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FINAL REPORT FORM (FORM 4.5)

IRB Protocol No.

Date Received (D/M/Y):

Protocol Title:

Sponsor:

Principal & Sub
Investigators:

Primary Reviewers:

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 Number of subjects who withdrawn/discontinued the research _____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 _____

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

Reviewer's
Comments:

Final Action:

- () Accept
- () Requires submission with corrections
- () Others: _____

Acknowledged by:

Name of Reviewer
IRB Member

Signature

Date