**[CTN XXX] SITE INITIATION VISIT/TRAINING REPORT** *(This template may be modified for study specific needs/requirements.)*

|  |  |
| --- | --- |
| **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?**

*[ ]* Issue(s) IdentifiedComments:       | **[ ]**  | **[ ]**  | **[ ]**  |
| Were the roles and responsibilities of the QI/Site Investigator and designated site study personnel discussed?*[ ]* Issue(s) IdentifiedComments:       | **[ ]**  | **[ ]**  | **[ ]**  |
| Has the Delegation of Authority Log been appropriately completed?*[ ]* Issue(s) Identified*[ ]* Copy ObtainedComments:       | **[ ]**  | **[ ]**  | **[ ]**  |
| **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?**

Protocol Version:      *[ ]* Issue(s) IdentifiedComments:       | **[ ]**  | **[ ]**  | **[ ]**  |
| 1. **Were the protocol deviation reporting and sign-off procedures reviewed?**

*[ ]* Issue(s) IdentifiedComments:       | **[ ]**  | **[ ]**  | **[ ]**  |
| 1. **Was participant recruitment (including procedures, timelines, advertising, documentation) discussed?**

*[ ]* Issue(s) IdentifiedComments:       | **[ ]**  | **[ ]**  | **[ ]**  |
| 1. **Were the informed consent process and documentation requirements reviewed?**

*[ ]* Issue(s) IdentifiedComments:       | **[ ]**  | **[ ]**  | **[ ]**  |
| 1. **Were adverse event definitions, handling and reporting procedures reviewed?**

*[ ]* Issue(s) IdentifiedComments:       | **[ ]**  | **[ ]**  | **[ ]**  |
| 1. **Were data collection procedures and Case Report Forms (including CRF completion, transmittal and query/data correction procedures) discussed?**

 *[ ]* Issue(s) IdentifiedComments:       | **[ ]**  | **[ ]**  | **[ ]**  |
| **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) IdentifiedComments:       | **[ ]**  | **[ ]**  | **[ ]**  |
| 1. **Was the storage of IP (security, temperature, other conditions as applicable) discussed?**

*[ ]* Issue(s) IdentifiedComments:       | **[ ]**  | **[ ]**  | **[ ]**  |
| 1. **Were the IP storage area and conditions found to be satisfactory?**

*[ ]* Issue(s) IdentifiedComments:       | **[ ]**  | **[ ]**  | **[ ]**  |
| 1. **Was the receipt of other clinical study supplies (quantity, storage and conditions) discussed?**

*[ ]* Issue(s) IdentifiedComments:       | **[ ]**  | **[ ]**  | **[ ]**  |
| **Additional Comments/Issues:** |

| **LABORATORY/BIOLOGICAL SAMPLES [ ]  N/A** | **YES** | **NO** | **N/A** |
| --- | --- | --- | --- |
| 1. **Were local laboratory requirements and procedures discussed?**

[ ]  Issue(s) IdentifiedComments:       | **[ ]**  | **[ ]**  | **[ ]**  |
| 1. **Were central laboratory requirements and procedures discussed?**

[ ]  Issue(s) IdentifiedComments:       | **[ ]**  | **[ ]**  | **[ ]**  |
| 1. **Were local laboratory facilities and storage conditions reviewed?**

[ ]  Issue(s) IdentifiedComments:       | **[ ]**  | **[ ]**  | **[ ]**  |
| 1. **Was medical review of Laboratory Results discussed?**

*[ ]* Issue(s) IdentifiedComments:       | **[ ]**  | **[ ]**  | **[ ]**  |
| 1. **Were labeling and storage of specimens for the central lab(s) discussed?**

*[ ]* Issue(s) IdentifiedComments:       | **[ ]**  | **[ ]**  | **[ ]**  |
| 1. **Were handling and shipment of biological samples discussed?**

*[ ]* Issue(s) IdentifiedComments:       | **[ ]**  | **[ ]**  | **[ ]**  |
| **Additional Comments/Issues:**  |

| **MONITORING PROCEDURES** | **YES** | **NO** | **N/A** |
| --- | --- | --- | --- |
| 1. **Were monitoring procedures (including requirements, frequency, site contacts) discussed?**

*[ ]* Issue(s) IdentifiedComments:       | **[ ]**  | **[ ]**  | **[ ]**  |
| 1. **Were source documentation requirements (including availability, direct access, location, electronic medical record access) discussed?**

 *[ ]* Issue(s) IdentifiedComments:       | **[ ]**  | **[ ]**  | **[ ]**  |
| **Additional Comments/Issues**:       |

| **ETHICS** | **YES** | **NO** | **N/A** |
| --- | --- | --- | --- |
| 1. **Were local Ethics Committee procedures discussed?**

*[ ]* Issue(s) IdentifiedComments:       | **[ ]**  | **[ ]**  | **[ ]**  |
| 1. **Were central Ethics Committee procedures discussed?**

*[ ]* Issue(s) IdentifiedComments:       | **[ ]**  | **[ ]**  | **[ ]**  |
| 1. **Were regulatory procedures discussed?**

*[ ]* Issue(s) IdentifiedComments:       | **[ ]**  | **[ ]**  | **[ ]**  |
| 1. **Were essential documents/Investigator Site File (ISF) reviewed**?

[ ]  Issue(s) Identified [ ]  Site Start Up Checklist attached (SOPPM\_13\_T01)Comments:       | **[ ]**  | **[ ]**  | **[ ]**  |

|  |  |  |  |
| --- | --- | --- | --- |
| **REGULATORY PROCEDURES** | **YES** | **NO** | **N/A** |
| 1. **Were the Health Canada documents on file?**

**[ ]  Drug/Biologic or Natural Health Product or Medical Device authorization, e.g. No Objection Letter****[ ]  Qualified Investigator Undertaking (QIU)****[ ]  Clinical Trial Site Information Form (CTSIF)****[ ]  Issue(s) Identified****Comments:** | **[ ]** **[ ]** **[ ]**  | **[ ]** **[ ]** **[ ]**  | **[ ]** **[ ]** **[ ]**  |
| **Were the US FDA documents on file?****[ ]  Issue(s) Identified****Comments:** | **[ ]**  | **[ ]**  | **[ ]**  |

|  |  |  |  |
| --- | --- | --- | --- |
| **TRAINING** | **YES** | **NO** | **N/A** |
| 1. **Was Good Clinical Practice (GCP) training for all study team members on file?**

**[ ]  Issue(s) Identified****Comments:** | **[ ]**  | **[ ]**  | **[ ]**  |
| 1. **Was Health Canada Division 5 training for all study team members on file?**

**[ ]  Issue(s) Identified****Comments:** | **[ ]**  | **[ ]**  | **[ ]**  |
| 1. **Was Tri-Council Policy (TCPS2) training for all study team members on file?**

**[ ]  Issue(s) Identified****Comments:** | **[ ]**  | **[ ]**  | **[ ]**  |
| 1. **Was Privacy training on file?**

**[ ]  Issue(s) Identified****Comments:** | **[ ]**  | **[ ]**  | **[ ]**  |
| 1. **Was study specific training on file?**

**[ ]  Protocol****[ ]  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****Comments:** | **[ ]**  | **[ ]**  | **[ ]**  |
| 1. **Were site Standard Operating Procedures (SOPs) noted, and was training on file?**
 | **[ ]**  | **[ ]**  | **[ ]**  |

|  |  |  |  |
| --- | --- | --- | --- |
| **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) IdentifiedComments:       | **[ ]**  | **[ ]**  | **[ ]**  |
| 1. **[Insert other study/site specific issues as necessary]**
 | **[ ]**  | **[ ]**  | **[ ]**  |
| **Additional Observations/Comments:**       |

|  |
| --- |
| **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):       |

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