1. Introduction

This Standard Operating Procedure (SOP) describes the process and requirements; for Quality Assurance for research sponsored by the University Hospitals of Leicester NHS Trust (UHL), and defines the conduct and frequency of audit visits.

The UHL 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 UHL Monitoring 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. Scope

This SOP applies to all research studies sponsored by the UHL.

3. Quality Assurance Audits

3.1 Frequency & 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.

3.2 Organisational Assurance

Quality Assurance will also be arranged to assure the Trust that the R&I office is operating in line with the Standard Operating Procedures and that there is consistency applied. Therefore, an Audit visit arranged may not be specifically to review a study conduct, it may be to review the Sponsor process as well.

3.3 Vendor Quality Assurance

As Sponsor, UHL 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.

4. 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).

4.1 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.

4.1.1 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

5. Reporting Timelines

The auditor will produce a report and send it directly to the sponsor in accordance with the timelines set out in the contractual agreement between the UHL and the auditor.

The UHL as Sponsor will review the report and send to the CI / PI along with a partially completed Audit/Monitoring CAPA. The Audit/Monitoring CAPA will usually follow the format set out in SOP S-1007 UHL but may differ depending on the contractor.

The CI/PI will have 28 calendar days to respond to the findings in the format of the Audit CAPA document using the relevant sections If the Audit/Monitor CAPA response document has not been received by the Sponsor, a reminder will be sent giving the CI/PI a further 14 days to respond. Failure to respond after the reminder will result in the Non-compliance SOP S-1016 UHL being implemented at a minimum of a MAJOR finding.

The lack of a response to the request for Audit Visit Reports will be escalated to the Head of Research Operations within 5 working days if non-compliance and/or areas of concern have been identified for escalation in accordance with the Non-compliance SOP S-1016 UHL. 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 Sponsor.

6. Responsibilities

	Responsibility	Undertaken by	Activity
1.	Sponsor	Auditor	Establish a clear list of objectives prior to each visit.
2.	Sponsor	Monitor	Request that all site staff and documentation required are available for the visit.
3.	Sponsor	Monitor	Review the Audit Visit Report and initiate any necessary actions
4.	Sponsor	CI or delegate	Complete Audit / Monitor CAPA and return within 28 calendar days detailing action taken and planned.
5.	Sponsor	Monitor	Follow up on Audit / Monitor CAPA requesting update of outstanding corrective action.

7. Legal Liability Statement

Guidelines or Procedures issued and approved by the Trust are considered to represent best practice. Staff may only exceptionally depart from any relevant Trust guidelines or Procedures and always only 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 to be fully recorded in the patient's notes and in the research site file.

8. Monitoring and Audit Criteria

Key Performance Indicator	Method of Assessment	Frequency	Lead
All research sponsored by UHL has appropriate Risk Assessment	Included in the monitoring / audit programme.		Head of Research Operations or their Delegate

9. Supporting Documents and Key References

SOP S-1007

SOP S-1016

10. Key Words

Research, Innovation, Volunteers, Participants, CTIMPS, Trials, Quality Assurance, Audit, Monitoring

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This table is used to track the development and approval and dissemination of the document and any changes made on revised / reviewed versions

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Author / Lead Officer:	Carolyn Maloney / Lisa Wann / Julie James	**Job Title:** Head of Research Operations / Team Leader, Senior Support Officer / Clinical Trials Monitor
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Date	**Issue Number**	**Reviewed By**	**Description Of Changes (If Any)**
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Jan, Sep 2018	3	CM JJ, LW, CCL	[Jan] Minor Changes [Sep] No additional changes, update to logo
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