

**PROGRESS REPORT FORM (FORM 4.1)**

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**

 **Please check** (√) **each of the boxes that pertains to your report.**

1. Recruitment History:

\_\_\_\_Accrual ceiling set by Sponsor

\_\_\_\_The total number recruited

\_\_\_\_Numbers screened

\_\_\_\_Screen Failure

\_\_\_\_Number of enrolled participants

\_\_\_\_Withdrawn

\_\_\_\_Active participants

\_\_\_\_Number of participants completed the study

2. Number of Amendments:

3. Number of Protocol Deviations/Violations from the approved protocol:

4. Number of on-site SAE’s and SUSARs:

5. Any change in participant population, recruitment or selection criteria since the last review? \_\_\_\_Yes \_\_\_\_No

(Explain the changes)

6. Any change in the Informed consent process or documentation since the last review?

\_\_\_\_Yes \_\_\_\_No

(Explain the changes)

7. Is there any new information in recent literature or similar research that may change the risk/benefit ratio for participants in the study?

 \_\_\_\_Yes \_\_\_\_No

(Explain the changes)

8. Any new investigator that has been added to or removed from the study research since the last review?

\_\_\_\_Yes \_\_\_\_No

(Pls. submit the name, CV and GCP Certificates of the new investigators.)

9. Are there other new sites that were added or deleted since the last review?

\_\_\_\_Yes \_\_\_\_No

 (Pls. identify the sites and note the addition or deletion.)

116

116

**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

117

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

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

 **Summary of Recommendations:**

 **Decision:**

**( ) Accepted**

**( ) Request further information**

**( ) Require specific action**

**Acknowledged by:**

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

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