

**PROTOCOL DEVIATION/VIOLATION FORM (Form 4.4)**

IRB Protocol Code: Date Received (D/M/Y):

Protocol Title: Sponsor:

Principal & Sub Primary Reviewers:

Investigators:

**SECTION 1: TO BE FILLED UP BY PRINCIPAL INVESTIGATOR**

|  |
| --- |
| 1. **NATURE OF THE REPORT** |
| **Major Minor** |
| 1. **DETAILED DESCRIPTION OF REPORTED DEVIATION/VIOLATION AND EXPLANATION WHY IT HAPPENED** |
|  |
| 1. **DEVIATIONS FROM THE APPROVED PROTOCOL** |
|  |
| 1. **EXPLANATION FOR DEVIATION/VIOLATION** |
|  |
| 1. **IMPACT OF DEVIATION/VIOLATION ON PARTICIPANTS’ RISKS/HARMS AND INTEGRITY OF DATA** |
|  |
| 1. **CORRECTIVE ACTIONS and PREVENTIVE ACTIONS** |
|  |

**INVESTIGATOR’S ATTESTATION**

I certify that the information provided in this report is complete and accurate.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature over Printed Name of Principal Investigator Date

*(IRB Use only)* Received by:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature over Printed Name Date

**SECTION 2: TO BE FILLED UP BY RESPECTIVE IRB MEMBER**

|  |
| --- |
| **Type of Review**  **Expedited Full Board** |

**Summary of Recommendations:**

**( ) Submission of additional information**

**( ) Submission of corrective/Preventive actions**

**( ) Invitation for a clarificatory interview with the Principal Investigator**

**( ) Site visit**

**( ) Suspension of recruitment**

**( ) Withdrawal of Ethical Clearance**

**( ) Suspension of the study**

**( ) Acknowledge with no further action**

**Decision:**

**Acknowledged by:**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Name and Signature of IRB MEMBER**