Serious Adverse Event/Effect Report - Form C
UoL Sponsored Medical Device Studies

|  |  |  |
| --- | --- | --- |
| **Sponsor Ref Number:** | **IRAS Ref Number:** | **MHRA Ref Number:** |
| **Study Title:** |  |
| **Patient Study Number and Initials:** |  |
| **Site:** |  |

**This form is to be completed within 24 hours of becoming aware of the Serious Adverse Event/Serious Adverse Device Effect**

**1. Type of Report**  **Initial**  **Follow-Up** **Final**   **Initial & Final**

(Tick one box only)

Date of Report

Date of Onset

Date of Study

Team Aware

Time team became aware (24 hr clock) :

Date reported to MHRA (if applicable)

Date reported to REC (if applicable)

**2. Event** Enter keywords that best summarise the event

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**3. Serious Criteria:**

(Tick one box only)

## [ ]  Death

## [ ]  Life threatening illness & injury

## [ ]  Hospitalisation or prolongation of hospitalisation

## [ ]  Permanent impairment of body structure or body function

[ ]  Medical or surgical intervention required to prevent any of the above

## [ ]  Led to foetal distress, foetal death or congenital anomaly or birth defect

## [ ]  Other (maybe protocol specific) – Specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## **4. Narrative - Briefly describe the event (attach anonymised supporting documentation if applicable)**

Admission Date Discharge Date

Event narrative:

**5. Study Medical Device Information:**

Subject has been fitted/used/treated with the device ? If No - Give Reason (i.e. screening)

**------------------------------------------------------------------------------------------------------------------------------------------------------------**

If Yes, provide details below**:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name of Device** | **Indication for use** | **Route of administration/use** | **Date of first use** | **Date of last use** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

**6. Assessment**

**If more than one device is being used, please complete an assessment for each device.**

**Name of Device (if applicable): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Both the Causality & Expectedness MUST be completed by the CI/PI or other delegated medically qualified Investigator, as agreed by the Sponsor.**

**Causality and Expectedness:**

**Detail all possible and suspected causes including relevant medical history.**

****

**Causality: Relationship to Procedure**

Not Related [ ]  Unlikely[ ]  Possibly [ ]  Probable [ ]  Casual Relationship (Related) [ ]

**Causality: Relationship to Device**

Not Related [ ]  Unlikely[ ]  Possibly [ ]  Probable [ ]  Casual Relationship (Related) [ ]

**Expectedness**

**The assessment of expectedness must be based on the information contained in the approved Investigator Brochure and/or Risk Analysis Report and/or Protocol**

Anticipated [ ]  Unanticipated [ ]

|  |
| --- |
| **If more than one device is being used, please complete an assessment for each device****Name of Device (if applicable): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****Both the Causality & Expectedness MUST be completed by the CI/PI or other delegated medically qualified Investigator, as agreed by the Sponsor.****Causality and Expectedness:****Detail all possible and suspected causes including relevant medical history:****Causality: Relationship to Procedure**Not Related [ ]  Unlikely[ ]  Possibly [ ]  Probable [ ]  Casual Relationship (Related) [ ] **Causality: Relationship to Device**Not Related [ ]  Unlikely[ ]  Possibly [ ]  Probable [ ]  Casual Relationship (Related) [ ] [ ]  **Expectedness** **The assessment of expectedness must be based on the information contained in the approved Investigator Brochure and/or Risk Analysis Report and/or Protocol**Anticipated [ ]  Unanticipated [ ]  **If the event is related and unanticipated it is an Unexpected Serious Adverse Device Event (USADE) and requires expedited reporting. Inform the Sponsor immediately rgosponsor@le.ac.uk.**  |

**7.** **Is the Study Device Blinded or Unblinded?**

Blinded [ ]  Unblinded[ ]

**8. Has the subject been unblinded? Yes** [ ]  No [ ]  N/A [ ]

**9. Was the event related to a protocol violation?**

 Yes [ ]  No [ ]

**10. Was the subject withdrawn due to this event?**

 Yes [ ]  No [ ]

**11. Action taken regarding study device:**

[ ]  None

[ ]  Device schedule adjusted

[ ]  Device Permanently Removed/Discontinued Date:

[ ]  Other – provide details \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Detail treatment given \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  Unknown at time of report

[ ]  Not applicable

**12. Outcome of the Event**

[ ]  Recovered Date of Recovery:

[ ]  Recovered with Sequelae Date of Recovery:

[ ]  On-going – *details:* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  Unknown at present

[ ]  Fatal Date of Death:

Cause of Death: ...................................................................................................................................

Cause of death obtained from (tick one)

Working Diagnosis Coroner’s Inquest Death Certificate

*Supporting documentation to be supplied with SAE/SADE*

|  |  |
| --- | --- |
| Person completing report:  | Principal Investigator/delegated medically qualifiedindividual as agreed by the Sponsor: |
| Name:  | Name: |
| Role: | Role: |
| Signature: | Signature: |
| Date: | Date:  |
| Contact No: | Contact No: |

**Please return the completed form and copies of any additional anonymised documents to rgosponsor@le.ac.uk**

**Reporting of USADEs to the Research Ethics Committee and Regulatory Authority for UoL sponsored studies will be undertaken in accordance with SOP S-1043**