UNIVERSITY OF LEICESTER, UNIVERSITY OF LOUGHBOROUGH
&
UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

JOINT RESEARCH & DEVELOPMENT SUPPORT OFFICE

STANDARD OPERATING PROCEDURES

University of Leicester (UoL) Research Governance Office
SOP S-1044 UoL

Version 1, June 2017

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

OFFICE BASE

Research Governance Office
Research & Enterprise Division
University of Leicester
Fielding Johnson Building
University Road
Leicester
LE1 7RH

Effective Date: January 2018

1 Introduction

This Standard Operating Procedure (SOP) describes the process and requirements for Quality Assurance for 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 Scope

This SOP applies to all research sponsored by the UoL.

3 Quality Assurance Audits

3.1 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.

3.2 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.

3.3 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.

NB: Paper copies of this document may not be most recent version. The definitive version is held on the College of Medicine, Biological Sciences and Psychology Website, Research Governance Pages

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.

4.2 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

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 UoL and the auditor.

The UoL as Sponsor will review the report and send to the CI / PI along with a partially completed CAPA. 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 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 the Non-compliance SOP S-1016 UoL 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 Research Governance Manager within five (5) working days if non-compliance and/or

NB: Paper copies of this document may not be most recent version. The definitive version is held on the College of Medicine, Biological Sciences and Psychology Website, Research Governance Pages

areas of concern have been identified for escalation in accordance with the Non-compliance SOP S-1016 UoL. 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.

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 visit report response and return within 28 calendar days detailing action taken and planned.
5.	Sponsor	Monitor	Follow up on audit visit report response requesting update of outstanding corrective action.

7 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.

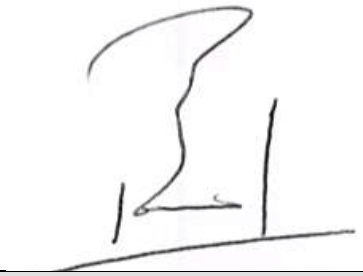
8 Monitoring and Audit Criteria

Key Performance Indicator	**Method of Assessment**	**Frequency**	**Lead**
All research sponsored by UoL has appropriate Risk Assessment.	Included in the monitoring / audit programme.	Random audits / monitoring conducted on 10% of research activity.	Research Governance Manager or their delegate

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

DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT		
Author / Lead Officer:	Dr Diane Delahooke	**Job Title:** Acting Research Governance Manager
Reviewed by:	University of Leicester Research Sponsorship Management and Operations Group	

NB: Paper copies of this document may not be most recent version. The definitive version is held on the College of Medicine, Biological Sciences and Psychology Website, Research Governance Pages

Approved by:	Professor Nigel Brunskill 	**Date Approved:** 4/12/17

REVIEW RECORD			
Date	**Issue Number**	**Reviewed By**	**Description Of Changes (If Any)**

DISTRIBUTION RECORD:			
Date	**Name**	**Dept**	**Received**

NB: Paper copies of this document may not be most recent version. The definitive version is held on the College of Medicine, Biological Sciences and Psychology Website, Research Governance Pages