**Do not use this form to report safety events relevant to clinical trials.**

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Section 1: Project Details** | | | | | | | |
| 1. **HREC reference number:** |  | | | | | |
| 1. **Project title:** |  | | | | | |
| 1. **Chief Investigator** |  | | | | | |
| 1. **Approving HREC:** |  | | | | | |
| 1. **Type of report** | **Initial**  **Follow up** | | | | | |
| **Section 2: Details of the event** | | | | | | |
| 1. **Date of occurrence** |  | | | | | |
| 1. **Location of occurrence** |  | | | | | |
| 1. **Has the event or incident been resolved** | **Yes**  **No** | | | | | |
| 1. **Who was affected by the event or incident** | **Party Affected** | **Yes** | **No** | **If yes, provide further detail such as number of participants/records, names of researchers etc.** | | |
| Research Participants |  |  |  | | |
| Researchers |  |  |  | | |
| Research Records, Data or Property |  |  |  | | |
| 1. **Did the event result in or cause any of the following?** | * Death * Life-threatening * Hospitalisation * Prolongation of existing hospitalisation * persistent or significant disability or incapacity * congenital anomaly or birth defect | | | | | |
| 1. **Describe the incident using lay language. Include details of any negative consequences, harm or damage that has occurred because of the incident.** | | | | | | |
|  | | | | | | |
| 1. **What has been identified as the cause of the incident?** | | | | | | |
|  | | | | | | |
| 1. **Describe the corrective steps that have occurred and those that are to occur following this report.** | | | | | | |
|  | | | | | | |
| 1. **Describe the preventative steps to stop reoccurrence.** | | | | | | |
|  | | | | | | |
| 1. **Has the event/incident had an impact on the ethical acceptability of the research** | | | | | **Yes** | **No** |
| 1. **Was the event/incident related to the study design and / or procedure?** | | | | | **Yes** | **No** |
| 1. **Was the event/incident anticipated in the in the risks section of the approved project description?** | | | | | **Yes** | **No** |
| 1. **Will the event/incident adverse event raise additional safety concerns for the participants of this research or affect participants’ willingness to continue participation** | | | | | **Yes** | **No** |
| 1. **If the incident involved ACU property or assets has a report been submitted via Riskware** | | | | | **Yes** | **No** |
| **Section 3: Declaration** | | | | | | |
| By submitting this form, I Chief Investigator declare that:  The information contained in this report is true and accurate. | | | | | **Yes** | **No** |