Part A

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

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

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| **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)*: |

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| **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: | | |

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| **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.* |

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| **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 |

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

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| **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*** |

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

Part B

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| **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 | |  | | | | |