

LOUGHBOROUGH UNIVERSITY RESEARCH OFFICE STANDARD OPERATING PROCEDURE

Loughborough University (LU) Research Office SOP-1012 LU

Management and Production of Corrective And Preventative Action plan (CAPA) for NHS Research Sponsored by Loughborough University

Effective Date: January 2016

1.0 Introduction

This Standard Operating Procedure (SOP) describes the process to be followed when breaches/deviations of research 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 Plan (CAPA) 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.

2.0 Procedures

A potential breach/deviation 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/deviation, the individual must notify the Sponsor in the first instance.

In all cases a named individual must be nominated by the Chief Investigator/Principal Investigator (CI/PI) to lead communication with the Sponsor.

It is expected that the Loughborough University CAPA form will be used (Appendix A).

Completion of the CAPA

The identified breach/deviation 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 form must be completed.

On first identifying the breach/deviation the CAPA must be opened. The Sponsor will categorise the breach adhering to the definitions as per the Non-Compliance SOP -1016 LU.

Progress during completion of the CAPA will be monitored by the Research Governance Officer using the CAPA tracking log (Appendix B). The lead individual will be responsible for ensuring that all actions identified are completed in accordance with the CAPA plan. Failure to comply will result in the non compliance SOP process being implemented. A final version of the CAPA plan must be sent to the Sponsor to close the breach.

3.0 Multi-centre studies

Where LU is the Sponsor for Multi-Centre studies, it is expected that the Sponsor SOP and documentation be used at all sites.

4.0 Responsibilities

	Responsibility	Undertaken by	Activity
1.	All Individuals	All Individuals	Notify LU as Sponsor on identification of a breach of protocol or ICH GCP
2.	All Individuals / Research Team	All Individuals / Research Team	Liaise with Sponsor to determine documentation and process to be followed
3.	All Individuals / Research Team	All Individuals / Research Team	Liaise with sponsor to facilitate tracking and appropriate conclusion of the event

5. Monitoring and Audit Criteria

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

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:	Jackie Green		Job Title: Research Governance Officer
Approved by:	Ethics Committee		Date Approved: 5/2/16
REVIEW RECORD			
Date	Issue Number	Reviewed By	Description Of Changes (If Any)
DISTRIBUTION RECORD:			
Date	Name	Dept	Received

Appendix A

Corrective Action Preventative Action (CAPA) Form Sponsor Reference Number:

No	Category as below	Date/Finding	Immediate Action	Corrective Action	Preventative Action	Date completed

Category definition : CRITICAL	Category definition MAJOR	Category definition: OTHER
<p>The safety, well being or confidentiality of participants has been jeopardised. Reported data are unreliable or absent Inappropriate, insufficient or untimely corrective action has taken place regarding a major non compliance</p>	<p>Major Significant and unjustified non-compliance with relevant legislation or Good Clinical Practice (ICH GCP). A number of breaches of legislation or GCP within one area, indicating systematic quality assurance failure A failure to comply with legislative requirements including annual reporting requirements</p>	<p>Other Findings that are neither critical nor major</p>

P.I. Name (Print)

P.I. Signature

Date.....

CAPA Completion Guidelines

This form should ideally be completed electronically, but can be hand written. The form can be used to capture single or multiple breaches/deviations, when more than one breach is identified at a time.

- | | | |
|--------------|----------|--|
| 1. The Title | | Complete Sponsor reference number and short study title |
| 2. Column 1 | Number | Enter number of finding referred to on this form i.e. 1 if singular or 2 etc if multiple findings recorded. |
| | Column 2 | Category |
| | | Enter Critical, Major or Other. A full explanation of these three definitions can be found on the CAPA form and in the non compliance Standard Operating Procedure SOP-1012. If further advice is required contact the Research Governance Office. |
| | Column 3 | Date and Finding |
| | | Enter the date of the event/finding and add a brief description of the finding. Additional Supporting documentation can be supplied. |
| | Column 4 | Immediate Action |
| | | Enter the details of the immediate action taken with regards to the breach/deviation. |
| | Column 5 | Corrective Action |
| | | Enter the details of the Corrective actions put in place following the breach/deviation |
| | Column 6 | Preventative Action |
| | | Enter details of what processes have been reviewed/updated to ensure there is no repeat of the breach/deviation |
| | Column 7 | Date of completion |
| | | Date of completion of all actions on the CAPA. |
3. The Chief/Principal Investigator must print their name and sign and date the form.

The completed form should be sent by email to the Research Governance Officer Email to researchpolicy@lboro.ac.uk

Appendix B

LU CAPA Tracking Log

Sponsor Ref Number	Date of Finding	Finding(brief description)	Date Sent to C.I./P.I.	Response received Y/N	Review date	Closed date