

INSTRUCTIONS: Complete this form if the subject has either permanently discontinued study drug but remains in the trial OR permanently withdrew from the Trial after being randomized.

Section A: KEY IDENTIFYING INFORMATION

- A1. Study Identification Number _____ - _____ - _____ - _____ - _____
- A2. Date of form completion _____ / _____ / _____
M M D D Y Y Y Y
- A3. Name of person completing form _____
PRINT FULL NAME INITIALS

Section B: WITHDRAWAL OF STUDY DRUG

- B1. Date last dose of study drug taken _____ / _____ / _____
M M D D Y Y Y Y
(Enter '01/01/0101' for any subject who withdraws from study drug without ever taking an initial dose, then skip to question B10)
- B2. Phase of study drug administration UPTITRATION1 MAINTENANCE 2
- B3. Last dose of study drug prescribed _____ . _____ mg/kg
(Enter '-5' if subject taking MAX dose of study drug)
- B4. Last total daily dose of study drug taken _____ . _____ mg/day

Indication(s) for permanent withdrawal of study drug

(Answer ALL questions B5-B12)

- B5. Intolerance to study drug
- B6. Increase in serum creatinine despite dose adjustments
- B7. Increase in serum potassium despite dose adjustments
- B8. Increase in liver function tests (ALT and/or AST) despite dose adjustments
- B9. Pregnancy or planned pregnancy

YES	NO
1	2
1	2
1	2
1	2
1	2

COMPLETE ADRQ FORM A116 IF 'YES' TO ANY QUESTION B5 - B8

- B10. Study drug discontinued by study physician or attending cardiologist
YES..... 1 NO 2 (B11)
- a. Specify reason(s) _____

B11. Other indication for discontinuation YES..... 1 NO 2 **(B12)**

a. Specify other indication _____

B12. Any comments? YES..... 1 NO 2 **(B13)**

a. Comments: _____

B13. Study drug discontinued because subject is requesting open-label drug.

YES..... 1 NO 2 **(Z1)**

a. Specify reason(s) _____

Section Z: TIME TO COMPLETE FORM AND SIGNATURE

Z1. How long did it take to complete this form? _ _ _ minutes

Signature of PI: _____ Date: _____

END OF FORM