## 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 within 24 hours of the PI becoming aware of the event.

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

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

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| 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 [ ]  |

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| 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 |  |

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

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