**Protocol Deviation Log for Research Involving Human Participants**

**Form # KSU-IRB 022-E**

**PROTOCOL DEVIATION LOG**

|  |  |  |  |
| --- | --- | --- | --- |
| **Protocol ID/Number:** |  | **Site Name/Number:** |   |
| **Protocol Title:** |  |
| **Sponsor/Not Applicable:** |  |
| **Principal Investigator:** |  | **Page number**  |   |
| **RefNo.** | **SubjectID** | **Date of Deviation** | **Deviation Description** | **Dev. Type**  | **Did Subject Continue in Study?** | **Meets IRB Reporting Req.(Yes/No)** | **IRB Reporting Date** |
| **1** |   |   |    |    |   |   |   |
| **2** |   |   |    |    |   |   |   |
| **3** |   |   |    |    |   |   |   |
| **4** |   |   |    |    |   |   |   |
| **5** |  |  |  |  |  |  |  |
| **6** |  |  |  |  |  |  |  |

**CAPA: Corrective And Preventive Actions *plan***

|  |  |
| --- | --- |
| **1** |   |
| **2** |     |
| **3** |  |
| **4** |  |
| **5** |  |
| **6** |  |

**CAPA reviewed** (PI/ Compliance Monitor/IRB)

**Corrective And Preventive Actions taken according to the *Plan Yes\_\_\_\_\_ / No \_\_\_\_\_\_***

**Findings**

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**Resolved.**

**Comments:**

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**Signatures:**

Principal Investigator. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

KSU-Compliance Monitor.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*For more information, please visit the website of Research Ethics Committee in King Saud University (*http://dsrs.ksu.edu.sa/ar/comm\_Policies*)*