TMPL\_059

**FOR MHRA USE ONLY:**

|  |  |
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| **GCP Unique ID:** |  |
| **Triaging Inspector** |  |

**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.gsi.gov.uk**](mailto:GCP.SeriousBreaches@mhra.gsi.gov.uk) OR MHRA, Block 14, First Floor, 14F A06/07, FERA (The Food and Environment Research Agency), Sand Hutton, York YO41 1LZ

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Your Name:** | | | | **Your Organisation:** |
| **Your Contact Details:** | | | | **Date Breach Identified by Sponsor:** |
| **Date Breach Notified to MHRA:** |
|  | | | | |
| **Details of Individual or Organisation committing breach:** | | | | **Details of related study** (if applicable)**:** (e.g. EudraCT No, CTA number, study title) |
| **Report:**  Tick appropriately | | **Initial**  **Report** | | **Follow-up**  **Report** |
| **Please give details of the breach** | | | | |
| ***Potential impact to patient safety and/or data credibility:*** | | | | |
|  | Patient safety | |  | Scientific value / data credibility |
|  | Patient confidentiality | |  | NA/None |
|  | Approval Issues | |  | Other Non-compliances (specify) |
|  | IMP | |  |
| ***Background:***  *(continue on additional sheets if required)* | | | | |
| ***Other relevant information:***  *(i.e. study status, site(s), ethics, trust, CRO /sponsor details etc.)*  *(continue on additional sheets if required)* | | | | |

TMPL\_059 Serious Breach Report Form

|  |  |  |  |
| --- | --- | --- | --- |
| **Please give details of the action taken:** | | | |
| *This should include: Any investigations by your organisation, details of investigations by other organisations (e.g. CRO/ethics/trust), the results and outcomes of the investigations (if known or details of when they will be available/submitted), how it will be reported in the final report/publication, the corrective & preventative action implemented to ensure the breach does not occur again.*  *(continue on additional sheets if required)* | | | |
| ***Actual impact to patient safety and/or data credibility:*** | | | |
|  | Patient safety |  | Scientific value / data credibility |
|  | Patient confidentiality |  | NA/None |
|  | Approval Issues |  | Other Non-compliances (specify) |
|  | IMP |  |