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. While the severity of the breach/deviation is irrelevant it is important that a proportionate process to determine the root cause is undertaken along with appropriate implementation of preventative action.

It is important to recognise that breaches/deviations may not be deliberate or intentional, but action must be taken to prevent repeat occurrences.

Where it is identified that a breach/deviation necessitates an amendment to the protocol, the amendment itself will form part of the CAPA plan.

2. Scope

This SOP applies to all research studies sponsored by UHL.

3. Procedure

A potential breach 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 the individual must notify the UHL Monitoring Team in the first instance, who will then notify the Sponsor representative.

Where the Sponsor is external to UHL a separate SOP is provided. In all cases a named individual will be nominated to lead communication between the Sponsor and the Chief Investigator / Principal Investigator / study team.

It is expected that the CAPA template be used (Appendix 1) unless specific research team reporting arrangements have been made in advance of a breach being identified e.g. alternative electronic data capture (Q-Pulse)

3.1 Completion of the CAPA

The identified breach 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.

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

On first identifying the breach the CAPA must be opened. The UHL Monitoring Team will liaise with the study team in respect of categorising the breach, and will adhere to the definitions as per the Non-Compliance SOP S-1016 UHL in discussion with the Head of Research Operations or their delegate.

3.2 Progressing the CAPA

Progress during completion of the CAPA will be monitored by the UHL Monitoring Team completing the appropriate workflow in the EDGE database. The lead individual will be responsible for ensuring 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 S-1016 UHL process being implemented at a minimum of a MAJOR finding. A final version of the CAPA plan must be sent to the UHL Monitoring Team to close the breach.

5. Multi-Centre Studies

Where the UHL is the Sponsor for multi-centre studies, it is expected that the Sponsor / agreed delegate SOPs and documentation be used at the site.

6. Responsibilities

	Responsibility	Undertaken by	Activity
1.	All Individuals	All Individuals	Notify UHL Monitoring Team on identification of a breach of protocol or ICH GCP
2.	Monitor	Monitor or Research Team members	Liaise with Sponsor to determine documentation and process to be followed
3.	Monitor	Monitor or Research Team members	Liaise with research team and Sponsor to facilitate tracking and appropriate conclusion of the event

7. Monitoring & Audit Criteria

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 a Risk Based assessment	Head of Research Operations, Clinical Trials Monitor & Trainer

8. 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.

9. Supporting Documents and Key References

SOP S-1012 Appendix 1

SOP S-1016

10. Key Words

Research, Innovation, Volunteers, Participants, ATIMPS, CTIMPS, Trials, CAPA, Q-Pulse, Breach, Monitor, Audit, ICH, GCP

This line signifies the end of the document

This table is used to track the development and approval and dissemination 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:	UHL Research Management Meeting	
Approved by:	Professor Nigel Brunskill	**Date Approved:** 16/2/21

REVIEW RECORD			
Date	**Issue Number**	**Reviewed By**	**Description Of Changes (If Any)**
August 2016	4	CM, LW, JJ	Consistency checks.
Nov 2016	5	CM	Add in alternative reporting option
Feb 2017	6	CM	Update Logo
Jan 2018	7	CM	Revised tracking to include EDGE
Sep 2018	8	CCL, LW, JJ	General review, no changes. Updated R&I logo throughout
Nov 2020	9	LW, JJ,AM	Reformatting to new template, Consistency checks, No changes

DISTRIBUTION RECORD:			
Date	**Name**	**Dept.**	**Received**