# **Study Close Down Checklist for UCLH-Hosted Studies**

**General Information**

|  |  |
| --- | --- |
| Study Title: |  |
| IRAS Number: |  |
| Sponsor: |  |
| Investigator: |  |
| Date when this checklist was completed:  |  |
| Name & role of staff member who completed this checklist: |  |

**Study Status**

|  |  |
| --- | --- |
| Date of when the study closed to recruitment: |  |
| Planned recruitment number:  |  |
| Actual number of participants recruited:  |  |
| Number of participants withdrawn: |  |
| Number of participants lost to follow up:  |  |
| Comments: |  |

1. **Contacts List**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sections Verified** | **Yes** | **No** | **N/A** | **Comments** |
| Is there an updated contacts list on file? | [ ]  | [ ]  | [ ]  |  |

1. **Protocol**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sections Verified** | **Yes** | **No** | **N/A** | **Comments** |
| Is the current approved protocol on file? | [ ]  | [ ]  | [ ]  |  |
| Is the current approved protocol signed and dated by the Sponsor & PI? | [ ]  | [ ]  | [ ]  |  |
| Are superseded protocols on file and correctly superseded? | [ ]  | [ ]  | [ ]  |  |
| Are superseded protocols signed and dated by the Sponsor & PI? | [ ]  | [ ]  | [ ]  |  |
| Are there protocol deviations and/or violations logs on file? | [ ]  | [ ]  | [ ]  |  |
| Have protocol deviations/violations been reported and reviewed by the PI? | [ ]  | [ ]  | [ ]  |  |
| Further Comments: |  |

1. **Regulatory Approvals**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sections Verified** | **Yes** | **No** | **N/A** | **Comments** |
| Is the fully signed IRAS form on file? | [ ]  | [ ]  | [ ]  |  |
| Are all original HRA/REC/CAG applications/approvals on file? | [ ]  | [ ]  | [ ]  |  |
| Is there a ‘MHRA Notice of Acceptance’ Letter or an email confirming that the study does not fall under the Clinical Trial Regulations? | [ ]  | [ ]  | [ ]  |  |
| Is there a ‘MHRA No Objection for a Clinical Investigation’ confirmation on file (for medical device studies only)? | [ ]  | [ ]  | [ ]  |  |
| Is there an ARSAC research certificate/IRMER approval on file (Radiation studies only)? | [ ]  | [ ]  | [ ]  |  |
| Is GTAC favourable opinion on file? (for gene therapy studies only) | [ ]  | [ ]  | [ ]  |  |
| Have all substantial amendment(s) been filed and implemented correctly? | [ ]  | [ ]  | [ ]  |  |
| Have all non-substantial amendment(s)been filed and implemented correctly?  | [ ]  | [ ]  | [ ]  |  |
| Notification of trial completion on file, and notified to the JRO? | [ ]  | [ ]  | [ ]  |  |
| HRA, MHRA, REC & JRO correspondence on file? | [ ]  | [ ]  | [ ]  |  |
| Further Comments: |  |

1. **Study Set-Up**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sections Verified** | **Yes** | **No** | **N/A** | **Comments** |
| Is there evidence of a feasibility assessment prior to the start of the study (e.g. submission of the UK Local Information Pack to site)? | [ ]  | [ ]  | [ ]  |  |
| Is there a completed risk assessment on file (where applicable)? | [ ]  | [ ]  | [ ]  |  |
| Is there an Insurance Certificate/Statement on file? | [ ]  | [ ]  | [ ]  |  |
| Is evidence of UCLH Confirmation of Capacity & Capability on file (formerly referred to NHS Permission or R&D Approval)? | [ ]  | [ ]  | [ ]  |  |
| Is the Sponsor’s ‘Open to Recruitment’ letter on file? | [ ]  | [ ]  | [ ]  |  |
| Further Comments: |  |

1. **Investigator Site Personnel**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sections Verified** | **Yes** | **No** | **N/A** | **Comments** |
| Have the end dates been added for all research personnel named on the Delegation Log? | [ ]  | [ ]  | [ ]  |  |
| Has the PI signed off the Delegation Log? | [ ]  | [ ]  | [ ]  |  |
| Are all CVs/GCP certificates/training records up-to-date and on file? | [ ]  | [ ]  | [ ]  |  |
| Further Comments: |  |

1. **Study Documentation**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sections Verified** | **Yes** | **No** | **N/A** | **Comments** |
| Is the current approved Patient Information Sheet & Consent Form on file? | [ ]  | [ ]  | [ ]  |  |
| Are all superseded Patient Information Sheets & Consent Forms on file? | [ ]  | [ ]  | [ ]  | NOTE: Correctly superseding old documents involves:* Striking a single line diagonally across the front page of the old document
* Noting the version number of the new document which the old document will be superseded by, at the top of the old document
* Noting the date of when the old document was superseded, at the top of the old document
* Noting the name of the person who superseded the old document, at the top of the old document
 |
| Is a template of the current Case Report Form on file? | [ ]  | [ ]  | [ ]  |  |
| Are all superseded Case Report Forms on file?  | [ ]  | [ ]  | [ ]  | If eCRFs are used, please provide a File Note describing their location. |
| Further Comments: |  |

1. **Participant Documentation**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sections Verified** | **Yes** | **No** | **N/A** | **Comments** |
| Is the current screening log template on file? | [ ]  | [ ]  | [ ]  |  |
| Is the screening log complete? | [ ]  | [ ]  | [ ]  |  |
| Is the current enrolment log template on file?  | [ ]  | [ ]  | [ ]  |  |
| Is the enrolment log complete and up to date to indicate that all participants have completed or withdrawn from the study? | [ ]  | [ ]  | [ ]  |  |
| Further Comments: |  |

1. **Standard Operating Procedures**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sections Verified** | **Yes** | **No** | **N/A** | **Comments** |
| Are details of where to access current Sponsor SOPs on file? | [ ]  | [ ]  | [ ]  |  |

1. **Safety Reporting (N/A** [ ]  **)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sections Verified** | **Yes** | **No** | **N/A** | **Comments** |
| Are SAE reporting guidelines on file? | [ ]  | [ ]  | [ ]  |  |
| Is there a current SAE form template on file? | [ ]  | [ ]  | [ ]  |  |
| Are SAE reports and associated acknowledgement correspondence from Sponsor/Research Office filed in the Site File? | [ ]  | [ ]  | [ ]  |  |
| Are SUSAR reporting guidelines on file? | [ ]  | [ ]  | [ ]  |  |
| Are SUSAR reports and associated acknowledgement correspondence from Sponsor/Research Office on file? | [ ]  | [ ]  | [ ]  |  |
| Are emergency unblinding details on file? | [ ]  | [ ]  | [ ]  |  |
| Is there a 24-hour contact card on file? | [ ]  | [ ]  | [ ]  |  |
| Is the most current Investigator Brochure (IB) on file? | [ ]  | [ ]  | [ ]  |  |
| Are all previous versions of the IB on file and correctly superseded? | [ ]  | [ ]  | [ ]  | NOTE: Correctly superseding old documents involves:* Striking a single line diagonally across the front page of the old document
* Noting the version number of the new document which the old document will be superseded by, at the top of the old document
* Noting the date of when the old document was superseded, at the top of the old document
* Noting the name of the person who superseded the old document, at the top of the old document
 |
| Is the most current version of the Summary of Product Characteristics (SPC) on file? | [ ]  | [ ]  | [ ]  |  |
| Further Comments: |  |

1. **Randomisation (N/A** [ ]  **)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sections Verified** | **Yes** | **No** | **N/A** | **Comments** |
| Is there documentation of the randomisation process on file? | [ ]  | [ ]  | [ ]  |  |

1. **Informed Consent**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sections Verified** | **Yes** | **No** | **N/A** | **Comments** |
| Are all wet-ink consent forms/electronically signed consent forms present and correctly completed? | [ ]  | [ ]  | [ ]  |  |
| Is the informed consent process properly documented in the medical/trial notes? | [ ]  | [ ]  | [ ]  |  |
| Further Comments: |  |

1. **Monitoring/Audit/Inspection**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sections Verified** | **Yes** | **No** | **N/A** | **Comments** |
| Are study monitoring/audit visit documentation and responses on file? | [ ]  | [ ]  | [ ]  |  |
| Is there a completed Monitoring Log on file? | [ ]  | [ ]  | [ ]  |  |
| Are all Monitoring Reports on file? | [ ]  | [ ]  | [ ]  |  |
| If applicable, have all CAPAs been completed and closed? | [ ]  | [ ]  | [ ]  |  |
| Further Comments: |  |

1. **Clinical Laboratory (N/A** [ ]  **)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sections Verified** | **Yes** | **No** | **N/A** | **Comments** |
| Are certificates of accreditation/laboratory SOPs on file? | [ ]  | [ ]  | [ ]  |  |
| Are normal reference ranges on file? | [ ]  | [ ]  | [ ]  |  |
| Is a lab manual or instructions for sample processing and storage on file? | [ ]  | [ ]  | [ ]  |  |
| Are sample shipment receipts/tracking records on file? | [ ]  | [ ]  | [ ]  |  |
| Is there clear evidence that all specimens/samples which are not being retained under the original REC application following study closure have been destroyed as per relevant laboratory SOP? | [ ]  | [ ]  | [ ]  |  |
| Are details of where samples are to be held for future research complete and on file together with the relevant contact details of personnel responsible for sample for sample/specimen maintenance? Please be aware that once specimens/samples are not covered by the REC application, they must be stored on HTA-licensed premises.  | [ ]  | [ ]  | [ ]  |  |
| Further Comments: |  |

1. **IMPs/Devices/Equipment (N/A** [ ]  **)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sections Verified** | **Yes** | **No** | **N/A** | **Comments** |
| Have all unused IMPs/Devices destroyed or returned to Sponsor (as per site agreement/supply agreements)? | [ ]  | [ ]  | [ ]  |  |
| Has Pharmacy been contacted to inform them of study close down? | [ ]  | [ ]  | [ ]  |  |
| Has the Pharmacy Site File been retrieved for archiving with the same ISF? | [ ]  | [ ]  | [ ]  | If not archived together, please state where the Pharmacy File is being archived, and where this can be retrieved.  |
| Are all calibration records/certificates filed in the ISF? | [ ]  | [ ]  | [ ]  |  |
| Further Comments: |  |

1. **Financial/Legal Agreements**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sections Verified** | **Yes** | **No** | **N/A** | **Comments** |
| Are all completed documents relating to contracts, finance, funding, indemnity and Sponsorship on file? | [ ]  | [ ]  | [ ]  |  |

1. **Annual/Final Reports**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sections Verified** | **Yes** | **No** | **N/A** | **Comments** |
| Are all annual progress reports to REC on file? | [ ]  | [ ]  | [ ]  |  |
| Are Sponsor confirmations of annual reports on file? | [ ]  | [ ]  | [ ]  |  |
| Further Comments: |  |

1. **Publication**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sections Verified** | **Yes** | **No** | **N/A** | **Comments** |
| Are copies of all study analysis publications on file? | [ ]  | [ ]  | [ ]  |  |

1. **Correspondence**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sections Verified** | **Yes** | **No** | **N/A** | **Comments** |
| Is all study-related correspondence on file? | [ ]  | [ ]  | [ ]  |  |

1. **Source Data Verification**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sections Verified** | **Yes** | **No** | **N/A** | **Comments** |
| Are all CRFs complete and all data queries resolved? | [ ]  | [ ]  | [ ]  |  |
| Has all patient identifiable data been removed during data input to the Sponsor’s trial database? | [ ]  | [ ]  | [ ]  |  |
| Confirmation that Data Lock point has been achieved?  | [ ]  | [ ]  | [ ]  |  |
| Further Comments: |  |

1. **Data Protection**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sections Verified** | **Yes** | **No** | **N/A** | **Comments** |
| Are computer records and files containing patient identifiable data stored on a remote and secure server? | [ ]  | [ ]  | [ ]  |  |
| Is an emergency recovery procedure for retrieving data available? | [ ]  | [ ]  | [ ]  |  |
| Is access to electronic study records and files password protected? | [ ]  | [ ]  | [ ]  |  |
| Is there confirmation that all personal data will be removed according to the timespan stated within the REC application? | [ ]  | [ ]  | [ ]  |  |
| Has the study been closed on Epic? | [ ]  | [ ]  | [ ]  |  |
| Have monitor/auditor EpicCare Link accounts been closed? | [ ]  | [ ]  | [ ]  | *Please refer to UCLH SOP 12: Monitors Access to EpicCare Link for instruction* |
| Are there provisions in place for suitable archiving of study documentation and electronic source data? | [ ]  | [ ]  | [ ]  |  |
| Further Comments: |  |

1. **Other/Miscellaneous**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sections Verified** | **Yes** | **No** | **N/A** | **Comments** |
|  | [ ]  | [ ]  | [ ]  |  |
| Further Comments: |  |

**Please ensure the ‘End of Study Declaration’ form, found on the HRA website (**[**https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/ending-your-project/**](https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/ending-your-project/)**) , is completed and filed in the UCLH site file.**

**Please ensure the following documents are sent to the UCLH/UCL JRO (****uclh.randd@nhs.net****) upon study closure:**

* ‘End of Study Declaration’ Form
* Sponsor confirmation of study closure
* Regulatory Body acknowledgement letter of study closure

# **Signatures:**

Principal Investigator’s Name:

Principal Investigator’s Signature:

Date:

Confirmation by Sponsor/Sponsor’s Delegate that study is ready for closure:

Name:

Signature:

Date:

Job Title:

Company:

**Please file this completed checklist in the site file.**