

DAC Study Form 337 – Cessation Committee: “Review of Permanent Discontinuation of Therapy” Form

1. Patient Identification Number....._____
2. Name Code....._____
3. a. Date of Permanent Discontinuation of Therapy (Form 336, Q. 7)..... __ / __ / _____
b. Date of this review __ / __ / _____
4. Stop point the clinic felt the patient had reached?....._____
0 = CC unblinded to randomized meds, but not a stop point
1 = New diagnosis that requires use of the study drug or another anti-platelet or anti-thrombotic agent
2 = Patient insists on taking study drug
3 = Referring physician insists on giving this patient study drug
4 = Serious adverse event that precludes further use of study drug
5 = Life threatening side effects
6 = Annoying side effects persisting on re-challenge
11 = Fistula clotted from thrombosis
13 = Patient reached end point for the graft study due to access procedure or thrombosis
14 = Prevalent patient reached end point in the graft study due to 12 weeks passing without access being used
15 = Incident patient reached end point in the graft study due to loss of both audible bruit and palpable thrill before the first use of the access
16 = Fistula patient had to stop study drug for a medical condition or a planned surgery toward the end of the 6 week drug administration period (no time to re-start drug)
17 = Graft was ligated and abandoned because of steal syndrome within 30 days of placement
19 = Patient has withdrawn his consent to take the study medications
20 = Patient's physician will no longer allow patient to continue
22 = Severe non-life threatening side effects
23 = Patient is lost to follow-up (e.g., patient chose to withdraw from the study, renal transplantation, change to peritoneal dialysis, transfer to a facility where cannot be followed, protocol violation).
5. a. Consensus of Clinical Management Subcommittee and DCC....._____
0 = Not a stop point
1 = Confirm the stop point the clinic felt the patient had reached
2 = A different stop point
b. If "2", which stop point? (use codes from item 4)____
6. Necessity of Unblinding_____
1 = Do not unblind
2 = Unblind
3 = Already unblinded

DAC Study Form 337 – Cessation Committee: “Review of Permanent Discontinuation of Therapy” Form

7. a. Which blinded medication does the Primary Cessation Review Subcommittee stop point reviewer believe the patient was on?.....__
- 1 = The reviewer has been unblinded and knows it is placebo
 - 2 = The reviewer believes this patient was randomized to placebo
 - 3 = The reviewer does not know
 - 4 = The reviewer believes it is active drug
 - 5 = The reviewer has been unblinded and know it is active drug
- b. If 1 or 5, date of unblinding __/__/____
8. Does the Primary Cessation Review Subcommittee stop point reviewer think this was related to the patient's randomized drug intervention? (0=no, 1=yes, 9=couldn't tell)__
9. Comments of reviewer. (Write in as much as you wish. Use back of sheet if necessary.)

201. Date this form completed..... __/__/____

202. User ID of person completing this form_____

<i>Clinical Center Use Only</i>
Date Form Entered __/__/____
Person Entering this Form_____