**SERIOUS ADVERSE EVENT REPORT FORM**

Whenever there is any SAE event in any research approved by the URERB, it has to be reported by the principal investigator (PI) to the URERB.

*Section I. This form should be filled up by the PI.*

Protocol Code\*

Study Protocol Title

Principal Investigator

Report Date:

 Initial Onset Date Follow –up

Title of Report

Subject’s initial number:\_\_\_\_\_\_\_\_\_ Age:\_\_\_\_\_\_\_\_\_\_\_\_\_ Male Female

Subject’s history:

Laboratory Findings:

SAE: Treatment:

 Outcome: Resolved Ongoing

Seriousness: Relation to

 Death Life Threatening Drug Device Study

 Hospitalization Not Related

 Initial Prolonged Possibly

 Disability/Incapacity Probably

 Congenital Anomaly Definitely Related

 Others Unknown

Note: P.I. should attach standard SAE report form to this form.

*Section 2 (to be filled up by the designated URERB representative) Document receipt by the URERB*

Name of URERB Secretariat Signature Date

Reviewer/s Recommendations

Reviewer’s Name Signature Date

Changes to the study protocol recommended Yes No

Comments:

Changes to the informed consent recommended Yes No

Comments:

URERB Final Action: Type of Review:

 Request an amendment to the study protocol Expedited Full Board Review

 Request an amendment to the informed consent

 Request further information Date of Meeting:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Suspend or terminate the study

 Take note and no further action is needed

 Others

Name of Member Secretary Signature Date