



Off Protocol

Patient ID ___ - ___ - ___

Date form completed (mm/dd/yy): ___ / ___ / ___

Instructions: Complete this form to report a deviation from protocol, at the time that the occurrence becomes known.

Protocol Deviation (check one):

1 Ineligible patient enrolled

2 Follow-Up evaluation not completed in-person, specify reason _____

Time-point: 1 8 Week 2 6 Month 3 12 Month

Method of follow-up (check all that apply): Telephone Medical record

PCP Other _____