Header Annotations

Participant ID:	NUM 6 (101001 – 118999)
Participant Initials:	CHR 3
Clinical Center:	NUM 2 (01 – 18)
Visit Date:	DT (cannot be less than 05/01/2009)
Visit Number:	NUM 2 (01 – 12)
CRC Initials:	CHR 3

Sites:

01 - University of Texas
02 - Mount Sinai School of Medicine
03 - University of California – San Francisco
04 - Washington University School of Medicine
05 - University of Maryland
06 - University of Florida
07 - Henry Ford Hospital
08 - Mayo Clinic College of Medicine
09 - Hospital of the University Of Pennsylvania
10 – Vanderbilt University
11 - Intermountain Medical Center
12 - Marshfield Clinical Research Foundation
13 - Duke University Medical Center
14 - Georgia Health Sciences
15 - University of Alabama at Birmingham
16 - University of Utah Health Care
17 - Tulane University
18 – Montefiore Medical Center

Participant ID: **Participant Initials:** **Clinical Center:**

ADVERSE EVENTS

Event #	Code*	AE description	Grade*	Serious event?	Outcome	Relationship	Action taken with study treatment	Start date *mm/dd/yyyy*	Stop date *mm/dd/yyyy*
NUM 3 (1-999)	NUM 8 (1-99999999)	Linked to MedDRA Dictionary	NUM 1 (1-5)	NUM 1 (1,0)	NUM 2 (1-5, 88)	NUM 1 (1-4)	NUM 2 (1-4, 88, 99)	DT	DT

**Refer to the NIH website for MedDRA code and corresponding grade (http://safetyprofiler-ctep.nci.nih.gov/CTC/CTC.aspx).*

AE codes table				
Grade	**Serious event?**	**Outcome**	**Relationship**	**Action taken with study treatment**
1 = Mild 2 = Moderate 3 = Severe 4 = Life threatening/disabling 5 = Death	1 = Yes 0 = No	1 = Recovered/ resolved with no sequelae 2 = Recovering/ resolving 3 = Not recover ed/not resolved 4 = Recovered/ resolved with sequelae 5 = Fatal 88 = Unknown	1 = Not related 2 = Unlikely related 3 = Possibly related 4 = Related	1 = Drug withdrawn 2 = Dose reduc ed 3 = Dose increa sed 4 = Dose not ch anged 88 = Unknown 99 = Not applicable

CONCOMITANT MEDICATIONS

*Refer to the Concomitant Medications (**CMED**) guidelines in the Manual of Procedures (**MOP**) for completion instructions.*

Line #	Medication name	Medication code	Medication status	Visit number associated with status	Medication update	Visit number associated with update
NUM 3 (1-999)	Auto-populated from the first bank data dictionary, based on the medication code.	NUM 6 (1-999999)	NUM 1 (1,2)	NUM 2 (1-12)	NUM 1 (1,2)	NUM 2 (1-12)

Medication code	Medication status	Medication update
Refer to the Medication Reference Tool	1 = Reported at baseline 2 = New drug during the study	1 = Continued until study completion 2 = Stopped during study participation

Participant ID:	Participant Initials:	Clinical Center:
Visit Date:	Visit Number:	CRC Initials:

COAG CONSENT

Agreement to participate in the COAG study:

1. Participant agrees to participate in the COAG study, which includes the use of genetics data and measurements of other factors in the blood to study response to warfarin dosing..... **NUM 1 (1,0)** ☐1 Yes ☐0 No

2. Participant agrees to allow the COAG study to notify the participant about genetic conditions that may have potentially important meaning for his/her health and treatment: ..... ☐1 Yes ☐0 No

3. Participant agrees to allow the COAG study to notify the participant's physician about genetic conditions that may have potentially important meaning for the participant's health and treatment:..... ☐1 Yes ☐0 No

4. Participant gives permission to study genetics and other biological factors for other health conditions:..... ☐1 Yes ☐0 No

Agreement for future use of COAG blood sample and information collected in the COAG study:

5. Participant agrees to give permission to study his/her genetics and other biological factors for other health conditions besides response to warfarin therapy: **NUM 1 (1,0)** ☐1 Yes ☐0 No

6. Participant agrees to allow future studies to make genetic and other information available on a controlled access website to approved researchers ..... ☐1 Yes ☐0 No
[*Such information cannot be used to identify the participant; permission is given to have coded genetic information and coded medical information placed in a special database for use only by approved researchers.*]

7. Participant agrees to allow researchers from private companies to have access to DNA and genetic data which may be used to develop laboratory tests or pharmaceutical therapies that could benefit other people: ..... ☐1 Yes ☐0 No

8. Participant gives permission to be contacted in the future to see if he/she is willing to provide additional biological samples or follow-up information about his/her health or medical care:..... ☐1 Yes ☐0 No

Participant ID:	**Participant Initials:**	**Clinical Center:**
Visit Date:	**Visit Number:**	**CRC Initials:**

DUKE ANTICOAGULATION SATISFACTION SURVEY (DASS)

We would like to know how your anti-clot treatment (warfarin/Coumadin) affects you, and what you know and feel about your anti-clot treatment. Please check the answer that best fits your situation. If a question does not apply to you, then check "Not at all".

		Not at all	A little	Some-what	Moder-ately	Quite a bit	A lot	Very much
1a.	How much does the possibility of bleeding or bruising limit you from taking part in physical activities (*for example, housework, gardening, dancing, sports, or anything else you would usually do*)?… ..... **NUM 1 (1-7)**	☐1	☐2	☐3	☐4	☐5	☐6	☐7
1b.	How much does the possibility of bleeding or bruising limit you from traveling?	☐1	☐2	☐3	☐4	☐5	☐6	☐7
1c.	How much does the possibility of bleeding or bruising limit you from getting the medical care you need (*for example, visiting a dentist, chiropractor, or doctor of your choice*)?	☐1	☐2	☐3	☐4	☐5	☐6	☐7
1d.	How much does the possibility of bleeding or bruising limit your ability to work for pay?	☐1	☐2	☐3	☐4	☐5	☐6	☐7
1e.	Overall, how much does the possibility of bleeding or bruising affect your daily life?	☐1	☐2	☐3	☐4	☐5	☐6	☐7

Being on anti-clot treatment may mean changing some of your other habits as well.

2a.	How much does anti-clot treatment limit your choice of food (*diet*)? .... **NUM 1 (1-7)**	☐1	☐2	☐3	☐4	☐5	☐6	☐7
2b.	How much does anti-clot treatment limit the alcoholic beverages you might wish to drink?	☐1	☐2	☐3	☐4	☐5	☐6	☐7
2c.	How much does anti-clot treatment limit the over-the-counter medications (*for example, aspirin, ibuprofen, vitamins*) you might wish to take?	☐1	☐2	☐3	☐4	☐5	☐6	☐7
2d.	Overall, how much does anti-clot treatment affect your daily life?	☐1	☐2	☐3	☐4	☐5	☐6	☐7

Participant ID:	Participant Initials:	Clinical Center:
Visit Date:	Visit Number:	CRC Initials:

DUKE ANTICOAGULATION SATISFACTION SURVEY (DASS)

Being on anti-clot treatment means doing a lot of things, some every day and some less often.

Daily tasks could include: remembering to take your medicine at a certain time, taking the correct doses of your medicine, not drinking much alcohol, following a moderate diet, avoiding bruising and bleeding, and so forth.

Occasional tasks could include: traveling to the clinic for blood check-ups, contacting the clinic in case of bleeding or other important events, and so forth.

	Not at all	A little	Some-what	Moder-ately	Quite a bit	A lot	Very much
3a. How much of a hassle (*inconvenience*) are the daily tasks of anti-clot treatment? .....**NUM 1 (1-7)**	☐1	☐2	☐3	☐4	☐5	☐6	☐7
3b. How much of a hassle (*inconvenience*) are the occasional tasks of anti-clot treatment?	☐1	☐2	☐3	☐4	☐5	☐6	☐7

Considering anti-clot treatment as a whole (that is, both the daily and occasional tasks), please consider the following.

3c. How complicated do you find your anti-clot treatment to be? .....**NUM 1 (1-7)**	☐1	☐2	☐3	☐4	☐5	☐6	☐7
3d. How time-consuming do you find your anti-clot treatment to be?	☐1	☐2	☐3	☐4	☐5	☐6	☐7
3e. How frustrating do you find your anti-clot treatment to be?	☐1	☐2	☐3	☐4	☐5	☐6	☐7
3f. How painful do you find your anti-clot treatment to be?	☐1	☐2	☐3	☐4	☐5	☐6	☐7
3g. Overall, how much of a burden do you find your anti-clot treatment to be?	☐1	☐2	☐3	☐4	☐5	☐6	☐7
3h. Overall, how confident are you about handling your anti-clot treatment?	☐1	☐2	☐3	☐4	☐5	☐6	☐7

DUKE ANTICOAGULATION SATISFACTION SURVEY (DASS)

These last questions ask what you know and feel about your anti-clot treatment.

	Not at all	A little	Some-what	Moder-ately	Quite a bit	A lot	Very much
4a. How well do you feel that you <u>understand the medical reason</u> for your anti-clot treatment? .....**NUM1 (1-7)**	☐1	☐2	☐3	☐4	☐5	☐6	☐7
4b. How much do you <u>feel reassured</u> because of your anti-clot treatment?	☐1	☐2	☐3	☐4	☐5	☐6	☐7
4c. How much do you <u>worry about bleeding and bruising</u>?	☐1	☐2	☐3	☐4	☐5	☐6	☐7
4d. <u>Overall</u>, how much has anti-clot treatment had a <u>positive impact</u> on your life?	☐1	☐2	☐3	☐4	☐5	☐6	☐7
4e. <u>Overall</u>, how much has anti-clot treatment had a <u>negative impact</u> on your life?	☐1	☐2	☐3	☐4	☐5	☐6	☐7
4f. <u>Overall</u>, how <u>satisfied</u> are you with your anti-clot treatment?	☐1	☐2	☐3	☐4	☐5	☐6	☐7
4g. Compared with other treatments you have had, how <u>difficult is your anti-clot treatment to manage</u>?	☐1	☐2	☐3	☐4	☐5	☐6	☐7
4h. How likely would you be to <u>recommend</u> this form of anti-clot treatment to someone else with your disease or medical condition?	☐1	☐2	☐3	☐4	☐5	☐6	☐7

Research Coordinator: Please check the appropriate box to indicate who completed the CRF. **NUM1 (1-3)**

☐1 Participant ☐2 Interviewer ☐3 Both

Participant ID:	Participant Initials:	Clinical Center:
Visit Date:	Visit Number:	CRC Initials:

DIET INFORMATION

1. Indicate if you consume any of the following foods on a regular basis:

a.	Avocado:	☐1 Yes	☐0 No	**NUM 1 (1,0)**
b.	Broccoli:	☐1 Yes	☐0 No	
c.	Brussel sprouts:	☐1 Yes	☐0 No	
d.	Cabbage:	☐1 Yes	☐0 No	
e.	Chickpeas:	☐1 Yes	☐0 No	
f.	Greens (*e.g. beet, collard, dandelion, mustard, turnip*): ..	☐1 Yes	☐0 No	
g.	Green peas:	☐1 Yes	☐0 No	
h.	Green tea:	☐1 Yes	☐0 No	
i.	Kale:	☐1 Yes	☐0 No	
j.	Lettuce:	☐1 Yes	☐0 No	
k.	Spinach:	☐1 Yes	☐0 No	
l.	Liver:	☐1 Yes	☐0 No	

2. Do you drink coffee? ..... ☐1 Yes ☐0 No

If yes,

a. What kind of coffee do you drink? .....
☐1 Caffeinated
☐2 Decaffeinated
☐3 Both
NUM 1 (1-3)

b. When you drink coffee, what is the average amount? ....
__ __ cups **NUM 2 (0-99)**
☐1 per day **NUM 1 (1-3)**
☐2 per week
☐3 occasionally/rarely

3. Do you drink other caffeinated beverages (*e.g. iced tea, cola drinks*)? ..... ☐1 Yes ☐0 No **NUM 1 (1,0)**

If yes,

a. When you drink other caffeinated beverages, what is..... the average amount?
__ __ cans/glasses **NUM 2 (0-99)**
☐1 per day **NUM 1 (1-3)**
☐2 per week
☐3 occasionally/rarely

DIET INFORMATION

4. Do you drink alcoholic beverages? ..... ☐1 Yes ☐0 No **NUM 1 (1,0)**

If yes,

a. How often do you drink alcoholic beverages? ..... **NUM 1 (1-8)**
- ☐1 Every day
- ☐2 Nearly every day
- ☐3 3 to 4 times a week
- ☐4 2 times a week
- ☐5 Once a week
- ☐6 2 to 3 times per month
- ☐7 Once a month
- ☐8 Less than once a month

b. How much do you drink on a typical drinking day? ..... __ __ drinks **NUM 2 (0-99)**
(1 drink = 10 oz can/bottle of beer
or 4 oz glass of wine
or 1 oz shot of hard liquor)

c. In the past 12 months, what is the highest number of drinks you can recall having on one occasion? ..... __ __ drinks

Research Coordinator: Please check the appropriate box to indicate who completed the CRF. **NUM 1 (1-3)**

☐1 Participant ☐2 Interviewer ☐3 Both

Participant ID:	Participant Initials:	Clinical Center:
Visit Date:	Visit Number:	CRC Initials:

DIET INFORMATION – FOLLOW-UP

1. Since the last study visit, how many meals did you eat away from home (*that is, at a restaurant or cafeteria, including at work*)? ..... __ __ __ **NUM 3 (0-999)**

2. Have you been eating more than usual since your last study visit?..... ☐1 Yes ☐0 No ☐88 Don't know **NUM 2 (1,0,88)**

3. Have you been eating less than usual since your last study visit?..... ☐1 Yes ☐0 No ☐88 Don't know

4. Have you made any other changes in your diet since your last study visit?..... ☐1 Yes ☐0 No ☐88 Don't know

5. Have you had a weight gain since your last study visit?. ☐1 Yes ☐0 No ☐88 Don't know

6. Have you had a weight loss since your last study visit? . ☐1 Yes ☐0 No ☐88 Don't know

7. Indicate if any of the following foods were consumed in the past 7 days and if there was a change in the amount consumed compared with your usual diet:

	Not consumed	No change	Less than usual	Greater than usual
a. Avocado:.....**NUM 1 (0-3)**	☐0	☐1	☐2	☐3
b. Broccoli:.....	☐0	☐1	☐2	☐3
c. Brussel sprouts:.....	☐0	☐1	☐2	☐3
d. Cabbage:.....	☐0	☐1	☐2	☐3
e. Chickpeas:.....	☐0	☐1	☐2	☐3
f. Greens (*e.g. beet, collard, dandelion, mustard, turnip*):.....**NUM 1 (0-3)**	☐0	☐1	☐2	☐3
g. Green peas:.....	☐0	☐1	☐2	☐3
h. Green tea:.....	☐0	☐1	☐2	☐3
i. Kale:.....	☐0	☐1	☐2	☐3
j. Lettuce:.....	☐0	☐1	☐2	☐3
k. Spinach:.....	☐0	☐1	☐2	☐3
l. Liver:.....	☐0	☐1	☐2	☐3

DIET INFORMATION – FOLLOW-UP

8. Since the last study visit did you drink coffee? ..... ☐1 Yes ☐0 No **NUM 1 (1,0)**

   If yes,

   a. Did you consume: ..... ☐1 Less than usual
   ☐2 More than usual **NUM 1 (1-3)**
   ☐3 About the same

9. Since the last study visit did you drink other caffeinated beverages? ..... ☐1 Yes ☐0 No **NUM 1 (1,0)**

   If yes,

   a. Did you consume: ..... ☐1 Less than usual
   ☐2 More than usual **NUM 1 (1-3)**
   ☐3 About the same

10. Since the last study visit did you drink alcoholic beverages? ..... ☐1 Yes ☐0 No **NUM 1 (1,0)**

    If yes,

    a. Did you consume: ..... ☐1 Less than usual
    ☐2 More than usual **NUM 1 (1-3)**
    ☐3 About the same

Research Coordinator: Please check the appropriate box to indicate who completed the CRF.

☐1 Participant ☐2 Interviewer ☐3 Both **NUM 1 (1-3)**

Participant ID: **Participant Initials:** **Clinical Center:**

DOSE REQUISITION – INITIATION PERIOD

NUM 2 (0-99) **Study day**	DT (≥ 05/01/2009) **Date** mm/dd/yyyy	NUM 1 (1) **Participant unavailable**	NUM 2.2 (0-99.0-99) NUM 2 (99) **INR to use for dose calculation**	NUM 1 (1-2) **Participant location** 1 = Inpatient 2 = Outpatient	NUM 1 (1) **Genetics data not available, calculate dose**	NUM 1 (0-99) **# of days of additional capsules?***	NUM 1 (1) **Do not dispense calculated dose**	NUM 1 (1) **Dosed off-protocol?****
1	__ __/__ __/__ __ __ __	☐1	__ __ . __ __ ☐99 No INR	___	☐1	__ __	☐1	☐1
2	__ __/__ __/__ __ __ __	☐1	__ __ . __ __ ☐99 No INR	___	☐1	__ __	☐1	☐1
3	__ __/__ __/__ __ __ __	☐1	__ __ . __ __ ☐99 No INR	___	☐1	__ __	☐1	☐1
4	__ __/__ __/__ __ __ __	☐1	__ __ . __ __ ☐99 No INR	___	☐1	__ __	☐1	☐1
5	__ __/__ __/__ __ __ __	☐1	__ __ . __ __ ☐99 No INR	___	☐1	__ __	☐1	☐1

Check "No INR" box if INR value is not collected on that study day.

**Enter a value if additional capsules need to be requested from the pharmacy; leave blank if no additional capsules need to be requested.*

***Check box if participant receives warfarin that is not a protocol-based calculated dose, contact the medical monitor and complete the UNBLIND CRF.*

Participant ID: Participant Initials: Clinical Center:

DOSE REQUISITION – TITRATION PERIOD

NUM 2 (06-30) Study day	DT (≥05/01/2009) Date *mm/dd/yyyy*	NUM 2.2 (0-99.0-99) INR to use for dose calculation	NUM 1 (1-2) Participant location 1 = Inpatient 2 = Outpatient	NUM 2 (0-99) # of days of additional capsules?	NUM 1 (1) Do not dispense calculated dose*	NUM 1 (1) Dosed off-protocol?**
	__ __/__ __/__ __ __ __	__ __ . __ __	___	__ __	☐1	☐1
	__ __/__ __/__ __ __ __	__ __ . __ __	___	__ __	☐1	☐1
	__ __/__ __/__ __ __ __	__ __ . __ __	___	__ __	☐1	☐1
	__ __/__ __/__ __ __ __	__ __ . __ __	___	__ __	☐1	☐1
	__ __/__ __/__ __ __ __	__ __ . __ __	___	__ __	☐1	☐1
	__ __/__ __/__ __ __ __	__ __ . __ __	___	__ __	☐1	☐1
	__ __/__ __/__ __ __ __	__ __ . __ __	___	__ __	☐1	☐1
	__ __/__ __/__ __ __ __	__ __ . __ __	___	__ __	☐1	☐1
	__ __/__ __/__ __ __ __	__ __ . __ __	___	__ __	☐1	☐1
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	__ __/__ __/__ __ __ __	__ __ . __ __	___	__ __	☐1	☐1
	__ __/__ __/__ __ __ __	__ __ . __ __	___	__ __	☐1	☐1
	__ __/__ __/__ __ __ __	__ __ . __ __	___	__ __	☐1	☐1
	__ __/__ __/__ __ __ __	__ __ . __ __	___	__ __	☐1	☐1
	__ __/__ __/__ __ __ __	__ __ . __ __	___	__ __	☐1	☐1

***Check box if the medical monitor is contacted to resolve an override of a calculated dose.*

***Check box if the participant has received warfarin that is not a protocol-based calculated dose, contact the medical monitor and complete the UNBLIND CRF.*

Participant ID:	Participant Initials:	Clinical Center:
Visit Date:	**Visit Number:**	**CRC Initials:**

ELIGIBILITY CONFIRMATION

Inclusion criteria: *Responses to questions 1-6 must be "1 - Yes".*

1.	Is the participant 18 years of age or older?	☐$_1$ Yes	☐$_0$ No	**NUM 1 (1,0)**
2.	Is the participant able and willing to sign the informed consent?	☐$_1$ Yes	☐$_0$ No	
3.	Is the participant able to be followed in the outpatient anticoagulation clinic?	☐$_1$ Yes	☐$_0$ No	
4.	Is the expected duration of warfarin therapy at least one (1) month or longer?	☐$_1$ Yes	☐$_0$ No	
5.	Is the in-patient and/or outpatient clinician who is and will be managing the participant's anti-coagulation (*AC*) willing to adhere to the dosing algorithms and dose titration plans for this study?	☐$_1$ Yes	☐$_0$ No	
6.	Is the participant's target INR in the range of 2 to 3?	☐$_1$ Yes	☐$_0$ No	

Exclusion criteria: *Responses to questions 7-20 must be "0 - No" or "99 - N/A".*

7.	Is the participant currently taking warfarin?	☐$_1$ Yes	☐$_0$ No	
8.	Was the participant previously on warfarin therapy with known required stable dose?	☐$_1$ Yes	☐$_0$ No	
9.	In the clinician's opinion does warfarin dosing needs to be adjusted for reasons not accounted for by dosing algorithm?	☐$_1$ Yes	☐$_0$ No	
10.	Was the baseline INR (*prior to heparin or warfarin*) elevated?	☐$_1$ Yes	☐$_0$ No	
11.	Is warfarin treatment contraindicated for at least 3 months?	☐$_1$ Yes	☐$_0$ No	
12.	Is the participant's life expectancy less than 1 year?	☐$_1$ Yes	☐$_0$ No	
13.	Is the female participant pregnant? (*Must have a documented negative pregnancy test.*)	☐$_1$ Yes ☐$_{99}$ N/A (males/post-menop. females)	☐$_0$ No	**NUM 2 (1,0,99)**
14.	Is the female participant unwilling to use medically-approved method of birth control?	☐$_1$ Yes ☐$_{99}$ N/A (males/post-menop. females)	☐$_0$ No	**NUM 2 (1,0,99)**
15.	Is the participant unable to follow-up on a regular basis with anti-coagulation practitioners participating in the trial?	☐$_1$ Yes	☐$_0$ No	**NUM 1 (1,0)**

ELIGIBILITY CONFIRMATION

16. Are there any factors likely to limit adherence to warfarin?			
a. Dementia (*unless minor problem*):	☐1 Yes	☐0 No	**NUM 1 (1,0)**
b. Current alcohol or substance abuse:	☐1 Yes	☐0 No	
c. Plans to move in the next six months:	☐1 Yes	☐0 No	
d. History of unreliability in medication taking or appointment keeping:	☐1 Yes	☐0 No	
e. Significant concerns about participation in the study from spouse, significant other, or family members:	☐1 Yes	☐0 No	
f. Lack of support from primary health care provider:	☐1 Yes	☐0 No	
17. Is the participant unable to provide consent or follow study procedures due to cognitive or other limitations?	☐1 Yes	☐0 No	
18. Is the participant participating in another clinical trial in the next 6 months?	☐1 Yes	☐0 No	
19. Has the participant had an estimated blood loss of >1000 cc requiring blood transfusions within 48 hours prior to randomization?	☐1 Yes	☐0 No	
20. If the participant has received previous genetic testing, are the results of CYP2C9 or VKORC1 known?	☐1 Yes	☐0 No	
21. Is the participant eligible for participation in the study?	☐1 Yes	☐0 No	

Participant ID:	Participant Initials:	Clinical Center:
Visit Date:	Visit Number:	CRC Initials:

ENROLLMENT INFORMATION

1. Date of birth:..... __ __/__ __/**19**__ __ (mm/dd/yyyy) **DT**

   a. Age: __ __ years **NUM 2 (18-99)**

2. Gender: ..... ☐1 Male ☐2 Female **NUM 1 (1,2)**

   NUM 1 (1,2)

3. Ethnicity:..... ☐1 Hispanic / Latino ☐2 Non-Hispanic

4. Race (*check all that apply*):..... ☐1 American Indian or Alaska Native
   ☐1 Asian **NUM 1 (1)**
   ☐1 Black or African American
   ☐1 Native Hawaiian or Other Pacific Islander
   ☐1 White
   ☐1 Refused to respond

5. Height (*self-reported or most current available*): .....

   __ ft __ __ in **NUM 1,2 (3-7,0-11)**

6. Weight (*self-reported or most current available*):..... __ __ __ lbs **NUM 3 (0-999)**

7. Diabetes (*include diet-controlled*): ..... ☐1 Yes ☐0 No **NUM 1 (1,0)**

8. Is the primary indication for warfarin therapy treatment of a stroke?..... ☐1 Yes ☐0 No

9. Currently on fluvastatin (*Lescol*): ..... ☐1 Yes ☐0 No

10. Currently on amiodarone (*Cordarone*):..... ☐1 Yes ☐0 No

11. Current smoker: ..... ☐1 Yes ☐0 No

12. Record all current indications for warfarin therapy:

    a. Antiphospholipid antibody syndrome:..... ☐1 Yes ☐0 No

    b. Aortic valve replacement: ..... ☐1 Yes ☐0 No

    c. Atrial fibrillation: ..... ☐1 Yes ☐0 No

    d. Atrial flutter:..... ☐1 Yes ☐0 No

    e. Cardiomyopathy:..... ☐1 Yes ☐0 No

    f. Cerebrovascular accident (*CVA*):..... ☐1 Yes ☐0 No

    g. Deep vein thrombosis (*DVT*): ..... ☐1 Yes ☐0 No

    h. Mitral valve replacement:..... ☐1 Yes ☐0 No

    i. Mural thrombus:..... ☐1 Yes ☐0 No

ENROLLMENT INFORMATION

12. Record all current indications for warfarin therapy: *.....continued*

j.	Orthopedic surgery:	☐1 Yes	☐0 No	**NUM 1 (1,0)**
k.	Post-cardiac ablation procedure:	☐1 Yes	☐0 No	
l.	Post myocardial infarction (*MI*):	☐1 Yes	☐0 No	
m.	Pulmonary embolism (*PE*):	☐1 Yes	☐0 No	
n.	Other:	☐1 Yes	☐0 No	
n1.	If yes, specify:	_____		**CHR 250**

13. Is the primary indication for warfarin therapy treatment of deep vein thrombosis (*DVT*) or pulmonary embolism (*PE*)? ☐1 Yes ☐0 No **NUM 1 (1,0)**

14. Recruited during an inpatient stay or from an outpatient clinic: ..... **NUM 1 (1,2)**
☐1 Inpatient stay ☐2 Outpatient clinic

15. What is the planned duration of warfarin therapy? .....
☐1 at least 1 month
☐2 >1 month, up to 2 months
☐3 >2 months, up to 3 months **NUM 1 (1-7)**
☐4 >3 months, up to 4 months
☐5 >4 months, up to 5 months
☐6 >5 months, up to 6 months
☐7 >6 months

Participant ID:	**Participant Initials:**	**Clinical Center:**
Visit Date:	**Visit Number:**	**CRC Initials:**

EQ-5D ™ HEALTH QUESTIONNAIRE (*EUROQOL*)

By placing a checkmark in one box in each group below, please indicate which statements best describe your own health state today.

1. Mobility:

   ☐1 I have no problems in walking about
   ☐2 I have some problems in walking about
   ☐3 I am confined to bed

NUM 1 (1-3)

2. Self-Care:

   ☐1 I have no problems with self-care
   ☐2 I have some problems washing or dressing myself
   ☐3 I am unable to wash or dress myself

3. Usual Activities (*e.g. work, study, housework, family or leisure activities*)

   ☐1 I have no problems with performing my usual activities
   ☐2 I have some problems with performing my usual activities
   ☐3 I am unable to perform my usual activities

4. Pain/Discomfort:

   ☐1 I have no pain or discomfort
   ☐2 I have some pain or discomfort
   ☐3 I have extreme pain or discomfort

5. Anxiety/Depression:

   ☐1 I am not anxious or depressed
   ☐2 I am moderately anxious or depressed
   ☐3 I am extremely anxious or depressed

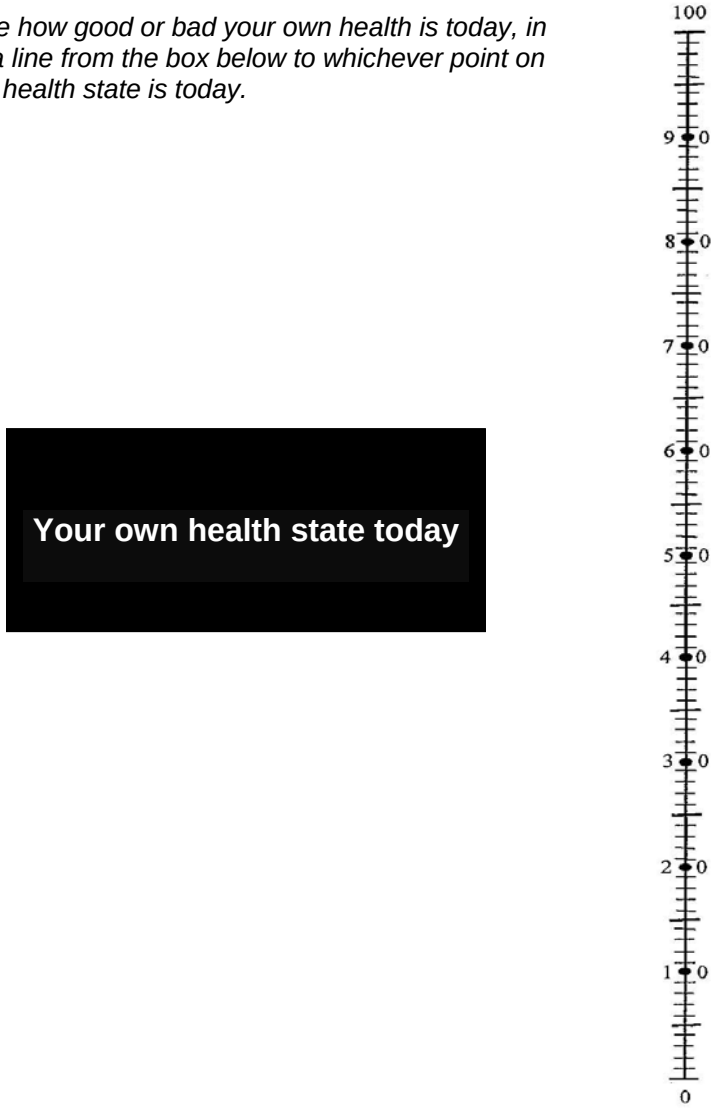
Please continue on the next page……

EQ-5D ™ HEALTH QUESTIONNAIRE (*EUROQOL*)

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Best imaginable health state



Worst imaginable health state

6. Score: __ __ __ **NUM3 (0-100)**

Research Coordinator: Please check the appropriate box to indicate who completed the CRF.

☐1 Participant ☐2 Interviewer ☐3 Both **NUM 1 (1-3)**

MEDICAL EVENTS

Section I: Warfarin/Coumadin

Check N/A if warfarin/Coumadin was not stopped: ☐99 N/A (*go to Section II*) **NUM 2 (99)**

1. Date your warfarin/Coumadin was stopped: __ __/__ __/__ __ __ __ (*mm/dd/yyyy*) **DT (≥ 05/01/2009)**
   ☐88 Unknown **NUM 2 (88)**
   NUM 1 (1,0)
2. Were you hospitalized for a procedure at the time? ☐1 Yes ☐0 No (*go to q. 3*)

   If yes in question 2, what type of procedure was it…?

   a. Cardioversion: ☐1 Yes ☐0 No
   b. Cardiac catheterization or angioplasty: ☐1 Yes ☐0 No
   c. Cardiac surgery: ☐1 Yes ☐0 No
   d. Other surgery: ☐1 Yes ☐0 No
   e. Other procedure: ☐1 Yes ☐0 No

      e1. If yes in question 2e, specify: _____ **CHR 500**
      NUM 1 (1,0)
3. If no in question 2, was it prior to an outpatient procedure? ☐1 Yes ☐0 No (*go to q. 4*)

   If yes in question 3, what type of procedure was it…?

   a. Cardioversion: ☐1 Yes ☐0 No
   b. Cardiac catheterization: ☐1 Yes ☐0 No
   c. Dental procedure: ☐1 Yes ☐0 No
   d. Other procedure: ☐1 Yes ☐0 No

      d1. If yes in question 3d, specify: _____ **CHR 500**
4. Was your warfarin/Coumadin stopped because of bleeding? ☐1 Yes ☐0 No **NUM 1 (1,0)**
   NUM 1 (1,0)
5. Was it due to other reasons? ☐1 Yes ☐0 No (*go to q. 6*)

   a. If yes in question 5, specify: _____ **CHR 500**
   NUM 1 (1,0)
6. Was your warfarin/Coumadin restarted? ☐1 Yes ☐0 No (*go to S. II*)

   a. When was your warfarin/Coumadin restarted? __ __/__ __/__ __ __ __ (*mm/dd/yyyy*) **DT**
   ☐88 Unknown **NUM 2 (88)**

   NUM 2 (0-99) **NUM 2 (88)**

   b. Total number of days warfarin/Coumadin stopped: __ __ days ☐88 Unknown

If warfarin/Coumadin is stopped for 2 or more days during dose initiation, revision or titration period (day 1 through 28), contact the Medical Monitor.

MEDICAL EVENTS

Section II: Emergency Room Visit or Hospitalization

Check N/A if participant was not seen in the emergency room or hospitalized: ☐99 N/A (*go to Section III*) **NUM 2 (99)**

NUM 1 (1,0)

7. Was the emergency room visit or hospitalization for bleeding? ☐1 Yes ☐0 No (*go to q. 18*)

If yes in question 7, what type of bleeding was it…?

NUM 1 (1,0)

8. Nose bleed: ☐1 Yes ☐0 No (*go to q. 9*)
   a. Were you seen in an emergency room only or were you hospitalized? **NUM 1 (1,2)** ☐1 ER only ☐2 Hospitalized

NUM 1 (1,0)

9. Blood in stool: ☐1 Yes ☐0 No (*go to q. 10*)
   a. Was the blood in stool the result of a procedure (e.g. colonoscopy)? ☐1 Yes ☐0 No **NUM 1 (1,0)**
   b. Were you seen in an emergency room only or were you hospitalized? **NUM 1 (1,2)** ☐1 ER only ☐2 Hospitalized
   c. Did you see the red blood in the stool? ☐1 Yes ☐0 No **NUM 1 (1,0)**
   d. Did you see black tarry stools? ☐1 Yes ☐0 No
   e. Was the blood invisible to you and only detected by a routine screening test? ☐1 Yes ☐0 No
   f. Did you have endoscopy, colonoscopy, upper GI or lower GI series for the blood in stool? ☐1 Yes ☐0 No

10. Vomiting blood: ☐1 Yes ☐0 No (*go to q. 11*)
    a. Were you vomiting blood as a result of a procedure (e.g. endoscopy)? ☐1 Yes ☐0 No **NUM 1 (1,0)**
    b. Were you seen in an emergency room only or were you hospitalized? **NUM 1 (1-2)** ☐1 ER only ☐2 Hospitalized
    c. Did you vomit red blood? ☐1 Yes ☐0 No **NUM 1 (1,0)**
    d. Did you vomit coffee ground material? ☐1 Yes ☐0 No
    e. Did you have endoscopy, colonoscopy, upper GI or lower GI series for the vomiting blood? ☐1 Yes ☐0 No

11. Coughing up blood: ☐1 Yes ☐0 No (*go to q. 12*)
    a. Were you seen in an emergency room only or were you hospitalized? **NUM 1 (1,2)** ☐1 ER only ☐2 Hospitalized
    b. Did you have a bronchoscopy for coughing up blood? ☐1 Yes ☐0 No **NUM 1 (1,0)**

MEDICAL EVENTS

Section II: Emergency Room Visit or Hospitalization……*continued*

12. Bleeding after cut or blood draw:	☐1 Yes	☐0 No (*go to q. 13*)	**NUM 1 (1,0)**
a. Were you seen in an emergency room only or were you hospitalized?	☐1 ER only	☐2 Hospitalized	**NUM 1 (1,2)**
13. Blood in urine:	☐1 Yes	☐0 No (*go to q. 14*)	**NUM 1 (1,0)**
a. Were you seen in an emergency room only or were you hospitalized?	☐1 ER only	☐2 Hospitalized	**NUM 1 (1,2)**
b. Did you see bright red blood?	☐1 Yes	☐0 No	**NUM 1 (1,0)**
c. Was the blood invisible to you and only detected by a urine test?	☐1 Yes	☐0 No	
d. Was the bleeding the result of a procedure i.e. a catheter insertion or cystoscopy?	☐1 Yes	☐0 No	
e. Did you have a cystoscopy for blood in urine?	☐1 Yes	☐0 No	
14. Bleeding in head:	☐1 Yes	☐0 No (*go to q. 15*)	
a. Were you seen in an emergency room only or were you hospitalized?	☐1 ER only	☐2 Hospitalized	**NUM 1 (1,2)**
15. Other type of bleeding:	☐1 Yes	☐0 No (*go to q. 16*)	**NUM 1 (1,0)**
a. If yes in question 15, specify: _____			**CHR 500**
b. Were you seen in an emergency room only or were you hospitalized?	☐1 ER only	☐2 Hospitalized	**NUM 1 (1,2)**
16. Was your warfarin/Coumadin held 3 or more days because of any of the bleeding events?	☐1 Yes	☐0 No	**NUM 1 (1,0)**
17. For any of the bleeding events described, did you require…?			
a. Blood transfusion:	☐1 Yes	☐0 No	
b. Surgery:	☐1 Yes	☐0 No	
c. Nasal packing:	☐1 Yes	☐0 No	
d. Cauterization:	☐1 Yes	☐0 No	
e. Other procedure:	☐1 Yes	☐0 No	
e1. If yes in question 17e, specify: _____			**CHR 500**

MEDICAL EVENTS

Section II: Emergency Room Visit or Hospitalization……*continued*

18. Was the emergency room visit or hospitalization for a stroke or TIA (*mini-stroke*)? ☐1 Yes ☐0 No (*go to q. 19*) **NUM 1 (1,0)**

    a. If yes, were you seen in emergency room only or were you hospitalized? ☐1 ER only ☐2 Hospitalized **NUM 1 (1,2)**

19. Was the emergency room visit or hospitalization for a blood clot? ☐1 Yes ☐0 No **NUM 1 (1,0)**

If yes in question 19, ask questions 20 through 25. If no, go to question 24.

20. Was it for a clot in the veins of your legs? ☐1 Yes ☐0 No **NUM 1 (1,0)**

    a. If yes, were you seen in emergency room only or were you hospitalized? ☐1 ER only ☐2 Hospitalized **NUM 1 (1,2)**

21. Was it for a clot in your lungs? ☐1 Yes ☐0 No **NUM 1 (1,0)**

    a. If yes, were you seen in emergency room only or were you hospitalized? ☐1 ER only ☐2 Hospitalized **NUM 1 (1,2)**

22. Was it for a clot in your hands or feet? ☐1 Yes ☐0 No **NUM 1 (1,0)**

    a. If yes, were you seen in emergency room only or were you hospitalized? ☐1 ER only ☐2 Hospitalized **NUM 1 (1,2)**

23. Was it for a clot in your kidney? ☐1 Yes ☐0 No **NUM 1 (1,0)**

    a. If yes, were you seen in emergency room only or were you hospitalized? ☐1 ER only ☐2 Hospitalized **NUM 1 (1,2)**

24. Were you hospitalized for any other bleeding or blood clot event? ☐1 Yes ☐0 No **NUM 1 (1,0)**

    a. If yes in question 24, specify: _____ **CHR 500**

25. Were you seen in the emergency room for any other bleeding or blood clot event? ☐1 Yes ☐0 No **NUM 1 (1,0)**

    a. If yes in question 25, specify: _____ **CHR 500**

MEDICAL EVENTS

Section III: Out-patient Care

Check N/A if participant did not receive outpatient care: ☐99 N/A **NUM 2 (99)**

26. Since your last visit, have you seen a healthcare provider for bleeding, not as an inpatient and not in the emergency room? ☐1 Yes ☐0 No (*go to q. 39*) **NUM 1 (1,0)**

    a. If yes, how many visits? __ __ visits **NUM 2 (1-99)**

If yes, what type of bleeding was it…?

27. Nose bleed: ☐1 Yes ☐0 No **NUM 1 (1,0)**

28. Blood in stool: ☐1 Yes ☐0 No (*go to q. 29*) **NUM 1 (1,0)**

    a. Was the blood in stool the result of a procedure (e.g. colonoscopy)? ☐1 Yes ☐0 No

    b. Did you see the red blood in the stool? ☐1 Yes ☐0 No

    c. Did you see black tarry stools? ☐1 Yes ☐0 No

    d. Was the blood invisible to you and only detected by a routine screening test? ☐1 Yes ☐0 No

    e. Did you have endoscopy, colonoscopy, upper GI or lower GI series for the blood in stool? ☐1 Yes ☐0 No

29. Vomiting blood: ☐1 Yes ☐0 No (*go to q. 30*)

    a. Were you vomiting blood as a result of a procedure (e.g. endoscopy)? ☐1 Yes ☐0 No **NUM 1 (1,0)**

    b. Did you vomit red blood? ☐1 Yes ☐0 No

    c. Did you vomit coffee ground material? ☐1 Yes ☐0 No

    d. Did you have endoscopy, colonoscopy, upper GI or lower GI series for the vomiting blood? ☐1 Yes ☐0 No

30. Coughing up blood: ☐1 Yes ☐0 No (*go to q. 31*)

    a. Did you have a bronchoscopy for coughing up blood? ☐1 Yes ☐0 No

31. Bleeding after a cut or blood draw: ☐1 Yes ☐0 No

MEDICAL EVENTS

Section III: Out-patient Care……*continued*

32. Blood in urine:.....	☐1 Yes	☐0 No (*go to q. 33*)	**NUM 1 (1,0)**
a. Did you see red blood?.....	☐1 Yes	☐0 No	
b. Was the blood invisible to you and only detected by a routine urine test?	☐1 Yes	☐0 No	
c. Was the bleeding the result of a procedure i.e a catheter insertion or cystoscopy?	☐1 Yes	☐0 No	
d. Did you have a cystoscopy for blood in urine?	☐1 Yes	☐0 No	
33. Bleeding in head:.....	☐1 Yes	☐0 No	
34. Was it for bruising?.....	☐1 Yes	☐0 No	
35. Vaginal or menstrual bleeding:.....	☐1 Yes	☐0 No	
36. Any other type of bleeding?.....	☐1 Yes	☐0 No	
a. If yes in question 36, specify:.....	_____		**CHR 500**
37. Was your warfarin/Coumadin held 3 or more days because of any of the bleeding events?	☐1 Yes	☐0 No	**NUM 1 (1,0)**
38. For any of the bleeding events described did you require…?			
a. Blood transfusion:	☐1 Yes	☐0 No	
b. Surgery:.....	☐1 Yes	☐0 No	
c. Nasal packing:	☐1 Yes	☐0 No	
d. Cauterization:.....	☐1 Yes	☐0 No	
e. Other procedure:.....	☐1 Yes	☐0 No	
e1. If yes in question 38e, specify:.....	_____		**CHR 500**

MEDICAL EVENTS

Section III: Out-patient Care……*continued*

39. Since your last visit, have you seen a healthcare provider for a <u>new</u> clot, not as an inpatient and not in the emergency room? ..... ☐1 Yes ☐0 No (*go to q. 40*) **NUM 1 (1,0)**

    a. If yes, how many visits? ..... __ __ visits **NUM 2 (1-99)**

    b. Was it for a clot in the veins of your legs? ..... ☐1 Yes ☐0 No **NUM 1 (1,0)**

    c. Was it for a clot in your lungs? ..... ☐1 Yes ☐0 No

    d. Was it for a clot in your hands or feet? ..... ☐1 Yes ☐0 No

    e. Was it for a clot in your kidney? ..... ☐1 Yes ☐0 No

    f. Were you seen for any other bleeding or blood clot event? ..... ☐1 Yes ☐0 No

    f1. If yes in question 39f, specify: ..... _____ **CHR 500**

40. Was the visit with your healthcare provider for a <u>new</u> stroke or TIA (*mini-stroke*)? ..... ☐1 Yes ☐0 No **NUM 1 (1,0)**

MEDICAL EVENTS

Section IV: Stroke, TIA (mini stroke) or Bleeding during Hospitalization

Check N/A if participant did not have stroke, TIA (mini stroke) or bleeding during hospitalization: ☐99 N/A (*stop here*) **NUM 2 (99)**

NUM 1 (1,0)

41. Did you experience bleeding during hospitalization? ☐1 Yes ☐0 No (*go to q. 52*)

If yes in question 41, what type of bleeding was it…?

42. Nose bleed: ☐1 Yes ☐0 No (*go to q. 43*)
    a. If yes, did the nose bleed prolong your hospitalization? ☐1 Yes ☐0 No

43. Blood in stool: ☐1 Yes ☐0 No (*go to q. 44)*

If yes,

    a. Was the blood in stool the result of a procedure (e.g. colonoscopy)? ☐1 Yes ☐0 No
    b. Did the blood in your stool prolong your hospitalization? ☐1 Yes ☐0 No
    c. Did you see the red blood in the stool? ☐1 Yes ☐0 No
    d. Did you see black tarry stools? ☐1 Yes ☐0 No
    e. Was the blood invisible to you and only detected by a routine screening test? ☐1 Yes ☐0 No
    f. Did you have endoscopy, colonoscopy, upper GI or lower GI series for the blood in stool? ☐1 Yes ☐0 No

44. Vomiting blood: ☐1 Yes ☐0 No (*go to q. 45*)

If yes,

    a. Were you vomiting blood as a result of a procedure (e.g. endoscopy)? ☐1 Yes ☐0 No
    b. Did vomiting blood prolong your hospitalization? ☐1 Yes ☐0 No
    c. Did you vomit red blood? ☐1 Yes ☐0 No
    d. Did you vomit coffee ground material? ☐1 Yes ☐0 No
    e. Did you have endoscopy, colonoscopy, upper GI or lower GI series for the vomiting blood? ☐1 Yes ☐0 No

MEDICAL EVENTS

Section IV: Stroke, TIA (mini stroke) or Bleeding during Hospitalization……*continued*

NUM 1 (1,0)

45. Coughing up blood: ☐1 Yes ☐0 No (*go to q. 46*)

If yes,

a. Did coughing up blood prolong your hospitalization? ☐1 Yes ☐0 No

b. Did you have a bronchoscopy for coughing up blood? ☐1 Yes ☐0 No

46. Bleeding after cut or blood draw: ☐1 Yes ☐0 No (*go to q. 47*)

a. If yes, did bleeding after a cut or the blood draw prolong your hospitalization? ☐1 Yes ☐0 No

47. Blood in urine: ☐1 Yes ☐0 No (*go to q. 48*)

If yes,

a. Did the blood in your urine prolong your hospitalization? ☐1 Yes ☐0 No

b. Did you see bright red blood? ☐1 Yes ☐0 No

c. Was the blood invisible to you and only detected by a urine test? ☐1 Yes ☐0 No

d. Was the bleeding the result of a procedure i.e. a catheter insertion or cystoscopy? ☐1 Yes ☐0 No

e. Did you have a cystoscopy for blood in urine? ☐1 Yes ☐0 No

48. Bleeding in head: ☐1 Yes ☐0 No (*go to q. 49*)

a. If yes, did the bleeding in your head prolong your hospitalization? ☐1 Yes ☐0 No

49. Other type of bleeding: ☐1 Yes ☐0 No (*go to q. 50)*

If yes,

a. Specify: _____ **CHR 500**

b. Did this bleeding prolong your hospitalization? ☐1 Yes ☐0 No **NUM 1 (1,0)**

50. Was your warfarin/Coumadin held 3 or more days because of any of the bleeding events?
☐1 Yes
☐0 No
☐99 N/A (*if not on warfarin*)
NUM 2 (1,0,99)

MEDICAL EVENTS

Section IV: Stroke, TIA (mini stroke) or Bleeding during Hospitalization……*continued*

51. For any of the bleeding events described, did you require…?

a.	Blood transfusion:	☐1 Yes	☐0 No	**NUM 1 (1,0)**
b.	Surgery:	☐1 Yes	☐0 No	
c.	Nasal packing:	☐1 Yes	☐0 No	
d.	Cauterization:	☐1 Yes	☐0 No	
e.	Other procedure:	☐1 Yes	☐0 No	
e1.	If yes in question 51e, specify: _____			**CHR 500**

52. Did you experience stroke or TIA (mini-stroke) during your hospitalization? ☐1 Yes ☐0 No (*go to q. 53*) **NUM 1 (1,0)**

a.	If yes, did the stroke or TIA (mini-stroke) prolong your hospitalization?	☐1 Yes	☐0 No

53. Did you experience blood clots during your hospitalization? ☐1 Yes ☐0 No

If yes in question 53, ask questions 54 through 58. If no, stop here.

54.	Was it for a clot in the veins of your legs?	☐1 Yes	☐0 No
a.	If yes, did the clot in the veins of your legs prolong your hospitalization?	☐1 Yes	☐0 No
55.	Was it for a clot in your lungs?	☐1 Yes	☐0 No
a.	If yes, did the clot in your lungs prolong your hospitalization?	☐1 Yes	☐0 No
56.	Was it for a clot in your hands or feet?	☐1 Yes	☐0 No
a.	If yes, did the clot in your hands or feet prolong your hospitalization?	☐1 Yes	☐0 No
57.	Was it for a clot in your kidney?	☐1 Yes	☐0 No
a.	If yes, did the clot in your kidney prolong your hospitalization?	☐1 Yes	☐0 No

58. Did you experience any other bleeding or blood clot events during your hospitalization? ☐1 Yes ☐0 No

If yes,

a.	Specify: _____			**CHR 500**
b.	Did the bleeding or blood clot event(s) prolong your hospitalization?	☐1 Yes	☐0 No	**NUM 1 (1,0)**

Participant ID:	**Participant Initials:**	**Clinical Center:**
Visit Date:	**Visit Number:**	**CRC Initials:**
Laboratory ID: Local / Central	**Genotype attempt: __ __**	

GENOTYPING INFORMATION

Completed by the Research Coordinator:

1. Date and time specimen collected:	__ __/__ __/__ __ __ __ (*mm/dd/yyyy*) **DT (≥05/01/2009)** __ __ : __ __ (*military time*) **NUM 2:2 (0-24:0-59)**
2. Date and time specimen transferred/shipped to the genotyping laboratory:	__ __/__ __/__ __ __ __ (*mm/dd/yyyy*) **DT (≥05/01/2009)** __ __ : __ __ (*military time*) **NUM 2:2 (0-24:0-59)**

Completed by the genotyping laboratory personnel:

3. Date and time specimen received at the genotyping laboratory:	__ __/__ __/__ __ __ __ (*mm/dd/yyyy*) **DT (≥05/01/2009)** __ __ : __ __ (*military time*) **NUM 2:2 (0-24:0-59)**
4. Date and time specimen was analyzed:	__ __/__ __/__ __ __ __ (*mm/dd/yyyy*) **DT (≥05/01/2009)** __ __ : __ __ (*military time*) **NUM 2:2 (0-24:0-59)**
5. Check box if the specimen is not analyzable or the results are not available:	☐88 Results missing in item # 6 and 7 **NUM 2 (88)**
6. VKORC1 *(-1639 / 3673)*:	☐0 GG ☐2 AA **NUM 2 (0-2,88)** ☐1 AG ☐88 Missing
7. CYP2C9 (*check one*):	**NUM 2 (1-6,88) CYP2C9*2 CYP2C9*3** ☐1 *1*1 ..... CC AA ☐2 *1*2 ..... CT AA ☐3 *1*3 ..... CC AC ☐4 *2*2 ..... TT AA ☐5 *2*3 ..... CT AC ☐6 *3*3 ..... CC CC ☐88 Missing ..... Missing Missing
8. DNA concentration:	__ __ __ ng/µL **NUM 3 (0-999)**
9. Total DNA:	__ __ __ . __ __ µg **NUM 3.2 (0-999.0-99)**

Place label here

Test results recorded by (signature): **NOT ENTERED**

Test results confirmed by (signature): **NOT ENTERED**

Enter genotyping results in the data management system (DMS) immediately.
Fax completed case report form to the CTCC at (215) 573-4790.

Participant ID:	**Participant Initials:**	**Clinical Center:**
Visit Date:	**Visit Number:**	**CRC Initials:**
Sequence #:		

HOSPITALIZATION INFORMATION

Complete one CRF for each hospitalization or emergency room visit event reported by the participant.

1. Is this a newly reported hospitalization or an emergency room visit? ..... ☐1 Yes ☐0 No **NUM 1 (1,0)**

2. Does the participant remain hospitalized at this study visit? ..... ☐1 Yes ☐0 No **NUM 1 (1,0)**

If the response is Yes in question 2, stop here.
[ICD-9 codes are recorded after the participant is discharged from the hospital or emergency room.]

3. Are medical records available for this hospitalization or emergency room visit? ..... ☐1 Yes ☐0 No **NUM 1 (1,0)**

4. Admission date: ..... __ __/__ __/__ __ __ __ (mm/dd/yyyy) **DT (≥ 05/01/2009)**
☐88 Not available/Unknown **NUM 2 (88)**

5. Discharge date: ..... __ __/__ __/__ __ __ __ (mm/dd/yyyy) **DT (≥ 05/01/2009)**
☐88 Not available/Unknown **NUM 2 (88)**

6. Discharge status: ..... ☐1 Alive and home **NUM 2 (1-3,88)**
☐2 Alive and sent to a skilled facility
☐3 Deceased
☐88 Status not available/Unknown

If the response is No in question 3, stop here.

7. Are these ICD 9 or ICD 10 codes: ..... ☐1 ICD 9 ☐2 ICD 10 **NUM 1 (1,2)**

[If ICD-9 <u>and</u> ICD-10 codes are available in medical records, record ICD-9 codes.]

8. Primary diagnosis ICD 9/10 code: ..... _____ **CHR 8**

9. Secondary diagnosis ICD 9/10 codes: ..... (***Limit to top 5 secondary codes***)
a. _____
b. _____
c. _____
d. _____
e. _____

10. Did the participant undergo any procedures during this hospitalization or emergency room visit? .....
☐1 Yes ☐0 No (***Stop***) **NUM 1 (1,0)**

11. List any available ICD-9 procedure codes or CPT codes related to the hospitalization or emergency room visit: (***Limit to top 5 procedure codes or CPT codes***) .....
a. _____ **CHR 8**
b. _____
c. _____
d. _____
e. _____

Participant ID: **Participant Initials:** **Clinical Center:**

INR LOG

NUM 3 (1-999) **INR #**	DT (≥ 05/01/2009) **INR date** *mm/dd/yyyy*	NUM 2:2 (0-24:0-59) NUM 2 (88) **Time INR drawn** *military time*	NUM 2.2 (0-99.0-99) **INR value**	NUM 2 (1,2,88) **Type of blood used** 1 = Venous 2 = Capillary 88 = Unknown	NUM 1 (1,0) **Protocol-required INR?** 1 = Yes 0 = No	NUM 1 (1,2) **INR source** 1 = Study recognized lab. 2 = Other source(s)	NUM 1 (1,0) **INR used for dose titration?** 1 = Yes 0 = No	NUM 1 (1,0) ***Heparin use?** 1 = Yes 0 = No
	__ __/__ __/__ __ __ __	__ __ : __ __ ☐88 Unknown	__ __ . __ __					
	__ __/__ __/__ __ __ __	__ __ : __ __ ☐88 Unknown	__ __ . __ __					
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	__ __/__ __/__ __ __ __	__ __ : __ __ ☐88 Unknown	__ __ . __ __					
	__ __/__ __/__ __ __ __	__ __ : __ __ ☐88 Unknown	__ __ . __ __					
	__ __/__ __/__ __ __ __	__ __ : __ __ ☐88 Unknown	__ __ . __ __					
	__ __/__ __/__ __ __ __	__ __ : __ __ ☐88 Unknown	__ __ . __ __					
	__ __/__ __/__ __ __ __	__ __ : __ __ ☐88 Unknown	__ __ . __ __					
	__ __/__ __/__ __ __ __	__ __ : __ __ ☐88 Unknown	__ __ . __ __					
	__ __/__ __/__ __ __ __	__ __ : __ __ ☐88 Unknown	__ __ . __ __					
	__ __/__ __/__ __ __ __	__ __ : __ __ ☐88 Unknown	__ __ . __ __					

** If the participant has used heparin, complete the **CMED** form.*

Participant ID:	Participant Initials:	Clinical Center:
Visit Date:	Visit Number:	CRC Initials:

MEDICAL HISTORY

Does the participant have a history of the following? **NUM 2 (1,2,88)**

1. Congestive heart failure:	☐1 Yes	☐0 No	☐88 Don't know
2. Heart attack or MI:	☐1 Yes	☐0 No	☐88 Don't know
3. Liver disease:	☐1 Yes	☐0 No	☐88 Don't know
If yes, was it….?			
a. Cirrhosis:	☐1 Yes	☐0 No	☐88 Don't know
b. Chronic or acute hepatitis: (*exclude history of hepatitis*)	☐1 Yes	☐0 No	☐88 Don't know
c. Fatty liver or nonalcoholic steatohepatitis (*NASH*):	☐1 Yes	☐0 No	☐88 Don't know
d. Other:	☐1 Yes	☐0 No	☐88 Don't know
d1. If yes in question 3d, specify:	_____		
4. Hyperthyroidism:	☐1 Yes	☐0 No	☐88 Don't know
5. Hypothyroidism:	☐1 Yes	☐0 No	☐88 Don't know
6. Kidney disease:	☐1 Yes	☐0 No	☐88 Don't know
a. If yes, specify:	_____		
b. Is the participant on dialysis for this?	☐1 Yes	☐0 No	☐88 Don't know
c. Most recent creatinine value:	__ __ . __ __ mg/dl		**NUM 2.2 (0-99.0-99)**
	Date: __ __/__ __/__ __ __ __ (*mm/dd/yyyy*) **DT**		

MEDICAL HISTORY

NUM 2 (1,0,88)

7. Diagnosis of cancer in the past 5 years:	☐1 Yes	☐0 No	☐88 Don't know
If yes, is/was it cancer of the….?			
a. Breast:	☐1 Yes	☐0 No	☐88 Don't know
b. Prostate:	☐1 Yes	☐0 No	☐88 Don't know
c. Melanoma:	☐1 Yes	☐0 No	☐88 Don't know
d. Lung:	☐1 Yes	☐0 No	☐88 Don't know
e. Stomach:	☐1 Yes	☐0 No	☐88 Don't know
f. Liver:	☐1 Yes	☐0 No	☐88 Don't know
g. Colon/rectal:	☐1 Yes	☐0 No	☐88 Don't know
h. Brain:	☐1 Yes	☐0 No	☐88 Don't know
i. Throat/laryngeal:	☐1 Yes	☐0 No	☐88 Don't know
j. Blood/leukemia/lymphoma:	☐1 Yes	☐0 No	☐88 Don't know
k. Other:	☐1 Yes	☐0 No	☐88 Don't know
k1. If yes in question 7k, specify: _____		CHR 500	

NUM 2 (1,0,88)

8. Hypertension or high blood pressure:	☐1 Yes	☐0 No	☐88 Don't know
9. Diabetes:	☐1 Yes	☐0 No	☐88 Don't know
If yes, does the participant take….?			
a. Insulin:	☐1 Yes	☐0 No	☐88 Don't know
b. Oral medications:	☐1 Yes	☐0 No	☐88 Don't know
c. Diet only:	☐1 Yes	☐0 No	☐88 Don't know
10. Peptic or stomach ulcer disease:	☐1 Yes	☐0 No	☐88 Don't know
11. Gastritis:	☐1 Yes	☐0 No	☐88 Don't know
12. Malabsorption syndrome:	☐1 Yes	☐0 No	☐88 Don't know
13. Current problem with diarrhea:	☐1 Yes	☐0 No	☐88 Don't know

MEDICAL HISTORY

Does the participant have a history of the following (*exclude current diagnoses for which participant is initiating warfarin use*)…..?

14. Stroke: ☐1 Yes ☐0 No ☐88 Don't know **NUM 2 (1,0,88)**

    a. If yes, is it current or past? ☐1 Current ☐2 Past ☐88 Don't know **NUM 2 (1,2,88)**

15. TIA or mini stroke (*or infarct on brain imaging*): ☐1 Yes ☐0 No ☐88 Don't know **NUM 2 (1,0,88)**

    a. If yes, is it current or past? ☐1 Current ☐2 Past ☐88 Don't know **NUM 2 (1,2,88)**

16. Pulmonary embolism: ☐1 Yes ☐0 No ☐88 Don't know **NUM 2 (1,0,88)**

    a. If yes, is it current or past? ☐1 Current ☐2 Past ☐88 Don't know **NUM 2 (1,2,88)**

17. Deep vein thrombosis: ☐1 Yes ☐0 No ☐88 Don't know **NUM 2 (1,0,88)**

    a. If yes, is it current or past? ☐1 Current ☐2 Past ☐88 Don't know **NUM 2 (1,2,88)**

---

18. Indicate the participant's smoking status:
    [*Current = within 1 month of enrollment*
    Recent = stopped between 1 month and 1 year prior to enrollment
    Former = stopped more than 1 year prior to enrollment
    Never = never smoked]
    ☐1 Current smoker
    ☐2 Recent smoker **NUM 1 (1-4)**
    ☐3 Former smoker
    ☐4 Never smoked

    a. If current, recent or former smoker, how many years did/has the participant smoke(d)? __ __ years **NUM 2 (0-99)**

    b. How often did/does the participant smoke?
    ☐1 Every day
    ☐2 Nearly every day
    ☐3 3 to 4 times a week **NUM 1 (1-6)**
    ☐4 2 times a week
    ☐5 Once a week
    ☐6 Sporadic/less than once a week

    c. How much did/does the participant smoke on a typical smoking day? __ __ __ cigarettes **NUM 3 (0-999)**

MEDICAL HISTORY

NUM 2 (1,0,88)

19. Does the participant have a family history of venous thrombo-embolism (*VTE*)? ☐1 Yes ☐0 No ☐88 Don't know

20. Has the participant taken warfarin/Coumadin prior to the planned study use? ☐1 Yes ☐0 No ☐88 Don't know

Research Coordinator: Please check the appropriate box to indicate the source of information.

☐1 Participant ☐2 Electronic medical records ☐3 Both **NUM 1 (1-3)**

Participant ID: **Participant Initials:** **Clinical Center:**

MEDICAL MONITOR CONTACT

1. Date and time of call: **DT (must be ≥ 05/01/2009)** **NUM2 (0-24)** **NUM2 (0-59)** (*military time*) Study day: **NUM3 (0-999)**
2. Site name: **CHR 500** Caller name: **CHR 500**
3. Caller contact number(s): **NOT ENTERED**
4. Last INR: **NUM2.2 (0-99.0-99)** Date: **DT (must be ≥ 05/01/2009)**
5. Adverse event reported: 1 Yes 0 No **NUM 1 (1,0)**
   a. Is it a serious adverse event: 1 Yes 0 No **NUM 1 (1,0)**
   b. Is it an unexpected adverse event: 1 Yes 0 No **NUM 1 (1,0)**
      b1. If yes, describe **CHR 2500**
   c. Date of event: **DT (must be ≥ 05/01/2009)**
   d. Event type: 1 Bleeding and bruising; 1 Thromboembolism; 1 Death; 1 Other **NUM 1 (1)**
   e. Intervention: 1 Study warfarin stopped; 1 Reversal of anticoagulation; 1 Parenteral anticoagulation; 1 Other; 1 No intervention **NUM 1 (1)**
6. Dosing issue: 1 Yes 0 No **NUM 1 (1,0)**
   a. Request: 1 Dose override **NUM 2 (1-3,98)** → 2 Dose QC; 3 Dose unblinding; 98 Other
      1 Drug interaction; 1 Adherence/compliance; 1 Participant dosing error; 1 NPO; 1 Invasive treatment; 1 Other **NUM 1 (1)**
   b. Protocol-specified dose adjustment: **NUM 2 (0-99)** % 1 Increase 2 Decrease **NUM 1 (1,2)**
   c. Report: 1 2 or more doses missed in last week 2 2 or more doses given off-protocol **NUM 1 (1,2)**
7. Decision: **NUM 1 (1)**
   1 Today **NUM 1 (1-3)**
   1 Dose as per protocol
   2 Approve dose override **NUM 2 (0-99)**% 1 Increase 2 Decrease **NUM 1 (1,2)**
   3 Continue prior dose (*dose unchanged*)
   1 Weekly **NUM 1 (1-3)**
   1 Continue dose as per protocol
   2 Approve dose override **NUM 2 (0-99)**% 1 Increase 2 Decrease **NUM 1 (1,2)**
   3 Continue prior dose (*dose unchanged*)
   1 Discontinue study drug
   1 Unblind dose
   1 Withdraw participant
8. Site pharmacy contacted: 1 Yes 0 No **NUM 1 (1,0)**
   a. If yes, pharmacist name **NOT ENTERED**
9. Signature: **NOT ENTERED** Date: **DT (must be ≥ 05/01/2009)**
10. Comments: **CHR 5000**

Fax completed CRF to Gargi Parikh (CTCC) at (215) 573-4790.

Participant ID:	Participant Initials:	Clinical Center:
Visit Date:	Visit Number:	CRC Initials:

MODIFIED MORISKY SCALE (*MMS*)

NUM 1 (1,0)

1.	Do you ever forget to take your medicine?	☐1 Yes	☐0 No
2.	Are you careless at times about taking your medicine?	☐1 Yes	☐0 No
3.	When you feel better do you sometimes stop taking your medicine?	☐1 Yes	☐0 No
4.	Sometimes if you feel worse when you take your medicine, do you stop taking it?	☐1 Yes	☐0 No
5.	Do you know the long-term benefit of taking your medicine as told to you by your doctor or pharmacist?	☐1 Yes	☐0 No
6.	Sometimes do you forget to refill your prescription medicine on time?	☐1 Yes	☐0 No

Research Coordinator: Please check the appropriate box to indicate who completed the CRF.

☐1 Participant ☐2 Interviewer ☐3 Both **NUM 1 (1-3)**

Participant ID:	Participant Initials:	Clinical Center:
Visit Date:	Visit Number:	CRC Initials:

PERSONAL HISTORY FORM

Check one response for items 1 through 4.

1. What is your current marital status? ..... (*check one response*)
   - ☐ 1 Currently married
   - ☐ 2 Separated/divorced
   - ☐ 3 Widowed
   - ☐ 4 Never married
   - ☐ 5 Living with partner
   - ☐ 97 Refused to respond

   NUM 2 (1-5,97)

2. What is the highest education that you have completed? ..... (*check one response*)
   - ☐ 1 8th grade or less
   - ☐ 2 Did not complete high school
   - ☐ 3 Graduated from high school / completed GED
   - ☐ 4 Technical/vocational school degree
   - ☐ 5 Some college education/did not graduate
   - ☐ 6 College degree
   - ☐ 7 Graduate degree/professional degree
   - ☐ 97 Refused to respond

   NUM 2 (1-7, 97)

3. What is your employment status? ..... (*check one response*)
   - ☐ 1 Working
   - ☐ 2 Unemployed
   - ☐ 3 Retired
   - ☐ 4 Disabled
   - ☐ 97 Refused to respond

   NUM 2 (1-4,97)

4. What is your total annual household income? ..... (*check one response*)
   - ☐ 1 $20,000 or under
   - ☐ 2 $20,001 – $50,000
   - ☐ 3 $50,001 – $100,000
   - ☐ 4 More than $100,000
   - ☐ 97 Refused to respond

5. What type of health insurance do you have? ..... (*check all that apply*)
   - ☐ 1 No insurance
   - ☐ 1 Medicare benefits
   - ☐ 1 Medicaid benefits
   - ☐ 1 Private (*e.g. Blue Cross*)
   - ☐ 1 Group health plan (*e.g. HMO, PPO, POS*)
   - ☐ 1 Veteran Affairs (*VA*) benefits
   - ☐ 1 CHAMPUS or other military benefits
   - ☐ 1 Other, specify _____ **CHR 500** _____
   - ☐ 1 Don't know

   NUM 1 (1)

Research Coordinator: Please check the appropriate box to indicate who completed the CRF.

☐ 1 Participant ☐ 2 Interviewer ☐ 3 Both **NUM1 (1-3)**

RANDOMIZATION

Blood sample should be collected for genotyping prior to randomization.

Responses are required for questions 1 through 3 to proceed with randomization.

1. Has the participant signed a written consent for the study? ..... ☐$_1$ Yes ☐$_0$ No **NUM 1 (1,0)**

   a. If yes, date participant signed the consent: ..... __ __/__ __/__ __ __ __ (*mm/dd/yyyy*) **DT (≥ 05/01/2009)**

2. Based on the responses to the inclusion and exclusion criteria, is the participant eligible and ready for randomization in the study?..... ☐$_1$ Yes ☐$_0$ No **NUM 1 (1,0)**

3. Did the healthcare provider order warfarin therapy for the participant?..... ☐$_1$ Yes ☐$_0$ No **NUM 1 (1,0)**

Participant ID:	**Participant Initials:**	**Clinical Center:**
Visit Date:	**Visit Number:**	**CRC Initials:**

HEALTH STATUS QUESTIONNAIRE (*SF-36*™)

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Thank you for completing this survey.

NUM 1 (1-5)	Excellent	Very Good	Good	Fair	Poor
1. In general, would you say your health is:	☐1	☐2	☐3	☐4	☐5

	Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
2. Compared to one year ago, how would you rate your health in general now?	☐1	☐2	☐3	☐4	☐5

3. The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

NUM 1 (1-3)	Yes, limited a lot	Yes, limited a little	No, not limited at all
a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports:	☐1	☐2	☐3
b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf:	☐1	☐2	☐3
c. Lifting or carrying groceries:	☐1	☐2	☐3
d. Climbing several flights of stairs:	☐1	☐2	☐3
e. Climbing one flight of stairs:	☐1	☐2	☐3
f. Bending, kneeling, or stooping:	☐1	☐2	☐3
g. Walking more than a mile:	☐1	☐2	☐3
h. Walking several hundred yards:	☐1	☐2	☐3
i. Walking one hundred yards:	☐1	☐2	☐3
j. Bathing or dressing yourself:	☐1	☐2	☐3

HEALTH STATUS QUESTIONNAIRE (*SF-36™*)

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

NUM 1 (1-5)	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down the amount of time you spent on work or other activities:	☐1	☐2	☐3	☐4	☐5
b. Accomplished less than you would like:	☐1	☐2	☐3	☐4	☐5
c. Were limited in the kind of work or other activities:	☐1	☐2	☐3	☐4	☐5
d. Had difficulty performing the work or other activities (*for example, it took extra effort*):	☐1	☐2	☐3	☐4	☐5

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (*such as feeling depressed or anxious*)?

NUM 1 (1-5)	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down the amount of time you spent on work or other activities:	☐1	☐2	☐3	☐4	☐5
b. Accomplished less than you would like:	☐1	☐2	☐3	☐4	☐5
c. Did work or other activities less carefully than usual:	☐1	☐2	☐3	☐4	☐5

NUM 1 (1-5)	Not at all	Slightly	Moderately	Quite a bit	Extremely
6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?	☐1	☐2	☐3	☐4	☐5

HEALTH STATUS QUESTIONNAIRE (*SF-36™*)

NUM 1 (1-6)	None	Very Mild	Mild	Moderate	Severe	Very severe
7. How much bodily pain have you had during the past 4 weeks?	☐1	☐2	☐3	☐4	☐5	☐6

NUM 1 (1-5)	Not at all	A little bit	Moderately	Quite a bit	Extremely
8. During the past 4 weeks, how much did pain interfere with your normal work (*including both work outside the home and housework*)?.....	☐1	☐2	☐3	☐4	☐5

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks…

NUM 1 (1-5)	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Did you feel full of life?	☐1	☐2	☐3	☐4	☐5
b. Have you been very nervous?.	☐1	☐2	☐3	☐4	☐5
c. Have you felt so down in the dumps nothing could cheer you up?.....	☐1	☐2	☐3	☐4	☐5
d. Have you felt calm and peaceful?	☐1	☐2	☐3	☐4	☐5
e. Did you have a lot of energy?..	☐1	☐2	☐3	☐4	☐5
f. Have you felt downhearted and depressed?.....	☐1	☐2	☐3	☐4	☐5
g. Did you feel worn out?.....	☐1	☐2	☐3	☐4	☐5
h. Have you been happy?.....	☐1	☐2	☐3	☐4	☐5
i. Did you feel tired?.....	☐1	☐2	☐3	☐4	☐5

Participant ID:	**Participant Initials:**	**Clinical Center:**
Visit Date:	**Visit Number:**	**CRC Initials:**

HEALTH STATUS QUESTIONNAIRE (*SF-36*™)

NUM 1 (1-5)	All of the time	Most of the time	Some of the time	A little of the time	None of the time
10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (*like visiting friends, relatives, etc.*)?	☐1	☐2	☐3	☐4	☐5

11. How TRUE or FALSE is each of the following statements for you?

NUM 1 (1-5)	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a. I seem to get sick a little easier than other people:.....	☐1	☐2	☐3	☐4	☐5
b. I am as healthy as anybody I know:	☐1	☐2	☐3	☐4	☐5
c. I expect my health to get worse:	☐1	☐2	☐3	☐4	☐5
d. My health is excellent:	☐1	☐2	☐3	☐4	☐5

Thank you for completing these questions!

Research Coordinator: Please check the appropriate box to indicate who completed the CRF.

☐1 Participant ☐2 Interviewer ☐3 Both **NUM 1 (1-3)**

Participant ID:	**Participant Initials:**	**Clinical Center:**
Visit Date:	**Visit Number:**	**CRC Initials:**

STUDY STOP AND CLOSE-OUT

1. Did the participant successfully complete the COAG study (*through Visit 12*)?

☐$_1$ Yes ☐$_0$ No **NUM 1 (1,0)**

a. If no, check reason(*s*) for early withdrawal (*check all that apply*): **NUM 1 (1)**

☐$_1$ Adverse event or serious adverse event (*e.g. medical condition/surgical intervention that necessitates stopping warfarin, AE(s) due to warfarin use*)

AE number as recorded on ***AE*** __ __ __ **NUM 3 (0-999)**

☐$_1$ Anti-coagulation clinician or healthcare provider's discretion (*e.g. participant non-compliant*)

Specify _____ **CHR 500** _____

☐$_1$ Participant's decision (*e.g. refusal, dissatisfaction with warfarin treatment*) **NUM 1 (1)**

Specify _____ **CHR 500** _____

☐$_1$ Eligible, but did not start warfarin treatment post-randomization **NUM 1 (1)**

Specify _____ **CHR 500** _____

☐$_1$ Other reason(s) **NUM 1 (1)**

Specify _____ **CHR 500** _____

b. Indicate last COAG study visit completed:

__ __ **NUM 2 (1-12)**

c. Date last COAG study visit completed:

__ __/__ __/__ __ __ __ (*mm/dd/yyyy*) **DT**

2. Principal Investigator comments (*optional*): **NOT ENTERED**

_____

_____

_____

_____

_____

_____

STUDY STOP AND CLOSE-OUT

SIGNATURES:

I verify that all information collected on the ***COAG*** study CRFs for this participant is correct to the best of my knowledge and was collected in accordance with the procedures outlined in the COAG study protocol and Manual of Procedures (***MOP***).

3. Principal Investigator signature:

☐$_1$ Yes ☐$_0$ No

_____ __ __/__ __/__ ___ __ ___
Principal Investigator signature *Date*

4. Research Coordinator signature:

☐$_1$ Yes ☐$_0$ No

_____ __ __/__ __/__ ___ __ ___
Research Coordinator signature *Date*

UNBLINDING

*If unblinding involves discontinuation of warfarin treatment, complete Early Warfarin Stop (**WSTOP**) CRF.*

1. Type of unblinding:

   a. Dose

   ☐1 Yes ☐0 No **NUM 1 (1,0)**

   b. Randomization

   ☐1 Yes ☐0 No

2. Date of unblinding:

   __ __/__ __/__ __ __ __ (*mm/dd/yyyy*) **DT**

3. Reason(s) for unblinding (*check all that apply*):

   ☐1 Adverse event or serious adverse event **NUM 1 (1)**
   (*e.g. medical condition/surgical intervention that necessitates stopping warfarin, AE(s) due to warfarin use*)

   AE number as recorded on Adverse Events (***AE***) CRF__ __ __ **NUM 3 (0-999)**

   ☐1 Anti-coagulation clinician or healthcare provider's discretion (*e.g. participant non-compliant*) **NUM 1 (1)**

Deleted Specify _____ **CHR 500** _____

   ☐1 Participant's decision (*e.g. refusal, dissatisfaction with warfarin treatment*) **NUM 1 (1)**

Deleted Specify _____ **CHR 500** _____

   ☐1 Accidental unblinding of randomization **NUM 1 (1)**

Deleted Specify _____ CHR 500 _____

   ☐1 Other reason(s) **NUM 1 (1)**

Deleted Specify _____

4. Person requesting unblinding:

   ☐1 Principal Investigator (*PI*)
   ☐2 Research Coordinator (*RC*) **NUM 2 (1-3,98)**
   ☐3 Medical Monitor
   ☐98 Other, specify _____

   a. If someone other than the Principal Investigator (*PI*) requested unblinding, was the PI contacted prior to unblinding?

   ☐1 Yes ☐0 No **NUM 1 (1,0)**

UNBLINDING

5. Was the Medical Monitor (*or designee*) contacted?

☐1 Yes ☐0 No ☐99 N/A (*if Medical Monitor requests unblinding*) **NUM 2 (1,0,99)**

a. If no, specify reason for not contacting the Medical Monitor:

Deleted

_____ **CHR 500** _____

b. If no, the person who assisted with unblinding:

Deleted

_____ **CHR 500** _____

6. Person contacted at the site's Investigation Drug Service (*IDS*):

Deleted

_____ **CHR 500** _____

7. Additional comments on the event that led to the unblinding request: **CHR 500**

Deleted

_____

_____

_____

_____

_____

_____

8. Principal Investigator signature and date:

Deleted

_____ _____/_____/_____**DT**

Participant ID:	**Participant Initials:**	**Clinical Center:**
Visit Date:	**Visit Number:**	**CRC Initials:**

FOLLOW-UP VISIT FORM

Type of follow-up: .....
☐1 In-person
☐2 Phone
☐3 Missed visit (*stop here*) **NUM 1 (1-3)**

This form is not applicable for a missed participant visit.

Questions 1 though 9 completed by interviewing the participant.

1. Since your last study visit, have you had your warfarin/Coumadin stopped for any reason? .....
☐1 Yes
☐0 No **NUM 2 (1,0,99)**
☐99 N/A (***if not on warfarin therapy***)

   If yes, complete EVENTS form, Section I.

2. Since your last visit, have you taken any warfarin that was not given to you by the study? ..... ☐1 Yes ☐0 No **NUM 1 (1,0)**

   a. How many days did you take the non-study warfarin? ..... __ __ days **NUM 2 (0-99)**

   If off-protocol dosing for 2 or more days on days 1 through 28, contact the Medical Monitor.

3. Since your last study visit, have you been seen in an emergency room or were you hospitalized? ..... ☐1 Yes ☐0 No **NUM 1 (1,0)**

   If yes, complete HOSPINFO for each hospitalization and emergency room visit and continue to question 3a

   a. Was it for bleeding, a stroke or TIA (mini-stroke) or a blood clot? ..... ☐1 Yes ☐0 No **NUM 1 (1,0)**

   b. Did you experience bleeding, a stroke, or TIA (mini-stroke) or a blood clot during hospitalization?
   ☐1 Yes
   ☐0 No **NUM 2 (1,0,99)**
   ☐99 N/A (***if not hospitalized***)

   If yes in question 3a, complete EVENTS form Section II and AE form. If no in question 3a, complete AE form.
   If yes in question 3b, complete EVENTS form Section IV and AE form. If no in question 3b, complete AE form.

4. Since your last visit have you seen your healthcare provider for [any other] bleeding or a blood clot, not as an inpatient and not in the emergency room? ..... ☐1 Yes ☐0 No **NUM 1 (1,0)**

   If yes, complete EVENTS form Section III and AE form.

5. Since your last visit have you experienced any other bleeding or any bruising that did not require you to see your healthcare provider? ..... ☐1 Yes ☐0 No

   a. Was this a new bleeding or bruising event? ..... ☐1 Yes ☐0 No

   b. Since its occurrence, is it…? .....
   ☐1 Getting better
   ☐2 Getting worse
   ☐3 No change **NUM 1 (1-3)**

6. Since the last study visit, have you experienced any other serious health problems that required you to be hospitalized? ..... ☐1 Yes ☐0 No **NUM 1 (1,0)**

   If yes, complete AE and HOSPINFO (one for each hospitalization and emergency room visit).

Participant ID:	Participant Initials:	Clinical Center:
Visit Date:	Visit Number:	CRC Initials:

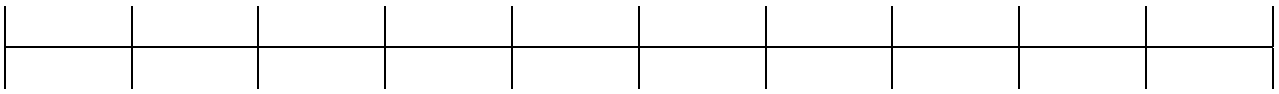
FOLLOW-UP VISIT FORM

Check "N/A / 99"if the participant discontinued warfarin more than 7 days ago for questions 7 and 8.

7. Did you skip taking any warfarin capsules in the past 7 days?..... ☐1 Yes ☐0 No ☐99 N/A **NUM 2 (1,0,99)**
   a. How many days did you skip taking warfarin capsules? ..... __ __ days **NUM 1 (0-7)**
8. Did you take extra warfarin capsules in the past 7 days?..... ☐1 Yes ☐0 No ☐99 N/A **NUM 2 (1,0,99)**
   a. How many days did you take extra warfarin capsules?..... __ __ days **NUM 1 (0-7)**

If the participant missed 2 or more days or took 2 or more extra doses, contact the Medical Monitor.

Put a cross on the line below at the point showing your best guess about how much of your warfarin you have taken since your last study visit. For example, 0% means you have taken no dose, 50% means you have taken half of your prescribed doses, and 100% means you have taken all of your prescribed doses.



0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

9. Score: ..... __ __ __ **NUM 3 (0-100)**
   ☐99 N/A (***if not on warfarin***) **NUM 2 (99)**

Complete the following questions based on the warfarin capsules dispensed, as noted on the returned bottle(s).

Questions 10 through 13 are completed during visits 2 through 7 only; for all other visits check N/A and go to question 14: ..... ☐99 N/A **NUM 2 (99)**

10. Did the participant return the bottles from the previous visit? ..... ☐1 Yes ☐0 No **NUM 2 (1,0,99)** ☐99 N/A (***if inpatient, at visits 1-7***)

If yes, continue. If no or N/A, go to question 14.

11. # of warfarin capsules dispensed: ..... Bottle A: __ __ **NUM 2 (0-99)**
    Bottle B: __ __ ☐99 N/A **NUM 2 (99)**
12. # of warfarin capsules returned: ..... Bottle A: __ __
    Bottle B: __ __ ☐99 N/A **NUM 2 (99)**
13. # of warfarin capsules lost/unusable: ..... Bottle A: __ __
    Bottle B: __ __ ☐99 N/A **NUM 2 (99)**

Data for questions 14 is obtained through medical chart review.

14. Has the participant's target INR changed since the last study visit? . ☐1 Yes ☐0 No **NUM 1 (1,0)**
    a. New range:..... **NUM 2.2 (0-99.0-99)** __ __ . __ __ to __ __ . __ __ ☐88 Unknown **NUM 2 (88)**
    b. Date range changed: ..... __ __/__ __/__ __ __ __ (*mm/dd/yyyy*) **DT (≥ 05/01/2009)**

WARFARIN LOG

(Completed between Visits 8 and 12 or if participant takes off-protocol dose between Visits 1 and 7)

NUM 3 (1-999) Line #	DT Start date mm/dd/yyyy	DT Stop date mm/dd/yyyy	NUM 3.2 (0-999.0-99) Weekly dose (in mg)	NUM 1 (1-7) Frequency 1 = Daily 2 = Once a week 3 = 2 X/week 4 = 3 X/week 5 = 4 X/week 6= 5 X/week 7= 6 X/week

Participant ID:	Participant Initials:	Clinical Center:
Visit Date:	Visit Number:	CRC Initials:

EARLY WARFARIN STOP

[Completed by the Clinical Center Principal Investigator]

1. Did the participant permanently discontinue warfarin treatment (*prior to Visit 12*)?

   ☐$_1$ Yes ☐$_0$ No **NUM 1 (1,0)**

2. Date when last took warfarin:

   __ __/__ __/__ __ __ __ (*mm/dd/yyyy*) **DT**

3. Indicate last COAG study visit completed:

   Visit #: __ __ **NUM 2 (1-12)**

4. Check reason(s) for permanently discontinuing warfarin treatment prior to week 12 visit (*check all that apply*):

   ☐$_1$ Adverse event or serious adverse event **NUM 1 (1)**
   (*e.g. medical condition/surgical intervention that necessitates stopping warfarin, AE(s) due to warfarin use*)

   AE number as recorded on ***AE*** __ __ __ **NUM 3 (1-999)**

   ☐$_1$ Anti-coagulation clinician or healthcare provider's discretion (*e.g. participant non-compliant*) **NUM 1 (1)**

   Specify reason _____ **CHR 500** _____

   ☐$_1$ Participant's decision (*e.g. refusal, dissatisfaction with warfarin treatment*) **NUM 1 (1)**

   Specify reason _____ **CHR 500** _____

   ☐$_1$ Other reason(*s*) **NUM 1 (1)**

   Specify reason _____ **CHR 500** _____

5. Did the participant stop warfarin treatment due to participation in the <u>blinded dosing trial</u>?

   ☐$_1$ Yes ☐$_0$ No **NUM 1 (1,0)**

   a. If yes, specify: _____ **CHR 500** _____

6. Is the participant willing to continue with study visits without warfarin treatment?

   ☐$_1$ Yes ☐$_0$ No **NUM 1 (1,0)**

*If no, complete the Study Stop and Close-Out (**SSTOP**) CRF.*

Additional Comments: _____ **NOT ENTERED** _____

_____

_____