|  |
| --- |
| **Pharmacy Initiation and Outstanding Actions Report** |
| **Title:** |  |
| **Chief Investigator:** |  | **IRAS Number:** |  |
| **Sponsor Reference Number** |  | **Lead site EDGE Number:** |  |
| **Overview of the Protocol and background/purpose of the research:** |  |
| **Overview of IMP(s)/Device(s) (if applicable):** |  |

# Site Information

|  |  |  |  |
| --- | --- | --- | --- |
| **Site Number:**  |  | **Site Name:** |  |
| **Principal Investigator (PI):** |  | **Main Site Contact:** |  |
| **Date of Site Initiation Visit:** |  | **Initiation Visit Method:** | [ ]  Onsite [ ]  Remote  |
| **Conducted by** |  |  **Date of Report:** |  |

*Attendees must sign the SIV Attendance Log. Those unable to attend must ensure they undergo appropriate training and be signed-off on the Delegation of Authority and Signature Log prior to conducting any research-related activities.*

# Pharmacy Personnel

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comment** |
| **Pharmacy representative listed on Delegation of Authority and Signature log** |[ ] [ ] [ ]   |
| **Pharmacy personnel listed on Pharmacy signature Log and Training log** | [ ]  |[ ] [ ]   |
| **Signed and dated CV for all pharmacy staff** | [ ]  |[ ] [ ]   |
| **GCP training for all pharmacy staff** | [ ]  |[ ] [ ]   |

#  Trial Documentation

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comment** |
| **Trial Contact Details**  |[ ] [ ] [ ]   |
| **Combined Review Approvals (i.e., REC/HRA/MHRA)** | [ ]  |[ ] [ ]   |
| **R&D/I Approval** | [ ]  |[ ] [ ]   |
| **Current approved protocol** | [ ]  |[ ] [ ]   |
| **Pharmacy mannual** | [ ]  |[ ] [ ]   |
| **Approved Investigator Brochure/SmPC**  | [ ]  |[ ] [ ]   |
| **Approved clinical trial labels** | [ ]  |[ ] [ ]   |
| **Document version control history** | [ ]  |[ ] [ ]   |

# Trial Synopsis

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comment** |
| **Trial Synopsis** | [ ]  |[ ] [ ]   |

# Dispensing Procedure

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comment** |
| **Summary of dispensing procedure**  | [ ]  |[ ] [ ]   |
| **Pre-printed labels**  | [ ]  | [ ]  |[ ]   |

# Drug Accountability Procedure

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comment** |
| Master Inventory Logs per drug/dose | [ ]  | [ ]  |[ ]   |
| Master Patient Specific*NB that a pharmacy may be using separate individual logs or may be using a combined log* | [ ]  |[ ] [ ]   |

# Prescriptions

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comment** |
| **Master Prescription template** | [ ]  |[ ] [ ]   |

# Order and Receipt Procedure

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comment** |
| **Summary of orders & receipts procedure** | [ ]  |[ ] [ ]   |
| **Records of Orders to date** | [ ]  |[ ] [ ]   |
| **Records of Receipts to date** | [ ]  |[ ] [ ]   |
| **Evidence of temperature monitoring for all receipts** | [ ]  |[ ] [ ]   |
| **Certificate of Analysis/QP Release Certificates** | [ ]  |[ ] [ ]   |
| **Re-labelling requirements** | [ ]  |[ ] [ ]   |

# Returns and Destruction Procedure

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comment** |
| **Summary of returns & destruction procedure** | [ ]  |[ ] [ ]   |
| **Documentation** | [ ]  |[ ] [ ]   |

# Unblinding and Code Break Procedure

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comment** |
| **Unblinding Procedure** | [ ]  |[ ] [ ]   |

# Temperature Monitoring

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comment** |
| **Temperature monitoring system details** | ☐ | ☐ |[ ]   |
| **Location of temperature monitoring records** | ☐ | ☐ |[ ]   |
| **Temperature Deviation reporting procedure** | [ ]  | [ ]  |[ ]   |
| **Remote Storage Monitoring Information** |[ ] [ ] [ ]   |

# Monitoring

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comment** |
| **Monitoring Plan** |[ ] [ ] [ ]   |
| **Monitoring visit requirements** |[ ] [ ] [ ]   |

# Pharmacy Risk Assessments

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comment** |
| **Completed Pharmacy Risk Assessment**  |[ ] [ ] [ ]   |
| **Remote Storage Risk Assessment Documentation** |[ ] [ ] [ ]   |

# Finance

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items Discussed/verified** | **Yes** | **No** | **N/A** | **Comment** |
| **Fee Structure and Finance Contract** |[ ] [ ] [ ]   |
| **Invoices** |[ ] [ ] [ ]   |

**Additional Comments/Visit Overview**