

Institutional Review Board

**PROTOCOL & GCP DEVIATION FORM FOR RESEARCH INVOLVING HUMAN PARTICIPANTS**

(**Form # KSU-IRB 021-E**)

As per KSU-IRB Policy, the Principal Investigators have to report to the IRB all protocol deviations in a quarterly manner. The major protocol deviation(s) which affect subject’s safety, risks or benefits, data integrity is subjected to immediate submission(s) to the IRB as soon as possible, but no later than 7 days.

The PI or delegated study staff should document all minor protocol deviations along with the Corrective And Preventive Actions and submit to the IRB within a period of three (3) months (quarterly reporting) for review.

Name of Principal Investigator:

Study Title:

IRB Project No.

Subject ID No. (if any):

Date of Deviation:

**DEVIATION DETAILS:**

Is this a major or minor deviation? Yes \_\_ No \_\_ (if yes, please select below)

* + affects subject safety
  + risks or benefits
  + data integrity

Description of Deviation:

Explain the reasons why the event was occurred:

Description of any follow-up, (if any):

Corrective And Preventive Action Plans: (*mention the action plans to avoid recurrence in the* *future*)

PI Signature and Date:

*For more information, please visit the KSU website of Research Ethics Committee at:* <http://dsrs.ksu.edu.sa/ar/comm_Policies>