**Section 1: Clinical Trial Details**

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| **Date** |  | **HREC Number** |  |
| **Protocol Title** |  | **Coordinating Principal Investigator** |  |
| **Site Name** |  | **Approving HREC** |  |

**Section 2: Root Cause Analysis**

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| **Describe the non-compliance issue.** |  |
| **List the date this was discovered.** |  |
| **Explain why the non-compliance occurred.** |  |
| **Select what the non-compliance affects.** | ☐ Regulatory requirements.  ☐ Reliability or robustness of the trial design or outcomes.  ☐ Human subject protection or safety. |
| **Indicate whether this non-compliance is isolated or systemic.** | **Systemic:** *The non-compliance is systemic (e.g., persistent or systematic non-compliance with the instructions for completing consent forms, safety monitoring forms, case report forms, or data collection tools, resulting in continued missed or incomplete data collection).*  **Isolated:** *The non-compliance is isolated (e.g., it has occurred only once, with no previous non-compliance affecting participant safety, regulatory requirements, or the robustness of the trial in this trial).* |
| **Explain how this determination was made if there were no effects on human subject protection or safety, regulatory requirements, or the reliability/robustness of the trial design or outcomes. The root cause analysis process should include engagement with one or all of the following to make this determination:**  ** ***Principal Investigator (PI)****: The PI oversees the study and ensures compliance with protocols and regulations.*  ** ***Research Team****: Other research team members who are directly involved in conducting the trial and monitoring compliance.*  ** ***Ethics Committee****: The Human Research Ethics Committee (HREC) or Institutional Review Board (IRB) may guide ethical considerations and compliance with regulations.*  ** ***Regulator****: Someone who specialises in regulatory requirements for clinical trials and can provide insight into compliance issues.*  ** ***Data Management and Quality Assurance****: Professionals responsible for data collection, management, and ensuring the reliability and robustness of trial outcomes.*  ** ***Site Research Governance Officer***  ** ***Legal Counsel****: Legal advice may be sought to ensure adherence to legal requirements in cases involving significant compliance issues.* |  |
| Attach any supporting documentation that evidences engagement or consultation regarding this non-compliance issue. Provide a list of all documentation attached. |  |
| **Indicate the overall significance of the issue** | Minor  Moderate  Serious |

**Section 3: Corrective and Preventative Action Plan**

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| **Issue**  **­­­­­** | *[Briefly describe or outline the topic/process/problem being documented; it can be formatted as a paragraph, numbered list, or bulleted items]* |
| **Root Cause Analysis:** | *[The reason(s) that the issue arose]* |
| **Corrective Action Plan:** | *[Description of the corrective actions taken or planned by the site personnel. If the site was instructed to perform these corrective actions (i.e., by the sponsor or monitor), indicate by whom and as of what date. If the status of reports, records, or data will remain incomplete or unavailable, make a statement regarding your failed attempts or describe when/how the records will be retrieved or completed.]* |
| **Implementation:** | *[Description of the procedures used to document the resolution of the problem, the personnel responsible for the procedures, etc.]* |
| **Effective date of resolution:** | *[Effective date for corrective action]* |
| **Preventive Action:** | *[Description of the preventive actions taken or planned by the site personnel. If the site was instructed to perform these preventive actions, indicate by whom and as of what date.]* |
| **Evaluation / Follow-up:** | *[Any plan/procedure to evaluate the implementation and completion, personnel responsible for the evaluations, timeframe for the evaluation, etc.]* |
| **Nature of Issue** | **Deviation:** *Any breach, divergence or departure from the requirements of Good Clinical Practice or the clinical trial protocol.*  **Serious Breach:** *A breach of Good Clinical Practice or the protocol that is likely to affect to a significant degree:*  *a) The safety or rights of a trial participant, or*  *b) The reliability and robustness of the data generated in the clinical trial.*  **Significant Safety Issue:** *A safety issue that could adversely affect the safety of participants or materially impact the trial's continued ethical acceptability or conduct.*  **Suspected Breach:** *A report judged by the reporter as a possible serious breach but has yet to be formally confirmed as a serious breach by the sponsor.*  **Urgent Safety Measure:** *A measure must be taken to eliminate an immediate hazard to a participant’s health or safety.* |

**Section 4: Further Reporting**

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| **Further Reporting:**  Not Applicable or complete below | **Yes** | **No** | **Date Reported**  **(dd/mm/yyyy)** | **Documentation Attached** |
| **TGA** |  |  |  | Yes  No |
| **Approving HREC** |  |  |  | Yes  No |
| **Site** |  |  |  | Yes  No |
| **Other (please specify):** |  |  |  | Yes  No |

**Section D: Signature**

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| **Principal Investigator Name and Signature** |  |
| **Date** |  |