

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. Date of form completion _____ / _____ / _____ - _____ - _____ - _____
M M / D D / Y Y Y Y

Replaced by age at form completion

comp_age	A3. <created var>Age at completion of form, days
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A4. Name of person completing form _____
PRINT FULL NAME INITIALS

Removed to protect privacy

Section B: CLINICAL ASSESSMENT

B1. Date of hospital admission _____ / _____ / _____ - _____ - _____ - _____
M M / D D / Y Y Y Y

Replaced by age at hospital admission

hadm_age	B1. <created var>Age at hospital admission, days
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B2. Date of hospital discharge _____ / _____ / _____ - _____ - _____ - _____
M M / D D / Y Y Y Y

Replaced by age at hospital discharge

hdis_age	B2. <created var>Age at hospital discharge, days
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B3. Single ventricle palliative surgery? YES 1 NO 2 **(B10)**

PALSURG	[Added Version B] B3. Single Ventricle Palliative Surgery?
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a. Timing of SV palliative surgery
 PRIOR TO END OF SCREENING 1 **(B7a)**
 AFTER END OF SCREENING 2

PSRGWHEN	[Added Version B] B3a. Timing of SV Palliative Surgery
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B4. Date of SV palliative surgery _ / _ / _
M M / D D / Y Y Y Y

Replaced by age at surgery

psrg_age	B4. <created var>Age at single ventricle palliative surgery, days
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B5. Type of SV palliative surgery

**Surgical Procedure Code
(See Code List B)
[code required for data entry]**

- a. Level 1 **B 1**
- b. Level 2 ___ ___
- c. Level 3 ___ ___
- d. Level 4 ___ ___

Surgical Procedure Name Worksheet
a1.
b1.
If coding = <u>B1-01-06</u> , you must specify here:
c1.
d1.

bprocode	[Added Version B] <created var>B5. Type of SV palliative surgery code
BPROC_S	[Added Version B] B5c1: Specify if coding = B1-01-06

B6. Number of other surgical procedures concurrent with SV palliative surgery ___ ___ (0-5) (If 0, skip to **B7a**)

BNUMCON	[Added Version B] B6. Other surgical procedures concurrent with SV palliative surg
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Concurrent Surgical Procedures			
Code	Procedure Name	Code	Procedure Name
01	Aortic arch repair*	11	Repair of totally anomalous pulmonary venous connection
02	Atrial septectomy*		
03	Atrioventricular valve oversewn		
04	Atrioventricular valve replacement	14	Semilunar valve replacement
06	Division of main pulmonary artery*	16	Subaortic stenosis surgery
07	Ligation of main pulmonary artery		
08	Pacemaker insertion		
09	Patch repair of pulmonary artery stenosis		
10	Repair of atrioventricular valve regurgitation	99	Other

***DO NOT SELECT IF CODING FOR QUESTIONS B5a-b ARE B1-05.**

Concurrent Surgical Code (See codes above)

- a. ___ ___ 1. If Other (99), specify: _____
- b. ___ ___ 1. If Other (99), specify: _____
- c. ___ ___ 1. If Other (99), specify: _____
- d. ___ ___ 1. If Other (99), specify: _____
- e. ___ ___ 1. If Other (99), specify: _____

BCONCOD_0	[Added Version B] B6a. Concurrent Surgical Code (Code List B)
BCON_S_0	[Added Version B] B6a1. Specify Other Concurrent Surgical Code

B7. Status during SV palliative surgery:

a. Bypass time _____ minutes

BYPASST	B7a. Palliative Surgery: Bypass time
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b. Cross clamp time _____ minutes

CLAMPT	B7b. Palliative Surgery: Cross clamp time
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c. Circulatory arrest YES 1 NO 2 **(B8)**

ARREST	B7c. Palliative Surgery: Circulatory arrest
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1. Total circulatory arrest time _____ minutes

ARRESTT	B7c1. Total circulatory arrest time
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B8. Total ICU stay following SV palliative surgery _____ days

B9. Total time on ventilator support following SV palliative surgery _____ days

Any time spent in the ICU or on ventilator support counts as 1 day, even if <24 hr period

HICU	B8. Total ICU stay following SV palliative surgery
HVENT	B9. Total time on ventilator support following SV pall. surg.

B10. Number of interventional cardiac catheterizations after enrollment to hospital discharge _____ (0-8) (If 0, skip to **B11**)

[DO NOT include diagnostic catheterizations]

HNUMCATH	B10. Number of interventional cardiac catheterizations
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Cardiac Catheterization Intervention Code (See Code List F) [code required for data entry]						6. Date of Interventional Cardiac Catheterization
1. Level 1	2. Level 2	3. Level 3	4. Level 4	5. Level 5		
a.	_ _ - _ - _ - _ - _ - _ - _ -	_ _ - _ - _ - _ - _ - _ - _ -	_ _ - _ - _ - _ - _ - _ - _ -	_ _ - _ - _ - _ - _ - _ - _ -	_ _ - _ - _ - _ - _ - _ - _ -	_ _ / _ _ / _ _ _ _ _ _ M M D D Y Y Y Y
						Name of intervention
b.	_ _ - _ - _ - _ - _ - _ - _ -	_ _ - _ - _ - _ - _ - _ - _ -	_ _ - _ - _ - _ - _ - _ - _ -	_ _ - _ - _ - _ - _ - _ - _ -	_ _ - _ - _ - _ - _ - _ - _ -	_ _ / _ _ / _ _ _ _ _ _ M M D D Y Y Y Y
						Name of intervention
c.	_ _ - _ - _ - _ - _ - _ - _ -	_ _ - _ - _ - _ - _ - _ - _ -	_ _ - _ - _ - _ - _ - _ - _ -	_ _ - _ - _ - _ - _ - _ - _ -	_ _ - _ - _ - _ - _ - _ - _ -	_ _ / _ _ / _ _ _ _ _ _ M M D D Y Y Y Y
						Name of intervention
d.	_ _ - _ - _ - _ - _ - _ - _ -	_ _ - _ - _ - _ - _ - _ - _ -	_ _ - _ - _ - _ - _ - _ - _ -	_ _ - _ - _ - _ - _ - _ - _ -	_ _ - _ - _ - _ - _ - _ - _ -	_ _ / _ _ / _ _ _ _ _ _ M M D D Y Y Y Y
						Name of intervention
e.	_ _ - _ - _ - _ - _ - _ - _ -	_ _ - _ - _ - _ - _ - _ - _ -	_ _ - _ - _ - _ - _ - _ - _ -	_ _ - _ - _ - _ - _ - _ - _ -	_ _ - _ - _ - _ - _ - _ - _ -	_ _ / _ _ / _ _ _ _ _ _ M M D D Y Y Y Y
						Name of intervention

hcath	<created var> All interventional cardiac cath: screening to discharge (Code List F)
hcath_age_0	B10.6 <created var> Age at 1 st cardiac catheterization, days
hcath_sp	<created var> All 'specify other' interventional cardiac cath: screening to discharge

B11. Number of other cardiac surgical procedures after enrollment to hospital discharge _____ (0-5) (If 0, skip to **C1**)

[DO NOT include catheterization procedures listed in B10a-e]

HNUMSURG	B11. Number of other cardiac surgical procedures
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Cardiac Surgical Procedures	
Code	Procedure Name
01	Chest closure
02	Chest exploration without intervention
03	Diaphragm plication
04	Pacemaker insertion
05	Percutaneous enteral gastrostomy
07	Pleurodesis
08	Pulmonary artery band revision
09	Pulmonary artery plasty
10	Shunt revision or Thrombectomy
11	Thorocentesis
12	Thoracic duct ligation
13	Thoracostomy tube
99	Other

Cardiac Surgical Code (See codes above)

- a. _____ 1. If Other (99), specify: _____
- b. _____ 1. If Other (99), specify: _____
- c. _____ 1. If Other (99), specify: _____
- d. _____ 1. If Other (99), specify: _____
- e. _____ 1. If Other (99), specify: _____

hsurgcode	<created var> All cardiac surgical codes: screening to discharge
hsurg_sp	<created var> All 'specify other' cardiac surgeries: screening to discharge
HSURGCOD_0 - HSURGCOD_9	B11a-B11j. Cardiac Surgical Code (from screening to discharge) (0-9)
HSURG_S_0 - HSURG_S_9	B11a1-B11j1. Specify other cardiac surgery (from screening to discharge) (0-9)

Section C: DISCHARGE CLINICAL ASSESSMENT

C1. Number of discharge medications, other than the study drug _____ (0-10) (If 0, skip to **C2a**)

HNUMMED	C1. Number of discharge medications, other than the study drug
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**Medication Code
(See Code List D)
[Code required for data entry]**

a. ____ . ____

b. ____ . ____

c. ____ . ____

d. ____ . ____

e. ____ . ____

f. ____ . ____

g. ____ . ____

h. ____ . ____

i. ____ . ____

j. ____ . ____

Medication Name Worksheet
a1.
b1.
c1.
d1.
e1.
f1.
g1.
h1.
i1.
j1.

hmedcode	<created var> All discharge medications (Code List D)
hmedcode_0 - hmedcode_14	<created var> Discharge medication (Code List D) (0-14)
HMEDNAME_0 – HMEDNAME_14	C1a-C1o. Specify other discharge medication (0-14)

Feeding at discharge	a.		b.	c.
	Type of Feeding		Caloric Density	Daily Volume
	YES	NO		
C2. Bottle	1	2 (C3)	__ . __ __ Kcal/cc Unknown -8	__ __ __ __ cc/day Unknown -8
C3. Breast	1	2 (C4i)	__ . __ __ Kcal/cc Unknown -8	__ __ __ __ cc/day Unknown -8
C4. NG/GT				
i. Breast milk	1	2 (C4ii)	__ . __ __ Kcal/cc Unknown -8	__ __ __ __ cc/day Unknown -8
ii. Formula	1	2 (C5)	__ . __ __ Kcal/cc Unknown -8	__ __ __ __ cc/day Unknown -8

BBOTTLE	C2a. Type of Feeding: Bottle
BBOTCAL	C2b. Caloric Density: Bottle, Kcal/cc
BBOTVOL	C2c. Daily Volume: Bottle, cc/day
BBREAST	C3a. Type of Feeding: Breast
BBRSTCAL	C3b. Caloric Density: Breast, Kcal/cc
BBRSTVOL	C3c. Daily Volume: Breast, cc/day
BNGBR	C4ia. Type of Feeding: Breast Milk
BNGBRCAL	C4ib. Caloric Density: Breast Milk, Kcal/cc
BNGBRVOL	C4ic. Daily Volume: Breast Milk, cc/day
BNGF	C4iia. Type of Feeding: Formula
BNGFCAL	C4iib. Caloric Density: Formula, Kcal/cc
BNGFVOL	C4iic. Daily Volume: Formula, cc/day
TOTCAL	<created var> Daily calories (Kcal/day)
Feedgrp	<created var> Feeding Mechanism

C5. Oxygen saturation at discharge __ __ __ % UNKNOWN-8

a. Type of air ROOM AIR1 OXYGEN 2

HOSAT	C5. Oxygen saturation at discharge, %
HAIRTYPE	C5a. Type of air

Additional variables from previous version of form:

HNUMCOMP	[Version A Only] B6. Number of in-hospital complications
hcompcode	[Version A Only]<created var> All in-hosp. complication codes after palliative surgery (Code List C)
hcomp_sp	[Version A Only]<created var> All 'specify other' in-hospital complications after palliative surgery
HCOMPCOD_0 - HCOMPCOD_22	[Version A Only] B6.1. In-hosp complication code post-palliative surg. (Code List C) (0-22)
HCOMP_S_0 - HCOMP_S_22	[Version A Only] B6.1a. Specify other in-hosp complication code post-palliative surg. (0-22)
hcomp_age_0 - hcomp_age_22	[Version A Only] <created var>Age at onset of 1 st -23 rd post-palliative surgery complication, days
DISCHARG	[Version A Only] B7. Was patient already discharged at time of screening?