Part A

|  |
| --- |
| **Project details** |
| Protocol title:  |
| IRAS number:  |

|  |
| --- |
| **Name and contact details of person reporting/completing the form** |
| Name:  |
| Role within project if relevant:  |
| Email:  |
| Tel:  |

|  |
| --- |
| **Details of Site where breach occurred**  |
| Name of Site : |
| Site Number –(If not single centre):  |
| Name of Principal Investigator:  |
| Email of PI:  |
| Number of breaches reported at this site, including this one (*information from Site’s Breach Log)*:  |

|  |
| --- |
| **Have you informed any other parties? If so, who and when? *Do NOT enter*** *names, only the date when informed. Add rows as required.* |
|  | **Date**  | **Method** *i.e., email, phone, verbal* |
| Has the person who may have committed the breach been notified? (*If different from person reporting the breach)* |  |  |
| Principal Investigator |  |  |
| REC |  |  |
| Funder |  |  |
| Other (*Identify all, but if none, then enter n/a under space for date)* |  |  |
| **Timeline** |
| Date breach identified:  |
| Date breach occurred:  |
| Date of notification to Sponsor:  |
| Provide brief explanation if not same date: |

|  |
| --- |
| **Summary of breach** |
| *Detail what has been breached- i.e., GCP, Protocol, SOPs, GDPR**Explain the breach in layman’s terms and what has happened. Include any background information and context to understand the incident.* |

|  |
| --- |
| **Actual impact** (s*elect all that apply if known at this time*.) |
| Patient Safety, physical or mental integrity [ ] Data Integrity (scientific value of the trial) [ ] No significant impact [ ]   |

|  |
| --- |
| **Corrective action taken** |
| *Provide details of action taken to correct this breach. If none, you must explain why not.*  |

|  |
| --- |
| **Preventative action proposed** |
| *Provide a clear measurable plan on what is being put in place to stop this happening in the future. Must include:****A timeline for implementation, detail who is responsible for each action and provide information on how this will be included in final report***  |

|  |
| --- |
| **Send to the Sponsor/Breach Team** |
| *Please forward this form to tascpotentialbreach@dundee.ac.uk* |

Part B

|  |
| --- |
| **For Sponsor use only** *Do not complete this section if you are reporting the breach* |
| Date of review |  |
| Confirm category: \* Onward report as appropriate Part C |
| Not a breach[ ]  | Non-serious[ ]  | Serious \*[ ]  | Insurance \*[ ]  | GDPR/Data \*[ ]  | CSO Indemnity \*[ ]  |
| Comments: |
| Name of reviewer |  |
| Designation |  |
| Date of Closure |  |