

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Number of patients withdrawn	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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

2. Protocol

Items discussed/verified	Yes	No	N/A	Comments
Is the current approved protocol on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is the protocol signed and dated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are superseded protocols on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are superceded protocols signed and dated?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Is there a protocol deviation log on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Have protocol deviations been reported/reviewed by PI?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Comments/Findings				

3. Ethics/HRA

Items discussed/verified	Yes	No	N/A	Comments
Are all original applications/authorisations on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are all substantial amendment/s complete and on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are all non-substantial amendment/s complete and on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Notification of trial completion on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Ethics/HRA correspondence on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are all substantial amendment/s complete and on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are all non-substantial amendment/s complete and on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Notification of trial completion on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Research Office correspondence on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Has the Principal Investigator signed off the Delegation of Authority Log?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Confirm that all CVs/GCP/training records are up to date and on file	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Comments/Findings				

6. Study Documentation

Items discussed/verified	Yes	No	N/A	Comments
Is the current approved patient documentation on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are all superseded patient documents on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are previous versions of study documentation marked as superseded?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is there a copy of the current Case Report Form on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are all superseded Case Report Forms on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Comments/Findings				

7. Subject Documentation

Items discussed/verified	Yes	No	N/A	Comments
Is there a current screening log template on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is the subject screening log complete?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is there a current enrolment log template on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is the enrolment log complete and up to date to indicate that all patients have completed or withdrawn from the study?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Comments/Findings				

9. Safety Reporting if N/A

Items discussed/verified	Yes	No	N/A	Comments

Are SAE reporting guidelines on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is there a current SAE form template on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are SAE reports and associated acknowledgement correspondence from Sponsor/Research Office filed in the Investigator Site File?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are SUSAR reporting guidelines on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are SUSAR reports and associated acknowledgement correspondence from Sponsor/Research Office on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Comments/Findings				

10. Randomisation if N/A

Items discussed/verified	Yes	No	N/A	Comments
Is there documentation of the randomisation process on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Comments/Findings				

11. Informed Consent

Items discussed/verified	Yes	No	N/A	Comments
Are all consent forms present and correctly completed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is the informed consent process properly documented in the medical/trial records?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Comments/Findings				

12. Monitoring/Audit

Items discussed/verified	Yes	No	N/A	Comments
Are study monitoring/audit visit documentation and responses on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Comments/findings				

13. Clinical Laboratory if N/A

Items discussed/verified	Yes	No	N/A	Comments
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Are certificates of accreditation/laboratory SOPs on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are normal reference ranges on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are lab manual/sample processing and storage instructions on file	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are completed sample logs on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are freezer temperature monitoring records for duration of sample storage/study on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are sample shipment receipt/tracking records on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are records of sample destruction/method complete as per relevant laboratory SOP and on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are all maintenance and calibration records completed and on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Comments/Findings				

15. Financial/Legal agreements

Items discussed/verified	Yes	No	N/A	Comments
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Are all completed documents relating to contracts, finance, funding, indemnity and sponsorship on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Comments/Findings				

16. Annual/Final Reports

Items discussed/verified	Yes	No	N/A	Comments
Are annual progress reports to the Ethics Committee on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are Sponsor confirmations of annual report receipt on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Comments/Findings				

17. Publication

Items discussed/verified	Yes	No	N/A	Comments
Are copies of all study analysis publications on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Comments/Findings				

18. Correspondence

Items discussed/verified	Yes	No	N/A	Comments
Is all study related correspondence on file?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Comments/Finding				

19. Source Data Verification

Items discussed/verified	Yes	No	N/A	Comments
Are all CRFs complete and all data queries resolved?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Has all patient identifiable data been removed?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Confirmation that Data Lock point has been achieved?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Confirmation that a Statistical Analysis Plan (SAP) is in place?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is the emergency recovery procedure for retrieving data available	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is access to electronic study records and files password protected?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Are electronic data files for analysis anonymised?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Confirmation that all personal data will be removed according to the timespan stated within the ethical application?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Is there provision in place for suitable archiving? If yes are details logged with the Sponsor office?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Comments/Findings				

21. Other/Miscellaneous

Items discussed/verified	Yes	No	N/A	Comments
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Comments/Findings				

Principal Investigators Name (Print).....

Signature.....

Date

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

Name (Print)

Signature