## ICREC and SETREC

## Report of Serious Adverse Event (SAE)

The principle Investigator should report any SAE that is both related to the research procedure and is unexpected. Please send the report to the [Ethics and Research Governance Co-ordinator](mailto:rgitcoordinator@imperial.ac.uk) within 24 hours of the PI becoming aware of the event.

|  |  |
| --- | --- |
| Details of Principal Investigator and study description | |
| Name |  |
| Faculty and Department |  |
| Telephone |  |
| Email *(College not personal)* |  |

|  |  |
| --- | --- |
| Details of the Study | |
| Full title of study |  |
| ICREC/SETREC reference number |  |
| Research Sponsor |  |
| Sponsors reference for this report (if applicable) |  |

|  |
| --- |
| Type of event*Please categorise this event by ticking all appropriate actions* |
| Death  Persistent or Significant disability or incapacity  Life threatening  Hospitalisation or Medical Treatment  Injury  Other |

|  |  |
| --- | --- |
| 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 implications, if any, for safety of study participants and how will these be addressed? |  |
| Date SAE resolved |  |

|  |  |
| --- | --- |
| Declaration | |
| Signature of Principal Investigator |  |
| Print name |  |
| Date of submission |  |

|  |  |
| --- | --- |
| Acknowledgement of receipt by ICREC/SETREC | |
| **Signed** |  |
| **Name** |  |
| **Position on ICREC/SETREC** |  |
| **Date** |  |