

**INSTRUCTIONS: Complete this form for all randomized and observation subjects at the time of a qualifying event, i.e., transplant or death. In addition, complete this form annually until study end or the subject is deceased.**

**Section A: KEY IDENTIFYING INFORMATION**

- A1. Study Identification Number \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_
- A2. Acrostic Identifier \_\_\_\_\_
- A3. Study visit
  - STUDY VISIT 3 (12 months).....3
  - STUDY VISIT 5 (2 years) .....5
  - STUDY VISIT 6 (3 years) .....6
  - STUDY VISIT 7 (4 years) .....7
  - STUDY VISIT 8 (5 years) .....8
  - STUDY VISIT 9 (6 years) .....9
  - STUDY VISIT 10 (7 years) .....10
  - STUDY VISIT 11 (8 years) .....11
  - STUDY VISIT 12 (9 years) .....12
  - STUDY VISIT 13 (10 years) .....13
  - STUDY VISIT 14 (11 years) .....14
- A4. Follow-up
  - ~~PRIOR TO 12 MONTHS.....1~~
  - ~~PRIMARY OUTCOME (12 months).....2~~
  - ~~FOLLOW UP PRIOR TO END OF MAIN TRIAL .....3~~
  - ~~END OF MAIN TRIAL CONTACT (MID-2009)...4~~
  - ~~POST MAIN TRIAL CONTACT .....5~~
- A5. Date of form completion \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_
- A6. Name of person completing form \_\_\_\_\_

PRINT FULL NAME

INITIALS

**Section B: SUBJECT STATUS**

- B1. Type of subject
    - RANDOMIZED.....1
    - OBSERVATION.....2
  - B2. Source of vital status
    - a. Family Member YES.....1 NO.....2
    - b. MD/Medical Records YES.....1 NO.....2
    - c. Social Security Death Index (SSDI) YES.....1 NO.....2
    - d. Other YES.....1 NO.....2
- 1 Specify source: \_\_\_\_\_

- B3. Vital status
- ALIVE ..... 1
  - DEAD..... 2
  - LOST TO FOLLOW-UP ..... 3
  - NO INFORMATION.....4 **(END)**

**NOTE:**

In the two-year period before a subject can be categorized as lost to follow-up (See QxQ for LTFU designation requirements), 4 (NO INFORMATION) should be selected in question B3.

- a. Date of death or last known alive           /           /
- M M / D D / Y Y Y Y
- (Record date, then: Skip to B8 if alive OR End form if lost to follow-up)**

- B4. Was death related to SV diagnosis or surgery? YES ..... 1 NO ..... 2

- B5. Primary cause of death
- CARDIAC ..... 1
  - NON-CARDIAC ..... 2
  - UNKNOWN..... -8 **(B7)**

- a. Was subject's death related to the shunt s/he received?
- NOT RELATED ..... 1
  - POSSIBLY RELATED ..... 2
  - DEFINITELY RELATED ..... 3

- b. Primary cause:           **(See codes below)**
1. If other, specify: \_\_\_\_\_

- B6. Number of secondary causes of death:           (0-4) **(If 0, skip to B7)**

**Cause of Death codes (See codes below)**

- a.           1. If Other (99), specify: \_\_\_\_\_
- b.           1. If Other (99), specify: \_\_\_\_\_
- c.           1. If Other (99), specify: \_\_\_\_\_
- d.           1. If Other (99), specify: \_\_\_\_\_

B7. Cause of death description: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

Code	Cause of Death	Code	Cause of Death
01	Surgical complication	08	Sudden cardiac death
02	Multi-organ failure	09	Heart failure
03	Acute catheterization complication	10	Myocardial ischemia
04	Thrombotic event	11	Pulmonary hypertension
05	Arrhythmia	12	Respiratory failure
06	Pulmonary vein stenosis	13	Respiratory arrest
07	Infection	14	Neurologic injury (CVA)
		99	Other

B8. Heart transplant status

NO LISTING OR TRANSPLANT..... 1 **(END)**  
 LISTED FOR TRANSPLANT ..... 2 **(B8b)**  
 TRANSPLANTED..... 3

a. Date of transplant

\_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
 M M / D D / Y Y Y Y

b. Date of initial listing

\_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
 M M / D D / Y Y Y Y

c. Initial listing status

1A (US) / 2, 3, 3.5, 4 (Canada) ..... 1  
 1B (US)..... 2  
 2 (US) / 1 (Canada) ..... 3  
 7 (US) / 0 (Canada) ..... 4

d. Current listing status or status prior to transplant or death

1A (US) / 2, 3, 3.5, 4 (Canada) ..... 1  
 1B (US)..... 2  
 2 (US) / 1 (Canada) ..... 3  
 7 (US) / 0 (Canada) ..... 4

**END OF FORM**