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

|  |
| --- |
| **Section 1: Project Details** |
| 1. **HREC/HREAP 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** |
| **Section 3: Declaration**  |
| By submitting this form, I Chief Investigator declare that:The information contained in this report is true and accurate. | [ ]  **Yes** | [ ]  **No** |