1. Introduction and Who Policy Applies To

This Standard Operating Procedure (SOP) describes the process for identifying, reporting and managing breaches in research sponsored or hosted by University Hospitals of Leicester NHS Trust (UHL), including where UHL is acting as a research location.

This includes breaches of:

- the conditions and principles of good clinical practice (GCP)
- the approved research protocol or clinical investigation plan (CIP)
- UK clinical trial regulations
- UHL policy
- applicable information governance and data protection requirements
- clinical trial agreements (CTA) or other contractual agreements

The purpose of this SOP is to ensure that:

- the safety, rights and wellbeing of participants and integrity of research data are protected
- breaches are appropriately identified, assessed, reported and managed
- there is a proportionate process in place to determine root cause
- appropriate corrective and preventative actions (CAPA) are undertaken to prevent repeat occurrence
- all actions and decisions are clearly documented to ensure traceability and auditability

This SOP applies to:

- all research sponsored or hosted by UHL, including where UHL is a research location
- all individuals conducting research within UHL

For cases of suspected **fraud** or **research misconduct**, follow the UHL Counter Fraud, Bribery & Corruption policy (A1/2010) and associated Trust procedures.

2. Definitions

Protocol	For the purposes of this SOP, the term 'protocol' is used to describe any research protocol, CIP, working instruction or process approved for the conduct of research
Breach	An umbrella term covering all protocol deviations and non-compliance. A breach is any failure to comply with the approved protocol, applicable legislation, regulatory requirements, GCP, or relevant sponsor and host policies and procedures
Protocol deviation	Any unplanned or unintended departure from the approved protocol, CIP or established research procedures which does not result in significant harm to research participants or significantly affect the scientific value of the research (e.g. a participant attending on the wrong visit date)
Non-compliance	A failure to comply with the approved protocol, regulatory requirements, GCP or relevant organisational policies and procedures.

Non-compliance (continued)	Non-compliance is classified as either 'critical', 'major' or 'other', in line with audit and inspection processes of regulatory authorities:
	• A **critical** non-compliance can include instances where:
	  ○ The safety, well-being or confidentiality of participants has been jeopardised or has the potential to be jeopardised
	  ○ Reported data are unreliable or absent
	  ○ Inappropriate, insufficient or untimely corrective action has taken place regarding major non-compliance
	  ○ Inadequate documentation is available to reconstruct research activity or there is failure to maintain an appropriate Trial Master File (TMF) or Investigator Site File (ISF)
	• A **major** non-compliance can include instances of :
	  ○ Significant and unjustified non-compliance with relevant legislation or conditions and principles of GCP
	  ○ A number of breaches of legislation or GCP within one area, indicating a systematic quality management failure
	  ○ A failure to comply with legislative requirements, including reporting
	• Other findings
	  ○ Relevant findings that are neither critical nor major are classified as '**other**'

Serious Breach	A breach of the protocol or GCP which is **likely** to affect, <u>to a significant degree</u>: • participant safety • the physical or mental integrity of research participants • the scientific value of the research
Urgent Safety Measure (USM)	A protocol deviation (or change) that is urgently required in response to an immediate hazard to a research participant. USMs may be implemented without prior approval from the sponsor, Research Ethics Committee (REC) or regulator - Health Research Authority (HRA) or Medicines and Healthcare products Regulatory Agency (MHRA). Subsequent notification and reporting must be undertaken in accordance with applicable sponsor and regulatory requirements - see sponsor guidance for more information. For UHL-sponsored research, refer to SOP S-1026: *Urgent Safety Measure in Sponsored Research in UHL*.
Corrective and Preventive Action (CAPA)	A documented process used to identify the root cause of a breach, implement actions to correct the issue, and establish measures to prevent recurrence.

3. Policy Standards and Procedures

Chief Investigators (CI) and Principal Investigators (PI) are responsible for ensuring that research conducted under their oversight complies with the approved protocol, applicable legislation, GCP, sponsor requirements and relevant organisational procedures.

Breaches of research protocols and GCP occur commonly during the conduct of clinical research. Although the majority of these are unintentional and are not intended to mislead or deceive, all breaches must be reported so they can be objectively assessed and managed proportionately according to their actual or potential impact. This will ensure any underlying causes have been addressed, promote learning and reduce the risk of recurrence.

3.1. Breach Identification

Breaches may be identified by anyone. Individuals do not have to be associated with the research activity to identify and escalate breaches. Methods for identifying breaches include:

- routine monitoring
- audit findings
- sponsor review
- regulatory authority inspections
- complaints or concerns raised by participants, members of staff or external organisations
- reported incidents (e.g. DATIX)
- contractual issues
- whistleblowing

3.2. Initial Assessment

An initial assessment must be undertaken immediately upon identification to establish the nature, impact, scope and urgency of the breach, and to determine whether immediate action or escalation is required.

Consider whether:

- there is an immediate hazard to participant safety or a risk to participant wellbeing
- the breach could affect the integrity, reliability or completeness of the research data, or otherwise compromise the scientific value of the research
- the breach represents, or may represent, a failure to comply with applicable regulatory requirements
- the breach is:
    - isolated or systemic
    - limited to a single participant, process or research location, or affecting multiple participants, processes or research locations

Based on the initial assessment, and using the definitions in Section 2 as a guide, a provisional classification should be assigned (this may be refined following further investigation):

1. Protocol deviation
2. Non-compliance (critical / major / other)
3. Potential serious breach - **requires urgent escalation (see section 3.4)**

Where there is uncertainty regarding classification, staff should refer to guidance on the MHRA website (Notification of Serious Breaches of GCP or the trial protocol - GOV.UK), or seek advice from senior managers or the Research & Innovation (R&I) Quality Assurance (QA) team (via the R&I Governance mailbox: uhl-tr.rigovernancemailbox@nhs.net).

If classification remains unclear following advice, or support is unavailable, the breach should be managed according to the highest reasonably applicable category until further assessment has been completed.

3.3. Reporting

Reporting requirements will vary according to the research type and severity of the breach.

3.3.1. Reporting a Protocol Deviation

Single protocol deviations that are not considered serious - and are not the result of an USM – do not need to be reported to the Sponsor but must be logged and reviewed to determine whether further investigation or action is required. Where required, and particularly if a deviation is noted on more than one occasion, appropriate corrective and preventive action must be undertaken.

Breaches of data protection regulation should be managed in accordance with Sponsor or host organisation policies and procedures.

3.3.2. Reporting Non-Compliance (Critical, Major or Other)

i. Reporting Critical Non-Compliance

For UHL-hosted research: upon becoming aware of a critical non-compliance, the PI must immediately alert the R&I Office (uhl-tr.riadmin@nhs.net). The initial notification must include an outline of the non-compliance and any immediate corrective action undertaken or planned.

Depending on the nature of the non-compliance, R&I may suspend the research at a location with immediate effect where this is considered the most appropriate course of action. Before the research is suspended, the implications must be discussed with the research team, following liaison with the sponsor and R&I Director. In rare circumstances, it may be necessary to suspend all research activity associated with the same PI.

Where cases of critical non-compliance have been identified from within UHL, the nominated R&I Research Support Officer (RSO) will notify the research sponsor or representative. Identification of critical non-compliance may also trigger audit or close monitoring of associated research activities.

The PI must ensure that the R&I Sponsor Office is copied into all subsequent correspondence relating to the critical non-compliance until the matter is resolved.

Prior to restarting suspended research, the R&I Sponsor Office must confirm continued Capacity and Capability.

Where appropriate, consistent failure to respond to reported critical non-compliance may result in referral under the applicable UHL procedure for suspected fraud and misconduct in research.

For UHL-sponsored research: where a critical non-compliance is identified in research sponsored by UHL, it is the responsibility of the nominated RSO to alert the CI by email immediately upon identification, outlining the issue and any immediate action required. This must be followed by a detailed report **within 7 calendar days**.

Depending on the severity of the non-compliance, the research may be suspended with immediate effect. R&I may also suspend any associated research involving the same CI, at its discretion and in consultation with the R&I Director. Identification of critical non-compliance may also trigger audit or close monitoring of associated research.

Where UHL-sponsored research is suspended, the RSO, on behalf of the Sponsor, will notify the REC, HRA, all active research locations and the MHRA, as appropriate.

The CI must respond **within 30 calendar days** from receipt of the detailed notification. The response must include an appropriate CAPA plan, setting out the actions to be taken. It is not necessary for all actions to be completed within 30 calendar days, but the plan must clearly describe how and when actions will be completed. Failure to respond within this timeframe will result in suspension of the research, possible suspension of any associated research activities and referral under the applicable UHL procedure for suspected fraud or misconduct in research.

If appropriate, submission of a substantial modification (amendment) to restart the research may be permitted by the Sponsor once the non-compliance has been resolved, or once adequate plans are in

place to prevent recurrence. Research restarted after suspension will be subject to close monitoring: before restart, at the point the first new participant or data is entered, and regularly thereafter until the Sponsor is satisfied that the research remains compliant.

ii. Reporting Major Non-Compliance

For UHL-hosted research: the PI must notify the R&I Office by email (uhl-tr.riadmin@nhs.net) within **14 calendar days** of becoming aware of a major non-compliance. Initial notification should include an outline of the non-compliance and any corrective action already taken or planned.

Where cases of major non-compliance have been identified from within UHL, the nominated RSO will notify the sponsor or their representative, as appropriate.

The PI must ensure that the R&I Office is copied into all subsequent correspondence relating to the major non-compliance until the matter is resolved.

Evidence of multiple major non-compliances, repeated failures within the same area of research activity, or failure to respond within the required timeframe may indicate a systemic quality management issue and may result in escalation to a Critical non-compliance.

For UHL-sponsored research: where a major non-compliance is identified in research sponsored by UHL, the nominated RSO will be responsible for notifying the CI by email to outline the issue and request a response.

The CI must respond **within 30 calendar days** of notification. The response must include an appropriate CAPA plan describing the actions that will be taken to address the non-compliance and prevent recurrence. It is not necessary for all actions to have been completed within 30 calendar days, but the plan must clearly describe how and when actions will be completed.

Evidence of multiple major non-compliances, or failure to respond within the required timeframe, may indicate a systemic quality management issue and may result in escalation to a critical non-compliance and further action by the Sponsor.

iii. Reporting all other non-compliance

For UHL-hosted research: where any other non-compliance is identified, it is the responsibility of the PI to notify the R&I Office by email (uhl-tr.riadmin@nhs.net) **within 30 calendar days** of becoming aware of the issue.

Following notification, the R&I QA team will be available to support the PI and research team in carrying out any relevant CAPA requirements. Where a sponsor CAPA is not available, the UHL CAPA process may be followed (see section 3.6). The R&I QA team will also advise on appropriate legislative processes and act as a key contact for the Sponsor, where required

For UHL-sponsored research: where other non-compliance is identified, it is the responsibility of the R&I Sponsor Office to alert the CI, who will have **30 calendar days** from the date of notification to formulate an action plan in response to the non-compliance. This requires the CI to explain what action will be taken, but does not require all actions to be completed within the 30 calendar days. A CAPA must be completed in accordance with the relevant CAPA process.

Failure to respond to the non-compliance notification will constitute major non-compliance and may result in further escalation by the Sponsor.

iv. Multi-centre research – UHL-sponsored research only

Where non-compliance is identified at a research location, the Sponsor, in collaboration with the CI and PI or location R&I Manager will manage instances in line with the relevant sections of this policy.

3.3.3. Reporting a Serious Breach

A suspected serious breach of the approved research protocol or GCP must be reported to the Sponsor or CI **within 24 hours** of becoming aware of the breach. This can be done by any member of the research team.

The Initial report must include:

- the research title and reference number
- a brief description of the suspected breach, including how it was identified and rationale for classification (e.g. safety, data)
- details of immediate actions taken to protect participants or research integrity

For UHL-hosted research: an initial report must be submitted directly to the sponsor team in accordance with sponsor reporting guidance, as outlined in the approved protocol or initiation visit. The initial notification, and all subsequent correspondence relating to the serious breach, must be copied to the R&I Governance mailbox (uhl-tr.rigovernancemailbox@nhs.net). It is expected that the sponsor will notify the MHRA, HRA, and REC as appropriate, in accordance with current regulations.

For UHL-sponsored research: an initial report must be submitted by the CI or member of the research team using the Serious Breach Notification Form (R&I Template T-1105) to the R&I Sponsor Office (uhl-tr.uhlsponsor@nhs.net).

The R&I Sponsor Office will allocate the breach an internal reference number and nominate an appropriate individual to coordinate assessment, reporting and communication with the research team and other relevant stakeholders.

For CTIMPs, if the Sponsor has clear and unequivocal evidence that a serious breach has occurred, this must be reported to the MHRA **within 7 calendar days** of the sponsor becoming aware of the breach. This is the responsibility of the R&I QA team.

Notifications should be sent to the following email address: GCP.SeriousBreaches@mhra.gov.uk

In some cases, a degree of investigation and assessment may be required prior to MHRA notification in order to confirm that a serious breach has actually occurred. In such cases, a pragmatic approach to clock start can be employed. However, the investigation must be expedited to meet the seven-day timeline as closely as possible.

Where applicable, R&I QA team (on behalf of UHL as sponsor) will also notify participating organisations and other relevant parties in accordance with regulatory requirements.

Further guidance on serious breach reporting for CTIMPs is available from the MHRA website:

Guidance for the Notification of Serious Breaches of GCP or the Trial Protocol

For other regulated research, the Sponsor must assess whether additional notifications are required to the HRA, REC, participating organisations or other oversight bodies in accordance with the applicable regulatory framework and approval conditions.

Where applicable, the R&I QA team will coordinate these notifications on behalf of UHL as Sponsor, and maintain appropriate records of all communications within the approved R&I systems (e.g. EDGE or Florence).

3.4. Investigation

All breaches, however identified, must be investigated appropriately. An investigation should start as soon as reasonably practical following identification of the breach and must be proportionate to the actual or potential impact of the breach.

The investigation must seek to establish:

- when and where the breach occurred
- how the breach was identified
- what occurred

- which participants, processes, systems or research locations were affected
- whether participant safety, rights, wellbeing, confidentiality, data integrity or scientific validity have been adversely affected
- whether the breach represents an isolated occurrence or evidence of a wider systemic issue
- whether any immediate actions are required to protect participants or research integrity
- whether regulatory notification or escalation requirements apply
- whether research activities should be restricted, suspended or subject to additional oversight pending resolution

Investigations should be based on objective evidence and may include review of:

- source documents
- research records
- investigator files (ISF/TMF)
- electronic systems and audit trails
- monitoring, audit or inspection reports
- training records
- correspondence
- interviews or discussions with relevant members of the research team

3.4.1. Root Cause Analysis

Where corrective or preventive action is required, the investigation must seek to identify the underlying cause or causes of the breach rather than addressing only the immediate consequence.

Potential contributory factors may include:

- deficiencies in training, competency or supervision
- inadequate procedures or guidance
- protocol design or complexity
- communication failures
- system or process failures
- resource constraints
- human error
- failures in sponsor or organisational oversight

The depth of root cause analysis should be proportionate to the severity and recurrence of the breach.

3.4.2. Investigation Outcomes

On completion of the investigation, the findings must be reviewed to determine whether:

- the original classification remains appropriate
- re-classification is required
- the breach constitutes or contributes to non-compliance
- the breach meets the definition of a serious breach
- additional reporting or regulatory notification is required
- a CAPA is required
- further monitoring, audit or training is necessary
- escalation should be considered under UHL procedures for suspected fraud or misconduct in research

The rationale for all decisions must be documented (see section 3.6).

3.4.3. Escalation During Investigation

Where new information becomes available during an investigation indicating a greater level of risk than originally identified, the breach must be immediately re-assessed and managed according to the highest reasonably applicable classification.

Where participant safety, participant rights, data integrity, or the scientific value of the research may be significantly affected, **immediate escalation** must occur without waiting for completion of the investigation.

All findings, decisions and actions arising from the investigation must be documented and retained within the relevant research files.

3.5. Corrective and Preventive Action (CAPA)

A CAPA is a documented process used to help identify the root cause of a breach, implement actions to correct the issue, and establish measures to prevent recurrence.

A CAPA must be initiated as soon as it is identified that corrective or preventive action will be required and does not need to wait until an investigation has been fully completed. A single CAPA may be used to address one issue or multiple related issues, where appropriate. Some examples of when a CAPA may be required:

- a significant protocol deviation or non-compliance
- monitoring, audit or inspection findings
- a serious breach
- a complaint
- a health and safety incident
- a data breach
- any findings where recurring or systemic issues are identified

A CAPA would not normally be required for isolated protocol deviations or other minor breaches where corrective or preventive actions are considered unnecessary following assessment.

Corrective actions should focus on addressing the identified finding, resolving any immediate or underlying issues, and restoring compliance with applicable protocols and regulatory, sponsor or organisational requirements. This may include training, revised procedures, additional oversight or protocol modifications.

Preventive actions should focus on reducing the risk of recurrence, and may include process changes, revised documentation, additional training, enhanced oversight/monitoring activities, protocol modifications and other proportionate measures.

For UHL-hosted research: the research sponsor's CAPA process must be followed. Where no suitable sponsor process exists, the UHL CAPA process and template should be used (R&I template T-1106).

***For UHL-sponsored research*:** the UHL CAPA process must be followed, unless alternative arrangements have been formally approved by the Sponsor.

Investigators (CI/PI) and relevant research managers are responsible for ensuring that agreed actions are implemented and maintained within the agreed timescales. Persistent failure to engage with or implement agreed CAPA actions will normally be treated as at least Major non-compliance.

3.5.1. DATIX Investigations

Where a DATIX investigation has adequately:

- established the root cause of the breach
- identified appropriate corrective and preventive actions
- assigned responsibilities and completion dates
- documented implementation and closure of actions

a separate CAPA is not normally required.

In such circumstances, the DATIX record will serve as the formal corrective and preventive action plan, provided it contains sufficient detail to demonstrate appropriate investigation, action planning, implementation and oversight.

The R&I QA Team will maintain oversight of relevant DATIX investigations and liaise with the responsible individuals or departments to support timely completion of agreed actions.

Where the available DATIX documentation is insufficient to demonstrate appropriate root cause analysis, action planning, implementation or closure, a separate CAPA may be requested.

3.5.2. Producing a CAPA plan

Use the CAPA template (R&I template T-1106) to clearly describe the issue being addressed. Where a breach involves multiple failures, contributory factors or affected processes, it may be necessary to separate the issue into individual components to facilitate investigation and action planning.

The CAPA must:

- categorise the breach (as critical, major or other)
- identify the root cause(s) and contributory factors identified during investigation
- describe any immediate corrective actions already undertaken
- identify further corrective or preventive actions required to reduce the risk of recurrence
- assign responsibility for each action
- define target completion dates
- assign a RAG rating for each finding (Red: not started, Amber: in progress, Green: completed)

Each section of the CAPA template must be completed. Corrective and preventive actions must be proportionate to the nature, severity and potential impact of the breach.

3.5.3. CAPA Review and Oversight

Regardless of sponsorship arrangements, all CAPAs relating to breaches in research within UHL must be provided to the R&I QA Team for review. The QA Team will review CAPAs to ensure that:

- the identified issue has been adequately investigated
- root causes have been appropriately considered
- actions are proportionate and achievable
- responsibilities and timelines are clearly defined
- appropriate evidence of completion is obtained

Copies of CAPAs, associated correspondence and supporting documentation must be retained on the relevant R&I research database and within any associated sponsor oversight records (e.g. TMF/ISF).

The individual responsible for each action remains accountable for ensuring completion within the agreed timescales. Where delays occur, revised timelines and justification must be documented.

The R&I QA Team is responsible for monitoring the progress of CAPAs submitted to R&I using the relevant EDGE workflow and associated tracking systems, and for following up overdue actions as appropriate.

Failure to implement agreed CAPA actions may result in escalation under this SOP and may lead to reclassification of the breach where appropriate.

3.5.4. CAPA Closure and Effectiveness Review

A CAPA may only be closed once sufficient evidence exists to demonstrate completion of all required actions. Prior to closure, consideration should be given to whether the implemented actions have effectively addressed the identified issue and reduced the risk of recurrence.

The final CAPA must be signed by the PI (or CI, where applicable) and submitted to the R&I QA Team for review. Where the QA Team is satisfied that all required actions have been completed, the CAPA will be closed and formally signed-off by the R&I Head of Quality.

Following closure, the R&I QA Team will undertake follow-up review to assess whether implemented actions have remained effective and whether any similar issues have subsequently been identified.

Where further concerns are identified, additional investigation, escalation or CAPA may be required.

3.6. Documentation requirements

Records relating to breaches must be maintained in sufficient detail to permit reconstruction of the events, decisions, investigations, corrective and preventive actions, and outcomes.

Breach records should be kept with relevant research records, such as:

- the ISF or TMF
- the participant Case Report Form (CRF)
- participant medical records
- R&I governance records (EDGE, Florence or other approved R&I systems)

All records must be attributable, legible, contemporaneous, original and accurate.

Protocol deviations that are not considered serious must be documented in the ISF using a signed and dated file note and deviation tracking log, where supplied.

For UHL-sponsored research: the UHL Deviation Tracking Log must be used (R&I Template T-1107) and retained.

Documentation relating to breaches across multiple research locations must be collated centrally by the CI and retained within the TMF together with any associated correspondence, investigations and CAPAs.

4. Monitoring Compliance

What will be measured to monitor compliance	How will compliance be monitored	Monitoring Lead	Frequency	Reporting arrangements
Timely reporting of critical non-compliance and serious breaches in accordance with this SOP	Audit of breach records, EDGE workflows and associated governance records	R&I Head of Quality	As per R&I audit and monitoring schedule	Significant findings reported to R&I Governance Meeting
Breaches appropriately investigated and documented in accordance with this SOP	Audit of a sample of breach records, investigations and associated research records	R&I Head of Quality	As per R&I audit and monitoring schedule	Trends and recurring findings reported to R&I Governance Meeting
Effectiveness of completed CAPAs	Review of follow-up checks, repeat findings, recurring breaches and CAPA effectiveness reviews	R&I Head of Quality	As per R&I audit and monitoring schedule	Trends and recurring findings reported to R&I Governance Meeting

5. Equality Analysis Assessment

The Trust recognises the diversity of the staff and local community it serves. Our aim therefore is to provide a safe environment free from discrimination, harassment and victimisation and treat all individuals fairly with dignity and respect and, as far as is reasonably possible, according to their needs.

As part of its development, an Equality Analysis on this policy has been undertaken and its impact on equality have been reviewed and no detriment was identified.

EDI Statement

We are fully committed to being an inclusive employer and oppose all forms of unlawful or unfair discrimination, bullying, harassment and victimisation.

It is our legal and moral duty to provide equity in employment and service delivery to all and to prevent and act upon any forms of discrimination to all people of protected characteristic: Age, Disability (physical, mental and long-term health conditions), Sex, Gender reassignment, Marriage and Civil Partnership, Sexual orientation, Pregnancy and Maternity, Race (including nationality, ethnicity and colour), Religion or Belief, and beyond.

We are also committed to the principles in respect of social deprivation and health inequalities.

Our aim is to create an environment where all staff are able to contribute, develop and progress based on their ability, competence and performance. We recognise that some staff may require specific initiatives and/or assistance to progress and develop within the organisation.

We are also committed to delivering services that ensure our patients are cared for, comfortable and as far as possible meet their individual needs.

6. Supporting references

UHL Counter Fraud, Bribery & Corruption policy (A1/2010)

R&I Template T-1054: File Note

R&I Template T-1105: Serious Breach Notification Form

R&I Template T-1106: CAPA Form

R&I Template T-1107: Protocol or CIP Deviation Tracking Log

7. Key Words

Research, Innovation, Clinical, Trial, CTIMP, Breach, Serious, Non-compliance, CAPA, Reporting, Critical, Major

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

CONTACT AND REVIEW DETAILS	
Policy Lead: Adam Lewszuk R&I Head of Quality	**Executive Lead:** Professor Nigel Brunskill Director of Research and Innovation
REVIEW RECORD	

This SOP is a merger of the following R&I policies, which are now obsoleted:

- SOP S-1012: *Management and Production of CAPA in Sponsored Research in UHL*
- SOP C-2014: *Management & Production of CAPA for Hosted Research in UHL Research & Innovation*
- SOP S-1013: *Standard Operating Procedure for Identifying and Reporting Deviations and Serious Breaches of GCP and/or the Protocol/ Clinical Investigation Plan for Clinical Trials sponsored by University Hospitals of Leicester NHS Trust (UHL)*
- SOP C-2015: *Identifying & Reporting Deviations / Serious GCP Breaches / Protocol for Hosted Research in UHL*
- SOP S-1016: *UHL Procedure in event of non-compliance*
- SOP C-2013: *Procedure in event of non-compliance for hosted research in UHL*

Guidance updated, monitoring section strengthened and SOP moved to new UHL template.