REPORT OF SERIOUS ADVERSE EVENT (SAE)

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

The Chief Investigator should report any SAE that is both related to the research procedures and is unexpected. Send the report to the Research Ethics Committee that gave a favourable opinion of the research within 15 days of the CI becoming aware of the event.

**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: |  |
| 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 significant disability 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 receipt by main REC (please insert name):**

The [ ]Research Ethics Committeeacknowledges receipt of the above.

|  |  |
| --- | --- |
| Signed: |  |
| Name: |  |
| Position on REC: |  |
| Date: |  |

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

*Copy to be kept for information by main REC.*