

**Nova Southeastern University
Office of Clinical Research**

Protocol Violation/Deviation

Protocol Number and Title:

Subject ID # _____

Is this a (check one): Protocol Violation Protocol Deviation

Date of Event _____

Date Event Became Known to Investigator _____

Date Form Completed _____

Type of Protocol Violation/Deviation

- Randomization of ineligible patient
- Eligibility criteria exception
- Screening procedure required by protocol not done
- Screening or on-study procedure/lab done outside the protocol required time
- Incorrect therapy given to patient
- On-study procedure required by protocol not completed
- Visit non-compliance
- Medication non-compliance
- Other: _____

Narrative Description of Protocol Violation/Deviation

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Action Taken

- Patient withdrawn
- Patient remains on study but data analysis will be modified
- Sponsor notified date ____/____/____
- Other _____

Signatures

_____ ____/____/____
Research Coordinator/Reporter Date

_____ ____/____/____
Principal Investigator Date