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| **Study Title:** |  | **Sponsor Ref:****REC Ref:**  |  | **CI/PI:** |  |
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| **Incident No.** | **Date incident added to log** | **Incident date** | **Participant number** | **Site name** | **Description of deviation** | **Site corrective action** | **Site preventive action** | **Sign/ Date (Close out -all actions complete)** |
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**NB: If the event could potentially have impacted upon (i) patient safety and/or (ii) study outcome and/or (iii) data protection, complete a Breach Form (TMP-QA-20)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **CI/PI Name:**  |  | **Signature:** |  | **Review Date:** |  |
| **Sponsor rep Name:** |  | **Signature:** |  | **Review date:** |  |
| **Research Monitor Name:** |  | **Signature:** |  | **Review date:** |  |

*All non-conformances are considered as deviations, unless classed as a breach. Please ensure any non-conformances on monitoring reports issued by NHSG Research Monitors are included on this log.*

 **The completed deviation log should be submitted to** **phamaco@abdn.ac.uk** **three monthly for interventional research projects\*. For other non-interventional projects, sponsored or co-sponsored by University of Aberdeen and/or NHS Grampian, deviation logs should be maintained by the study team and made available to monitors as part of a monitoring visit.**

**Definitions:**

Corrective Action: The immediate action taken when a deviation is discovered. The PI, or delegate, will detail in the deviation log how the deviation was corrected (if applicable) at the time of discovery, and how this will be documented in the Investigator Site File.

Preventive Action: Includes investigation into the root cause of the deviation, assessing possible impact and risk, and whether the event is part of a systemic issue. Actions taken to ensure the deviation is not repeated will also be detailed. The PI, or delegate, will detail in the deviation log how recurrence of this deviation will be prevented and how this will be documented in the Investigator Site File.

\* Interventional research projects include Clinical Trials of Investigational Medicinal Product (CTIMP) and other interventional studies (eg surgical studies, Medical Device Clinical Investigations (MDCI), non CTIMP drug studies and any other projects deemed to be ‘interventional’ by Sponsor).