

Serious Adverse Event/Effect Report Form C

UoL Sponsored Medical Device Studies

Guidance Document

All Serious Adverse Events and Serious Adverse Device Effects MUST be reported within 24 hours of the research team becoming aware of the event.

The initial report may be submitted without a PI/delegated medically qualified individual (as agreed by the Sponsor) 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 days. If the patient is still an inpatient or there is an unavoidable delay in the provision of further information, inform the Research Governance 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 Research Governance Office. This MUST be documented to enable the Research Governance Office to identify the study.
IRAS Ref	IRAS reference can be located on HRA approval letter.
MHRA Ref	MHRA Reference number can be located on Clinical Trial Authorisation document.
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.
Site	Enter site name.

NO OTHER PATIENT IDENTIFIABLE DATA MUST BE ENTERED ON THIS FORM

1. Type of Report Tick one box only

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 and outcome of the event are complete on the first submission of the report.

Date of Report

Date you are completing this report. If you are sending amended, follow-up or final reports, please ensure that you are using the current date and are not back-dating reports to the date on the report from the original submission.

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 UK/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/SADE must be submitted within 24 hours of this date.**

Time Team Aware

Where possible the time that study team were made aware should be entered. If this is not known mark as unknown (UK).

Date Reported to MHRA

All reportable events as detailed in SOP S-1043 where there is an imminent risk of death, serious injury, or serious illness and that requires prompt remedial action for other patients must be reported to the MHRA immediately but no later than 2 calendar days after becoming aware of the event. Any other reported event must be reported immediately, but no later than 7 calendar days after becoming aware of the event.

Date Reported to REC

All reportable events as detailed in SOP S-1043 should be reported to the REC within 15 days of becoming aware of the event.

2. Event

Enter keywords that best summarise the event

3. Seriousness Criteria

Choose one box only from the menu. If there is more than one criteria, choose the **most significant** one. Multiple Serious Adverse Event/Effects **MUST** be reported on individual forms.

4. Narrative

If the SAE/SADE is due to an admission to hospital, provide the admission and discharge dates (if known). 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/SADE, who may not be experts in the disease area or investigational medicinal/device products. Abbreviations of clinical conditions should not be used. Summarise any relevant laboratory or diagnostic tests. Include details of discharge if appropriate and if known.

Where applicable enter date of admission and date of discharge if known.

5. Study Medical Device Information

Indicate by ticking the box, if applicable whether or not the subject has been fitted with/used or treated with the device.

If Yes: Complete boxes to indicate the name of the device or devices if multiple the route of administration and use. Also include the date of first and last use.

6. Assessment

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

Provide details of possible causes for the device issue (i.e. malfunction).

Consider any relevant medical history which may have had an effect.

Complete the causality assessment- relationship to procedure and device:

- | | |
|--------------------|---|
| Not related | There is no evidence of causal relationship to the procedure/Investigational Device. |
| Unlikely | The relationship with the use of the procedure/device seems not relevant and/or the event can be reasonable explained by another cause. |
| Possibly | The relationship with the use of the procedure/device is weak but cannot be ruled out completely. |
| Probable | The relationship with the procedure/device seems relevant and/or the event cannot reasonably be explained by another cause. |

Causal Relationship: The serious event is associated with the procedure/device beyond reasonable doubt.

The expectedness of the event must be based on the safety information available with regards to the device. This safety information may be found in the Investigator's Brochure/Risk Analysis Report and the Clinical Investigation Plan/Protocol.

If more than one device is under investigation the additional section should be completed. Where required addition sections can be added to the form.

If the event is related and unexpected it is an Unexpected Serious Adverse Device Effect (USADE) and requires expedited reporting. Inform the Sponsor via rgosponsor@le.ac.uk

7. Is the study Blinded or Unblinded ?

Detail if the study device that subjects are using/treated with are known to the Investigator and research team or are the Investigator and research team blinded.

8. Has the study been Unblinded?

If the event is classified as a USADE where the research team are blinded. The subject must be unblinded as per the study unblinding procedure.



- 9. Is the event related to a protocol violation?** Answer Yes or No.
If Yes - Further information should be supplied on a separate protocol deviation form.
- 10. Was the subject withdrawn due to this event?** Answer Yes or No.
- 11. Action taken with regard to the study device(s)?** Tick one box only to indicate action taken following the event.
Where device not utilised marked as not applicable
- 12. Outcome of event** Tick one box only at the time of the report:
- Ongoing** - the adverse event/effect must be followed-up until resolution.
- Fatal** – Where the event is fatal details of the date of death and the cause of death **MUST** be obtained. Detail where the information was obtained to support cause of death. Supporting anonymised documents must be supplied with SAE/SADE.

NOTE: All supporting documentation must be anonymised and have all patient identifiable data removed. The documents MUST only be identified with the addition of the patient 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 **agreed by the Sponsor** to undertake this role. The person must be named and delegated the duty on the Delegation of Authority and Signature Log.

Reporting and completion of Serious Adverse Events/Serious adverse Device Effects for Medical Device Studies must be undertaken in accordance with UoL SOP S-1043 Standard Operating Procedure for Processing and Reporting Serious Adverse Events, Serious Adverse Device Effects and Unexpected Serious Adverse Device Effects for Medical Device Studies sponsored by University of Leicester (UoL).

Please submit the completed form and any anonymised copies of supporting documents to rgosponosr@le.ac.uk