**SERIOUS ADVERSE EVENT REPORT FORM**

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

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

Protocol Code\*

Study Protocol Title

Principal Investigator

 Initial Onset Date Follow –up

Report Date:

Title of Report

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

Participant’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 TSURERC representative) Document receipt by the TSURERC Secretariat*

Name of TSURERC Secretariat Signature Date

Reviewer/s Recommendations

Reviewer’s Name Signature Date

Changes to the study protocol recommended Yes No

Comments:

Changes to the study protocol recommended Yes No

Comments:

TSURERC 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

<Printed Name & Signature> \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Member Secretary, TSURERC Date

<Printed Name & Signature> \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Chairperson, TSURERC Date