REPORT OF SERIOUS ADVERSE EVENT (SAE)

**(For all University of Surrey sponsored studies except clinical trials of investigational medicinal products)**

The Chief Investigator has a responsibility to report **all** SAEs to the sponsor (University of Surrey/RIGO) and, if applicable, to the HRA/NHS REC. Chief Investigators should report all SAEs to RIGO unless the SAE is specifically exempted by the protocol.

Send the report to the RIGO@surrey.ac.uk within 3 days of the SAE.

If the SAE is **both:**

* related to the research procedures (resulted from administration of any of the research procedures)

and

* is unexpected (a type of event is not listed in the protocol as an expected occurrence)

then the SAE must also be reported to the NHS REC that issued your approval. The HRA’s SAE report form, alongside further information can be found at [Safety reporting - Health Research Authority (hra.nhs.uk)](https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/safety-reporting/). Please contact RIGO@surrey.ac.uk as the sponsor must keep a record and we can help in the completion and submission of the SAE form to the NHS REC.

**1. Details of Chief Investigator**

|  |  |
| --- | --- |
| Name: |  |
| Address: |  |
| Telephone: |  |
| Email: |  |
| Fax: |  |

**2. Details of study**

|  |  |
| --- | --- |
| Full title of study: |  |
| Name of main REC: |  |
| Main REC reference number: |  |
| IRAS number: |  |
| Research sponsor: |  |
| Sponsor’s reference for this report:(if applicable) |  |

**3. Type of event**

*Please categorise this event, ticking all appropriate options:*

|  |  |  |
| --- | --- | --- |
| Death | Life threatening | Hospitalisation or prolongation of existing hospitalization  |
| Persistent or significantdisability or incapacity | Congenital anomaly or birth defect | Other |

**4. Circumstances of event**

|  |  |
| --- | --- |
| Date of SAE: |  |
| Location: |  |
| Describe the circumstances of the event:*(Attach copy of detailed report if necessary)* |  |
| What is your assessment of the implications, if any, for the safety of study participants and how will these be addressed? |  |

**5. Declaration**

|  |  |
| --- | --- |
| Signature of Chief Investigator: |  |
| Print name: |  |
| Date of submission: |  |

**6. Acknowledgement of SAE by RIGO**

The Research Integrity and Governance Office acknowledges receipt of the above.

|  |  |
| --- | --- |
| Signed: |  |
| Name: |  |
| Job title: |  |
| Date: |  |

*Signed original to be sent back to Chief Investigator (or other person submitting report)*

*Copy to be kept for information by RIGO*