

**Section A: KEY IDENTIFYING INFORMATION**

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

blind_id	Blinded ID
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A2. Acrostic Identifier \_\_\_\_\_  
**Removed to protect privacy**

A3. Study visit  
 STUDY VISIT 3 (12 months).....3  
 STUDY VISIT 5 (2 years) .....5

VISIT	A3. Study visit
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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

FOLLOWUP	A4. Follow-up
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A5. Date of form completion \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
 M M / D D / Y Y Y Y

**Replaced by age at date of form completion, days**

R108_age	<created var> Age at date of form completion, days
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A6. Name of person completing form \_\_\_\_\_  
 PRINT FULL NAME INITIALS

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**Section B: PATIENT STATUS**

B1. Type of patient  
 RANDOMIZED.....1  
 OBSERVATION.....2

TYPEPT	B1. Type of patient
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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

Pediatric Heart Network: Single Ventricle Reconstruction Trial and Extension Study

Form R108: Primary Outcome  
(Not All Variables are Shown)

1. Specify source: \_\_\_\_\_

SOURCE	B2. Source of Vital Status
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	B3a <created var> Age at date of 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?
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B5. Primary cause of death CARDIAC ..... 1  
NON-CARDIAC ..... 2  
UNKNOWN..... -8 (B7)

a. Was patient'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: \_\_\_\_\_

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Form R108: Primary Outcome  
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c. \_\_\_\_ 1. If Other (99), specify: \_\_\_\_\_

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

**Removed to protect privacy**

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

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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

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
HTINTSTATUS	B8c. Initial listing status or status prior to transplant or death
HTSTATUS	B8d. Current status or status prior to transplant or death