**Urgent Safety Measures (USM) Reporting Form**

*This form is to be completed and submitted to* *rgsponsor@le.ac.uk* *and a copy retained in the*

*Trial Master File/Investigator Site file*

# 1.0 Generic Study Details

|  |  |
| --- | --- |
| IRAS number |  |
| Chief Investigator Name |  |
| Chief Investigator Email |  |
| Chief Investigator Telephone Number |  |

# 2.0 Site Details

This section relates to the site where the hazard occurred leading to the implementation of the USM.

|  |  |
| --- | --- |
| Site Name/Number |  |
| Principal Investigator Name |  |

# 3.0 Details of the Hazard/Event

|  |  |
| --- | --- |
| Date and Time Hazard Identified |  |
| Date Urgent Safety Measure Implemented |  |
| Date Chief Investigator made aware of the Event |  |
| 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 who was involved, the circumstances giving rise to the urgent safety measure and the measures taken* |
|  |

# 4.0 Chief Investigator/delegates assessment

In this section, please confirm the Chief Investigator’s assessment of the impact of the hazard on the health and safety of study participants and the action required.

Impact;

[ ] Participant safety

[ ] Participant Confidentiality

[ ] Reaction to IMP/Intervention

[ ]  Other, please specify in the box below:

Action;

[ ] Requires site level USM

[ ] Requires study-wide USM

[ ] Requires a Temporary Halt

[ ] Other, please specify in the box below

In the box below please detail the CI assessment of impact and required actions if ‘Other’ has been selected above and add further details relating to;

* *Details of the measures taken and the reasons for taking these measures*
* *Any telephone conversations (time/date)*
* *Who contributed to the decisions taken? Any Independent Medical Assessor?*
* *Any further supporting information*

# 5.0 Designated representative contact with the MHRA

*In this section give details of person making contact with the MHRA including their name and role.*

|  |  |
| --- | --- |
| Name of Investigator who contacted the MHRA  |  |
| Role |  |
| Name of MHRA Contact |  |
| Date of telephone contact (dd/mm/yyyy) |  |
| Comments/outcome of discussion with MHRA Assessor including any agreed actions |
|  |
| Date of written submission to MHRA (dd/mm/yyyy) |  |

# 6.0 Designated representative contact with REC

*In this section give details of person making contact with the REC including their name and role.*

|  |  |
| --- | --- |
| Name of Investigator who contacted the REC |  |
| Role |  |
| Name of REC representative |  |
| Date of telephone contact ((dd/mm/yyyy) if applicable) |  |
| Comments/outcome of discussion with REC including any agreed action |
|  |
| Date of written submission to REC (dd/mm/yyyy) |  |

# 7.0 Multicentre studies notification

Applicable [ ] Yes [ ] No

*If Yes, list here site names and dates of notification and acknowledgement*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Site Name** | **Date of Notification (dd/mm/yyyy)** | **Date Site R&D/I office notified (dd/mm/yyyy)** | **Date site Pharmacy notified (if applicable)****(dd/mm/yyyy)** | **Date Actions Confirmed (dd/mm/yyyy)** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

*Add more rows to the table as required*

# 8.0 Information given to Participant(s)

*Provide details of any information given to participant(s), including the date given and ID number(s). If easier repeat the table per participant.*

|  |
| --- |
| Verbal:Written: |
| Name of investigator who contacted the Participant(s) |  |
| Signature |  |
| Date |  |

# 9.0 Form Completed by

|  |  |
| --- | --- |
| Print Name |  |
| Role |  |
| Signature |  |
| Date |  |