##### <Study title>

# Serious Adverse Event Reporting Form

**IRAS number:**

Please email the SAE form to the RGIT Inbox at 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=First2=Interim 3=Final |  |  |  | 1= Male2= Female |  cm | .  kg |

|  |  |
| --- | --- |
| **Why was the event serious?** *(choose most serious)* | **Where did the SAE take place?** |
|  | 1= Resulted in death2= Life-threatening3= Required inpatient hospitalisation or prolongation of existing hospitalisation4= Resulted in persistent or significant disability/incapacity 5= Resulted in congenital anomaly/birth defect6= Other medically important event |  | 1= Hospital2= Out-patient clinic3= Home4= Nursing home5= Hospice6= Other, specify…………………………………………….. |

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

|  |  |  |
| --- | --- | --- |
| SignatureAuthorised 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  |