LinCTU
Lincoln Clinical Trials Unit

UNIVERSITY OF LINCOLN

STANDARD OPERATING PROCEDURE

Audit and Monitoring

LinCTU SOP 15

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Next review: 02 years

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Version History	Reason for change
1.0	First LinCTU version

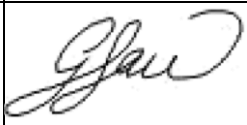
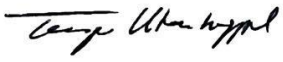
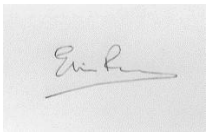
NOTE: All SOPs are subject to regular review.

Please ensure that the version of this SOP is the most up-to-date.

OUT OF DATE DOCUMENTS MUST NOT BE USED AND HARD COPIES SHOULD BE DESTROYED

The following have read, reviewed and advised on the SOP

Reviewer name	Role	Date	Signature

LinCTU Steering Committee		XX/XX/20XX	
Graham Law	Co-director of LinCTU	27/09/2023	
Tanja Kleinhappel	Clinical Data Manager	27/09/2023	
Elise Rowan	Clinical Data Manager	27/09/23	

1 PURPOSE

This Standard Operating Procedure (SOP) describes the general procedures for Audit and Monitoring for clinical and health-related studies and clinical trials involving the Lincoln Clinical Trials Unit (LinCTU) which is part of the University of Lincoln (UoL).

2 SCOPE

This SOP describes the internal and external auditing and monitoring that can be performed by LinCTU when undertaking audits for clinical studies/trials conducted/supported by LinCTU at UoL.

3 BACKGROUND

This SOP should be applied when undertaking LinCTU audit and monitoring activities. The delegated LinCTU auditor/monitor has overall responsibility to perform audits and monitoring by preparing and updating an audit plan and checklist. The audit plan and checklist development task can be formally delegated to the LinCTU Clinical Trials Coordinator or other delegated personnel provided that they take overall responsibility of performing audits and signing off the checklist.

4 CROSS REFERENCES

CG-QMS CGQM Clinical Governance - Quality Manual Final v2.0

CG-QMS SOP CG06 Clinical Trial Authorisation v3.0

ICH Official web site: ICH

ICH GCP E6 R2 (2017)

5 PROCEDURE 'Monitoring' is defined as in the ICH GCP Guideline E6(R2): "The act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s)."

This therefore includes both on-site and central activities and can apply to all types of studies. The purpose of monitoring activities includes the following, adapted from the ICH GCP Guideline E6(R2):

- *To verify that study participants' rights and well-being are protected.*
- *To verify that study data are accurate, complete, and verifiable from source documents.*
- *To verify that the study is in compliance with the study protocol, with GCP, and with any applicable regulatory requirements.*

The audit process is defined by the International Conference on Harmonisation (ICH) (section 1.6) Good Clinical Practice (GCP) guidelines as:

> *'A systematic and independent examination of trial-related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analysed and accurately reported according to the protocol, sponsors SOPs, GCP and the applicable regulatory requirements.*

An Auditee is defined as; a person or organisation that is audited.

Monitoring of LinCTU should be conducted annually according to the principles of GCP and any other applicable regulatory requirements. Staff conducting audits and monitoring should be familiar with the study protocol, the Quality Management and the Monitoring and Audit Plan. A risk assessment should be performed before the implementation of a study. The risk assessment reflects the risk identified for the study and the auditor should take this into account when performing any monitoring or audit tasks, more

details about the University of Lincoln risk assessment policy and guidance can be found here: universityoflincoln.sharepoint.com/sites/HS/RiskAssessment/Pages/Default.aspx

Acceptability of the study depends on the evaluation obtained after performing the Risk Assessment which are summarised as follows.

Risk Identification: Identify all the risk; evaluate the risks (low/ medium / high); describe all existing control measures and identify any further measures required.

Specific risk should be assessed on separate risk assessment form and cross referenced with the document. Specific assessments are available for biological agents, manual handling operations etc.

All LinCTU supported studies/trials should be reviewed and monitored internally throughout the study, but at least annually or when there is a significant change to the study design. A regular audit should be conducted to maintain compliance within the LinCTU.

Audit Plan

Audit plan should be prepared, and the audit checklist (see Appendix) should be updated by the auditor. The Auditor should check if the adequate monitoring is being conducted for all the ongoing studies within LinCTU.

It is the responsibility of the auditor to obtain the information needed to update the Audit Checklist. This includes (but may not be limited to) the following:

- Contact information for the Chief Investigator (CI), Principal Investigators (PIs), study team members (including LinCTU staff where necessary)
- Training certificates of LinCTU and study team members
- LinCTU and UoL SOP Compliance Certificates from LinkedIn learning LinCTU SOP Compliance (linkedin.com)
- Brief CVs which is a professional summary that includes qualification, career history and training should be collected from study team members (which may not be limited to PI, CI)
- Trial Master Files /site files.
- Cross check and monitor staff-restricted access* to study related systems which are compulsory and should include but may not be limited to, Castor Electronic Data Capture (EDC) **, electronic Trial Master File (eTMF) ***, Microsoft Teams groups, Sharepoint and OneDrive files. LinCTU Data manager support may be needed for some of these items.

*Access management should be maintained according to the user's level of access required, which include:

For Microsoft Teams:

- Owner access – users will have administrative role, and can add and remove team members, add guests and can also change settings.
- Members – users can interact with people within the team, can view, edit, upload documents, and change files.
- Guests – these are the users which are invited from outside of the organization by team owners, they have very limited access.

For Castor EDC:

The trial Data Manger will regularly check, update and provide access to the LinCTU members and the study team to Castor EDC. Details of this will be kept in the Data Management records within LinCTU. Castor EDC allows specific user roles to be defined for each study.

Audit Findings

ICH GCP E6 R2 - 5.19.3 "The observations and findings of the auditor(s) should be documented."

ICH GCP E6 R2 - 5.20.1 "Noncompliance with the protocol, SOPs, GCP, and/or applicable regulatory requirement(s) by an investigator/institution, or by member(s) of the sponsor's staff should lead to prompt action by the sponsor to secure compliance. If noncompliance that significantly affects or has the potential to significantly affect human subject protection or reliability of trial results is discovered, the sponsor should perform a root cause analysis and implement appropriate corrective and preventive actions.

The auditor will update the findings on the audit checklist with supporting documents and escalate any critical findings to Research and Enterprise Team.

Final Audit Report

After completion of the audit, the auditor will compile audit checklist with all the supporting documents and store it in the eTMF (electronic trial master file) to ensure good documentation practice.

Appendix

Audit Checklist.docx

** Castor Electronic Data Capture (EDC) is a software that helps in capture and management of trial data. It customizes forms and integrate data from various sources.

*** electronic Trial Master File (eTMF) is a formalised means of organizing and storing trials documents, images and other digital content that may be required for compliance with ethics and regulations.