

**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 1 (Norwood)..... 1

A4. Date of form completion  
 \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
 M M / D D / Y Y Y Y

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

r103_age	A4. <created var>Age at form completion date, days
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A5. Name of person completing form  
 \_\_\_\_\_  
 PRINT FULL NAME INITIALS

**Section B: NORWOOD PROCEDURE**

B1. Date of Norwood surgery  
 \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
 M M / D D / Y Y Y Y

**Replaced by age at Norwood, days**

norw_age	B1. <created var>Age at Norwood, days
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trt	<created var> Shunt type (ITT): 1=MBTS 2=RVPAS
ctrl	<created var> Shunt type at the end of Norwood operation: 1=MBTS 2=RVPAS
etrt	<created var> Shunt type at the end of Norwood hospitalization: 1=MBTS 2=RVPAS

B2. Date of Norwood discharge  
 \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_  
 M M / D D / Y Y Y Y

**Replaced by age at Norwood discharge, days**

nordis_age	B2. <created var>Age at Norwood hospital discharge, days (NORDIS_D-DOB+1)
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B3. Surgeon ID \_\_\_\_\_ - \_\_\_\_\_

**Removed to protect privacy**

B4. a Time units AM.....1 PM .....2 24-HOUR .....3

1. Time operation started \_\_\_\_\_ : \_\_\_\_\_

b Time units AM.....1 PM .....2 24-HOUR .....3

1. Time operation ended \_\_\_\_\_ : \_\_\_\_\_

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NORWS_T	B4a1. Time operation started
NORSTU	B4a. Time operation started: Units
NORWE_T	B4b1. Time operation ended
NORETU	B4b. Time operation ended: Units

B5. Total cross clamp time                    \_\_\_ \_\_\_ \_\_\_ minutes

CCLAMP_T	B5. Total cross clamp time, min
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B6. Was patient put on bypass?                    YES ..... 1                    NO ..... 2 **(B9)**

a. Total bypass time                    \_\_\_ \_\_\_ \_\_\_ minutes

b. Deep hypothermic circulatory arrest (DHCA)                    YES ..... 1                    NO ..... 2 **(c)**

1. Total deep hypothermic circulatory arrest time                    \_\_\_ \_\_\_ \_\_\_ minutes

c. Regional cerebral perfusion                    YES ..... 1                    NO ..... 2 **(B7)**

1. Regional cerebral perfusion time                    \_\_\_ \_\_\_ \_\_\_ minutes

2. Regional cerebral perfusion flow                    \_\_\_ \_\_\_ \_\_\_ cc/kg/min

BYPASS	B6. Was patient put on bypass
BYPASS_T	B6a. Total bypass time, min
DHCA	B6b. Deep hypothermic circulatory arrest
DHCA_T	B6b1. Total deep hypothermic circulatory arrest time, min
RCP	B6c. Regional cerebral perfusion
RCP_T	B6c1. Regional cerebral perfusion time, min
RCPFLOW	B6c2. Regional cerebral perfusion flow, cc/kg/min
newrcpdhca	<created var> 1=on DHCA only, 2=on RCP only (or RCP/DHCA with DHCA time<=10 min), 3=on RCP and DHCA (DCHA time >10 min)

B7. Lowest temperature obtained during bypass, regardless of location                    \_\_\_ \_\_\_ . \_\_\_ °C

LOWTEMP	B7. Lowest temperature obtained during bypass, Celsius
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B8. HCT                    \_\_\_ \_\_\_ . \_\_\_ %

LOW_HCT	B8. Lowest HCT, % [Updated by R800 C8]
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- B9. Was ultrafiltration used during or after the Norwood procedure? YES ..... 1 NO .....2 **(B10)**
- a. Ultrafiltration used during CPB? YES ..... 1 NO .....2
- b. Ultrafiltration used post-CPB? YES ..... 1 NO .....2

ULTRAFIL	B9. Was ultrafiltration used during or after Norwood procedure?
CONTINU	B9a. Ultrafiltration used during CPB?
POSTCPB	B9b. Ultrafiltration used post CPB?

- B10. Steroids YES ..... 1 NO .....2

STEROIDS	B10. Steroids
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- B11. Trasylol (Aprotinin) YES ..... 1 NO .....2

TRASYLOL	B11. Trasylol (Aprotinin)
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- B12. Alpha blockade YES ..... 1 NO .....2 **(B13)**
- a. Type PHENOXYBENZAMINE.....1  
PHENTOLAMINE.....2

ABLOCK	B12. Alpha blockade
ABLOCTYP	B12a. Alpha blockade: Specify

- B13. Was patient placed on extracorporeal membrane oxygenation (ECMO)? YES ..... 1 NO .....2

NECMO	B13. Was patient placed on extracorporeal membrane oxygenation
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**Section C: ANATOMIC OBSERVATIONS**

- C1. Exterior diameter of ascending aorta at sinotubular junction \_\_\_\_ . \_\_\_\_ mm

ASCAORTA	C1. Exterior diameter ascending aorta, mm
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- C2. Aberrant right subclavian artery YES ..... 1 NO ..... 2 NOT OBSERVED ..... 3

RSUBCLAV	C2. Aberrant right subclavian artery
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- C3. TAPVC YES ..... 1 NO.....2 **(C4)**
- a. Type SUPRACARDIAC .....1

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INFRACARDIAC .....2  
 CARDIAC .....3  
 MIXED.....4  
 NOT OBSERVED .....5

NTAPVC	C3. TAPVC
NTAPTYP	C3a. TAPVC: Type

C4. PAPVC YES ..... 1 NO .....2 **(D1)**  
 a. Type SUPRACARDIAC .....1  
 INFRACARDIAC .....2  
 CARDIAC .....3  
 MIXED.....4  
 NOT OBSERVED .....5

NPAPVC	C4. PAPVC
NPAPTYP	C4a. PAPVC: Type

**Section D: ARCH RECONSTRUCTION**

D1. Type of arch reconstruction CLASSIC ARCH RECONSTRUCTION 1  
 DIRECT PA ANASTOMOSIS TO ARCH 2  
 a. COARCTECTOMY YES.....1 NO.....2  
 b. PATCH YES.....1 NO.....2

TYPEARCHR	D1. Type of arch reconstruction
COARCTECTOMY	D1a. Coarctectomy
PATCH	D1b. Patch

D2. Origin – PTFE graft INNOMINATE..... 1  
 SUBCLAVIAN.....2  
 COMMON CAROTID .....3  
 AORTA .....4  
 RIGHT VENTRICLE .....5

GRAFTORG	D2. Origin - PTFE graft
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**Section E: SHUNT**

E1. Shunt to which patient randomized MBTS ..... 1 RV-to-PA .....2

SHUNTRND	E1. Shunt to which patient randomized
scsite	Center Single Ventricle Patient volume based on number of screened patients, 1:<=15/yr 2:<=20/yr 3:<=30/yr 4:>30/yr
scsrg	Surgeon Norwood Procedure volume based on screening data, 1:<=5/yr 2:<=10/yr 3:<=15/yr 4:>15/yr

E2. First shunt performed during Norwood surgery MBTS ..... 1 RV-to-PA .....2

SHUNTONE	E2. First shunt performed during Norwood surgery
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E3. At the conclusion of the Norwood surgery, did the patient receive the MBTS? YES ..... 1 NO .....2 (E4)

- a. Diameter of PTFE graft of shunt \_\_\_\_ . \_\_\_\_ mm
- b. Length of PTFE graft of shunt \_\_\_\_ \_\_\_\_ . \_\_\_\_ cm

SHNTMBTS	E3. At conclusion of Norwood surgery, did patient receive MBTS
MBTSDIA	E3a. Diameter of PTFE graft of shunt, mm
MBTSLEN	E3b. Length of PTFE graft of shunt, cm

E4. At the conclusion of the Norwood surgery, did the patient receive the RV-to-PA? YES ..... 1 NO .....2 (E5)

- a. Diameter of PTFE graft of shunt \_\_\_\_ . \_\_\_\_ mm
- b. Length of PTFE graft of shunt \_\_\_\_ \_\_\_\_ . \_\_\_\_ cm

SHNTRVPA	E4. At conclusion of surgery, did patient receive RV-to-PA?
RVPADIA	E4a. Diameter of PTFE graft of shunt, mm
RVPALEN	E4b. Length of PTFE graft of shunt, cm

E5. At the conclusion of the Norwood surgery, did patient receive the shunt to which s/he was randomized, or receive both shunts? YES ..... 1 (E6) NO ..... 2

Reason for Intraoperative Cross-over			
Code	Name	Code	Name

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01	Aberrant right subclavian artery and right carotid artery too small	05	Innominate artery too small
02	Coronary artery abnormality	06	Obstructing muscle bundle
03	Hypotension	07	Subclavian artery too small
04	Hypoxia	99	Other

**Code reason(s) for intraoperative cross-over (See codes above)**

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

CROSSOVR	E5. At conclusion of surgery, did patient receive the assign shunt or both shunts?
cross_r	E5. <created var> Concatenation of all reasons for intraoperative cross-over
CROSSCOD_0	E5a. Reasons for intraoperative cross-over
CROSSCOD_1	E5b. Reasons for intraoperative cross-over
CROSS_S_0	E5a. 'Specify other' reasons for intraoperative cross-over
CROSS_S_1	E5b. 'Specify other' reasons for intraoperative cross-over

E6. Were other procedures done at time of Norwood procedure?    YES ..... 1    NO ..... 2 **(F1)**

Other Procedures done at time of Norwood procedure	
Code	Name
01	AV valve repair
02	Pacemaker insertion
03	Branch pulmonary arterioplasty
04	Repair of PAPVC
05	Repair of TAPVC
99	Other

**Code procedure(s) done at time of Norwood procedure (See codes above)**

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

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NOTHPROC	E6. Were other procedures done at time of Norwood procedure?
opcode	E6. <created var> Concatenation of all other procedure codes
NOPCODE_0	E6a. Procedure done at time of Norwood
NOPCODE_1	E6b. Procedure done at time of Norwood
NOPCODE_2	E6c. Procedure done at time of Norwood
NOP_S_0	E6a. 'Specify other' procedure done at Norwood
NOP_S_1	E6b. 'Specify other' procedure done at Norwood
NOP_S_2	E6c. 'Specify other' procedure done at Norwood

**Section F: POST-NORWOOD ASSESSMENT**

F1. Date of return to ICU \_ M \_ M / \_ D \_ D / \_ Y \_ Y \_ Y \_ Y

**Replaced by age at date of return to ICU, days**

reticu_age	F1. <created var>Age at date of return to ICU, days
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F2. Time of return to ICU \_ \_ : \_ \_  
 a. Units AM.....1      PM.....2      24-HOUR .....3

RETICU_T	F2. Time of return to ICU
RETICUTU	F2a. Time of return to ICU: Units

F3. Date of discharge from ICU \_ M \_ M / \_ D \_ D / \_ Y \_ Y \_ Y \_ Y  
 a. Total days of ICU stay \_ \_ \_ days

**Replaced by age at date of discharge from ICU, days**

disicu_age	F3. <created var>Age at date of discharge from ICU, days
ICUDAYS	F3a. Total days of ICU stay

F4. Was patient extubated in the OR? YES.....1 **(b)**      NO .....2  
 a. Date of initial ; \_ M \_ M / \_ D \_ D / \_ Y \_ Y \_ Y \_ Y  
 b. Time of OR/initial extubation \_ \_ : \_ \_  
     1. Units AM .....1      PM.....2      24-HOUR .....3  
 c. Total days ventilated \_ \_ \_ days

NEXTUBOR	F4. Was patient extubated in the OR?
nextub_age	F4a. <created var>Age at date of initial extubation, days
NEXTUB_T	F4b. Time of OR/initial extubation
NEXTUBTU	F4b1. Time of OR/initial extubation:Units
NVENTDAYS	F4c. Total days ventilated

F5. Open sternum after Norwood? YES.....1      NO .....2

STERN_OPEN	F5. Sternal openings [Updated by R800 C14]
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F6. Placed on extracorporeal membrane oxygenation (ECMO)? YES..... 1 NO ..... 2

PNECMO	F6. Placed on extracorporeal membrane oxygenation
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F7. Did patient require cardiopulmonary resuscitation (CPR)? YES..... 1 NO ..... 2

PNCPR	F7. Did patient require cardiopulmonary resuscitation
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F8. Number of interventional cardiac catheterization procedures after Norwood \_\_\_\_\_ (0-8) (If 0, skip to **F9**)

[DO NOT include diagnostic catheterizations]

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

NNUMCATH	F8. Number of interventional cardiac catheterizations
nwdcath	F8. <created var> Concatenation of all cardiac catheterization codes
nwd_cath_0	F8a. <created var> Cardiac catheterization intervention code
ncath_age_0	F8a <created var> Age at date of interventional cardiac catheterization, days
NCATHNAM_0	F8a. Cardiac catheterization intervention name
nwd_cath_1	F8b. <created var> Cardiac catheterization intervention code
ncath_age_1	F8b <created var> Age at date of interventional cardiac catheterization, days
NCATHNAM_1	F8b. Cardiac catheterization intervention name

...

nwd_cath_9	F8j. <created var> Cardiac catheterization intervention code
ncath_age_9	F8j <created var> Age at date of interventional cardiac catheterization, days
NCATHNAM_9	F8j. Cardiac catheterization intervention name
nwd_cath_10	F8k. <created var> Cardiac catheterization intervention code
ncath_age_10	F8k <created var> Age at date of interventional cardiac catheterization, days
NCATHNAM_10	F8k. Cardiac catheterization intervention name

F9. Number of other surgical procedures \_\_\_\_\_ (0-5) (If 0, skip to **G1**)

**[DO NOT include catheterization procedures listed previously]**

Other Surgical Procedures			
Code	Procedure Name	Code	Procedure Name
01	Bowel surgery	13	Pulmonary artery reconstruction
02	Chest closure	14	Shunt revision <b>without</b> crossover
03	Chest exploration without intervention	15	Shunt crossover
05	Dialysis	17	Thorocentesis
06	Diaphragm plication	18	Thoracic duct ligation
07	Extracorporeal membrane oxygenation	19	Thoracostomy tube
08	Gastrostomy tube	20	Thrombectomy
09	Pacemaker insertion*	21	Tracheostomy
10	Pericardial window	22	Transplantation
11	Pleurodesis	23	Ventriculostomy/VP shunt
		99	Other surgical procedure

**\*If code 09 is selected, question F10 must be YES**

**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: \_\_\_\_\_

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NNUMSURG	F9. Number of other surgical procedures
nsurgcode	F9. <created var> Concatenation of all other surgical procedure codes
NSURGCOD_0	F9a. Other surgical procedure
NSURG_S_0	F9a. 'Specify other' other surgical procedure
NSURGCOD_1	F9b. Other surgical procedure
NSURG_S_1	F9b. 'Specify other' other surgical procedure

...

NSURGCOD_13	F9n. Other surgical procedure
NSURG_S_13	F9n. 'Specify other' other surgical procedure
NSURGCOD_14	F9o. Other surgical procedure
NSURG_S_14	F9o. 'Specify other' other surgical procedure

F10. Pacemaker placed? YES..... 1 NO..... 2 (G1)

a. Date of placement  $\frac{\quad}{M} \frac{\quad}{M} / \frac{\quad}{D} \frac{\quad}{D} / \frac{\quad}{Y} \frac{\quad}{Y} \frac{\quad}{Y} \frac{\quad}{Y}$

b. Type of pacemaker PERMANENT EPICARDIAL ATRIAL PACING..... 1  
 PERMANENT EPICARDIAL VENTRICULAR PACING ..... 2  
 PERMANENT EPICARDIAL DUAL CHAMBER PACING ..... 3  
 OTHER ..... 99

1. OTHER, specify \_\_\_\_\_

NPACER	F10. Pacemaker placed
NPACER_D	F10a. Date of placement
NPACERTY	F10b. Type of pacemaker
NPACER_S	F10b1. Type of pacemaker: Specify

**Section G: POST-NORWOOD IN-HOSPITAL COMPLICATIONS**

G1. Number of significant complications after Norwood \_\_\_\_\_ (0-8) (If 0, skip to H1)

**Complications Code(See Code List M)[Code required for data entry]**

**Specify[Use spaces below to write complications]**

a1. \_\_\_\_ - \_\_\_\_

a2. Date of onset

____ / ____ / ____ M M / D D / Y Y Y Y

b1. \_\_\_\_ - \_\_\_\_

b2. Date of onset

____ / ____ / ____ M M / D D / Y Y Y Y

c1. \_\_\_\_ - \_\_\_\_

c2. Date of onset

____ / ____ / ____ M M / D D / Y Y Y Y

d1. \_\_\_\_ - \_\_\_\_

d2. Date of onset

____ / ____ / ____ M M / D D / Y Y Y Y

NUMCOMP	G1. Number of significant complications after Norwood
ncompcode	<created var>Concatenation of all significant complications after Norwood
NCOMPCOD_0	G1a1. Complication after Norwood
ncomp_age_0	G1a <created var> Age at complication date of onset, days
NCOMP_S_0	G1a. 'Specify other' complications
NCOMPCOD_1	G1b1. Complication after Norwood
ncomp_age_1	G1b <created var> Age at complication date of onset, days
NCOMP_S_1	G1b. 'Specify other' complications

...

NCOMPCOD_29	G1E1. Complication after Norwood
ncomp_age_29	G1D <created var> Age at complication date of onset, days
NCOMP_S_29	G1E. 'Specify other' complications
NCOMPCOD_30	G1D1. Complication after Norwood
ncomp_age_30	G1E <created var> Age at complication date of onset, days
NCOMP_S_30	G1D. 'Specify other' complications

**Section H: DISCHARGE STATUS**

H1. Vital status at discharge ALIVE ..... 1 DEAD..... 2

**If patient died,  
End Form**

NORVITAL	H1. Vital status at discharge (include 2 deaths after heart transplantation during Norwood hospitalization)
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H2. Number of discharge medications \_\_\_\_\_ (0-10) (If 0, skip to H3)

**Medication Code(See  
Code List D)[Code  
required for data entry]**

<b>Medication Name Worksheet</b>	
a. _____ . _____	a1.
b. _____ . _____	b1.
c. _____ . _____	c1.
d. _____ . _____	d1.

NNUMMED	H2. Number of discharge medications
medcode	<created var>Concatenation of all discharge medication codes
medcode_0	H2a. <created var> Medication code
NMEDNAME_0	H2a1. Medication name (if other)
NMEDCAT_0	H2a. Medication class
medcode_1	H2b. <created var> Medication code
NMEDNAME_1	H2b1. Medication name (if other)
NMEDCAT_10	H2b. Medication class

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medcode_20	H2u. <created var> Medication code
NMEDNAME_20	H2u1. Medication name (if other)
NMEDCAT_20	H2u. Medication class
medcode_21	H2v. <created var> Medication code
NMEDNAME_21	H2v1. Medication name (if other)
NMEDCAT_21	H2v. Medication class

H3. Oxygen saturation at discharge                      \_\_\_ \_\_\_ \_\_\_ %                      UNKNOWN.....-8 **(END)**  
     a. Type of air    ROOM AIR.....1                      OXYGEN ..... 2

NO2SAT	H3. Oxygen saturation at discharge, %
NAIRTYPE	H3a. Type of air