

**REPORTABLE NEGATIVE EVENT REPORT (Form 4.3)**

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

Protocol Title: Sponsor:

Principal & Sub

Investigators:

**A: TITLE OF REPORT: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date of Event: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**B. SUMMARY OF SIGNIFICANT DATA:**

With Full Document Attachment With Partial Data Attachment

|  |  |
| --- | --- |
| RNE Report | |
| Start of the Study: | Expected end of the study: |
| Number of enrolled participants: | Number of required participants: |
| Description of Negative (harm, risk) Events:   1. Involving Participants 2. Involving members of the Study Team 3. Involving Data Safety and Integrity | Actions taken to prevent future RNEs, interventions and Outcomes |

**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:**

**( ) Request an amendment to the protocol or the consent form.**

**( ) Request further information**

**( ) Recommend further Action (indicate action)**

**( ) Take Note and No Further Action needed**

**( ) Others: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Final Action:**

**Acknowledged by:**

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

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Signature**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Name of Primary Reviewer**