmm-yyyy) | Action Description / Comments | Issue Status(New, Ongoing, Resolved) |
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| **XV. SUMMARY OF ACTIONS TO BE TAKEN BY MONITOR (to be followed until listed as resolved)** |
| Date First Reported(dd-mmm-yyyy) | Action Description / Comments | Issue Status(New, Ongoing, Resolved) |
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| Prepared by (Study Monitor) |  | Signature |  | Date (dd-mmm-yyyy) |
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| Reviewed by (Study Project Manager) |  | Signature |  | Date (dd-mmm-yyyy) |
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| Approved by (Sponsor or SI) |  | Signature |  | Date (dd-mmm-yyyy) |
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