59142

AFFIRM

Death

Fax to: (800) 547-0463

1. Date of clinical death:

Month / Day / Year

Days09

Affix Patient ID # Here

Print Acrostic Here

2. Time of clinical death: Hours : Minutes (24-hr clock)

Class I = Disopryamide or Flecainide or Moricizine or Procainamide or Propafenone or Quinidine) (0=No, 1=Yes)

3. Drugs taken at the time of onset of symptoms of terminal event:

No 0	Yes 1		No 0	Yes 1	
○	○	Amiodarone ⇒ Specify dose: ____ mg/day	○	○	Flecainide
○	○	Beta blocker	○	○	Moricizine
○	○	Digoxin	○	○	Procainamide
○	○	Diltiazem	○	○	Propafenone
○	○	Disopyramide	○	○	Quinidine
			○	○	Sotalol
			○	○	Verapamil
○	○	Other antiarrhythmics ⇒ Specif			

DRate09 - Beta Blocker or Digoxin or Diltiazen or Verapamil (0 = No, 1 = Yes)

DRhyth09 - Amiodarone or Disopyramide or Flecainide or Moricizine or Procainamide or Propafenone or Quinidine or Sotal01 or other antiarrhythmics (0 = No, 1 = Yes)

4. Medications not listed above taken at the time of onset of symptoms of terminal event:

No 0	Yes 1		No 0	Yes 1	
○	○	*ACE09* Angiotensin/ACE inhibitor	○	○	Lipid-lowering
○	○	Beta adrenergic stimulants	○	○	Nitrate
○	○	Calcium channel blockers (other than diltiazem or verapamil)	○	○	Other antihypertensive
			○	○	Theophylline
○	○	*Diuret09* Diuretic	○	○	Thyroid replacement therapy
○	○	Estrogen/progesterone therapy			
○	○	Other cardiac medications ⇒ Specify			

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5. **Antiplatelet/anticoagulant therapy at the time of onset of symptoms of terminal event:**

	No *0*	*Yes* *1*	
	○	○	Aspirin
	○	○	Heparin ⇒ Most recent PTT: ___.___ sec ___/___/___ (Month / Day / Year)
Warf09	○	○	Warfarin ⇒ Most recent INR: ___.___ ___/___/___ (Month / Day / Year)
AntiPo09	○	○	Other ⇒ Specify *(Aspirin or Heparin or Other)*

6. **If the patient was not taking warfarin, what contraindications had developed since randomization?**

No	*Yes*	
○	○	Bleeding ⇒ Specify:
○	○	Frailty/risk of falls
○	○	Physician refusal
○	○	Patient refusal
○	○	Surgery
○	○	None; warfarin discontinued per guidelines; patient was in normal sinus rhythm in the rhythm control arm
○	○	Other ⇒ Specify:

7. **Were any rate or rhythm control drugs permanently discontinued since last follow-up?**

○ No

○ Yes ⇒ Complete a Drug Discontinuation form for each drug that was stopped.

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☐☐ / ☐☐ / ☐☐

Month Day Year

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8. Had atrial fibrillation or flutter been documented by ECG since last follow-up

AF09

○ No (0) ⇒ Go to Question 9.

○ Yes (1) ⇒ Specify (if both atrial fibrillation and flutter recurred, mark "Atrial fibrillation"):

- ○ Atrial fibrillation
- ○ Atrial flutter

⇒ Specify whether atrial fibrillation or flutter was continuous since last follow-up:

- ○ Continuous
- ○ Intermittent ⇒ Date of first ECG-documented recurrence since last follow-up:

☐☐ / ☐☐ / ☐☐

Month Day Year

9. Was electrical or pharmacologic cardioversion for atrial fibrillation or flutter attempted since last follow-up?

○ No

○ Yes ⇒ Enter the total number of episodes and the number of successful episodes of cardioversion:

	Electrical	Pharmacologic	Used both
Total number of episodes:	☐☐	☐☐	☐☐
Number of successful episodes:	☐☐	☐☐	☐☐

If any episodes were electrical or used both, was internal electrical cardioversion administered? ○ No ○ Yes

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10. Was patient hospitalized since last follow-up (including treatment for the terminal event)?

Hosp09

○ No (0) ⇒ Go to Question 11.

○ Yes (1) ⇒ Mark number of inpatient days for each:

Total days: DaysT09

Critical care: DaysC09

Non-critical care: DaysNC09

Reason 09 ⇒ Reason for hospitalization: ○ Cardiovascular (1) ○ Non-cardiovascular (2)

11. Emergency room or short stay (<24 hours) visits since last follow-up (including treatment for the terminal event)?

Emerg09

○ No (0)

○ Yes (1) ⇒ Specify total number of visits:

12. Innovative therapy used since last follow-up?

○ No

○ Yes ⇒ Complete Innovative Therapy form.

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13. Events since last follow-up: ***(If yes, also complete Event Notification form.)***

No	*Yes*	
○	○	Torsades de pointes VT ⇒ Submit required materials.
○	○	Sustained ventricular tachycardia ⇒ Submit required materials.
○	○	Resuscitated cardiac arrest: VF, VT ⇒ Submit required materials.
○	○	Resuscitated cardiac arrest: EMD, brady, other ⇒ Submit required materials.
○	○	Disabling anoxic encephalopathy ⇒ Also complete CNS Disability form.
○	○	Ischemic stroke ⇒ Also complete CNS Disability form.
○	○	Intracranial bleeding ⇒ Also complete CNS Disability form.
○	○	Non-CNS hemorrhage (requiring transfusion, surgery, D/C warfarin)
○	○	Systemic embolism
○	○	Pulmonary embolism
○	○	Myocardial infarction
○	○	Minor bleeding ⇒ Event Notification form not needed, but specify type of bleeding:
○	○	Unexplained syncope ⇒ Event Notification form not needed

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14. Major procedures since last follow-up?

Proc09

○ 0 No

○ 1 Yes ⇒ Specify the procedure(s) performed:

No	*Yes*	
○ 0	○ 1	CABG
○	○	Interventional procedures (PTCA, atherectomy, stent)
		If yes, number of lesions treated:
○	○	Pacemaker implantation ⇒ Specify type: *(Mark one only.)* ○ Atrial ○ Ventricular ○ Dual chamber
○	○	Thrombolytic therapy
○	○	Valve surgery
○	○	Non-cardiac surgery (NCARD09)
○	○	Other procedure ⇒ Specify:

CARD09 (CABG or Interventional procedures or Pacemaker implantation or Valve Surgery)
(0 = No, 1 = Yes)

15. Was treatment strategy changed since last follow-up?

○ No

○ Yes ⇒ Complete Change of Treatment Strategy form.

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16. Cause of death:

○ 1 Non-cardiovascular ⇒ Go to Question 17.

Cause09 ○ 2 Vascular ⇒ Go to Question 18.

○ 2 Cardiac ⇒ Go to Question 19.

2 = Cardiovascular

17. For non-cardiovascular death, specify primary cause:

1 ○ Cancer

7 ○ Sepsis

7 ○ Trauma

4 ○ Pulmonary ⇒ Specify:

○ Amiodarone pulmonary toxicity

○ Not related to amiodarone

NCPrim09

7 ○ Non-cardiac surgery

7 ○ Suicide

7 ○ Other ⇒ Specify:

⇒ **Go to bottom of Page 10; print your name and today's date.**

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18. For vascular death, specify primary cause:

○ Non-CNS hemorrhage ⇒ Specify site:

○ Gastrointestinal ○ Retroperitoneal

○ Other:

○ Vascular catastrophe (aortic dissection, rupture of aortic aneurysm, etc.)

○ Systemic embolism ⇒ Specify site:

○ Pulmonary embolism

○ CNS event ⇒ Complete all of the following:

a. Specify type: ○ Ischemic stroke

○ Primary intraparenchymal hemorrhage

○ Subdural/subarachnoid hemorrhage

○ Other:

b. Complete CNS Disability form

⇒ **Go to bottom of Page 10; print your name and today's date.**

19. For cardiac death, was there any evidence of ischemia?

Ischem09 *0* ○ No

1 ○ Yes ⇒ Specify evidence for ischemia:

No	*Yes*	
○	○	Ischemic chest discomfort at onset of event
○	○	ECG changes
○	○	Enzyme changes
○	○	Other ⇒ Specify:

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20. For cardiac death, complete all of the following:

a. Were new symptoms present prior to cardiac death?

0 ○ No

1 ○ Yes ⇒ Specify duration:

CSymp09

○ <5 minutes ○ 5-59 minutes ○ 1-24 hours ○ >24 hours

9 ○ Unknown

b. Was death witnessed (i.e., was patient observed within 5 minutes prior to onset of terminal event)?

Witnes09

0 ○ No

1 ○ Yes

c. Was patient asleep when death occurred?

○ No

○ Yes

○ Unknown

d. Setting of onset of terminal event:

InHosp09

1 ○ In-hospital

0 ○ Out-of-hospital

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21. For cardiac death, was the rhythm associated with the terminal event documented b

- ○ Never monitored ⇒ Go to Question 22.
- ○ Monitored before and during collapse
- ○ Monitored only after collapse ⇒ Specify approximate time from onset of collapse to monitoring: ____ min

If monitored, characterize rhythm (if hospitalized and monitored, specify rhythm noted at onset of episode; if not hospitalized or not monitored at onset of event, specify rhythm note at onset of monitoring): (*Mark one only.*)

- ○ VF
- ○ VT
- ○ Torsade de pointes
- ○ Idioventricular
- ○ Severe bradycardia
- ○ 3rd degree AV block
- ○ EMD
- ○ Asystole
- ○ Other ⇒ Specify: ____

22. For cardiac death, specify primary cause:

1 ○ Arrhythmic ⇒ Documented by ECG?

○ No ○ Yes

CPrim09 *2* ○ Nonarrhythmic ⇒ Specify presumed cause of death:

- ○ CHF or shock ⇒ Specify whether accompanied by MI:
  - ○ Without MI ○ With MI
- ○ Cardiac surgery or procedure (e.g. PTCA)
- ○ Other ⇒ Specify: ____

2 ○ Uncertain mechanism

Name of person completing this form _____ **Date** _____

Please print mm/dd/yy

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