LOUGHBOROUGH UNIVERSITY RESEARCH OFFICE
STANDARD OPERATING PROCEDURE

Loughborough University (LU) Research Office
SOP–1013 LU

Identifying and Reporting Deviations and Serious Breaches of GCP and/or the Protocol for NHS Research Sponsored by Loughborough University

Effective Date: January 2016

1.0 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.

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

2.0 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&D /REC. This is defined as an Urgent Safety Measure under UK Regulation 30 (The Medicines for Human Use (Clinical Trials) Regulations 2004).

3.0 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.

The initial report to the Sponsor may be by email to researchpolicy@lboro.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 sponsor will make contact with the Chief Investigator to discuss the nature of the breach, or safety measure and to give guidance on completion of a CAPA in line with the CAPA SOP -1012 LU.

Protocol Deviation

These do not need to be reported to the Sponsor but must be documented in the Case Report Form and Trial Master File (TMF)/ Investigator Site Files (ISF) for multi-centre studies, using a signed and dated file note available on the College web pages. All Protocol Deviations must also be logged on the Protocol Deviation Tracking Log (Appendix A) which must be retained in the TMF / ISF. Appropriate corrective and preventative action must be taken in accordance with CAPA SOP -1012 LU in order to avoid reoccurrence of the deviation.

Serious Breach

The Chief Investigator or member of the research team must submit an initial report by email attaching the Serious Breach Notification Form (Appendix B) to the sponsor researchpolicy@lboro.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 -1012 LU.

The Sponsor will notify the R&D at the site & 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 TMF/ISF.

Urgent Safety Measures

The Investigator may take appropriate urgent safety measures to protect clinical trial subjects from any immediate hazard to their health and safety. Any required measures may be taken immediately. The Investigator must inform the Sponsor within 24 hours of the measures being taken. The Sponsor, in communication with the Chief Investigator, will inform the R&D & REC within THREE Days of implementation of the required measures. It is worth noting that all trials should only be conducted in accordance with the approved protocol unless an urgent safety issue arises.

4.0 Responsibilities

	Responsibility	Undertaken by	Activity
1	CI/Investigating Team	CI/Investigating Team	Identify and document all protocol deviations in the CRF and Master/Site File, in order for appropriate corrective and preventative actions to be taken.

	Responsibility	Undertaken by	Activity
2	CI/Investigating Team	CI/Investigating Team	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 Officer	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'

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

Protocol Deviation Tracking Log

Study Title:	UoL Ref Number:	Sponsor
Principal Investigator:	Site:	

Protocol Deviation: A protocol deviation is any un-intended 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. These do not need to be reported to the Sponsor but must be documented in the CRF and Trial Master File/ Investigator Site File. Appropriate corrective and preventative action must be taken

***If the deviation has an impact on patient safety or study outcomes this may constitute a serious breach and should be reported to the sponsor as per SOP -1013 LU.**

Event No.	Event Date	Participant ID/Initials	Description of Deviation	Deviation Code	Corrective /Preventative Action taken to avoid recurrence e.g. protocol amendment

Investigator Signature_____ Date _____

Deviation Codes: A. Consent procedure. B. Inclusion/Exclusion criteria, C. Serious Adverse event reporting/Unanticipated adverse device effect
D. Randomization Procedures/study drug dosing E. Study Procedures F. Laboratory assessments/procedures G. Visit schedule/Interval
H. Other

Protocol Deviation Tracking Log- Tool guidance document

Purpose of this document:
To record all protocol deviations that occurs at a study site.
This tracking log should provide a comprehensive list of all protocol deviations that occur at a study site. It is required for both observational and interventional clinical research studies
The tool is complementary to, and does not replace, the requirement to report potential serious breaches of the Protocol to the Sponsor and Regulatory Authorities as per SOP -1013 LU.

Completion of the log:

- Ensure Study Title/Sponsor reference number/ Sponsor/PI and site details are completed on all forms
- Record protocol deviations in the tracking log as they occur, to ensure completeness and accuracy of data.
- The site PI should sign each form after it has been completed.
- The Deviations should be reviewed and corrective preventive action completed and recorded. (i.e. amendment to the Protocol).
- Events should be numbered sequentially, commencing with no 1.
- The log should be filed in the Essential Documents Folder (i.e. Trial Master File/Investigator Site File) in either a specific labelled section (Protocol Deviations) or with the trial protocol.
- Pages should be filed in reverse chronological order, with the newest pages of the log placed at the front of the section.
- At the conclusion of the study, ensure all forms are complete and signed by the Principal Investigator.

Appendix B

Serious Breach Notification Form

Include details of the breach; include the rationale (e.g. patient safety/data integrity issue and relevant legislation if known).

Details of Breach	Action Taken

PI Name: …… PI Signature ……

Date ……