**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 S-1026 Urgent Safety Measures for Studies sponsored by the University Hospitals of Leicester NHS Trust.

The MHRA, HRA 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 UHL Research Office and a copy retained in the*

*Trial Master File/ Investigator Site file*

|  |  |
| --- | --- |
| Trial Name |  |
| EudraCT number  |  |
| IRAS/ 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 NameDetails of event |
| Designated representative contact with MHRA*In this section give details of person making contact with the MHRA including their name and role.*  |
| Contact made by – Name (print) | Name of MHRA Contact | Date of contact |
| Role - |  | --/---/---- |
| Comments/outcome of discussion with MHRA Assessor |  |  |

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| --- |
| Designated representative contact with MREC*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 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  *If Yes, list here site names and dates of notification and acknowledgement* |
| Site Name | Date of Notification--/---/---- | Date of Acknowledgement--/---/---- |
| Site Name | Date of Notification--/---/---- | Date of Acknowledgement--/---/---- |
| Site Name | Date of Notification--/---/---- | Date of Acknowledgement--/---/---- |
| Site Name | Date of Notification--/---/---- | Date of Acknowledgement--/---/---- |
| Site Name  | Date of Notification--/---/---- | Date of Acknowledgement--/---/---- |
| 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 byPrint NameRole: | Sign | Date --/---/---- |

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