



**UNIVERSITY OF LEICESTER,
&
UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST
JOINT RESEARCH & DEVELOPMENT SUPPORT OFFICE
STANDARD OPERATING PROCEDURES**

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

Version 4.1 September 2021

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

OFFICE BASE

Research Governance Office
Academic Department, Ground Floor
Leicester General Hospital
Gwendolen Road
Leicester
LE5 4 PW

Effective Date: October 2021



1. 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 Standard Operating Procedures 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. 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. SCOPE

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

3. 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. 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. MULTI-CENTRE STUDIES

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

6. RESPONSIBILITIES

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


7. MONITORING AND AUDIT CRITERIA

Key Performance Indicators	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 a risk-based assessment of research activities	Research Governance Manager

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

8. DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT

Author / Lead Officer:	Cat Taylor
Job Title:	Head of Research Assurance

Reviewed by:	UoL Research Management and Operations Group (RSMOG)
Approved by:	Professor Nigel Brunskill 
Date Approved	13/10/2021

9. REVIEW RECORD

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

10. DISTRIBUTION RECORD

Date	Name	Department	Received