




Research Governance Office Sponsorship Standard Operating Procedures

Process for Quality Assurance (Audit) in Trials

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1.0 Introduction and Scope

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

The UoL, when acting as Sponsor of a trial, has an obligation to ensure that trial 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 trial 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 trial, 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 and 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, trial related documentation and any relevant Standard Operating Procedures (SOPs).

3.1 Preparation for an Audit Visit by the Trial Team

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

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- 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 an Audit Visit

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

- A review of site and staff records e.g., training documents
- Subject status and recruitment rate
- Informed consent procedure
- Adverse Event review
- Protocol adherence
- Regulatory compliance
- Source record verification
- Drug accountability
- Randomisation procedures
- Laboratory/clinical procedures/biological samples
- Trial master file/Investigator site file review
- A meeting with the PI (or delegate)

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 Sponsor format but may differ depending on the contractor.

Unless otherwise specified, the CI/PI (or delegate) 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 within the agreed time will result in the non-compliance SOP S-1016 being implemented with a minimum of a major finding.

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 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.

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6.0 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

7.0 Development Record

The table below summarises the revisions introduced in this version. Full historical change records are available within archived SOP versions.

Date	Issue Number	Description Of Changes (If Any)
April 2026	2.0	<ul style="list-style-type: none"> • Minor revision to wording throughout • Removal of responsibilities table as responsibilities are laid out within the body of the SOP. • Removal of full historical SOP review record; only the latest approved revision is now displayed, with prior versions retained in the document archive.

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