

RESEARCH CENTRE-JEDDAH

Serious UNEXPECTED Adverse Event (SUAE) Report Form

Please complete this form for each unexpected, serious, adverse event and submit to the IRB within two working days of the occurrence.

IRB # _____

PI: _____

Date of serious unexpected adverse event: _____

Medical Record Number of Enrolled Research Subject: _____

Description of the event including patient/subject outcome:

Relationship of the event to the subject’s participation in the research project:

Definitely related

Possibly Related

Probably related

Definitely not related

If the SUAE is related to participation in this study, please check one of the following:

- The possibility of this SUAE is listed in the consent form and therefore the consent form does not need to be modified.
- The consent form has been modified and two copies are enclosed – one with all revisions highlighted, and one clean copy to be stamped with IRB approval.
- The SUAE was possibly related to the study; however the consent form does not need to be modified because:

Signature and I.D. # of P.I.: _____

Extension: _____

MBC: _____

Date of Report: _____

A serious adverse event (or adverse experience) or reaction is any untoward medical occurrence that results in death, is life-threatening or potentially life-threatening, requires inpatient hospitalization or prolongation of hospitalization, results in permanent or significant disability/incapacity, results in a congenital anomaly/birth defect, or the investigator considers significant.

“Unexpected” is any adverse event that is not listed in the consent form and/or the proposal and includes events that are unexpected in its occurrence, severity and/or frequency.

To be completed by IRB

SUAE No. for this project: _____

TO BE COMPLETED BY CHAIRMAN OF IRB

RECOMMENDATION:

- NO ACTION NEEDED UNTILL DISCUSSED BY THE FULL COMMITTEE AT THE NEXT SCHEDULED MEETING.
- SUSPEND ENROLLMENT UNTIL DISCUSSED BY THE FULL COMMITTEE
- MORE INFORMATION REQUIRED (please specify).

- OTHER RECOMMENDATION:

Signature of Chairman: _____

Date: _____