TURFLOOP RESEARCH ETHICS COMMITTEE

ADVERSE EVENT REPORTING FORM

This form must be completed and returned to the Research Ethics Officer, Ms Anastasia J Ngobe (anastasia.ngobe@ul.ac.za) as soon as possible within 7 days for serious adverse events, and within 15 days for other adverse and unexpected events. One form is to be completed per participant, even if several participants are involved in a similar adverse event.

Study Information:

Study Field:

Turfloop Research Ethics Committee Number:

Brief Description of the Adverse event:

Brief Description of the Intervention:

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1. FACILITY AND PARTICIPANT INFORMATION:

Facility Name:

Participant Id:

Participant Age:

Participant Gender:

Participant Ethnicity:

2. ADVERSE EVENT:

2.1 Adverse Event Report Type: Initial ☐ Follow-Up: ☐

2.2 Date of Adverse Event: (DD/MM/YY)

2.3 Adverse Event Reported by:

☐ Researchers returning to the site

☐ by other means, specify:

2. 2 COMPONENT OF STUDY, PARTICIPANT INVOLVED IN:	
1 ☐ Baseline	3. ☐ Six months
2 ☐ Six weeks	4. ☐ Other, specify:

2. **3 ADVERSE EVENT SEVERITY:**	
1 ☐ Mild	3 ☐ Severe
2 ☐ Moderate	4 ☐ Fatal

2.4 IS THE ADVERSE EVENT SERIOUS?*	1. ☐ Yes 2. ☐ No

*Serious Adverse Events Are Considered Fatal or Life Threatening That Require Hospitalization or Prolong Existing Hospitalization, or Result in Persistent or Significant Disability.

2.5 CLASSIFICATION OF ADVERSE EVENT	☐ Results in death ☐ Is life-threatening ☐ Requires inpatient hospitalization or prolongation of existing hospitalization ☐ Results in persistent or significant disability/incapacity ☐ Any other experience that suggests a significant hazard, contraindication, side-effect, or precaution that may require medical or surgical intervention to prevent one of the outcomes listed above ☐ Events changes the risk/benefit ratio of the study

TURFLOOP RESEARCH ETHICS COMMITTEE

2.6 AT THE TIME OF THIS REPORT, THE ADVERSE EVENT IS:	
1. ☐ Resolved*	(No additional follow-up necessary)
2. ☐ Unresolved*	(Additional follow-up necessary)

3. RESEARCH STAFF ASSESSMENT OF ADVERSE EVENT

3.1 IN YOUR JUDGEMENT, IS THE ADVERSE EVENT RELATED, POSSIBLE RELATED, UNKOWN, OR NOT RELATED TO THE PROTOCOL?	
1 ☐	Related
2 ☐	Possibly Related
3 ☐	Unknown
4 ☐	Not related

4. VERIFICATION

Staff Member:

Completed by (Please Print or Type):

First Name: Last Name:

Designation/Role On Research Project:

TURFLOOP RESEARCH ETHICS COMMITTEE

Staff Member Signature: Date:(DD/MM/YY)

Principal Investigator (Please Print or Type):

I have reviewed this AE Form for this participant and attest that the information recorded is accurate and complete.

Investigator's First Name:

Investigator's Last Name:

Investigator Signature: DATE: (DD/MM/YY)