# Research Ethics and Governance: Corrective Action, Preventative Action (CAPA) Form

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| --- | --- |
| **Study Ref:** |  |
| **Study Title:** |  |
| **Chief Investigator:** |  |
| **Student/Programme:** |  |
| **Date:** |  |
| **Summary of breach** |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Category as below** | **Date/Finding** | **Immediate Action** | **Corrective Action** | **Preventative Action** | **Date completed** |
|  |  |  |  |  |  |

**CRITICAL:** The safety, well-being or confidentiality of participants has been jeopardised. Reported data are unreliable or absent. Inappropriate, insufficient or untimely corrective action has taken place regarding a major non-compliance.

**MAJOR:** Significant and unjustified non-compliance with in which safety, well-being or confidentiality has not been jeopardised. A number of breaches within one area, indicating systematic quality assurance failure. A failure to comply with legislative requirements including annual reporting requirements.

**OTHER / Near Miss:** Findings that are neither critical nor major. Including an occurrence that, but for luck, skill or judgment, would in all probability have been a non-conformance.

Name (Print) …………………...................................................................... Signature …......................................................................................