

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 S-1029 UOL-Urgent Safety Measures for Studies sponsored by the University of Leicester.

The MHRA and 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 MHRA and 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 UoL Research Governance 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. <i>In this section include details of the site location, who was involved and the nature of the event.</i>		
Site number	PI Name	
Details of event		
Designated representative contact with MHRA <i>In this section give details of person making contact with the MHRA including their name and role.</i>		
Contact made by – Name (print)	Name of MHRA Contact	Date of contact
Role -		--/---/----
Comments/outcome of discussion with MHRA Assessor		

Designated representative contact with REC <i>In this section give details of person making contact with the REC including their name and role.</i>		
Contact made by	Name of REC representative	Date of contact
Name(print)		--/---/----
Role		
Comments/outcome of discussion with REC		
Summary of discussions/agreed actions – <i>Summarise here the agreed corrective/preventative actions and the plan for further amendments.</i>		
Corrective Preventative Action:		
Date of written submission to MHRA --/---/----	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		
<i>If Yes, list here site names and dates of notification and acknowledgement</i>		
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		
<i>Provide details of any information given to participant, including the date given</i>		
Verbal:		
Written:		
Contact made by Print Name Role:	Sign	Date --/---/----

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