**[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** |
| --- | --- | --- | --- |
| 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 [ ]  NoComments:       | **[ ]**  | **[ ]**  | **[ ]**  |
| 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 [ ]  NoComments:      | **[ ]**  | **[ ]**  | **[ ]**  |
| 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** |
| --- | --- | --- | --- |
| 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 [ ]  NoQualified Investigator Undertaking (QIU) on file? [ ]  Yes [ ]  NoClinical 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 [ ]  NoOther (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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