### Notification of Serious Breach of Good Clinical Practice or Trial Protocol

(Ref: UK Statutory Instrument 2004/1031 Regulation 29A, as amended by 2006/1928)

Please forward this notification to **GCP.SeriousBreaches@mhra.gov.uk**

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| **Initial Report**  | [ ]  |
| **Follow-up Report** | [ ]  |
| **Follow-up Report number** (number follow-up reports sequentially from 01). |  |
| **MHRA GCP ID** (if known) |  |
| **Name and Contact Details of Reporter** |  |
| **Organisation of Reporter** |  |
| **Details of Individual or Organisation committing breach** |  |
| **Confirm if the Individual or Organisation committing breach have been made aware**  | Yes | [ ]  |
| No  | [ ]  |
| **Contact details for Individual/Organisation committing breach** (if different from the above): |  |
| **Clinical trial details** (for each trial include as a minimum; EudraCT number, CTA number, IRAS number, study title, Sponsor, UK Chief Investigator name and REC name)  |  |
| **Trial/s type** | Commercial  | [ ]  |
| Non-Commercial  | [ ]  |
| **Confirm which other parties have been notified and when e.g. other competent authorities, EMA, CQC, HRA, REC, other GxPs etc** |   |
| **Date Breach Identified by Sponsor** |  |
| **Date Breach Notified to MHRA** |  |

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| **Please give details of the breach** |
| **Breach summary** *(provide a brief top-level summary of the breach):*  |
| ***Potential impact to (select all that apply):*** |
| Patient Safety or physical or mental integrity  | [ ]  | Data Integrity (scientific value of the trial)  | [ ]  |
| ***Incident information:*** *Explain the breach and what has happened. Include any background information, context required to understand the incident.* |
| ***Other relevant information:****(i.e. study status, site(s), ethics, trust, CRO /sponsor details etc.)* |
| **Please give details of the action taken:** |
| ***Impact Assessment****:* *What is the extent of the issue and the impact? This should be investigated and reported. The issue may need to be reviewed across sites, trials, sponsors, electronic systems etc to determine the extent of the issue and impact. Provide full details of the impact assessment, include what has been looked at and how this has been done i.e. methodology should also be included here. If this is not known at the time of report provide details of when this will be available and submitted as a follow-up report.* |
| ***Root Cause Investigation:*** *The root cause investigation by your organisation should be explained including details of investigations by other organisations (e.g. CRO/ethics/trust), the results and outcomes of the investigations. If this is not known at the time of report provide details of when this will be available and submitted as a follow-up report* |
| ***Corrective & Preventative Action (CAPA) Plan:*** *Provide a clear measurable CAPA plan including any actions already taken/implemented. Include details of which organisation is responsible for each action (e.g. Sponsor, CRO, CRA, site etc) and a timeline. Also include how the incident will be transparently reported in the final report/publication and how this incident will be documented in the TMF for future inspection. If this is not known at the time of report provide details of when this will be available and submitted as a follow-up report* |
| ***Actual impact to (select all that apply):*** |
| Patient Safety or physical or mental integrity  | [ ]  | Data Integrity (scientific value of the trial) | [ ]  |
| No significant impact | [ ]  |  |  |