**[Study no. or nickname] SITE INITIATION VISIT/TRAINING REPORT** *(This template may be modified for study specific needs/requirements.)*

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| **SITE NUMBER:** | **VISIT/CONTACT DATE(S):** | |
| **SITE NAME / ADDRESS**      Telephone: | | **METHOD OF CONTACT:**  On-site Visit  Virtual Meeting  Other:       *(specify)* |
| **REPORT PREPARED BY (name/role):** | | |

| **PARTICIPATION IN SIV / TRAINING** | |  | | |
| --- | --- | --- | --- | --- |
| **TITLE/ROLE** | **NAME** | **YES** | **NO** | **N/A** |
| **QI/Site Investigator** |  |  |  |  |
| **Sub-Investigator** |  |  |  |  |
| **Site Coordinator** |  |  |  |  |
| **Pharmacist** |  |  |  |  |
| **Other [specify]** |  |  |  |  |
| **CTN Staff Present (name/role):**  **None** | | | | |
| **Sponsor / SI Staff Present (name/role):**  **None** | | | | |
| **Monitoring Staff Present (name/role):**  **None** | | | | |
| **Comments:** | | | | |

| **SITE PERSONNEL AND FACILITIES** | **YES** | **NO** | **N/A** |
| --- | --- | --- | --- |
| 1. **Were any outstanding issues identified with respect to site facilities?**   **Comments:** |  |  |  |
| Were the roles and responsibilities of the QI/Site Investigator and designated site study personnel discussed?Issue(s) Identified?  Yes  No **Comments:** |  |  |  |
| Has the Delegation of Authority Log been appropriately completed?Issue(s) Identified?  Yes  NoCopy Obtained?  Yes  NoComments: |  |  |  |
| **Additional Comments/Issues:** | | | |

| **PROTOCOL AND STUDY RELATED PROCEDURES** | **YES** | **NO** | N/A |
| --- | --- | --- | --- |
| 1. **Were the current version of the protocol and related study procedures, including inclusion/exclusion criteria reviewed?**  Issue(s) Identified?  Yes  No **Protocol Version/Date**:        **Comments:** |  |  |  |
| 1. **Were the protocol deviation reporting and sign-off procedures reviewed?**   Issue(s) Identified? Yes  No  **Comments:** |  |  |  |
| 1. **Was participant recruitment (including procedures, timelines, advertising, documentation) discussed?**   Issue(s) Identified? Yes  No  **Comments:** |  |  |  |
| 1. **Were the informed consent process and documentation requirements reviewed?**   Issue(s) Identified? Yes  No  **Comments:** |  |  |  |
| 1. **Were adverse event definitions, handling and reporting procedures reviewed?**   Issue(s) Identified? Yes  No  **Comments:** |  |  |  |
| 1. **Were data collection procedures and Case Report Forms (including CRF completion, transmittal and query/data correction procedures) discussed?**   Issue(s) Identified? Yes  No  **Comments:** |  |  |  |
| **Additional Comments/Issues:** | | | |

| **INVESTIGATIONAL PRODUCT (IP) AND CLINICAL STUDY SUPPLIES**  **N/A** | **YES** | **NO** | **N/A** |
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| 1. **Were IP related procedures (quantity, receipt, dispensing, accountability, reordering as applicable) discussed?**   Issue(s) Identified?  Yes  No  **Comments:** |  |  |  |
| 1. **Was the storage of IP (security, temperature, other conditions as applicable) discussed?**   Issue(s) Identified?  Yes  No  **Comments:** |  |  |  |
| 1. **Were the IP storage area and conditions found to be satisfactory?**   Issue(s) Identified?  Yes  No  **Comments:** |  |  |  |
| 1. **Was the receipt of other clinical study supplies (quantity, storage and conditions) discussed?**   Issue(s) Identified?  Yes  No  **Comments:** |  |  |  |
| **Additional Comments/Issues:** | | | |

| **LABORATORY/BIOLOGICAL SAMPLES  N/A** | **YES** | **NO** | **N/A** |
| --- | --- | --- | --- |
| 1. **Were local laboratory requirements and procedures discussed?**   Issue(s) Identified?  Yes  No  **Comments:** |  |  |  |
| 1. **Were central laboratory requirements and procedures discussed?**   Issue(s) Identified?  Yes  No Comments: |  |  |  |
| 1. **Were local laboratory facilities and storage conditions reviewed?**   Issue(s) Identified?  Yes  No  **Comments:** |  |  |  |
| 1. **Was medical review of Laboratory Results discussed?**   Issue(s) Identified?  Yes  No  Comments: |  |  |  |
| 1. **Were labeling and storage of specimens for the central lab(s) discussed?**   Issue(s) Identified?  Yes  No  **Comments:** |  |  |  |
| 1. **Were handling and shipment of biological samples discussed?**   Issue(s) Identified?  Yes  No  **Comments:** |  |  |  |
| **Additional Comments/Issues:** | | | |

| **MONITORING PROCEDURES** | **YES** | **NO** | **N/A** |
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| 1. **Were monitoring procedures (including requirements, frequency, site contacts) discussed?**   Issue(s) Identified?  Yes  No  **Comments:** |  |  |  |
| 1. **Were source documentation requirements (including availability, direct access, location, electronic medical record access) discussed?**   Issue(s) Identified*?*  Yes  No  **Comments:** |  |  |  |
| **Additional Comments/Issues**: | | | |

| **ETHICS** | **YES** | | **NO** | **N/A** |
| --- | --- | --- | --- | --- |
| 1. **Were local Ethics Committee procedures discussed?**   Issue(s) Identified?  Yes  No  **Comments:** |  | |  |  |
| 1. **Were central Ethics Committee procedures discussed?**   Issue(s) Identified?  Yes  No  **Comments:** |  | |  |  |
| 1. **Were regulatory procedures discussed?**   Issue(s) Identified?  Yes  No  **Comments:** |  | |  |  |
| 1. **Were essential documents/Investigator Site File (ISF) reviewed**?   Issue(s) Identified?  Yes  No  Site Start Up Checklist attached (SOPPM\_13\_T01)?  Yes  No  **Comments:** |  |  | |  |
| **Additional Observations/Comments:** |  |  | |  |

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| **REGULATORY PROCEDURES** | **YES** | **NO** | **N/A** |
| 1. **Were Health Canada documents reviewed?**   Drug/Biologic or Natural Health Product or Medical Device authorization, e.g. No Objection Letter on file?  Yes  No  Qualified Investigator Undertaking (QIU) on file?  Yes  No  Clinical Trial Site Information Form (CTSIF) on file?  Yes  No  Issue(s) Identified?  Yes  No  **Comments:** |  |  |  |
| **B. Were the US FDA documents on file?**  Issue(s) Identified?  Yes  No  **Comments:** |  |  |  |
| **Additional Observations/Comments:** |  |  |  |

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| **TRAINING** | **YES** | **NO** | **N/A** |
| 1. **Was Good Clinical Practice (GCP) training for all study team members on file?**   Issue(s) Identified?  Yes  No  **Comments:** |  |  |  |
| 1. **Was Health Canada Division 5 training for all study team members on file?**   Issue(s) Identified?  Yes  No  **Comments:** |  |  |  |
| 1. **Was Tri-Council Policy (TCPS2) training for all study team members on file?**   Issue(s) Identified?  Yes  No  **Comments:** |  |  |  |
| 1. **Was Privacy training on file?**   Issue(s) Identified?  Yes  No  **Comments:** |  |  |  |
| 1. **Was study specific training on file?**   Protocol training on file?  Yes  No  Other (specify): **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**training on file?  Yes  No  **Comments:** |  |  |  |
| 1. **Were site Standard Operating Procedures (SOPs) noted, and was training on file?**   Issue(s) Identified?  Yes  No  **Comments:** |  |  |  |
| **Additional Observations/Comments:** |  |  |  |

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| **OTHER STUDY/SITE SPECIFIC ISSUES** | **YES** | **NO** | N/A |
| 1. **Were financial or contractual details/issues (including site reimbursement and other financial implications) discussed?**   Issue(s) Identified?  Yes  No  **Comments:** |  |  |  |
| 1. **[Insert other study/site specific issues as necessary]** |  |  |  |
| **Additional Observations/Comments:** | | | |

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| **STATUS OF ACTION ITEMS:** | | | | |
| **RESPONSIBLE PARTY** | Yes | No | CATEGORY/ISSUE | Resolution |
| QI/ Site Investigator/ Designate |  |  |  |  |
| Monitor/Training personnel |  |  |  |  |
| CTN |  |  |  |  |
| Sponsor/SI |  |  |  |  |
| Comments/Issues: | | | | |
| **Date of Next Visit:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  N/A | | | **Attachments:**   None  Site Start Up Checklist (SOPPM\_13\_T01)  Other (specify): | |

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| Reviewed by [Study Monitor or Study Project Manager]  Signature / Date |  |
| Approved by [Sponsor or SI]  Signature / Date |  |

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| Approved by [Sponsor or SI] |  | Signature |  | Date (dd-mmm-yyyy) |
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