



**UNIVERSITY OF LEICESTER
&
UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST**

JOINT RESEARCH SUPPORT OFFICE

STANDARD OPERATING PROCEDURES

**University of Leicester (UoL) Research Governance Office
SOP S-1029 UoL**

Version 3.1, September 2021

**Urgent Safety Measures for Studies Sponsored by University of
Leicester**

OFFICE BASE

Research Governance Office
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1. INTRODUCTION

This SOP details the procedures to be followed by the Sponsor, Chief / Principal Investigators or research teams where Urgent Safety Measures (USM) are required to protect study subjects against any immediate hazard to their health and / or safety.

An USM can be defined as any action required to be taken by the Sponsor and / or Investigator(s) to protect study subjects from any immediate hazard to their health and / or safety.

2. SCOPE

This SOP applies to all staff, and any external individual who are associated with any research activity where the UoL are acting as the Sponsor organisation.

3. PROCEDURE

USM should be implemented immediately. Notification and / or approvals are not required prior to their implementation but must be actioned immediately afterwards.

3.1 When Urgent Safety Measures may be required

- An increase in the rate of occurrence of an expected Serious Adverse Reaction (SAR) which is judged to be clinically important.
- Single case reports of an expected SAR with an unexpected outcome (e.g. a fatal outcome).
- A new event relating to the conduct or the development of an Investigational Medicinal Product (IMP) likely to affect the safety of the subjects.
- A serious event which could be associated with the study procedures and which could modify the conduct of the trial.
- A lack of efficacy of an IMP used for the treatment of a life-threatening disease.
- An organisation identifies that there is a significantly higher incidence of death at one UK site and as a result suspends recruitment at that site.

4. REPORTING REQUIREMENTS

The Chief Investigator (CI) or their delegate must notify the Sponsor by telephone, followed up by an email of the USM at the same time or immediately after notifying the MHRA. In addition, where the USM involves an IMP, the CI / delegate must notify Pharmacy by telephone, followed up by an email copied to the Sponsor.

4.1 MHRA Notification (Competent Authority)

The CI / delegate must inform the MHRA immediately and in any event within three (3) days that the USM(s) have been taken and the reason why.

The CI / delegate must phone the Clinical Trial Unit at the MHRA and discuss the issue. The discussion must be recorded using the Urgent Safety Measures Template (Appendix 1). Should further clarification be required the CI / delegate will be contacted by a MHRA Medical Assessor.

The CI / delegate must then contact the Sponsor to give a full appraisal of the conversation with the MHRA. Documentary evidence of this conversation will be required using Appendix 1.

The CI / delegate must work closely with the Sponsor to notify the MHRA and the REC, in writing, of the measures taken and the reason for the measures within three (3) days.

The notification must include:

- A covering letter detailing the measures taken and the reason for them
- Annex II substantial amendment form
- IRAS Substantial amendment form
- Any supporting documentation
- Relevant fee (where appropriate)

Submission details can be found on the [MHRA website](#)

Details of the Urgent Safety measure, copy of the written notification to the MHRA and a completed Urgent Safety Measures Template (Appendix 1) must be saved in the Trial Master File with copies to the Sponsor.

4.2 Research Ethics Committee (REC)

The CI / delegate must inform the REC immediately and in any event within three (3) calendar days that USM have been taken and the reason why they have been taken.

The initial notification to the REC must be by telephone. Notice in writing must then be sent within three calendar (3) days setting out the reasons for the USM and the plan for further action. Where the study involves an IMP the same documentation submitted to the MHRA may also be submitted to the REC.

The REC is not required to approve USM, however the Committee will review such notifications and consider whether the measures taken are appropriate in relation to the potential risk to the subjects, and will consider the further action proposed by the Sponsor and Investigator i.e. the submission of substantial amendments to the protocol.

Details of the USM, copy of the written notification to the REC and a completed Urgent Safety Measures Template (Appendix 1) must be saved in the Trial Master File with copies to the Sponsor.

4.3 Notification of sites in Multicentre studies

The CI / delegate must inform all Principal Investigators (PIs) at all collaborating sites of the USM immediately, or within a maximum of three (3) calendar days of the USM being taken. Notification must be in writing by email and must detail the required actions to be taken by the PIs at each site and must be copied to the Sponsor.

Written confirmation that these actions have been taken by the PIs at each collaborating site must be obtained by the CI / delegate within three (3) calendar. Email confirmation is acceptable.

The CI / delegate must confirm receipt of acknowledgement that the measures have been taken by the collaborating site(s) within (3) calendar days of notification.

Details of collaborating sites notification and acknowledgement must be documented on the Urgent Safety Measures Template (Appendix 1).

4.4 Notifying Study Participants

The study participants must be informed of the USM and given the option to continue in the trial with the modified trial procedures or withdraw from the trial. Study participants may be contacted initially by phone and then informed in writing of the rationale for the USM and the steps taken or new procedures required to minimise the risk.

All correspondence must be documented in the participant medical notes, Urgent Safety Measures Template (Appendix 1), and where applicable in the Case Report Form.

Participants who are willing to continue in the study, must be re-consented. A full record of all communication with participants must be maintained.


5. RESPONSIBILITIES

	Responsibility	Undertaken by	Activity
1	Chief Investigator	Chief Investigator or their Delegate	Notify Sponsor via UoL Research Governance Office on identification of the requirement for urgent safety measures implementation
2	Chief Investigator	Chief Investigator or their Delegate	Notify Pharmacy on identification of the requirement for urgent safety measure implementation
3	Chief Investigator	Chief Investigator or their Delegate	Notification of the REC and MHRA immediately but within 3 days of urgent safety measures being implemented
4	Chief Investigator	Chief Investigator or their Delegate	Completion of Urgent Safety Measure Template
5	Chief Investigator	Chief Investigator or their Delegate	Notify all PIs at all sites giving details of the urgent safety measures required, and obtaining confirmation that appropriate action has been taken
6	Chief Investigator	Chief Investigator or their Delegate	Keep the Sponsor informed at each stage

	Responsibility	Undertaken by	Activity
7	Principal Investigator	Principal Investigator or their Delegate	Implement Urgent Safety Measures at site, and confirm implementation to Chief Investigator
8	Chief Investigator & Principal Investigators	Chief Investigator & Principal Investigators at their site	Notify participants of Urgent Safety Measures, document conversations and re-consenting

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:	Cat Taylor
Job Title:	Head of Research Assurance
Reviewed by:	Research Sponsorship Management and Operations Group
Approved by:	Professor Nigel Brunskill 
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Review Record

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
July 2015	2	Wendy Gamble	Clarification of number of calendar days throughout document.
Oct 2016	3	Diane Delahooke	Change logo and address. Minor changes to bring in line with UHL.
September 2021	3.1	Cat Taylor	Administrative changes

Distribution Record

Date	Name	Department	Received