



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

**University of Leicester (UoL) Research Governance Office
SOP S-1013 UoL**

Version 4, October 2016

**Identifying and Reporting Deviations and Serious Breaches of GCP and/or the
Protocol for Trials 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: April 2017

1. Introduction

This Standard Operating Procedure (SOP) describes the process for the identification and reporting of serious breaches of GCP and / or the approved trial protocol in all studies sponsored by the University of Leicester (UoL).

The outcome is that the management of all Serious Breaches of Protocol and / or GCP, or Protocol Deviations are documented and appropriate Corrective Action and Preventative Action (CAPA) undertaken.

2. Scope

This SOP applies to all researchers conducting research studies sponsored by UoL.

3. Definitions

Protocol Deviation: A protocol deviation is any un-intended change or departure from the protocol, e.g. a protocol visit date deviation, which does not result in harm to the trial subjects or significantly affect the scientific value of the trial.

Serious Breaches of the Protocol and/or GCP: For the purposes of this regulation, a “serious breach” is a breach which is **likely** to affect to a significant degree:

- a) The safety or physical or mental integrity of the subjects of the trial; or
- b) The scientific value of the trial

Urgent Safety Issues: A protocol deviation/change may be implemented in response to an immediate hazard to a trial subject without prior approval from the Sponsor / R&I/ HRA / MHRA. This is defined as an Urgent Safety Measure under UK Regulation 30. Urgent Safety Measures are covered in [SOP S-1029 UoL](#).

4. Procedure.

In each case, any Serious Breaches or Urgent Safety Measures must be reported to the Sponsor by the Chief Investigator or any member of the research team within 24 hours of them becoming aware of the breach. Protocol Deviations not resulting in Urgent Safety Measures, do not need to be immediately reported to the Sponsor.

4.1 Serious Breaches

The initial report to the Sponsor may be by email to uolsponsor@le.ac.uk. The email must detail the name of the study, and give a brief outline of the suspected breach identified or safety measure required.

The Chief Investigator or member of the research team must submit an initial report by email attaching the Serious Breach Notification Form ([Appendix 1](#)) to the sponsor uolsponsor@le.ac.uk within 24 hours of becoming aware of the breach. The Sponsor will make contact with the Chief Investigator to discuss the nature of the breach, and to give guidance on completion of a CAPA in line with the [CAPA SOP S-1012 UoL](#).

In addition the Sponsor will satisfy its responsibilities under Regulation 29A of the Medicines for Human Use (Clinical Trials) Regulations 2004 [SI 2004/1031]: "29A (1) The Sponsor of a clinical trial shall notify the licensing authority in writing of any serious breach of:

- a) The condition and principles of GCP in connection with that trial; or
- b) The protocol relating to that trial, as amended from time to time in accordance with regulations 22 to 25, within 7 days of becoming aware of that breach.

Further guidance can be found on the MHRA website, Guidance for notification of serious breaches of GCP or the trial protocol: [MHRA Guidance](#)

The Sponsor will notify the MHRA, HRA, R&I at the site and the REC as appropriate within 7 days of becoming aware of the breach and will update as required following completion of a CAPA. All actions and documentation resulting from the CAPA must be filed in the Trial Master File (TMF) Investigator Site Files (ISF).

4.2 Protocol Deviation

These do not need to be reported to the Sponsor but must be documented in the Case Report Form and TMF and ISF for multi-centre studies, using a signed and dated file note available on the Research Governance web pages. All Protocol Deviations must also be logged on the Protocol Deviation Tracking Log ([Appendix 2](#)) which must be retained in the TMF / ISF. Appropriate corrective and preventative action must be taken in accordance with [CAPA SOP S-1012 UoL](#) in order to avoid reoccurrence of the deviation.


5. Responsibilities

Responsibility	Undertaken by	Activity
1 CI/Investigating Team/ Clinical Trial Monitor	CI/Investigating Team/Clinical Trial Monitor	Identify and document all protocol deviations in the CRF and Master/Site File, in order for appropriate corrective and preventative actions to be taken.
2 CI/Investigating Team/ Clinical Trial Monitor	CI/Investigating Team/ Clinical Trial Monitor	Report all potential serious breaches of the protocol and/or GCP to the Sponsor within 24hours of becoming aware of the breach, supplying as much information as possible
3 Sponsor	Research Governance Manager or delegate	If the breach is confirmed as 'serious' according to the MHRA definition, the Sponsor must complete a 'Notification of Serious Breach of GCP or Trial Protocol Form'

Responsibility	Undertaken by	Activity
4 Sponsor	Research Governance Manager or delegate	The completed notification form must be forwarded to GCP.SeriousBreaches@mhra.gsi.gov.uk OR GCP Inspectorate, MHRA, 2a Hunter house, 57 Goodramgate, York, YO1 7FX within 7 days of becoming aware of that breach.

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

6. Development and approval Record for this document

Author / Lead Officer:	Wendy Gamble
Job Title:	Research Governance Manager
Reviewed by:	UoL Research Management and Operations Group (RSMOG)
Approved by:	Professor Nigel Brunskill 
Date Approved	10/04/2017

7. Review Record

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
Oct 2013	2	Wendy Gamble	Version 1 revised following review of Sponsor processes
June 2015	3	Wendy Gamble	Version 2 revised to bring in line with UHL SOP.
Oct 2016	4	Wendy Gamble	Version 3 revised following implementation of HRA processes

8. Distribution Record

Date	Name	Department	Received