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| Date of Submission |  |

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**ADVERSE EVENT REPORTING FORM**

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| **To be completed electronically by the principal investigator in accordance with the Standard Operating Procedures for reporting adverse events of the REC for all adverse events (AE), serious adverse events (SAE), adverse drug reactions (ADR) and serious adverse drug reactions (SADR) and forwarded to the REC within 48hrs.** | | | | | | | | |
| Faculty: | | | | | | Department: | | |
| Title of the study: | | | | | | | | |
| Name of principal investigator  (researcher): | | | | | | Name and qualification of supervisor(s): | | |
| Highest qualification: | | | | | | Staff / Student Number: | | |
| Ethical approval number: | | | | | | Research site: | | |
| AE | SAE | ADR | SADR | | | Date of event: | | |
| Brief description of the event (include patient/participant reference number): | | | | | | | | |
| Relationship of event to research process: | | | | | | | | |
| Description of the outcome: | | | | | | | | |
| Description of intervention thus far: | | | | | | | | |
| **TO BE COMPLETED BY THE CHAIRPERSON OF THE REC.** | | | | | | | | |
| Date received: | | | | Review required: | | | | |
| Emergency: | | | | Standard |
| **Comments:** | | | | | | | | |
|  | | | | | **Signature:** | | **Date:** | |
| Researcher | | | | |  | |  | |
| Supervisor | | | | |  | |  | |
| Head of Department | | | | |  | |  | |
| Deputy Dean of Faculty/**Research Professor** | | | | |  | |  | |
| **Recommendations/interventions imposed by the REC:** | | | | | | | | |
|  | | | | **Signature:** | | | | **Date:** |
| Chairperson of REC | | | |  | | | |  |