DAC Study Form 336 - Permanent Discontinuation of Therapy

This Form should be completed by a study coordinator when a patient discontinues therapy. All randomized patients need to be followed until the primary outcome is reached or the study ends regardless whether they are taking the medication. For 30 days after the drug is discontinued, information on SAEs should be collected. The DCC will schedule a conference call with PI, coordinator, DCC and the Quality Control Committee to discuss any permanent discontinuation of therapy not related to reaching a primary outcome (reasons 11, 13, 14, 15).

1. Patient Identification Number.....__ __ __ __ __ __

2. Name Code.....__ __ __ __

3. Reason you have discontinued study drug.....__ __

   1 = New diagnosis that <u>requires</u> 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 <u>precludes</u> further use of study drug
   5 = Life threatening side effects
   6 = Annoying side effects persisting on rechallenge
   Note: Make sure to describe what you did to rechallenge when answering q.8.
   11 = Fistula clotted from thrombosis
   13 = Patient reached end point for the graft study due to access procedure or thrombosis
   14 = Patient who is undergoing regular hemodialysis 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   19 = Patient has withdrawn his consent to take the study medications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 to take the study medications
   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).
   Note: Make sure Form 338 is completed
   24 = Graft Study data collection ended

4. If Q.3 = 19, what is the consent status (Code 0 = no, 1 = yes, 9 = N/A to the study the pt was in.):
   a. Patient withdrew consent to do fistulograms.....__
   b. Patient withdrew consent to do transonic measurements .....__
   c. Patient withdrew consent for hospitalizations and bleeding tracking .....__
   d. Patient withdrew consent for database tracking .....__

5. Does the study team think this patient was on active drug or placebo?.....___
   Use codes 1 to 5
   1 = The team has been unblinded and knows it is placebo
   2 = The team believes this patient was randomized to placebo
   3 = The team does not know
   4 = The team believes this patient was randomized to active drug
   5 = The team has been unblinded and knows it is active drug
6. If q. 5 = 1 or 5, date of unblinding..... __ __ / __ __ / __ __ __ __
7. Date of discontinuation..... __ __ / __ __ / __ __ __ __
   Note: If the drug has not yet been started and must be permanently discontinued, enter the randomization date as the "date of discontinuation".
8. Describe in detail what happened in the text field below. Use the back of this sheet too.

201. Date this form completed ..... __ __/__ __/__ __ __ __
202. User ID of person completing this form.....__ __ __ __ __ __ __ __

Clinical Center Use Only

Date Form Entered __ __/__ __/__ __ __ __

Person Entering this Form_____