

<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 […@...]*