**ADDENDUM 1**



INCIDENT REPORT FORM WHEN CONDUCTING RESEARCH WITH HUMAN PARTICIPANTS

***Note: An incident is seen as an unanticipated situation or issue that arises while conducting your research and that has no direct cause/effect due to the approved research procedures and/or interventions.***

Please complete the form according to the following guidelines:

* Researchers need to complete Sections A to C.
* The Chairperson of the Human Social Sciences Research Ethics Committee (HSSREC) will complete Section D.

**SECTION A: GENERAL INFORMATION**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1. Project Leader/Principle Investigator/Study leader Details** | | | | | | | | |
| **Surname** |  | | | **Initials** |  | | **Title** |  |
| **School/**  **Research unit** |  | | | | | | | |
| **E-mail** |  | | | | | | | |
| **Telephone** | **Work** |  | | **Cell** |  | | **Fax** |  |
| **2. Student Details (if applicable)** | | | | | | | | |
| **Surname** |  | | | **Initials** |  | | **Title** |  |
| **School/**  **Research unit** |  | | | | | | | |
| **E-mail** |  | | | | | | | |
| **Telephone** | **Work** |  | | **Cell** |  | | **Fax** |  |
| **3. Details of approved research** | | | | | | | | |
| **Title** |  | | | | | | | |
| **Ethics Approval Number** | | |  | | | | | |
| **Approval date** |  | | | **Expiry date** | |  | | |
| **Last submission of a monitoring report** | | | | **Date:** | | | | |

**SECTION B: INCIDENT REPORT**

**Please describe the progress to date of the project (not more than 500 words):**

4 SOP HSSREC Incidents and Serious Adverse Events HSSREC\_2.3 (1 October 2021)

|  |  |  |  |
| --- | --- | --- | --- |
| **Please describe the incident that is being reported in detail (please ensure that you respond to the what, where, who, how, when of the incident):** | | | |
| **Please describe the action that has been taken to date, in detail, in order to contain the incident:** | | | |
| **Please indicate a possible strategy/action plan for correcting the incident:** | | | |
| **Please indicate a possible strategy/action plan for ensuring that it will not occur again:** | | | |
|  | **Yes** | **No** | **N/A** |
| **Will this incident require that the proposal will have to be changed?**  ***If yes, please ensure that an amendment request is submitted to the HSSREC as soon as possible.*** |  |  |  |

**SECTION C: SIGNATURE**

|  |  |  |  |
| --- | --- | --- | --- |
| **By signing this document, I certify that the information provided is accurate and complete.** | | | |
| **Signature by the primary investigator** |  | **Date** |  |

**SECTION D (for office use only):**

|  |  |  |  |
| --- | --- | --- | --- |
| **14. HSSREC report** | **Yes** | **No** | **N/A** |
| **Has the incident been satisfactorily reported?** |  |  |  |
| **Has the incident been satisfactorily addressed?** |  |  |  |
| **If yes, please explain the manner in which the incident was managed with the project leader/principle investigator/study leader and participant/s:** | | | |

|  |  |  |
| --- | --- | --- |
| **HSSREC Chairperson** | **Signature** | **Date** |
|  |  |  |
|  |  |  |