**Site Closedown Checklist for UoL Sponsored Non CTIMP Studies**

# Site Information

|  |  |
| --- | --- |
| **Site:** |  |
| **Study Title:** |  |
| **UoL study number:** |  |
| **Centre name:** |  |
| **Investigator:** |  |
| **Date of Visit:** |  |
| **Date of Report** |  |
| **Date Responses due by:** |  |

# List of site and monitoring personnel in attendance

|  |  |
| --- | --- |
| **Name** | **Position** |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

# Study Status

|  |  |
| --- | --- |
| Planned patient number |  |
| Number of patients randomised |  |
| Number of patients completed |  |
| Number of patients withdrawn |  |
| Number of patients lost to follow up |  |
| **Comments:** |  |

# 1. Contacts List

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed /verified** | **Yes** | **No** | **N/A** | **Comments** |
| Is there an updated contact list on file? |  |  |  |  |

# 2. Protocol

| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Is the current approved protocol on file? |  |  |  |  |
| Is the protocol signed and dated? |  |  |  |  |
| Are superseded protocols on file? |  |  |  |  |
| Are superceded protocols signed and dated? |  |  |  |  |
| Is there a protocol deviation log on file? |  |  |  |  |
| Have protocol deviations been reported/reviewed by PI? |  |  |  |  |

# 3. Ethics/HRA

| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Are all original applications/authorisations on file? |  |  |  |  |
| Are all substantial amendment/s complete and on file? |  |  |  |  |
| Are all non-substantial amendment/s complete and on file? |  |  |  |  |
| Notification of trial completion on file? |  |  |  |  |
| Ethics/HRA correspondence on file? |  |  |  |  |

# 4. R&I/R&D/Research Office

| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Are all original copies of relevant applications/ authorisations on file? |  |  |  |  |
| Are all substantial amendment/s complete and on file? |  |  |  |  |
| Are all non-substantial amendment/s complete and on file? |  |  |  |  |
| Notification of trial completion on file? |  |  |  |  |
| Research Office correspondence on file? |  |  |  |  |

# 5. Investigator Site Personnel

| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Have the end dates been updated for all research personnel named on the Delegation of Authority Log? |  |  |  |  |
| Has the Principal Investigator signed off the Delegation of Authority Log? |  |  |  |  |
| Confirm that all CVs/GCP/training records are up to date and on file |  |  |  |  |

# 6. Study Documentation

| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Is the current approved patient documentation on file? |  |  |  |  |
| Are all superseded patient documents on file? |  |  |  |  |
| Are previous versions of study documentation marked as superseded? |  |  |  |  |
| Is there a copy of the current Case Report Form  on file? |  |  |  |  |
| Are all superseded Case Report Forms on file? |  |  |  |  |

# 7. Subject Documentation

| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Is there a screening log template on file? |  |  |  |  |
| Is the subject screening log complete? |  |  |  |  |
| Is there a enrolment log template on file? |  |  |  |  |
| Is the enrolment log complete and up to date to indicate that all patients have completed or withdrawn from the study? |  |  |  |  |

| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Are details of where to access current Sponsor SOPs on file |  |  |  |  |

# 8. Standard Operating Procedures

# 9. Safety Reporting if N/A □

| **Items discussed/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 Investigator Site File? |  |  |  |  |
| Are SUSAR reporting guidelines on file? |  |  |  |  |
| Are SUSAR reports and associated acknowledgement correspondence from Sponsor/Research Office on file? |  |  |  |  |

# 10. Randomisation if N/A □

| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Is there documentation of the randomisation process on file? |  |  |  |  |

# 11. Informed Consent

| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Are all consent forms present and correctly completed? |  |  |  |  |
| Is the informed consent process properly documented in the medical/trial records |  |  |  |  |

# 12. Monitoring/Audit

| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Are study monitoring/audit visit documentation and responses on file? |  |  |  |  |

# 13. Clinical Laboratory if N/A □

| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Are certificates of accreditation/laboratory SOPs on file? |  |  |  |  |
| Are normal reference ranges on file? |  |  |  |  |
| Are lab manual/sample processing and storage instructions on file |  |  |  |  |
| Are completed sample logs on file? |  |  |  |  |
| Are freezer temperature monitoring records for duration of sample storage/study on file? |  |  |  |  |
| Are sample shipment receipt/tracking records on file? |  |  |  |  |
| Are records of sample destruction/method complete as per relevant laboratory SOP and 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/specimen maintenance?  Copy of document to be provided for sponsor records.  Please be aware that once specimens /samples are not covered by this ethical application, they must be stored in a HTA licensed area. |  |  |  |  |

# 14. Study Related Supplies if N/A □

| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Are all study related supplies documents completed and on file? |  |  |  |  |
| Are all maintenance and calibration records completed and on file? |  |  |  |  |

# 15. Financial/Legal agreements

| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Are all completed documents relating to contracts, finance, funding, indemnity and sponsorship on file? |  |  |  |  |

# 16. Annual/Final Reports

| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Are annual progress reports to the Ethics Committee on file? |  |  |  |  |
| Are Sponsor confirmations of annual report receipt on file? |  |  |  |  |

# 17. Publication

| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Are copies of all study analysis publications on file? |  |  |  |  |

# 18. Correspondence

| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Is all study related correspondence on file? |  |  |  |  |

# 19. Source Data Verification

| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Are all CRFs complete and all data queries resolved? |  |  |  |  |
| Has all patient identifiable data been removed? |  |  |  |  |
| Confirmation that Data Lock point has been achieved? |  |  |  |  |
| Confirmation that a Statistical Analysis Plan (SAP) is in place? |  |  |  |  |

# 20. Data Protection

| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- |
| Are computer records and files containing identifiable data stored on a remote and secure server? |  |  |  |  |
| Is the emergency recovery procedure for retrieving data available |  |  |  |  |
| Is access to electronic study records and files password protected? |  |  |  |  |
| Are electronic data files for analysis anonymised? |  |  |  |  |
| Confirmation that all personal data will be removed according to the timespan stated within the ethical application? |  |  |  |  |
| Is there provision in place for suitable archiving? If yes are details logged with the Sponsor office? |  |  |  |  |

# 21. Other/Miscellaneous

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Items discussed/verified** | **Yes** | **No** | **N/A** | **Comments** |
|  |  |  |  |  |
|  |  |  |  |  |

|  |  |
| --- | --- |
| **Principal Investigators Name** |  |
| **Signature** |  |
| **Date** |  |

**Confirmation by Sponsor/Sponsors delegate that study ready for closure**

|  |  |
| --- | --- |
| **Name** |  |
| **Signature** |  |
| **Date** |  |