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PROTOCOL DEVIATION/VIOLATION FORM (Form 4.6)

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

1. NATURE OF THE REPORT

Major

Minor

2. DETAILED DESCRIPTION OF REPORTED DEVIATION/VIOLATION AND EXPLANATION WHY IT HAPPENED

3. EFFECTS OF THE DEVIATION/VIOLATION TO THE FOLLOWING:

1. *Violation of the rights of the subjects*
_____ Yes. How? _____ No

2. *Health and well-being of the subjects*
_____ Yes. What? _____ None

3. *Compromised in the integrity of the research*
_____ Yes. How? _____ No

4. *Willingness of the subject to continue in the participation of the study*
_____ Yes. _____ No. Why?

5. *Continuation of the research*
_____ Yes. Why? _____ No.
Date of the termination of the study: _____

4. NEED TO REVISE THE PROTOCOL DUE TO THE PROTOCOL DEVIATION/VIOLATION

_____ Yes. How? _____ No. Why?

5. PLANS TO PREVENT THE RECURRENCE OF THE EVENT IN THE FUTURE

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:

- () Submission of additional information
- () Submission of corrective action
- () Clarificatory interview with the Principal Investigator
- () Site visit
- () Suspension of recruitment
- () Suspension of the study
- () Others: _____

Acknowledged by:

Name of Reviewer
IRB Member

Signature

Date