LOUGHBOROUGH UNIVERSITY RESEARCH OFFICE
STANDARD OPERATING PROCEDURE

Loughborough University (LU) Research Office
SOP–1016 LU

Procedure in the Event of Non-Compliance in NHS Research Sponsored by Loughborough University

Effective Date: January 2016

1.0 Introduction

This Standard Operating Procedure (SOP) describes the process of responding to any form of non-compliance identified in research sponsored by Loughborough University (LU), including audit findings, protocol violations, contractual issues, and whistleblowing not requiring implementation of the University's Whistleblowing and/or Research Misconduct Policies. .

2.0 Definitions

Forms of non-compliance are described as c*ritical, 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.

- 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.

- Any other finding can be identified as :
  - Any other finding that is neither critical nor major.

3.0 Procedure

Non-compliance identified by whatever means, will be investigated using appropriate monitoring and audit processes by the Research Office. 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, and finally by referral to the University's Whistleblowing or Research Misconduct Policies.

Critical Non-Compliance
On identification of a critical non-compliance as defined in section 2 the Chief Investigator/Principal Investigator (CI/PI) will be alerted by the Research Governance Officer.

Dependent on the nature of the non-compliance the trial may be suspended.

The Research Governance Officer may suspend all trials associated with the CI/PI at their discretion in consultation with the Director of the Research Office and Chief Operating Officer. Identification of a critical non-compliance may prompt audit and close monitoring of associated trials.

Suspension of the trial will be notified by the Sponsor to the Main Research Ethics Committee (REC) as a substantial amendment.

From the date of notification to the CI/PI there will be one month 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. Non-response in this timeframe will lead to suspension of the trial in all cases, and possible suspension of associated trials.

Submission of a significant amendment to restart the trial will be permitted by the Research Governance Officer once they are satisfied that the non-compliance is resolved.

Trials sponsored by LU that have been suspended will be closely monitored, prior to restarting, after the first new participant is entered and regularly thereafter until the Research Governance Officer is satisfied the trial is fully compliant.

Major Non-Compliance

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

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 one month in which to respond and complete the CAPA (corrective action preventative action) 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 will constitute a critical non-compliance as per section 2 and may result in suspension of the trial.

Other Non-Compliance

On identification of other non-compliance, that is neither major nor critical as defined in section 2 the CI / PI will be alerted by Research Governance Officer.

From the date of notification to the CI/PI there will be one month 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.

Failure to respond to notification of non-compliance will constitute a major non-compliance as per section 2.

Multi-Centre Studies

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

4.0 Responsibilities

	Responsibility Undertaken by		Activity
1	Chief Investigator/ Principal Investigator	Chief Investigator/Principal Investigator	The Chief Investigator / Principal Investigator is responsible for ensuring that the trial complies with legislation, Good Clinical Practice and the protocol for the trial.
2	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.
3	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 take informed participant consent and deliver the protocol (see SOP 1021 LU Informed Consent for Research)
4	Research Office	Research Governance Officer or delegate	The Research Governance Officer will undertake to monitor and utilise quality assurance audit for trials, according to risk assessment which will be influenced by findings of non-compliance

	Responsibility Undertaken by		Activity
5	Research Office	Research Governance Officer or delegate	The Research Governance Officer will report non-compliance to the Chief Investigator / Principal Investigator and request response from them
6	Research Office	Research Office/COO	The Research Office/COO will take the final decision whether to suspend a trial and associated trials
7	Research Governance Manager	Research Office	The Research Office will decide when action is sufficient to reinstate a trial or trials.
8	Research Office	Research Governance Officer or delegate	The Research Governance Officer will advise in respect of non-compliance and GCP training and consent assessment as appropriate.
9	Research Office	Research Governance Officer or delegate	The Research Governance Officer will escalate action if response is insufficient.
10	Research Office	Research Officer	The Research Office will undertake close monitoring and audit of reinstated trials.

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:	Jackie Green	**Job Title:** Research Governance Officer
Approved by:	**Ethics Committee**	**Date Approved: 5/2/16**

REVIEW RECORD			
Date	**Issue Number**	**Reviewed By**	**Description Of Changes (If Any)**

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