University of Leicester Research Governance Office
Standard Operating Procedures

SOP S-1044 UoL

Process for Quality Assurance (Audit) in Research Sponsored by the University of Leicester

Version 1.2, March 2024

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Effective Date: April 2024

This SOP will be implemented in line with this document's effective date for all UoL Sponsored research still in set up. For active clinical research that is already in the recruitment phase (or further) at the time of implementation, this SOP must be implemented within 3 months of the effective date.

1.0 Introduction and Scope

This Standard Operating Procedure (SOP) describes the process and requirements for Quality Assurance for all research sponsored by the University of Leicester (UoL) and defines the conduct and frequency of audit visits.

The UoL when acting as Sponsor of research has an obligation to ensure that research activity is conducted in accordance with relevant legislation and guidelines.

A Sponsor is required to regularly review the progress of research and to ensure that investigators comply with the relevant guidelines (including Sponsor SOPs) and legislation appropriate to the individual research activity. This is known as Quality Control and is carried out in a programme of monitoring activity conducted by the UoL Quality Assurance Team or external providers. Quality Assurance or audit is a check against these requirements to ensure that the expectations are being delivered.

The Auditor should be regarded as an officer or contractor of the Sponsor.

2.0 Quality Assurance Audits

2.1 Frequency and Level

The Sponsor will facilitate and determine the frequency and level of audit required. This will be dictated by the risk associated with the study, or may follow a temporary suspension or other triggered causes.

It is important to recognise that audit is not the same as monitoring and will often be carried out by different individuals or contractors.

2.2 Organisational Assurance

Quality Assurance will also be arranged to assure the University that the Research Governance Office is operating in line with the Standard Operating Procedures and that there is consistency applied. Therefore, an arranged audit visit may not be specifically to review a study's conduct, it may be to review the Sponsor process as well.

2.3 Vendor Quality Assurance

As Sponsor, UoL is required to undertake audit of third-party contractors to assure compliance in line with terms & conditions and/or roles and responsibilities of the contractor.

3.0 Preparation for an Audit Visit

It is expected that the auditor will be familiar with the protocol, monitoring plans, study related documentation and any relevant Standard Operating Procedures (SOPs).

3.1 Preparation for an Audit Visit by the Study Team

The CI/PI must make available all files relating to the research activity. This includes the following:

- Trial Master File/Investigator Site File
- All consent forms
- All Case Report Forms
- Medical notes as requested prior to the visit.

3.2 Expectations during Audit Visit

Study teams can expect that an audit visit may include some or all of the following:

- Site and staff Assessment
- Subject status and recruitment rate
- Informed consent procedure
- Adverse Event review
- Protocol adherence
- Regulatory compliance
- Source data verification
- Drug accountability
- Randomisation procedures
- Laboratory/clinical procedures/biological samples
- Trial master file/Investigator site file

4.0 Reporting Timelines

The auditor will produce a report along with a partially completed CAPA (or equivalent) and send it to the CI/PI or their delegate and the Sponsor in accordance with the timelines set out in the contractual agreement between the UoL and the auditor. The CAPA will usually follow the format set out in SOP S-1012 UoL but may differ depending on the contractor.

The CI/PI will have twenty eight (28) calendar days to respond to the findings in the format of the audit CAPA document using the relevant sections. If the audit response document has not been received by the auditor/Sponsor, a reminder will be sent giving the CI/PI a further fourteen (14) days to respond. Failure to respond after the reminder will result in escalation to the Head of College or the Research Sponsorship Committee.

All actions required will be followed up until resolution. All discrepancies that cannot be resolved will be documented in a file note and signed by the CI/PI, relevant site staff and the Sponsor.

5.0 Responsibilities

Responsibility	Undertaken by	Activity
Sponsor	Auditor	Establish a clear list of objectives prior to each visit.
Sponsor	Monitor	Request that all site staff and documentation required are available for the visit.
Sponsor	Monitor	Review the audit visit report and initiate any necessary actions.

Responsibility	Undertaken by	Activity
Sponsor	CI or delegate	Complete audit/CAPA and return within 28 calendar days detailing action taken and planned.
Sponsor	Monitor	Follow up on audit visit report response requesting update of outstanding corrective action.

6.0 Legal Liability Statement

Guidelines or Procedures issued and approved by the University are considered to represent best practice. Staff may only exceptionally depart from any relevant University guidelines or procedures providing that such departure is confined to the specific needs of individual circumstances. In healthcare delivery such departure shall only be undertaken where, in the judgement of the responsible healthcare professional, it is fully appropriate and justifiable – such a decision must be fully recorded in the patient's notes and in the research site file.

7.0 Monitoring and Audit Criteria

Key Performance Indicators	Method of Assessment	Frequency	Lead
Where required, studies have a Risk Assessment and a Monitoring Plan is developed in accordance with the Risk Assessment	Where applicable, research is included on the monitoring schedule	Where applicable, monitoring is conducted in accordance with the Monitoring Plan. Otherwise, risk-based monitoring conducted according to the risk profile of a study.	Head of Research Governance or their Delegate

8.0 Development and approval Record for this document

This table is used to track the development and approval of the document.

Author	Job title	Reviewed by	Approved by	Date approved
Cat Taylor	Head of Research Governance	UoL Research Management and Operations Group (RSMOG)	Professor Nigel Brunskill 	25/03/2024

9.0 Review Record

This table is used to track any changes made on revised/reviewed versions.

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
Sept 2021	1.1	Cat Taylor	Administrative changes.

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
March 2024	1.2	Cat Taylor	Administrative changes Minor updates to wording including an update to actions following non-compliance resulting in escalation to head of college and/or the Research Sponsorship Committee. Update to the monitoring and audit criteria Removal of distribution record