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EARLY TERMINATION REPORT FORM (FORM 4.3)

IRB Protocol No.

Date Received (D/M/Y):

Protocol Title:

Sponsor:

Principal & Sub
Investigators:

Primary Reviewers:

SECTION 1: TO BE FILLED UP BY PRINCIPAL INVESTIGATOR

IRB Approved Date

Date of Last Report

Starting Date of Research

Termination Date

No. of Participants
Enrolled

Reason/s for Early Termination (Pls. use separate sheet to explain the reason/s for early termination.)

A. Justification

- poor recruitment
- high number of SUSARs
- safety or benefit is doubtful or at risk
- undue or significant SAEs
- Conduct Breaches
- Others

B. Mechanism on care for and follow up of participants

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
- () Request further additional information
- () Request further additional action
- () Others: _____

Acknowledged by:

Name of Reviewer
IRB Member

Signature

Date