



**UNIVERSITY OF
LEICESTER**

**University of Leicester and University Hospitals of Leicester NHS
Trust joint Research Support Office Standard Operating Procedures**

**University of Leicester (UoL) Research Governance Office
SOP S-1016 UoL**

**Procedure in the Event of Non-Compliance in Research Sponsored by
University of Leicester**

Version 3.2 September 2023

Office Base

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Effective Date: October 2023

This SOP will be implemented in line with this document's effective date for all UoL Sponsored research still in set up. For active clinical research that is already in the recruitment phase (or further) at the time of implementation, this SOP must be implemented within 3 months of the effective date.

1.0 Introduction

This Standard Operating Procedure (SOP) describes the process for responding to any form of non-compliance identified in research sponsored by the University of Leicester (UoL), including audit findings, protocol and/or regulatory violations, contractual issues, and whistleblowing. This SOP will be referenced and implemented in line with the UoL Research Code of Conduct and the [UK Research and Innovation \(UKRI\) policy on Good Research Practice](#).

2.0 Scope

This SOP applies to all individuals conducting research sponsored by the UoL.

3.0 Definitions

Forms of non-compliance are described as *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 a major non-compliance.
 - Where there are a number of major non-compliances
 - Lack of adequate documentation available to reconstruct the study or failure to maintain an appropriate Trial Master File (TMF).
- A major non-compliance can include instances of:
 - Significant and unjustified non-compliance with relevant legislation or Good Clinical Practice (ICH GCP).
 - A number of breaches of legislation or GCP within one area, indicating systematic quality assurance failure.
 - A failure to comply with legislative requirements including annual reporting requirements.
- Another finding can be identified as:
 - Any other finding that is neither critical nor major.

4.0 Procedure

Non-compliance identified by whatever means, will be investigated using appropriate monitoring and audit processes by the Research Governance Office (RGO). The procedures described below are general, and each instance of non-compliance will be assessed and responded to on a case-by-case basis. Failure to respond to reported non-compliance will result in escalation from other to major to critical. In this instance the issue will be escalated to the UoL Research Sponsorship Committee who will decide an appropriate course of action referencing the UoL Research Code of Conduct.

4.1 Critical Non-Compliance

On identification of a critical non-compliance as defined in section 3 the Chief Investigator/Principal Investigator (CI/PI) will be alerted by the RGO. Depending on the nature of the critical non-compliance, it may be necessary to give a notification by email with an outline of immediate action required. The initial notification will be followed up within 7 calendar days with a detailed report.

Dependent on the nature of the non-compliance the study may be suspended with immediate effect.

The RGO may suspend all studies associated with the CI/PI at their discretion in consultation with the Director of Research and Innovation. Identification of a critical non-compliance may prompt audit and close monitoring of associated studies.

Suspension of the study will be notified by the Sponsor to the Main Research Ethics Committee (REC) via the Health Research Authority (HRA) and the Medicines and Healthcare products Regulatory Agency (MHRA) as appropriate.

The CI must respond within 30 calendar days from the date of receipt of a detailed notification. It is expected that the Corrective Action Preventative Action (CAPA) template as detailed in SOP S-1012 UoL will be used in all cases. This will ensure that the CI explains clearly what action they will take. It is not necessary that all the action will have been taken within the 30 days but it is expected that a plan of completion is outlined. Non-response within this timeframe will lead to suspension of the study in all cases, and possible suspension of associated studies.

If deemed appropriate, submission of a substantial amendment to restart the study will be permitted by the Sponsor once the non-compliance is resolved or adequate plans are in place to prevent repeat incidents.

Studies sponsored by UoL that have been suspended will be closely monitored, prior to restarting, after the first new participant is entered and regularly thereafter until the RGO is satisfied the study is fully compliant.

On identification of a critical non-compliance all research staff will be required to retrain in Good Clinical Practice and to be assessed/reassessed in taking consent.

4.2 Major Non-Compliance

On identification of major non-compliance as defined in section 2 the CI/PI will be alerted by the RGO.

It should be noted that evidence of several major non compliances has the potential to escalate findings to the level of critical non-compliance.

On identification of a major non-compliance the CI/PI will have 30 calendar days in which to respond and complete the CAPA plan. This requires the CI/PI to explain what action they will take, not necessarily take the action at this point.

Failure to respond to notification of major non-compliance within 30 calendar days will constitute a critical non-compliance as per section 3 and may result in suspension of the study.

4.3 Other Non-Compliance

On identification of other non-compliance, that is neither major nor critical as defined in section 3 the CI/PI will be alerted by RGO.

From the date of notification to the CI/PI there will be 30 calendar days in which to formulate an action plan in response to the non-compliance. This requires the CI/PI to explain what action they will take, not necessarily take the action. A CAPA plan must be completed as for 4.1 and 4.2.

Failure to respond to notification of non-compliance will constitute a major non-compliance as per section 3.

5.0 Multi-Centre Studies

Where non-compliance is identified at any site, the Sponsor, in collaboration with the CI and the Research and Development/Innovation (R&D/I) Manager at the site, will manage instances in line with local standard operating procedures. Where specific issues of non-compliance fall outside of local SOPs, the Sponsor SOPs will be used as referenced and may result in the site Sponsor permission being withdrawn.

In cases where the Sponsor SOP is used, the process will be the same as detailed in Section 4, but it is expected that the response be communicated back to the RGO through the CI.


6.0 Responsibilities

Responsibility	Undertaken by	Activity
Chief Investigator/ Principal Investigator	Chief Investigator/ Principal Investigator	The Chief Investigator / Principal Investigator is responsible for ensuring that the study complies with legislation, Good Clinical Practice and the protocol for the study.
Chief Investigator/ Principal Investigator	Chief Investigator/ Principal Investigator	The Chief Investigator / Principal Investigator is responsible for responding to notifications of non-compliance in line with this SOP.
Chief Investigator/ Principal Investigator	Chief Investigator/ Principal Investigator	The Chief Investigator / Principal Investigator is responsible for ensuring the research team are appropriately trained, experienced and qualified to deliver Good Clinical Practice, take informed participant consent and deliver the protocol (see SOP S-1020 UoL Training in Staff Engaged in Clinical Research and SOP S-1021 Informed Consent for Research).
Research Governance Office	Head of Research Governance or delegate	The Research Governance Office will undertake to monitor and utilise quality assurance audit for studies, according to risk assessment which will be influenced by findings of non-compliance.
Research Governance Office	Head of Research Governance or delegate	The Research Governance Office will report non-compliance to the Chief Investigator / Principal Investigator and request response from them.
Research Governance Office	Head of Research Governance and R&D/I Director	The Director of Research and Development / Innovation will take the final decision whether to suspend a study and associated studies.
Head of Research Governance	Head of Research Governance or delegate	The Head of Research Governance, or delegate, will decide when action is sufficient to reinstate a study or studies.
Research Governance Office	Head of Research Governance or delegate	The Head of Research Governance, or delegate, will advise in respect of non-compliance and provide access to GCP training and consent assessment as appropriate.
Research Governance Office	Head of Research Governance or delegate	The Research Governance Office will escalate action if response is insufficient.

Responsibility	Undertaken by	Activity
Research Governance Office	Head of Research Governance or delegate	The Research Governance Office will undertake close monitoring and audit of reinstated studies.

7.0 Development and approval Record for this document

This table is used to track the development and approval of the document.

Author	Job title	Reviewed by	Approved by	Date approved
Cat Taylor	Head of Research Governance	UoL Research Management and Operations Group (RSMOG)	Professor Nigel Brunskill 	28.09.2023

8.0 Review Record

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
July 2015	2	Wendy Gamble	Changes of logo front page and minor changes to bring in line with UHL SOP.
Oct 2016	3	Wendy Gamble	Addition of HRA process and correction of text relating to fraud and misconduct SOP, replacing with rewording to reference the University Code of Conduct, plus minor administrative changes.
Sept 2021	3.1	Cat Taylor	Administrative changes
September 2023	3.2	Cat Taylor	Administrative changes Removal of distribution record Addition of reference to the UK Research and Innovation (UKRI) policy on Good Research Practice.