LOUGHBOROUGH UNIVERSITY RESEARCH OFFICE
STANDARD OPERATING PROCEDURE

Loughborough University (LU) Research Office
SOP–1029 LU

Urgent Safety Measures for NHS Research Sponsored by Loughborough University

Effective Date: January 2016

1.0 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.

2.0 Scope

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

3.0 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 serious event which could be associated with the study procedures and which could modify the conduct of the trial.

- 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

4.0 Reporting Requirements

The Chief Investigator (CI) or their delegate must notify the Sponsor by telephone, followed up by an email of the USM.

4.1 Research Ethics Committee (REC)

The CI / delegate must inform the REC immediately and in any event within three (3) 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 (3) days setting out the reasons for the USM and the plan for further action.

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 A) must be saved in the Trial Master File with copies to the Sponsor.

4.2 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 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. Email confirmation is acceptable.

The CI / delegate must confirm receipt of acknowledgement that the measures have been taken by the collaborating site(s)**.**

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

4.3 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 minimize the risk.

All correspondence must be documented in the participant medical notes, Urgent Safety Measures Template (Appendix A), 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 LU Research Governance Officer 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 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
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:	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**

Appendix A

Urgent Safety Measures Template

An Urgent Safety Measure (USM) is an action that the Sponsor and/or Investigator may take in order to protect the subjects of a trial against immediate hazard to their health and/or safety. Reporting of an USM must be undertaken in accordance with SOP-1029 LU-Urgent Safety Measures for Studies sponsored by the Loughborough University.
The REC must be notified immediately and in any event, within 3 days that such a measure has been taken and the reason why it has been taken. The initial notification to the REC should be by telephone. A further notice in writing must be sent within 3 days.

This form is to be completed and submitted to the Research Office and a copy retained in the Trial Master File/ Investigator Site file

Trial Name	
EudraCT number	
REC Number	
Sponsor Number	
Chief Investigator	
Sponsor Green Light Date	
Protocol Version and Date	
Date Sponsor made aware of Event	
Date Pharmacy made aware of Event (if applicable)	
Reason for Report: Detailed description of event. *In this section include details of the site location, who was involved and the nature of the event.*	
Site number PI Name Details of event	

Designated representative contact with REC *In this section give details of person making contact with the REC including their name and role.*		
Contact made by	Name of REC representative	Date of contact
Name(print)		--/---/----
Role		
Comments/outcome of discussion with REC		

Summary of discussions/agreed actions –
Summarise here the agreed corrective/preventative actions and the plan for further amendments.

Corrective Preventative Action:

Date of written submission to REC --/---/----

List here any relevant documents/correspondence specifically related to the urgent safety measure and their location.

Multicentre studies notification Applicable Yes/No
If Yes, list here site names and dates of notification and acknowledgement

Site Name	Date of Notification --/---/----	Date Actions Confirmed --/---/----
Site Name	Date of Notification --/---/----	Date Actions Confirmed --/---/----
Site Name	Date of Notification --/---/----	Date Actions Confirmed --/---/----
Site Name	Date of Notification	Date Actions Confirmed

	--/---/----	--/---/----
Site Name	Date of Notification --/---/----	Date Actions Confirmed --/---/----
Add extra sites if applicable		
Information given to Participant *Provide details of any information given to participant, including the date given*		
Verbal: Written:		
Contact made by Print Name Role:	Sign	Date --/---/----

Form Completed by		
Print Name	Sign	Date
Role		--/--/----