

 <Title of Study>

 Adverse Event report

|  |  |  |
| --- | --- | --- |
| Site ID: | Participant ID: | Date of AE: |

|  |
| --- |
| Situation:Background:Assessment:Recommendation:Symptoms, cause, treatment, outcome? |
| Author: | Date:  |

|  |  |  |
| --- | --- | --- |
| **Reported to** | **Date complete / N/A** | **Reported by** |
| Case report form |  |  |
| PI |  |  |
| Sponsor |  |  |
| Local NHS reporting system |  |  |
| Local university reporting system |  |  |
| ***AEs involving equipment*** |
| Manufacturer |  |  |
| Health & Safety Executive |  |  |
| ***AEs involving a Medical Device (Report within 24h)*** |
| MHRA |  |  |
| Manufacturer |  |  |
| ***Radiation incident*** |
| CQC *or* Scottish Government  |  |  |

*Once complete, email a copy to […@...]*