Serious Adverse Event Report Form A

UHL Sponsored Clinical Trials of Investigational Medicinal Products

Guidance Document

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 reporting expectedness and causality within 7 days.

Once a signed initial report is received a follow up or final report should be submitted within 28 day. If the participant is still an inpatient or there is an unavoidable delay in the provision of further information, inform the R&I 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 dictated in the email.

Sponsor Ref	Study identifier given by the R&I department. This MUST be documented to enable the R&I office to identify the study.
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 you are completing this report. (Initial, Follow-up or Final)

Title of the Serious Adverse Event
Enter keywords that best summarise the event. i.e. 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 24 hours of this date.**

2. Seriousness Criteria

Choose from the 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

If the SAE is due to an admission to hospital, provide the admission and discharge dates. 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 or investigational medicinal products. Abbreviations of clinical conditions should not be used. Summarise any relevant laboratory or diagnostic tests. Include details of discharge if appropriate.

4. Causality and Expectedness

This section must be completed by the Principal Investigator or other delegated medically qualified investigator, **as agreed by the Sponsor,** and delegated this role on the Delegation of Authority and signature Log by the Principal Investigator.

All Investigational drugs should be entered and their causal relationship and expectedness, or not, **MUST** be reported.

If more than two drugs are under investigation an additional section can be added.

Study Drug 1 Enter details of IMP involved.

Evaluation of Causal relationship to drug – Mark relevant box

Related – if the causal relationship between study drug 1 and the SAE is at least a reasonable possibility i.e. the relationship cannot be ruled out

Not Related-If there is no causal relationship between study drug 1 and the SAE i.e. the event is caused by something other than the IMP e.g. underlying disease, a concomitant medication

Expectedness

The assessment of expectedness must be based on the information contained in the approved Reference Safety Information (RSI) e.g. Investigator Brochure and/or the Summary of Product Characteristics

Expected- The event is an expected reaction based on the information contained in the Investigator Brochure and/or Summary of Product Characteristics.

Unexpected The event is unexpected based on the information contained in the Investigator Brochure and/or Summary of Product Characteristics.

Study Drug 2 Enter second drug completing all details as above

If the event is related and unexpected it is a Suspected Unexpected Serious Adverse Reaction (SUSAR) and requires expedited reporting. Inform the R&I office immediately Telephone number 0116 258 8351

5. Is the study drug Blinded or Unblinded Detail if the study drug(s) the participants are receiving are known to the Investigator research team or are the research team blinded.

<u>If a SUSAR has been reported, blinded studies must be unblinded as per unblinding procedure.</u>

6. Event related to protocol violation Answer Yes or No.
If Yes - Further information should be supplied on a separate protocol deviation form.

7. Study Medication Information Answer Yes or No.
If Yes – Further information on when the study drug was given should be documented in the table provided within the form

8. Action taken with IMP Please indicate action taken.
If participant not taking IMP at time of event mark as not applicable.

9. Participant Withdrawn Answer Yes or No

10. Outcome

Resolved The Serious Adverse Event has resolved. e.g. participant has been hospitalised, received treatment and the event has been resolved. Provide details of the date of resolution of the SAE.

Resolved with Sequalae The Serious Adverse Event is resolved but there are still some residual problems as a result of the SAE e.g. the patient hospitalised for DVT and then discharged on warfarin. The

participant no longer requires hospital treatment but the pre-existing event continues.

Ongoing – The 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 participant 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 be either the Principal Investigator or a medically qualified individual as agreed by the 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 involving investigational medicinal products must be undertaken in accordance with SOP S-1009 UHL – 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

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 Clinical Trial Monitoring and training team. Contact details can be found on the R&I Website. http://www.leicestersresearch.nhs.uk