Serious Adverse Event - report form B

(For all UoL sponsored studies excluding clinical trials of investigational medicinal products)

**This form must be sent to rgosponsor@le.ac.uk within 24 hours of the research team becoming aware of the Serious Adverse Event**

**N.B. If the event is a pregnancy it should be reported on a UoL Pregnancy Notification Form**

# Study Details

| **Information Requested** | **Response** |
| --- | --- |
| Sponsor reference number |  |
| Study title or Acronym |  |
| Centre name or number |  |
| Chief Investigator |  |
| Principal Investigator |  |

# Participant Details

| **Information Requested** | **Response** |
| --- | --- |
| Participant ID |  |
| Participant initials |  |
| Participant **year** of birth |  |

# Report / event overview

| **Information Requested** | **Response** |
| --- | --- |
| Type of report *(select one box only)* | [ ]  Initial[ ]  Initial & final[ ]  Follow-up Number (Note if this is the first follow-up report enter 1): [ ]  Final  |
| Date of report *(dd/mm/yyyy)* |  |
| Title of Serious Adverse Event  |  |
| Is the event an Adverse Event of Special Interest (AESI)?(Please note some studies have specific forms for AESI reporting. Where this is the case complete the study specific AESI reporting form in place of this SAE reporting form.)  | [ ]  Yes[ ]  No |
| Has the title been updated since the initial report? | [ ]  Yes[ ]  No |
| Date of onset of symptoms *(dd/mm/yyyy)* |  |
| Date event became serious *(dd/mm/yyyy)* |  |
| Date study team became aware *(dd/mm/yyyy)* |  |

# Serious criteria

 (This should not change throughout the course of the SAE, the outcome of the SAE is recorded in Section 10)

| **Information Requested** | **Response** |
| --- | --- |
|  Please select the most relevant criteria which categorises this event as serious (select on box only) | [ ]  Resulted in death[ ]  Life threatening [ ]  In-patient hospitalisation or prolongation of existing hospitalisation [ ]  Persistent or significant disability/incapacity[ ]  Congenital anomaly/birth defect [ ]  Other (please specify e.g. AESI): |

# Narrative

| **Information Requested** | **Response** |
| --- | --- |
| Was the participant admitted to hospital? | [ ]  YesDate of admission *(dd/mm/yyyy)*:Date of discharge *(dd/mm/yyyy)*:[ ]  No |
| Describe the event *(please include information on how and when the research team became aware of the event any sequelae and attach any relevant pseudonymised supporting documentation such as medical reports, lab results and discharge summaries. Add continuation pages if needed)* |  |
| Please list any treatment given for the SAE |  |
| Please provide any relevant medical history |  |

## 5.1 Concomitant medication at time of event

| **Name of Medication** | **Indication (s) for Use** | **Dose** | **Date of First Administration** *(dd/mm/yyyy)* | **Date of Last Administration** *(dd/mm/yyyy)* |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

# Event Severity

|  **Information Requested** | **Response** |
| --- | --- |
| What is the severity of the event? *(Select one box only)* | [ ]  Mild[ ]  Moderate[ ]  Severe |

# Causality and Expectedness

**\*\*This question must be completed by the Principal Investigator or a qualified and delegated medic only, if not available at the time of reporting leave blank\*\***

| **Information Requested** | **Response** |
| --- | --- |
| Was the event related to a study procedure or intervention? | [ ]  Yes[ ]  No |
| If yes, is the event expected and what is your assessment of the implications, if any, for the safety of study participants and how will these be addressed? If no, mark as not applicable.  |  |

# Protocol Deviation

| **Information Requested** | **Response** |
| --- | --- |
| Was the event related to a protocol deviation? | [ ]  Yes *(please document on the protocol deviation log and complete a file note)*[ ]  No |

# Participant Withdrawal

| **Information Requested** | **Response** |
| --- | --- |
| Was the participant withdrawn from the study as a result of this event? | [ ]  Yes[ ]  No |

# Outcome

| **Information Requested** | **Response** |
| --- | --- |
| What is the outcome of the event? *(Select one box only)* | [ ]  ResolvedDate of resolution: [ ]  Resolved with SequelaeDetails of sequelae: [ ]  On-going[ ]  Unknown at present[ ]  Fatal  |

## 10.1 Fatal details

Complete this section if the event resulted in fatality, if not leave blank.

| **Information Requested** | **Response** |
| --- | --- |
| Date of death |  |
| Cause of death |  |
| Where was the cause of death obtained from?\* *(Select one box only)*\* **Redacted** supporting documentation to be supplied with SAE | [ ]  Working Diagnosis [ ]  Coroner’s Inquest [ ]  Death Certificate |

# Reporting persons

**\*Signatures should be ‘wet ink’ or, if electronic, needs to be an approved/verifiable eSignature e.g. via Adobe Sign or DocuSign. We cannot accept unverifiable electronic signatures on SAE reports for inspection purposes. If Adobe Sign or DocuSign are not available and the form has been completed electronically, please print a copy prior to signing. If it is not possible to obtain a ‘wet ink’ signature please send an unsigned document to** **rgosponsor@le.ac.uk** **and we can facilitate digital signatures via Adobe Sign.**

| **Information Requested** | **Reporting person**  | **Principal Investigator/delegated medically qualified individual as agreed by the Sponsor** |
| --- | --- | --- |
| Name |  |  |
| Role |  |  |
| Signature**\*** |  |  |
| Date |  |  |
| Contact Number or email |  |  |

# Assessment of relatedness of event

To be completed by the PI or delegated individual who assessed the relatedness of the event to the study procedure or intervention.

*I confirm that the relatedness of this event was assessed by myself and I have been delegated this task as per the Delegation of Authority Log.*

| **Information Requested** | **Response** |
| --- | --- |
| **Name** |  |
| **Signature** |  |

Please return the completed form and copies of any additional anonymised documents to the Research Governance Office, by email via rgosponsor@le.ac.uk

Reporting and completion of SAEs not involving investigational medicinal products must be undertaken in accordance with SOP S-1009 UoL Processing and Reporting of Serious Adverse Events, Serious Adverse Reactions and Suspected Unexpected Serious Adverse Reactions for all Research Sponsored by the University of Leicester