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 should managed by the Sponsor. Please liaise directly with your Sponsor for the correct procedures. USM 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 CAPA SOP C-2014 UHL may be used. It is expected that the CAPA 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-2014 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. Who Guideline Applies To

All staff within UHL and external to UHL who are delivering research.

7. Education and Training

The SOP is detailed so the process can be clearly followed. No flowchart is provided / required.

8. Education and Training

None

9. Monitoring Compliance

Key Performance Indicator	Method of Assessment	Frequency	Lead
All research sponsored by UHL has appropriate Risk Assessment	Included in the monitoring / audit programme.	Random audits / monitoring conducted on 10% of research activity.	Head of Research Operations, Clinical Trials Monitor & Trainer

10. Supporting Documents and Key References

SOP C-2015 Appendix 1

SOP C-2011

SOP C-2014

11. Key Words

Research, Innovation, EDGE, REC, MHRA, HRA, CAPA, GCP, Deviations, Breaches, Protocol

12. Contact and Review Details

CONTACT AND REVIEW DETAILS	
Guideline Lead (Name and Title) Lisa Wann R&I manager	**Executive Lead** **Medical director**
Details of Changes made during review: **Review and update**	

13.

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

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Author / Lead Officer:	Carolyn Maloney	**Job Title:** Head of Research Operations
Reviewed by:	R&I Governance Meeting	
Approved by:	**Professor Nigel Brunskill**	**Date Approved:** 09/07/2021.

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February 2019	3	CM, LW	Consistency check. Update to logo
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