UoL Non-CTIMP Monitoring/Audit Checklist

Site Information

Site :
Study Title:
Sponsor Reference Number:
Centre Name:
Investigator Name:
Date of Visit:
Date of Report:
Date Responses Due Back:

Findings from the monitoring/audit report will be categorised as Critical, Major or Other as SOP S-1016 UoL, Procedure in the event of non-compliance in clinical research. Response to all findings will be required in the format of a CAPA Corrective Action Preventative Action plan. A summary of all findings will be entered into a plan and submitted to the Principal Investigator for action. The CAPA must be returned to the Sponsor within 4 weeks of issue. This requires the CI / PI to explain what action they will take, not necessarily take the action at that point in time. The CAPA will be followed up by the Sponsor until completion/closure.

Critical

- **The safety, well-being or confidentiality of participants has been jeopardised.**
- **Reported data are unreliable or absent.**
- **Inappropriate, insufficient or untimely action has been taken place regarding a major non- compliance.**
- **Where there are a number of Major non-compliances across areas of responsibility, indicating a systematic quality assurance failure.**
- **Provision of the Trial Master File (TMF) does not comply with Regulation 31A 1-3, as the TMF is not readily available or accessible, or the TMF is incomplete to such an extent that it cannot form the basis of inspection and therefore impedes or obstructs inspectors carrying out their duties in verifying compliance with the regulations.**

Major

- **Significant and unjustified non-compliance with relevant legislation or Good Clinical Practice (ICH GCP)**
- **A number of breaches of legislation or GCP within one area, indication quality assurance failure**
- **A failure to comply with legislative requirements including annual reporting requirements**
- **Multiples findings in this category have the potential to escalate to a Critical finding.**

Other

- **Findings that are neither Major nor Critical.**
- **Multiples findings in this category have the potential to escalate to a Major finding.**

Summary/Purpose of Visit
Complete or delete section as applicable

Outstanding Actions from Last Monitoring Visits
Complete or delete section as applicable

List of Personnel in Attendance

Name	**Position**

Study Status

Planned patient number	
Planned recruitment timescale	
Number of patients randomised	
Number of patients on going	
Number of patients completed	
Number of patients withdrawn	
Number of patients ineligible	
Number of patients lost to follow up	
Comments:	

1. Study Team Contacts

Items Discussed/verified	Yes	No	N/A	Comments
Is there a contacts list on file?				
Comments/Findings				

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?				
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
Is the signed and dated IRAS submission form on file?				
Is the Site Specific Assessment (SSA) form on file?				
Is the Favourable Opinion Letter/HRA Approval on file/ details of Ethics committee constitution?				
Are Substantial Amendments on file?				
Are Non substantial amendments on file?				
Ethics Correspondence on file?				
Comments/Findings				

4. R&I

Items Discussed/verified	Yes	No	Comments
Is the Trust Application/Capability Assessment on file?			
Is the Trust Approval/Authorisation on file?			
Are there Substantial Amendment/s on file?			
Are there Non Substantial Amendment/s on file?			
Notification of Trial completion on file?			
Trust Correspondence on file?			
Comments/Findings			

5. Investigator Site Personnel

Items Discussed/verified	Yes	No	N/A	Comments
Is the Delegation of Authority and signature log on file and complete?				
Any changes in staff since last visit/audit?				
Are Original signed and dated CVs on file?				
Is there evidence of GCP training for all staff covering the duration of the study?				
Is there evidence of UHL consent training for all non medics taking consent?				
Multicentre studies				

Has an updated copy of the delegation log been supplied to the CI in the last 4 weeks? If no please forward copy of updated log and any relevant training records.				
Comments/Findings				

6. Standard Operating Procedures

Items Discussed/verified	**Yes**	**No**	**N/A**	**Comments**
Are there Current SOPs on File/staff aware of where to access most current SOPs ?				
Standard Operating Procedures Read List completed for all Study team members- if applicable?				
Comments/Findings				

7. Study Documentation

Items Discussed/verified	**Yes**	**No**	**N/A**	**Comments**
Is there a copy of the current approved Patient Information Leaflet on file?				
Is there a copy of the current approved Patient Consent Form on file?				
Is there a copy of the current approved Letter of Invitation on file?				
Is there a copy of the current approved GP Letter on file?				
Is there a copy of the current approved Questionnaires, if applicable?				
Is there a copy of the current approved Advert if applicable?				
Other study specific documents reviewed and documented?				
Are previous versions of study documentation marked as Superseded?				
Is there a copy of the current Case Report Form On file?				
Comments/Findings				

8. Subject Documentation

Items Discussed/verified	**Yes**	**No**	**N/A**	**Comments**
Is there a current master copy of the screening log template on file?				
Is the Subject Screening log complete and up to date?				
Is there a current master copy of the Enrolment Log template on file?				
Is the Enrolment Log complete and up to date?				
Comments/Findings				

9. Randomisation

Items Discussed/verified	Yes	No	N/A	Comments
Is there documentation of the Randomization Process on file?				
Where is the Master Randomization List held?				
Evidence of correct blinding as per study protocol?				
Comments/Findings				

10. Informed Consent

Items discussed/verified	Yes	No	N/A	Comments
Are all consent forms present and correctly completed?				
Have the correct versions of the PIL and consent been used according to the timelines of ethics and R&D/R&I approval?				
Have study participants been re consented on new PIL information if applicable?				
Where consent audit has been undertaken, is documentation of the audit on file?				
Are copies of the Patient Information Sheet and Consent present in the medical records and TMF/ISF?				
Is informed consent process properly documented in the medical/trial records?				
Comments/Findings				

11. Safety Reporting

Items discussed/verified	Yes	No	N/A	Comments
Are SAE reporting Guidelines/SOP and Pharmacovigilance/Governance contact on file?				
Is there a Current SAE form Template on file?				
Are SAE reports and associated acknowledgement correspondence from Sponsor on file?				
Comments/Findings				

12. Monitoring

Items discussed/verified	Yes	No	N/A	Comments
Has an initiation visit taken place (Higher risk Non CTIMPs only)?				
Is the Initiation report on file?				
Is the study specific monitoring plan on file (Higher risk Non CTIMPs only)?				
Is the Monitoring Log template on file?				
Is there a completed monitoring log?				
Are all monitoring visit reports on file?				
Comments/Findings				

13. Clinical Laboratory/Specimen Collections

Items Discussed/verified	Yes	No	N/A	
Are central Labs being used?				
Are the current and previous Central Lab accreditations on file?				
Is Central Lab normal reference ranges on file?				
Are Local Labs being used?				
Are the Local Laboratory current and previous accreditation certificates on file?				
Local Lab normal reference ranges on file?				
Are sampling and sample handling procedures documented/is there a lab manual on file?				
Are specimen results reviewed and signed and dated by PI?				
Are specimen results that are out of range marked as clinically significant or not clinically significant?				
Are all samples correctly stored in a suitable and secure environment?				
Are sample logs/records held?				
Are Lab kits available and in date?				
Are Sample shipment/ receipt tracking available?				
Are storage conditions monitored and recorded?				
Is there a contingency plan in place for storage facility failure?				
Comments/Findings				

14. Financial/Legal agreements

Items Discussed/verified	Yes	No	N/A	Comments
Are contracts in place with all Investigators and sub-contractors? Clinical Agreements etc.?				
Is confirmation of sponsorship on file?				
Is funding documentation on file?				
Are Insurance/Indemnity statements on file?				
Is Financial Correspondence on file?				
Are there Records of subject expenses?				
Comments/Findings				

15. Study Related Supplies

Items Discussed/verified	Yes	No	N/A	
Are shipment and delivery records on file?				
Is collection and return of equipment documented and on file?				
Are supply reorder form templates on file?				
Are completed supply request forms on file?				
Are records kept and retained for maintenance, calibration and validation of all equipment used as part of the study?				
Comments/Findings				

16. Annual/Final Reports

Items Discussed/verified	Yes	No	N/A	
Are annual progress and where applicable safety reports to the Ethics Committee on file?				
Are Sponsor confirmations of annual report receipt on file?				
Is their evidence of notification of trial completion to Sponsor, REC, Competent Authority and R&D/R&I?				
Comments/Findings				

17. Publication

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

18. Correspondence

Items Discussed/verified	Yes	No	N/A	
Are Meeting agendas and minutes on file?				
Are copies of study newsletters on file?				
Are copies of all correspondence between the Chief Investigator and collaborating centres on file (multicentre studies only?				
Is general study related correspondence on file?				
Comments/Findings				

19. Source Data Verification

Items Discussed/verified	Yes	No	N/A	
Are all source documents available to verify the data in the Case Report Form?				
Is the CRF completion timely and accurate?				
Have all CRF data queries resolved since previous visit?				
Has SDV been performed according to the monitoring plan (where applicable)?				
Location of source documents				
Is a Statistical Analysis Plan (SAP) in place?				
Comments/Findings				

20. Data Protection

Items Discussed/verified	Yes	No	N/A	
Is all study hard copy documentation stored in a restricted access area?				
Are all study related documentation designed to ensure that they are anonymised by the use of study patient identifier?				
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?				
Will any documentation be archived off site If yes are details logged with the Sponsor?				
Where a data access/sharing agreement exists (e.g. with HSCIC), has the data been accessed in accordance with the terms & conditions of the agreement?				
Comments/Findings				

21. Other

Items Discussed/verified	**Yes**	**No**	**N/A**	**Comments**
Comments/Findings				

Monitoring /Audit Visit Response Document for UoL.....

Visit Date: **Visit report date:** **Date response required:**

No	Category	Finding	Immediate/ Corrective Action	Preventative Action	Completed by Initials & Date Completed

Report Completed By:

Monitor :
Telephone
e-mail:
Signature:
Date:

Completed Responses Approved by PI:

PI Name:
PI Signature:
Date:

Completed Report Approved by:

Monitor :
Signature:
Date Monitoring Report Closed: