This form must be completed and returned to the HSRC REC Administrator, as soon as possible but 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 NAME:

DECSRIPTION OF THE INTERVENTION:

HSRC Research Ethics Committee Number:

1. CLINIC AND PARTICIPANT INFORMATION:

CLINIC NAME:
PARTICIPANT ID:
PARTICIPANT AGE:
PARTICIPANT GENDER:

2. ADVERSE EVENT:

2.1 AE REPORT TYPE: Initial ☐ Follow-Up: ☐

2.2 DATE OF ADVERSE EVENT: **/ /** (DD/MM/YY)

2.3 ADVERSE EVENT REPORTED TO RESEARCHERS BY:

☐ Study participant returning to the site

☐ By other means, specify:

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

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

2. 3 ADVERSE EVENT DESCRIPTION: PROVIDE A BRIEF DESCRIPTION OF INJURY/ADVERSE EVENT INCLUDING ANY ACTION TAKEN BY THE STUDY TEAM TO DATE ON BEHALF OF THE PARTICIPANT.

2.4 IS THE ADVERSE EVENT <u>SERIOUS?*</u>	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

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:

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)