RESEARCH & INNOVATION

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UNIVERSITY OF LEICESTER, LOUGHBOROUGH UNIVERSITY

&

UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

JOINT RESEARCH SUPPORT OFFICE

STANDARD OPERATING PROCEDURES

UHL Research Support Office
SOP C-2015 UHL V2 February 2017

Standard Operating Procedure for Identifying and Reporting Deviations and Serious Breaches of GCP and/or the Protocol for research where University Hospitals of Leicester NHS Trust (UHL) is the HOST Organisation or the Research SITE

PGC Registration: C275/2016

OFFICE BASE

Research & Innovation
Leicester General Hospital
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1. Introduction

This Standard Operating Procedure (SOP) describes the process for the identification and reporting of serious breaches of GCP and/ or the approved study protocol in all studies Hosted by the University Hospitals of Leicester NHS Trust (UHL).

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 hosted by the UHL.

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 study subjects or significantly affect the scientific value of the study

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

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

Urgent Safety Issues: A protocol deviation/change may be implemented in response to an immediate hazard to a study subject without prior approval from the Sponsor/HRA/R&I/MHRA/REC. This is defined as an Urgent Safety Measure under UK Regulation 30. Urgent Safety Measures are usually managed by the Sponsor but are referenced in the amendments SOP **C- 2011 UHL**

4. Procedure.

In each case, any Serious Breaches must be reported to the Sponsor or the Chief Investigator by any member of the research team within 24 hours of them becoming aware of the breach. It is expected that this process be detailed to the research team within Sponsor process documentation provided at the Site Initiation Visit.

4.1 Serious Breaches

The initial report to the Sponsor must be copied to the R&I Office using RIAdmin@uhl-tr.nhs.uk.

It is expected that the Sponsor will provide a CAPA template. However, where a template is not provided the example given in the SOP C-2014 UHL may be used. It is expected that the SOP C-2014 UHL will be followed to keep the R&I Office fully informed.

All correspondence relating to the Serious Breach must be copied to RIAdmin@uhl-tr.nhs.uk until resolved.

It is expected that the Sponsor will notify the MHRA, HRA, & REC as appropriate and in accordance with regulations.

4.2 Protocol Deviation

These do not need to be reported but must be documented in the Case Report Form and Investigator Site File (ISF) using a signed and dated file note. An example is available (Appendix 1) on the R&I web pages & can be used if a Sponsor document is not provided. Appropriate corrective and preventative action must be taken in accordance with **CAPA SOP C-1014 UHL** in order to avoid reoccurrence of the deviation.

5. Responsibilities

	Responsibility	Undertaken by	Activity
1	Research Team	Research Team	Identify and document all protocol deviations in the CRF and Investigator Site File, in order for appropriate corrective and preventative actions to be taken.
2	Research Team	Research Team	Report all potential serious breaches of the protocol and/or GCP to the Sponsor in accordance with sponsor guidelines

6. Legal Liability Statement

Guidelines or Procedures issued and approved by the Trust are considered to represent best practice. Staff may only exceptionally depart from any relevant Trust guidelines or Procedures and always only providing that such departure is confined to the specific needs of individual circumstances. In healthcare delivery such departure shall only be undertaken where, in the judgement of the responsible healthcare professional it is fully appropriate and justifiable – such a decision to be fully recorded in the patient's notes and in the research site file.

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:	Carolyn Maloney	**Job Title:** Head of Research Operations
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Site File Note

Study Title:

Date:

Details:

Actions:

Impact on patient safety:

_____

Name (Signature) Date

_____

Name (Print)

_____

PI (Signature) Date

_____

PI Name (Print)