

**FINAL REPORT FORM (FORM 4.6)**

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

Protocol Title: Sponsor:

Principal & Sub Primary Reviewers:

Investigators:

*Instructions to the Researcher: Please accomplish this form and ensure that you have included in your submission the following documents:*

***Basic requirements:***

☐ Full proposal / study protocol

☐ Summary of Amendments and the dates

☐ Total number of SAE’s on-site from the time of approval up to present

☐ Total number of SUSARs off-site from the time of approval up to present

☐ Number of Safety reporting and the dates

☐ Number of Protocol deviations submitted and the dates

☐ Number of progress reports and the dates

☐ Number of site visits and the dates

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

**1. Total number of subjects who participated in the research**

1. Target number of subjects approved \_\_\_\_\_\_\_\_\_\_\_\_

2. Number of subjects who were screened \_\_\_\_\_\_\_\_\_\_\_\_

3. Number of subjects who withdrawn/discontinued the research \_\_\_\_\_\_\_\_\_\_\_\_

4. Number of subjects who completed the study \_\_\_\_\_\_\_\_\_\_\_\_

**2. Occurrence of Serious Adverse Events (SAEs) or unanticipated problems involving risks to subjects, withdrawal of subjects from the research, or complaints about the research**

\_\_\_\_If present, pls. explain \_\_\_\_None

**3. Please provide a summary of your research findings to include a summary of recent literature or modifications to the research since the last IRB review (if not previously reported).**

**4. Date of permanent closure of the research\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**5. Dissemination plan on outcome/result of the Study.**

* **Submission of paper for publication**
* **Presentation in institutional/national/international conferences**

**INVESTIGATOR’S ATTESTATION**

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

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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:**

**( ) Accept**

**( ) Requires submission with corrections**

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

**Decision:**

**Acknowledged by:**

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

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