MINISTRY OF HEALTH, WELLNESS AND THE ENVIRONNMENT

ST. VINCENT AND THE GRENADINES

RESEACH ETHICS COMMITTEE

Adverse Event Report Form

Definition: An adverse event is defined as any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research The onset of the adverse reaction may be sudden or may develop over time.

All incidents of injury or other adverse events experienced by subjects must be reported to the Research Ethics Committee. A written report, along with a copy of the signed consent form (unless there is a waiver of written consent) should be submitted as soon as possible but **NOT LATER THAN FIVE (5) WORKING DAYS** after first awareness of the problem.

Date:

Principal Investigator:

Project Title:

_____

_____

Subject/Participant name:

Research Procedure Involved:

_____

_____

_____

Nature of Injury/Adverse Effect (Describe in detail):

_____

_____

_____

Injury/Adverse Event appears to be:

☐ Directly related to the research

☐ Indirectly related to the research.

The relationship appears to be:

☐ Remote

☐ Possible

☐ Probable

Response/Treatment:

Date:

What steps have been taken in response to the event:

_____

_____

_____

_____

_____

_____

By whom:

Describe any medical or psychological treatment provided:

_____

_____

_____

_____

By whom:

Where:

Will there be follow up? ☐ Yes ☐ No

If yes, describe the plan and indicate who will be responsible.

_____

_____

_____

_____

_____

_____

Reporting:

What reports have been submitted on this incident?

_____

_____

_____

What persons or agencies have been officially informed?

_____

_____

_____

Additional Comments: a letter explaining any other details may be attached if desired.

Signature of person reporting incident: _____

Printed name:

FOR RESEARCH ETHICS COMMITTEE USE:

□ Report acknowledged

□ Report accepted without recommendation

□ Not serious or life-threatening

□ Not unanticipated (i.e. the risk of this event was described in the general investigational plan or research protocol, or in the consent document)

□ Not related to the research

□ Other (Explain)

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□ Report accepted pending receipt of additional information to be submitted to the Research Ethics Committee

□ Report acknowledged. All three criteria (serious, unanticipated, and related to the research) apply, and the Event will be reported to the relevant authority and put on the Agenda for the next convened Research Ethics Meeting.