

**Section A: KEY IDENTIFYING INFORMATION**

A1. Study Identification Number \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_  
**Replaced by blinded subject ID**

|          |            |
|----------|------------|
| blind_id | Blinded ID |
|----------|------------|

A2. Acrostic Identifier \_\_\_\_\_

**Removed to protect privacy**

A3. Study visit END OF TRIAL VISIT .....88

|       |                 |
|-------|-----------------|
| VISIT | A3. Study visit |
|-------|-----------------|

A4. Follow-up END OF MAIN TRIAL CONTACT.....4

|          |               |
|----------|---------------|
| FOLLOWUP | A4. Follow-up |
|----------|---------------|

A5. Date of form completion \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
M M / D D / Y Y Y Y

|          |  |
|----------|--|
| r188_age | <created var>Age at form completion date, days |
|----------|--|

A6. Name of person completing form \_\_\_\_\_  
PRINT FULL NAME INITIALS

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**Section B: SUBJECT STATUS**

B1. Type of subject RANDOMIZED.....1

|        |                     |
|--------|---------------------|
| TYPEPT | B1. Type of patient |
|--------|---------------------|

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: \_\_\_\_\_

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|              |   |
|--------------|---|
| FAMILYMEMBER | B2a. Source of vital status: Family member                      |
| MEDICALREC   | B2b. Source of vital status: MD/Medical Records                 |
| SSDI         | B2c. Source of vital status: Social Security Death Index (SSDI) |
| SOURCE_OTHER | B2d. Source of vital status: Other                              |
| SOURCE_SP    | B2d1. Specify source  |

B3. Vital status ALIVE.....1  
DEAD.....2

LOST TO FOLLOW-UP.....3

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 Lost to Follow-up)**

|            |  |
|------------|--|
| OUTVITAL   | B3. Vital status   |
| status_age | B3. <created var> Age at death or last known alive, days |

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

|          |   |
|----------|---|
| DEATHSVR | B4. Was death related to SV diagnosis or surgery? |
|----------|---|

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

a. Was the 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: \_\_\_\_\_

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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: \_\_\_\_\_

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d. \_\_\_\_\_ 1. If Other (99), specify: \_\_\_\_\_

| 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                   |

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

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B8. Heart transplant status

NO LISTING OR TRANSPLANT ..... 1 **(Z1)**

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

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|             |  |
|-------------|--|
| HTYNLIST    | B8. Heart Transplant Status  |
| ht_age      | B8a. <created var> Age at date of transplant, days                 |
| htlist_age  | B8b. <created var> Age at date of initial listing, days            |
| HTINTSTATUS | B8c. Initial listing status or status prior to transplant or death |
| HTSTATUS    | B8d. Current status or status prior to transplant or death         |