3) Describe in detail specific violation/deviation: (use additional sheet of paper(s) if needed)

4) Explain how/why the deviation occurred. (use additional sheet of paper(s) if needed

5) Describe how the deviation/violation affected the following:

a. Risk/benefit ration for the subject: Was there a change? ☐ Yes, why? ☐ No, why?

b. Integrity of the research data: Was if compromised? ☐ Yes, why? ☐ No, why?

c. Does the subject wiling to continue study participation? ☐ Yes ☐ No, why?

6) Does this protocol deviation/violation require revision of the protocol and/or consent form?

☐ Yes *(if YES, please submit a completed amendment form and revised documents with changes marked)*

☐ No

7) Please describe: (i) corrective actions, if applicable, for the deviation/violation; and (ii) a plan for preventing the recurrence of the deviation/violation

By signing below, I declare that the above is an accurate and complete description of the protocol deviation/violation, and that upon receipt of the IRB's review, I will fully and immediately implement any corrective actions required by the IRB

_____ _____

Signature of PI Date

_____ _____

Signature of co-PI (If applicable) Date

PROTOCOL DEVIATION/VIOLATION FORM

ERC Reference #:_____ Protocol No._____

Principal Investigator:_____ Inst./Dept.:_____

Protocol Title: _____

_____

*Protocol Deviation means a minor or administrative departure from the IRB- approved protocol procedures (e,g. the protocol informed consent document, recruitment process or study materials) that was made without prior Sponsor and IRB approval. It is an accidental or unintentional change to, or non-compliance with the research protocol that does not increase risk or decrease benefit or, does not have a significant effect on the subject's rights, safety or welfare; and for on the integrity of the data. Adeviation may be due to the research subject's non-adherence, or unintentional change to or non-compliance with the research protocol on the part of the Principal Investigator or the Clinical Trial Staff.

Examples of a deviation include:

ii. A Reschedule study visit

ii. Failure to collect an ancillary self-report questionnaire

iii. Subjects refusal to compare scheduled research activities

Note: as described if there is lapse in IRB approval this report should also be submitted.

Protocol Violation: means an accidental or unintentional change to, or non-compliance with the IRB approved procedures (e,g. the protocol, informed consent document, recruitment process or study materials) without prior sponsor and IRB approval. Protocol violations generally increase rrisk or decrease benefit, affects the subject's rights, safety, or welfare, or the integrity of the research data.

Examples of protocol violations:

i. Failure to obtain valid informed consent (e,g. obtained informed consent on a non-date stamped form)

ii. Loss of laptop computer that contained identifiable, private information about subjects

iii. Accidental distribution of incorrect study medication dose

iv. Not following inclusion/exclusion criteria

I. Date of Occurrence:	Date of awareness:	Date of Report:

II. Characterization

The deviation/violation involves:

- ☐ Enrollment process *(Inclusion/exclusion, criteria etc.)*
- ☐ Consent process *(oral/written)*
- ☐ Drug/Device Administration *(dosage, schedule, route of administration, formulation, etc.)*
- ☐ Other protocol activities (research activities, data analysis, reporting, etc.
- ☐ Complaint from research subject
- ☐ Audit finding that requires corrective action
- ☐ Other_____

_____

III. Description

1. Participant ID (*If spplicable: if more than one participant is involved list all the IDs)*

2. If the purpose of this deviation report ia a lapse in IRB approval, please describe all study activities, including enrollement,, interventions data analysis that have accured during the lapse (use additional sheet of paper(s); if not proceed to no.2)