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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__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________
Nova Southeastern University
Office of Clinical Research

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☐ Patient withdrawn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