serious adverse event report form a

for uhl sponsored 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**

**Initial & Final**

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

(Tick relevant box)

Date of Report

Title of Serious Adverse Event\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Onset

Date Study

Team Aware

***NB If the event is a pregnancy it should be reported on a UHL Pregnancy Notification Form***

**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 anonymised supporting documentation if applicable)**

Admission Date Discharge Date

**Both the Causality & Expectedness MUST be completed by the Principal Investigator or other delegated medically qualified Investigator as agreed by the Sponsor**

**Causality**

**4a. Evaluation of causal relationship with study drug 1**

**Related- If the casual relationship between study drug 1 and the SAE is at least a reasonable possibility**

**Un-Related- If there is no causal relationship between study drug 1 and the SAE**

**(Name of study drug 1) ............................................................................................................**

Related [ ]  Unrelated [ ]

**4b. 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 [ ]  Unexpected [ ]

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

***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

**4a. Evaluation of causal relationship with study drug 2**

**Related- If the casual relationship between study drug 1 and the SAE is at least a reasonable possibility**

**Un-Related- If there is no causal relationship between study drug 1 and the SAE**

**(Name of study drug 2) ............................................................................................................**

Related [ ]  Unrelated [ ]

**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 [ ]  Unexpected [ ]

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

**5. Is the Study Investigational Medicinal Product Blinded or Unblinded?**

Blinded [ ]  Unblinded [ ]

**6. Was the event related to a protocol violation/deviation?**

 Yes [ ]  No [ ]

**7. Study Medication Information:**

|  |  |
| --- | --- |
| **Participant has been Administered Study Drug?** | [ ]  Yes *(Provide details in box below)* [ ]  No *(Give reason i.e. screening) .……………………………………………………………………...* |
| **Name of Medication** | **Indication(s) for Use** | **Dose (units)** | **Route of Administration** | **Date of First Administration** | **Date of Last Administration** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

**8. Action taken with investigational product due to event:**

[ ]  Dose not changed

[ ]  Temporarily discontinued Date:

[ ]  Permanently discontinued Date:

[ ]  Dose reduced - provide details\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

[ ]  Not applicable

**9. Was the participant withdrawn from the study as a result of this event?** Yes[ ]  No [ ]

**10. 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 Coroners Inquest Death Certificate

*Supporting documentation to be supplied with SAE*

|  |  |
| --- | --- |
| Reporting Person:  | 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 the Research & Innovation Office, to** **RIAdmin@uhl-tr.nhs.uk**

**Reporting of SUSARs to the Research Ethics Committee and Regulatory Authority for UHL sponsored studies will 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.**

**For Office Use Only**

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