PROTOCOL DEVIATION LOG

Protocol ID/Number:	Sponsor:
Principal Investigator:	Site:

This is a cumulative log for all protocol deviations that have occurred at this site. This log will be kept at your site and will be copied by the Monitor at each site visit. At the end of the study, the Monitor will retrieve the original log and leave a copy in the Investigator's Site file.

Date of Deviation (MM/DD/YYYY)	Subject ID		Describe Deviation	Deviation Type (A-J) See Codes page 2	Additional Comments (Include reason for deviation)	Study Personnel Signature
	Initials	ID Number				
01/01/2005	XYZ		Summarize Deviation	A		

Form Instructions

Deviation Type: (A - J) See codes below – Enter the appropriate deviation code from the list

Protocol Deviation Codes

- A - Informed Consent procedures
- B - Inclusion/Exclusion criteria
- C - Concomitant Medication/Therapy
- D - Laboratory Assessments/Procedures
- E - Study Procedures
- F - Serious Adverse Event Reporting/Unanticipated Adverse Device Effect
- G - Randomization Procedures/Study Drug Dosing
- H - Visit Schedule/Interval
- I - Efficacy Ratings
- J - Other

A copy of the form should be maintained in the Investigator's Site File