



Opus Institutional Review Board

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Significant Protocol Deviation Report

*OPUS IRB requires that investigators submit reports of significant protocol deviations **within 10 business days** of the site becoming aware of the deviation. The **Board may request additional information** from the sponsor or investigator in addition to what is required on this form.*

Significant Deviations are those that:

- A. Affect the safety, welfare or rights of the study subjects
- B. Affect the risk/benefit ratio
- C. Affect the scientific design of the study
- D. Violations of any ethical principles.

Protocol Deviation Information

PI
Protocol
Sponsor
Date of Deviation
Date of Report
Subject Initials or Identifier
Opus IRB #

Detailed Deviation Information

This deviation was done under the following conditions (select one of the following options).

- Emergency or Life Threatening Condition (necessary to protect the health, welfare and safety of the subject).
- Non-Emergency

Deviation noted by:

Investigator CRC Monitor Other

Subject Initials or Identifier

Opus IRB #

Check all that apply

Inclusion / Exclusion Violation

- Waiver obtained from Sponsor for enrollment. (attach supportive documentation)
- Inclusion Criteria Violation
- Exclusion Criteria Violation

Informed Consent Deviation

- Screened or Enrolled without informed consent
- Wrong consent used (another study consent used)
- Wrong version of consent used
- Use of unapproved or draft ICF
- Subject unable to give legal consent (mentally incompetent, cognitive impairment, subject medicated with narcotics / amnesiac / sedative drug(s), etc,)
- Person signing for subject was not the legally authorized representative (per state law)
- Consent not obtained prior to study procedures
- Omission of required signatures (witness, PI, person obtaining consent)
- Other:

Protocol required procedure / test not done (visit, lab test, questionnaire, procedure, etc.) List:

- Protocol procedure / requirement omitted
- Protocol procedure / requirement changed
- Protocol required follow-up omitted
- Protocol required follow-up done incorrectly or partially (not per protocol)
- Protocol required follow-up refused by subject
- Randomization error (attach supporting documentation)
- Device sterility expired / use of non-sterile device (only applicable if used on subject)

Emergency Use (attach additional pages if necessary)

Explain:

Medication Deviation

Medication:

- Incorrect Dosage Given
Dose per Protocol
Dose Given
- Contraindicated medication given

Randomization error (explain)
Yes No Resulted in AE or SAE

Explanation of deviation(s): (attach separate page if necessary)

**Indicate the Investigator's assessment of the impact of the deviation on the study data.
(Include comments whether you feel the deviation warrants an amendment to the protocol)**

Please explain to the IRB the measures you have initiated to prevent this from recurring in the future (attach separate page if necessary).

Yes No Has this event been reported to the Sponsor?

Yes No Does this deviation affect the rights, safety or welfare of subject?

Yes No Does this deviation affect the integrity of the study data?

Name of person completing this form

Date

Email Address

Phone #

Signature of Principle Investigator

Date

*Sub-Investigator may sign report if explanation attached