Serious Adverse Event Report Form B

For all studies EXCLUDING clinical trials of investigation medicinal products Guidance Document

This form is for the reporting of Serious Adverse Events in studies that **DO NOT** involve Investigational Medicinal products. **If your study involves Investigation Medicinal products you must use SAE Form A**

All Serious Adverse Events **MUST** be reported within 24 hours of the research team being aware of the event. The initial report may be submitted without a PI signature, but must be followed up with a signed copy within 7 days.

Once a signed initial report is received a follow up or final report should be submitted within 28 days. If the participant is still an inpatient or there is an unavoidable delay in the provision of further information, inform the Sponsor at the Research and Innovation office.

Should there be a requirement for clarification or further information required; an email detailing the request will be sent. Response to the request is required as per the timelines stated in the email.

Sponsor Reference Number	Study identifier given by the Sponsor. This can be found on the Sponsor green light letter. This MUST be given to enable Sponsor to identify the Trial.
Study Title	Full or short version of the study title as entered on the IRAS form
Study Number/Initials	Enter unique subject identifier and subjects initials.
Centre	Enter centre name.
	NO OTHER PARTICIPANT IDENTIFIABLE DATA MUST BE ENTERED ON THIS FORM
1. Type of Report	**Initial Report** The first time you are reporting this event. This may be a signed or unsigned report. At this time point either, not all details are available, the form is unsigned, or the event is marked as ongoing. **Follow Up Report** Follow up information to an initial report, is provided in this report. The event may still be marked as ongoing or resolved. If ongoing, further reports must be submitted until the resolution of the event. **Final report** When all follow up information is available for this Serious Adverse Event and the outcome for the event has been completed.

Initial and Final
All information on the SAE and outcome of the event are complete on the first submission of the SAE report.

Date of Report
Date SAE report completed.

Title of Serious Adverse Event
Enter keywords that best summarise the event .e.g. admission for chest pain.
Multiple Serious adverse events MUST be reported on individual forms.

Date of Onset
Date of onset of the event reported. If a full date is not known either on the first or subsequent reports then UNK/ Month /Year should be completed.

Date study Team Aware
The date that the event was reported to/or the study team became aware of the event. **The SAE must be submitted within 24hours of this date**

2. Seriousness Criteria

Choose from the indicated menu.
If there is more than one criteria, choose the **most significant** one.
Multiple Serious Adverse Events MUST be reported on individual forms.

3. Narrative

Provide admission and discharge date information if applicable

Provide an account of the event, similar to that of a discharge summary. The description must have sufficient details for evaluation by the individuals reviewing the SAE, who may not be experts in the disease area. Abbreviations of clinical conditions should not be used. Summarise any relevant laboratory or diagnostic tests. Include details of discharge if appropriate.

Assessment of implications – if the event is related to a study device or procedure or intervention. Document the safety implications and how these will be addressed i.e. protocol amendment.
If not relevant mark in box as not applicable

4. **Was the Event related to a study Device/procedure or intervention**

Answer Yes or No box as appropriate. If Yes - provide further information to the Sponsor.

***If the SAE is related to the research procedures and is unexpected. An HRA Serious Adverse Event form must be submitted to the Research Ethics Committee that gave a favourable opinion of the research within 15 days of the CI becoming aware of the event**.
Website:http://www.hra.nhs.uk/resources/during-and-after-your-study/progress-and-safety-reporting/

5. **Event related to protocol violation** Answer Yes or No.
If Yes - Further information should be supplied on a separate protocol deviation form/File note.

6. **Participant Withdrawn** Answer Yes or No

7. **Outcome**

Resolved- The Serious Adverse Event is no longer present e.g.participant has been hospitalised/prolongation of hospitalisation, received relevant treatment and the event has been resolved. Provide details of the date of resolution of the SAE.

Resolved with Sequelae. The Serious Adverse Event is resolved but there are still some residual problems as a result of the SAE . e.g. The participant was hospitalised for a DVT and discharged home on warfarin. The participant no longer requires hospital treatment but the pre-existing event continue.

Ongoing – The Adverse Event has not resolved at this time.
This will require follow up until resolution of event.

Unknown at Present- Information is not available at the present time Further information **MUST** be supplied until resolution of event.

Fatal- Where the event is fatal; details of the date of death and the cause of death **MUST** be obtained.

Cause of death obtained- detail where the information was obtained to support cause of death. Supporting documents to be supplied with SAE

Note* All supporting documentation must have all patient identifiable data removed. The documents MUST only be identified with the addition of the participant study ID and Initials.

Reporting Person Supply full details as indicated of person reporting the event. Please ensure contact phone number and email address are complete.

Principal Investigator/Delegated Medically Qualified Individual Supply full details.
Please note* the person signing this form must either be the Principal Investigator or a medically qualified individual as agreed by Sponsor to undertake this role. The person must be named and delegated the duty on the delegation of authority log.

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

Please return the completed form and any anonymised copies of supporting documents to the Research and Innovation Office, Leicester General Hospital by email to RIAdmin@uhl-tr.nhs.uk

If you have queries regarding your SAE submission, please contact the Research and Innovation Office . Contact details can be found on the UHL Website.
http://www.leicestersresearch.nhs.uk