1. 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 one 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 may form part of the CAPA plan.

2. Scope

This SOP applies to all research studies where the UHL are the HOST Organisation or research SITE.

3. 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 UHL R&I Office in the first instance by emailing RIAdmin@uhl-tr.nhs.uk. The R&I Office will nominate an individual to liaise with the research team and Sponsor.

3.1)
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.

It is expected that the Sponsor provide a CAPA template. However, when this doesn't occur the template at Appendix 1 can be utilised.

Each box of the CAPA template must be completed. (Appendix 1)

On first identifying the breach/deviation the CAPA must be opened. The R&I Office will liaise with the study team in respect of categorising the breach, and will adhere to the definitions as per the Non-Compliance SOP C-2013 UHL.

3.2)
Progressing the CAPA

The R&I Office Lead will be support the PI and research team to ensure that all actions identified are completed by the deadlines stated in the CAPA.

4. Non-Compliance

Failure to comply will result in the Non-compliance SOP C-2013 UHL process being implemented. A final version of the CAPA plan must be sent to the R&I Office to officially close the breach.

5. Responsibilities

	Responsibility	Undertaken by	Activity
1.	All Individuals	All Individuals	Notify R&IAdmin@uhl-tr.nhs.uk on identification of a breach
2.	R&I Office	R&I Office	Liaise with sponsor & research team to determine documentation and process to be followed

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-2014 Appendix 1

SOP C-2013

11. Key Words

Research, Innovation, EDGE, REC, MHRA, HRA, CAPA, Corrective and Preventative Action Plan

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

DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT		
Author / Lead Officer:	Carolyn Maloney	**Job Title:** Head of Research Operations
Reviewed by:	Research & Innovation Governance Meeting	
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REVIEW RECORD			
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