**[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** |
| Site Investigator |  | [ ]  | [ ]  | [ ]  |
| Co-Investigator(s) |  | [ ]  | [ ]  | [ ]  |
| Site Coordinator(s) |  | [ ]  | [ ]  | [ ]  |
| Other |  | [ ]  | [ ]  | [ ]  |
| Changes in personnel since last visit?       | [ ]  | [ ]  |  |
| **Comments:** |

|  |  |  |  |
| --- | --- | --- | --- |
| **II. SITE / REGULATORY FILE REVIEW** | **YES** | **NO\*** | **N/A** |
| A. All versions of protocol and amendments on file. | [ ]  | [ ]  |  |
| B. All versions of REB/IEC approved consents on file. | [ ]  | [ ]  |  |
| C. All REB/IEC approvals/yearly renewals on file. | [ ]  | [ ]  |  |
| D. Current Laboratory certifications on file. | [ ]  | [ ]  |  |
| E. Current Curriculum Vitae of Investigators & Co-Investigators on file. | [ ]  | [ ]  |  |
| F. Laboratory normal ranges on file. | [ ]  | [ ]  |  |
| G. All Safety Reports on file. | [ ]  | [ ]  |  |
| H. All versions of the Operations Manual on file. | [ ]  | [ ]  |  |
| I. Screening/Randomization Log on file, up-to-date & accurate. | [ ]  | [ ]  |  |
| J. All Site/Sponsor correspondence on file. | [ ]  | [ ]  |  |
| K. All CRFs completed. | [ ]  | [ ]  |  |
| L. Off Study CRF page completed and signed by Investigator, if applicable | [ ]  | [ ]  | [ ]  |
| M. All queries completed. | [ ]  | [ ]  |  |
| N. Notification to REB/IEC of Study Closing to Recruitment on File. | [ ]  | [ ]  |  |
| O. Monitoring Log on file. | [ ]  | [ ]  |  |
| P. Acknowledgement from REB/IEC of Study Closing to Recruitment on File. | [ ]  | [ ]  |  |
| **Comments** *(\*any "no" response requires comment)***:**  |

|  |  |  |  |
| --- | --- | --- | --- |
| **III. RECONCILIATION/RETURN OF STUDY-RELATED MATERIALS** | **YES** | **NO\*** | **N/A** |
| A. Accountability logs completed and on file. | [ ]  | [ ]  |  |
| B. Investigational product 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. 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** |  |

|  |
| --- |
| **VI. COMMENTS** |
|  |

|  |
| --- |
| **VII. 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) |
|  |  |  |
|  |  |  |

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