##### <Study title>

# Serious Adverse Event Reporting Form

**IRAS number:**

Please email the SAE form to the RGIT Inbox at [rgit@imperial.ac.uk](mailto:rgit@imperial.ac.uk) within 24h of notification of event

|  |  |
| --- | --- |
| Patient Initials: …………………………………………………………….… | Patient Study No: |
| Age: \_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| Treating Clinician:……………………………………………………….… | Hospital/Site: ……………………………………………………………..…. |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Type of Report** | |  | | Sex | | **Height** | **Weight** |
|  | 1=First  2=Interim  3=Final |  |  |  | 1= Male  2= Female | cm | .  kg |

|  |  |  |  |
| --- | --- | --- | --- |
| **Why was the event serious?** *(choose most serious)* | | **Where did the SAE take place?** | |
|  | 1= Resulted in death  2= Life-threatening  3= Required inpatient hospitalisation or prolongation of existing hospitalisation  4= Resulted in persistent or significant disability/incapacity  5= Resulted in congenital anomaly/birth defect  6= Other medically important event |  | 1= Hospital  2= Out-patient clinic  3= Home  4= Nursing home  5= Hospice  6= Other, specify…………………………………………….. |

|  |
| --- |
| **Briefly describe SAE** (*include relevant symptoms, body site, and relevant lab tests, treatments received)*  *continue on a separate sheet if necessary* |
|  |
|  |
|  |

|  |
| --- |
| **Serious Adverse Event name:**  **Grade:** |
| **Name of device:** |
| **Detail of possible and suspected causes (including relevant medical history:** |
| **Causality: Relationship to Device**  Unrelated  Unlikely  Possibly  Probable Definitely  Not assessable |
| **Expectedness:** was the event a recognised undesirable effect of the device?  Anticipated  Unanticipated  Version of CIP/Protocol/RA used to assess \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **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 |
| **Outcome of event:**  Recovered  Recovered with Sequelae  Ongoing- please give details \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Unknow at present  Fatal |

##### Imperial monoImperial College Col<Study title>

Patient’s Study Number 

|  |  |  |  |
| --- | --- | --- | --- |
| Signature Authorised Health Professional | ………………………………………………………….. | Print name……………………………………………………….… | |
| Contact telephone no……………………………………………………………….. | | **Date of report** | d d m m m y y |

|  |  |  |  |
| --- | --- | --- | --- |
| Sites to complete | | |  |
| Was SAE device related? | Yes | No | Event No |
| Was event unexpected? | Yes | No | ***Comments:*** |
| Was the event a USADE? | Yes | No |  |
| Date site aware | d d m m m y y | |  |
| Date reported to CI | d d m m m y y | |  |
| Date reported to Sponsor  d d m m m y y | | |  |
| **Form completed by xxx**  **(staff signature)**  …………………………………………… | | |  |
|  | | | Date  d d m m m y y |