serious adverse event report form B

for ALL STUDIES *EXCLUDING* clinical trials of investigational medicinal products

|  |  |
| --- | --- |
| **Sponsor Reference Number** |  |
| **Study Title:** |  |
| **Participant Study Number and Initials**  |  |
| **Centre:** |  |

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

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

(Tick relevant box)

Date of Report

Title of the Serious Adverse Event: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Onset

Date Study

Team Aware

**2. Serious Criteria** (Tick one 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

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

Admission Date Discharge date

|  |
| --- |
|  |
| What is your assessment of the implications, if any, for the safety of study participants and how will these be addressed? |  |

**Questions 4 & 5 must be completed by the Principal Investigator.**

**4) Was the event related to a study device/procedure or intervention?**

[ ]  Yes [ ]  No

**5) Was the event related to a protocol violation/deviation?**

[ ]  Yes [ ]  No

**6) Was the participant withdrawn from the study as a result of this event?**

 [ ]  Yes [ ]  No

**7) Outcome of the Event**

[ ]  Resolved Date of Resolution:

[ ]  Resolved with Sequelae

[ ]  Ongoing

[ ]  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

|  |  |
| --- | --- |
| Reporting Person:  | Principal Investigator/Delegated medically qualified individual 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 the Research and Innovation Office by email to****RIAdmin@uhl-tr.nhs.uk**

Reporting and completion of SAEs not 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 Leicester NHS Trust(UHL)

**For Office Use Only**

|  |  |  |
| --- | --- | --- |
| **Type of report** | **Date of review** | **Monitor signature** |
| **Initial**  |  |  |
| **Follow Up** |  |  |
| **Final** |  |  |
| **Initial & Final** |  |  |