University of Leicester and University Hospitals of Leicester NHS Trust joint Research Support Office Standard Operating Procedures

University of Leicester (UoL) Research Governance Office
SOP S-1012 UoL

Management and Production of Corrective And Preventative Action plan (CAPA) for Studies Sponsored by University of Leicester

Version 4.2 September 2023

Office Base

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Effective Date: October 2023

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.

Please note the appendices associated with this SOP may be subject to interim changes. Please ensure that appendices are downloaded from the RGO webpages prior to use to ensure the latest version of the document is being used.

1.0 Introduction

This Standard Operating Procedure (SOP) describes the process to be followed when breaches/deviations of the Protocol, Good Clinical Practice in research (ICH GCP), Sponsor/Host SOP or agreements have been identified. The severity of the breach/deviation is irrelevant and this procedure must be the basis for root cause analysis and preventative action.

A Corrective and Preventative Action (CAPA) Plan must be completed on each occasion, although it is acceptable to use a CAPA Plan for multiple items when more than one breach is identified at a given time. It is important to recognise that breaches/deviations may not be deliberate or intentional, but action must be taken to prevent future repeats.

Where it is identified that a breach/deviation necessitates an amendment to the Protocol, the amendment itself will form part of the CAPA plan.

2.0 Scope

This SOP applies to all research studies sponsored by the University of Leicester (UoL).

3.0 Procedures

A potential breach may be identified by any individual. An individual does not have to be associated with a research study to identify and escalate potential breaches.

On finding a potential breach, the individual must notify the Sponsor in the first instance. Please note that protocol deviations do not need to be reported to Sponsor.

In all cases, a named individual will be nominated to lead communication between the Sponsor and the Chief Investigator (CI)/Principal Investigator (PI)/study team.

It is expected that the CAPA template will be used (Appendix 1) unless specific research team reporting arrangements have been made in advance of a breach having been identified (e.g. alternative electronic data capture (i.e., Q Pulse)).

3.1 Completion of the CAPA Template

The identified breach must be written down as clearly as possible. It may be necessary to split the breach up into smaller parts, particularly where it is a complex issue. It is important to be clear but concise and factual.

Each section of the CAPA template must be completed (Appendix 1)

On first identifying the breach the CAPA must be opened. The Sponsor will categorise the breach, adhering to the definitions as per the non-compliance SOP S-1016 UoL.

3.2 Progressing the CAPA

Progress during completion of the CAPA will be monitored by the Sponsor. The lead individual will be responsible for ensuring that all actions identified are completed by the deadlines stated in the CAPA.

4.0 Non- Compliance

Failure to comply will result in the Non-compliance SOP S-1016 UoL process being implemented at a minimum of a MAJOR finding. A final version of the CAPA plan must be sent to the Sponsor to close the breach.

5.0 Multi-site studies

Where the UoL is the Sponsor for Multi-site studies, it is expected that the Sponsor/agreed delegate SOPs and documentation be used at all sites.

6.0 Responsibilities

Responsibility	Undertaken by	Activity
All Individuals	All Individuals	Notify the Sponsor on identification of a breach of Protocol or ICH GCP, Sponsor/Host Standard Operating Procedures or agreements.
Sponsor	Head of Research Governance or their delegate/Research Team	Liaise with Sponsor to determine documentation and process to be followed.
Sponsor	Head of Research Governance or their delegate/Research Team	Liaise with Sponsor to facilitate tracking and appropriate conclusion of the event.

7.0 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 	29/09/2023

8.0 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)
June 2015	2	Wendy Gamble	Reviewed to bring in line with R&I changes at UHL. Addition of scope.
Nov 2016	3	Diane Delahooke	Logo Updated. Use of Qpulse added. Consistency checks with UHL.
Nov 2017	4	Michelle Muessel	Reviewed in line with UHL R&I changes, added new address.

Sept 2021	4.1	Cat Taylor	Administrative changes
Sept 2023	4.2	Cat Taylor	Administrative changes Removal of distribution record Removal of monitoring and audit criteria Minor updates to the responsibilities table Appendix 1 – administrative changes and minor updates to wording