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**ADVERSE EVENTS REPORT**

**NELSON MANDELA UNIVERSITY RESEARCH ETHICS COMMITTEE (HUMAN)**

 **PLEASE READ THE INFORMATION CONTAINED IN THIS BLOCK (pp 1) PRIOR TO COMPLETING THE ADVERSE EVENTS REPORT. THIS INFORMATION BLOCK MUST BE REMOVED PRIOR TO SUBMISSION OF THE ADVERSE EVENTS. DEVIATION FROM THE INSTRUCTIONS MIGHT RESULT IN A DELAY IN THE REVIEW AND APPROVAL OF YOUR REPORT.**

**WHO NEEDS TO COMPLETE THIS REPORT?**The Primary Responsible Person is responsible for reporting any adverse event(s) experienced by a research participant / researcher / non-participant that is/may be related to the research procedures. **Any undesirable experience or response is considered an adverse event. The adverse event may be physical, emotional, psychological, or physiological in nature.**

**WHEN SHOULD THIS NOTICE BE SUBMITTED?**

The Primary Responsible Person must notify the Chairperson of the Research Ethics Committee (Human), through the submission of this completed form via Imtiaz.Khan@mandela.ac.za, about the occurrence of the adverse event as soon as possible but not later than one business day following the event.

**HOW TO COMPLETE THIS NOTICE:**

1. Complete Sections 1 to 5 (as from pp 2) in typescript (tab between fields, select from pull-downs, information may be pasted from existing Word® documents), and save the completed form. Handwritten forms will not be accepted. Use the “Save as” option to save the application with a filename containing your name(e.g.“**J Smith** REC-H Adverse Event 20YY.doc”, where YY is the current year). For clarification of the definition of terms, refer to the progress report (RECH-004) and/or application form template (RECH-001).
2. **REMOVE THE INSTRUCTION BLOCK** (pp 1).
3. **Electronic copy (signed) for submission**: Print the document, have each page initialled in the lower right-hand corner and get Section 6 signed by the relevant parties. Scan in the signed hard copy and all supporting documentation. Alternatively print the report as a PDF document, correctly appending all supporting documentation to it in a single PDF document, and sign the document digitally. Submit the signed form via email with the subject heading **RECH ADVERSE EVENTS REPORT (*your human ethics reference code*)** to REC-H (Imtiaz.Khan@mandela.ac.za). Any deviation from the instructions may result in a delay in processing your report.

**END OF INFORMATION BLOCK**

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| 1. **PROTOCOL INFORMATION**
 |
| **Reference code**\***:***\* Refer to letter(s) of approval* | **H** | **…………** | **…………** | **…………** | **…………** |
| **HUMAN** | **YEAR** | **FACULTY** | **DEPARTMENT** | **NUMBER** |
| **Current Ethics Approval is granted until**\***:***\* Refer to current letter of approval. The date to be stated is 1 calendar year after the date on which the approval letter was issued.*  | **Click or tap to enter a date.*****Signed copy of original approval letter must be******attached as addendum to this report.***  |
| **Approved title of study:** **Type title here** |
| **RESEARCHERS:*Please note -*** ***The Protection of Personal Information Act, 2013 (POPI Act) has been promulgated and implemented on 1 July 2020. All personal identifiable information provided by you shall be treated in accordance with this statute and only used for research ethics application and/or reporting processes, as indicated in the University’s Privacy Policy. By providing your information, you are giving your consent for the use of all of your personal identifiable information, provided to the University, for the aforesaid purposes.*** |
| 1. PRP identification and affiliation details:

**Type PRP staff number here Type PRP name here Type PRP Email address here**Faculty **Select Faculty Specify here, if “other”**  Department (or equivalent):  **Type department name here**  |
| 1. PI (may be same as PRP) identification and affiliation details:

**Type PI staff number/student number here Type PI name here Type PI Email address here**Faculty **Select Faculty**  **Specify here, if “other”**Department (or equivalent):  **Type department name here** |

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| 1. GENERAL DETAILS RELATED TO ADVERSE EVENT
 |
| 1. Who was affected by this adverse event? (*Select all that apply*) [ ] Participant(s) and/or [ ] Researchers/co-workers and/or [ ] Non-participants
 |
| 1. Was the adverse event attributable to a study procedure? **Choose an item.**

(If a relationship between the event and the study procedures can be ruled out, this form is not required). |
| 1. Is this adverse event described in the Risks section of the Application Form and in the Information Letter and Consent/Assent Form?  **Choose an item.**
 |
| 1. Has this type of adverse event previously occurred in this or a related study?  **Choose an item.**

If YES, when and how often?  **Type response here or select “Not applicable”**  |
| 1. Is this type of adverse event likely to occur again?  **Choose an item.**
 |
| 1. Have any changes to the study procedures been implemented as a result of this adverse event in order to reduce or eliminate the risk of the event happening again?  **Choose an item.**

If Yes,  **Type response here or select “Not applicable”***(Attach research methodology for ethics review as Appendix 1. NOTE: No new study participants may be involved in the study until any necessary revisions to the study procedure have received ethics clearance)* |
| 1. Will the adverse event require any modification to the Information Letter and Consent/Assent Forms?  **Choose an item.**

If Yes,  **Type response here or select “Not applicable”***(Attach a revised Information Letter and Consent/Assent Form for ethics review as Appendix 2. NOTE: No new study participants may be involved in the study until any necessary revisions to the Information Letter and Consent/Assent Form have received ethics clearance).* |

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| 1. DETAILS OF PERSON(S) INVOLVED
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| 1. Full Name(s):  **Type response here**
 |
| 1. Age(s):  **Type response here**
 |
| 1. Address(es):  **Type response here or select “Not applicable”**
 |
| 1. Date of Occurrence:  **Click to enter a date.** Time of Occurrence:  **Type response here**
 |
| 1. Location of Event: **Type response here**
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| 1. DETAILED DESCRIPTION OF ADVERSE EVENT AND OF ACTION TAKEN
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| 1. Describe the adverse event/incident that occurred.  **Type response here**
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| 1. Provide details (step-by-step) of the action(s) taken immediately following identification of the adverse event/incident.  **Type response here**
 |
| 1. Was medical or other intervention provided?  **Choose an item.**If Yes, provide the name of, and contact information for, any medical or other personnel involved. **Type response here or select “Not applicable”**
 |
| 1. If a participant was involved, was the participant discontinued from the study as a result of the adverse event?  **Choose an item.**
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| 1. Is there any plan for follow-up contact with the person(s) involved?  **Choose an item.**If Yes, explain.  **Type response here or select “Not applicable”**
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| 1. ADDITIONAL COMMENTS
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| I would like the REC-H to take note of the following additional information:  **Type response here or select “Not applicable”** |

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| 1. DECLARATION
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| I declare that the details contained in this adverse events report, including any attachments, are complete and accurate.  |
|  **29 August 2022**SIGNATURE: **Type name here** (Primary Responsible Person) Date |
|  **29 August 2022**SIGNATURE: **Type name here** (Principal Investigator/Researcher) Date |