**UHL Pharmacy Initial Visit Checklist**

**Site Information**

|  |  |
| --- | --- |
| **Site** | **Initiation Visit Method** |
| Sponsor Reference Number: | On Site [ ]   |
| Study Name: | Teleconference [ ]  |
| Study Phase: | Other (specify) [ ]  |
| Investigator: |  |
| Study Site: |  |
| Date of Initiation: |  |
| Conducted by: |

**Personnel in Attendance**

|  |  |
| --- | --- |
| Name | Title |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

**Study Overview**

|  |  |
| --- | --- |
| Items discussed/verified | Comment |
| Study IMP(s) |  |

**Training Log**

|  |  |  |  |
| --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | Comment |
| Signature log |[ ] [ ]   |

**Contact Details**

|  |  |  |  |
| --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | Comment |
| Contact details |[ ] [ ]   |

**1. Synopsis**

|  |  |  |  |
| --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | Comment |
| Study synopsis |[ ] [ ]   |
| Document version control history |[ ] [ ]   |

**2. Dispensing**

|  |  |  |  |
| --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | Comment |
| Dispensing procedure  |[ ] [ ]   |
| Labelling/ over-labelling |[ ] [ ]   |
| Master label |  |  |  |

**3. Drug Accountability**

|  |  |  |  |
| --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | Comment |
| Master inventory log |[ ] [ ]   |
| Master patient specific log |[ ] [ ]   |

**4. Prescriptions/Worksheets**

|  |  |  |  |
| --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | Comment |
| Master |[ ] [ ]   |

**5. Order and Receipt**

|  |  |  |  |
| --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | Comment |
| Procedure |[ ] [ ]   |
| Order |[ ] [ ]   |
| Receipt |[ ] [ ]   |
| C of A/QP release certificates |[ ] [ ]   |
| Re-labelling |[ ] [ ]   |

**6. Returns/Destruction**

|  |  |  |  |
| --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | Comment |
| Procedure |[ ] [ ]   |
| Documentation |[ ] [ ]   |

**7. Code Break Information**

|  |  |  |  |
| --- | --- | --- | --- |
| Items discussed/verified | Yes | No | Comment |
| Unblinding procedure and paperwork |[ ] [ ]   |

**8. Pharmacy Personnel**

|  |  |  |  |
| --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | Comment |
| Location of CVs and GCP certificates |[ ] [ ]   |
| Trial specific training documentation |[ ] [ ]   |

**9. Temperature Monitoring**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | N/A | Comment |
| Temperature monitoring file note |[ ] [ ]   |  |
| Temperature deviation information |[ ] [ ]   |  |
| Remote storage monitoring information |[ ] [ ]   |  |

**10. Correspondence**

|  |  |  |  |
| --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | Comment |
| Monitoring log and reports |[ ] [ ]   |
| Correspondence |[ ] [ ]   |

**11. Regulatory Documentation**

|  |  |  |  |
| --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | Comment |
| Amendment documentation |[ ] [ ]   |
| Original approvals |[ ] [ ]   |
| Completed pharmacy risk assessment |[ ] [ ]   |
| Remote storage risk assessment documentation |[ ] [ ]   |
| Completed clinical trials review form |[ ] [ ]   |
| Completed folder audit forms |[ ] [ ]   |

**12. Finance**

|  |  |  |  |
| --- | --- | --- | --- |
| Items Discussed/verified | Yes | No | Comment |
| Information |[ ] [ ]   |
| Fee structure and finance contract |[ ] [ ]   |

**13. Protocol**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Items discussed/verified | Yes | No | N/A | Comment |
| Protocol |[ ] [ ]   |  |
| Pharmacy manual |[ ] [ ]   |  |

**14. Investigator Brochure/SmPCs**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Items discussed/verified | Yes | No | N/A | Comment |
| Investigator Brochure |[ ] [ ]   |  |
| SmPCs |[ ] [ ]   |  |

**15. Superseded Pharmacy Documents**

|  |  |  |  |
| --- | --- | --- | --- |
| Items discussed/verified | Yes | No | Comment |
| Superseded documents |[ ] [ ]   |

**Additional Comments/ Visit Overview**

**SIV Completed By:**

|  |
| --- |
| Name:  |
| Role: |
| Telephone:  |
| e-mail:  |
| Signature:  |
| Date:  |

**Report Responses Completed By:**

|  |
| --- |
| Name:  |
| Telephone:  |
| e-mail:  |
| Signature:  |
| Date:  |

**Completed Responses Approved by PI:**

|  |
| --- |
| PI Name:  |
| PI Signature: |
| Date: |

**Completed SIV Report Approved/ Closed By:**

|  |
| --- |
| Name: |
| Role:  |
| Signature:  |
| Date:  |

UHL Site Initiation Final Outstanding Issue Sign Off

**Sponsor Reference and Short Title:**

**Date of Visit: Date of Report: Date Responses Due Back:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **No.** | **Outstanding Issue** | **Action required** | **Action Taken** | **Signature & Date** |
|  |  |  |  |  |
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