

# Patient Protocol Deviation Form

Patient ID \_\_\_\_\_

**This form is completed for any events performed outside the study guidelines outlined in the protocol. One protocol deviation form should be completed for each and every protocol deviation.**

1. Date of protocol deviation: \_\_\_\_\_

2. Type of protocol deviation:

- Visit Missed
- Visit Out-of-Window
- Visit/Assessment Incomplete (includes form not being complete)
- Informed Consent
- Eligibility
- Study Procedure/Assessment
- Other  
(Choose one.)

2a. If 'Other', please specify: \_\_\_\_\_

3. Does the site's IRB require this deviation to be reported to them?

- Yes
- No

4. Circumstances of the protocol deviation (if deviation is incomplete or missed assessments/visits then state visit/assessment for which the deviation occurred): \_\_\_\_\_