**[Study no. or nickname] CLOSE-OUT VISIT REPORT**

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

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

|  |  |  |  |
| --- | --- | --- | --- |
| **II. SITE / REGULATORY FILE REVIEW** | **YES** | **NO\*** | **N/A** |
| A. All versions of protocol and amendments on file. |  |  |  |
| B. All regulatory documents on file (e.g. NOL, QIU) as applicable. |  |  |  |
| C. All versions of the IB or PM on file, as applicable. |  |  |  |
| D. All training logs on file and up to date. |  |  |  |
| E. All versions of REB/IEC approved consents on file. |  |  |  |
| F. All REB/IEC approvals/yearly renewals on file. |  |  |  |
| G. Current Laboratory certifications on file. |  |  |  |
| H. Current Curriculum Vitae of QI/Site Investigator & Sub-Investigators on file. |  |  |  |
| I. Laboratory normal ranges on file. |  |  |  |
| J. All Safety Reports on file and reported as applicable. |  |  |  |
| K. All protocol deviations and SAEs documented and reported to Sponsor/SI and REB as applicable. |  |  |  |
| L. All versions of the Operations Manual on file. |  |  |  |
| M. Screening/Randomization Log on file, up-to-date & accurate. |  |  |  |
| N. All Site/Sponsor correspondence on file. |  |  |  |
| O. All CRFs (paper or electronic) completed. |  |  |  |
| P. “Off Study” CRF page completed and signed by Investigator, if applicable. |  |  |  |
| Q. All queries completed. |  |  |  |
| R. Study Closure Notification to REB/IEC. |  |  |  |
| S. Monitoring Log on file. |  |  |  |
| T. Study Closure Acknowledgement from REB/IEC on file. |  |  |  |
| **Comments** *(\*any "no" response requires comment)***:** | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **III. RECONCILIATION/RETURN OF STUDY-RELATED MATERIALS** | **YES** | **NO\*** | **N/A** |
| A. Investigational product (IP) accountability logs completed and on file. |  |  |  |
| B. IP returned or destroyed as per instructions; drug destruction documentation on file if applicable. |  |  |  |
| C. Randomization envelopes or lists returned as per protocol. |  |  |  |
| D. Unused CRFs and other used/unused study-related paper/electronic materials returned or destroyed as per protocol or instructions. |  |  |  |
| E. Equipment and supplies returned as per instructions. |  |  |  |
| **Comments** *(\*any "no" response requires comment)***:** | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **IV. LABORATORY/SPECIMEN INFORMATION** | **YES** | **NO\*** | **N/A** |
| 1. All versions of the Lab Manual on file. |  |  |  |
| 1. Specimen storage log on file and up-to-date. |  |  |  |
| 1. Specimen shipment log completed, accurate and up-to-date. |  |  |  |
| 1. Lab specimens shipped to Sponsor, SI or designated location for testing and/or storage. |  |  |  |
| **Comments** *(\*any "no" response requires comment)***:** | | | |

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

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **VI. CASE REPORT FORM REVIEW FOR SUBJECTS *NOT* PREVIOUSLY MONITORED** | | | | | | | | | |
|  | | | **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** |  |
|  |  |  | **Yes**  **No** | **Yes**  **No** | **Yes**  **No** | **Yes**  **No** | **Yes**  **No** | **Yes**  **No** |  |
|  |  |  | **Yes**  **No** | **Yes**  **No** | **Yes**  **No** | **Yes**  **No** | **Yes**  **No** | **Yes**  **No** |  |

|  |
| --- |
| **VII. COMMENTS** |
|  |

|  |  |  |
| --- | --- | --- |
| **VIII. 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) |
|  |  |  |
|  |  |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **IX. 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) | | |
|  | |  | | |  | | |
|  | |  | | |  | | |
|  | |  |  | |  |  |
| Prepared by (Study Monitor) | |  | Signature | |  | Date (dd-mmm-yyyy) |
|  | |  |  | |  |  |
|  | |  |  | |  |  |
| Reviewed by (Study Project Manager) | |  | Signature | |  | Date (dd-mmm-yyyy) |
|  | |  |  | |  |  |
|  | |  |  | |  |  |
| Approved by (Sponsor or SI) | |  | Signature | |  | Date (dd-mmm-yyyy) |