

Provider Protocol Deviation Form

Provider 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. This provider has been removed from the study and their data will be deleted.

- Yes
- No

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