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Number of patients withdrawn	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Are superseded protocols on file?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Are superceded protocols signed and dated?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?	☐	☐	☐	
Comments/Findings				

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?	☐	☐	☐	
Comments/Findings				

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?	☐	☐	☐	
Comments/Findings				

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	☐	☐	☐	

Comments/Findings

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Are all superseded patient documents on file?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Are previous versions of study documentation marked as superseded?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Are all superseded Case Report Forms on file?	☐	☐	☐	
Comments/Findings				

7. Subject Documentation

Items discussed/verified	Yes	No	N/A	Comments
Is there a current screening log template on file?	☐	☐	☐	
Is the subject screening log complete?	☐	☐	☐	
Is there a current 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?	☐	☐	☐	
Comments/Findings				

8. Standard Operating Procedures

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

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?	☐	☐	☐	
Comments/Findings				

10. Randomisation if N/A ☐

Items discussed/verified	Yes	No	N/A	Comments
Is there documentation of the randomisation process on file?	☐	☐	☐	
Comments/Findings				

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	☐	☐	☐	
Comments/Findings				

12. Monitoring/Audit

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

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.	☐	☐	☐	
Comments/Findings				

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?	☐	☐	☐	
Comments/Findings				

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?	☐	☐	☐	
Comments/Findings				

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?	☐	☐	☐	
Comments/Findings				

17. Publication

Items discussed/verified	Yes	No	N/A	Comments
Are copies of all study analysis publications on file?	☐	☐	☐	
Comments/Findings				

18. Correspondence

Items discussed/verified	Yes	No	N/A	Comments
Is all study related correspondence on file?	☐	☐	☐	
Comments/Finding				

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?	☐	☐	☐	
Comments/Findings				

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?	☐	☐	☐	
Comments/Findings				

21. Other/Miscellaneous

Items discussed/verified	**Yes**	**No**	**N/A**	**Comments**
	☐	☐	☐	
Comments/Findings				

Principal Investigators Name (Print)……

Signature……

Date ……..

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

Name (Print) ……..

Signature ……..