

**SECTION A: KEY IDENTIFYING INFORMATION**

A1. Study Identification Number

\_\_\_\_ - \_\_\_\_ - \_\_\_\_ - \_\_\_\_ - \_\_\_\_

Replaced by blinded subject ID

blind_id	Blinded ID
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A2. Study visit

SUPPLEMENTAL FORMS .....44

VISIT	A2. Study visit
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A3. Date of form completion

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

comp_age	A3. <created var> Age at form R800 completion, days
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A4. Name of person completing form

\_\_\_\_\_

PRINT FULL NAME

INITIALS

Removed to protect privacy

**SECTION B: BASELINE**

B1. Was the subject the product of a multiple birth?

YES .....1

Enter "-8" in ADEPT if UNKNOWN.

NO .....2

MULT_BIRTH	B1. Multiple birth
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**SECTION C: VISIT 1 (NORWOOD)**

C1. Date of admission for Norwood hospitalization

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

stg1admit_age	C1. <created var> Age at date of admission for Norwood hospitalization, days
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C2. Was the subject ever discharged home **prior** to the Norwood operation?

YES .....1

NO .....2 (C3)

a. If YES, date of discharge:

Enter "08/08/0808" if discharge date is unknown.

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

PRENORWDIS	C2. Was the subject ever discharged home prior to the Norwood operation?
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pnorwdis_age	C2a. <created var> Age at discharge if the subject was ever discharged home prior to the Norwood operation
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C3. Enteral feedings before the Norwood procedure

YES .....1

Pediatric Heart Network: Single Ventricle Reconstruction Trial

Form R800: Supplemental Data Form  
(Not All Variables are Shown)

NO .....2

PNORW_FEED	C3. Pre-Norwood feeding
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**Questions C4 – C11 refer to time spent in the Operating Room for the Norwood Procedure.**

C4. Weight at time of Norwood procedure \_\_\_\_\_ . \_\_\_\_\_ kg  
Obtain weight from perfusion record.

NORW_WEIGHT	C4. Weight at time of Norwood procedure, kg
norw_waz_who	<created var> Weight-for-age z score at time of Norwood procedure

C5. Cooling time during Norwood procedure \_\_\_\_\_ min (0 – 40)  
Please consult the perfusionist to record the duration from start of cooling to initiation of DHCA or RCP.

NORW_COOLT	C5. Cooling time, min
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C6. Blood gas management during cooling PH – STAT .....1  
ALPHA – STAT .....2

COOL_BLOODG	C6. Cooling blood gas
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C7. Blood gas management during warming PH – STAT .....1  
ALPHA – STAT .....2

WARM_BLOODG	C7. Warming blood gas
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C8. **Lowest** HCT obtained after initiation of CPB \_\_\_\_\_ . \_\_\_\_\_ %

LOW_HCT	C8. Lowest HCT, %
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C9. Did the subject receive the RVPAS at the conclusion of the Norwood? YES .....1  
NO .....2 (C10)

a. If YES, to which side of the neoaorta was the RVPAS placed? RIGHT .....1  
LEFT .....2

RVPAS	C9. Did the subject receive the RVPAS at the conclusion of the Norwood
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RVPAS_SIDE	C9a. Which side of the neoaorta was the RVPAS placed?
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C10. Was a transesophageal echo conducted during the Norwood operation? YES .....1  
NO .....2

TRANS_ECHO	C10. Was a transesophageal echo conducted during the Norwood operation
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C11. Was an epicardial echo conducted during the Norwood operation?

YES .....1  
NO .....2

EPI_ECHO	C11. Was an epicardial echo conducted during the Norwood operation
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**Questions C12 – C21 refer to time spent in the hospital after the Norwood procedure through hospital discharge.**

C12. Number of other surgical procedures

\_\_\_\_ (0 – 5)  
**[If 0, skip to C14]**

The number of surgical procedures recorded **must match** the number recorded in question F9 on form R103.

NORW_OTHER_N	C12. Number of other procedures
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C13. Number of above procedures for which subject was placed on cardiopulmonary bypass

\_\_\_\_ (0 – 5)  
**[If 0, skip to C14]**

	a. Procedure code (Code <b>must match</b> codes listed in Question F9a – F9e on form R103)	b. Bypass minutes	c. DHCA Yes= 1 No = 2	d. DHCA minutes	e. RCP Yes= 1 No = 2	f. RCP minutes	g. RCP flow cc/kg/min	h. Lowest temp in °C during bypass, regardless of location	i. HCT %
1.	____	_____	____	_____	____	_____	_____	____.____	____.____
	a1. If "other" procedure, specify: _____								
2.	____	_____	____	_____	____	_____	_____	____.____	____.____
	a1. If "other" procedure, specify: _____								
3.	____	_____	____	_____	____	_____	_____	____.____	____.____
	a1. If "other" procedure, specify: _____								

## Form R800: Supplemental Data Form

NORW_BYPAS_N	C13. Number of above procedures for which subject was placed on cardiopulmonary bypass
BP_CODE_0	C13.1a. Procedure code
BP_CODE_OTH_0	C13.1aa. Specify other Code
BP_MIN_0	C13.1b. Bypass time, minutes
DHCA_0	C13.1c. On DHCA
DHCA_MIN_0	C13.1d. DHCA time, minutes
RCP_0	C13.1e. On RCP
RCP_MIN_0	C13.1f. RCP time, minutes
RCP_FLOW_0	C13.1g. RCP flow, cc/kg/min
BP_TEMP_0	C13.1h. Lowest temperature obtained during bypass, Celsius
HCT_0	C13.1i. HCT, %
BP_CODE_1	C13.2a. Procedure code
BP_CODE_OTH_1	C13.2aa. specify other Code
BP_MIN_1	C13.2b. Bypass time, minutes
DHCA_1	C13.2c. On DHCA
DHCA_MIN_1	C13.2d. DHCA time, minutes
RCP_1	C13.2e. On RCP
RCP_MIN_1	C13.2f. RCP time, minutes
RCP_FLOW_1	C13.2g. RCP flow, cc/kg/min
BP_TEMP_1	C13.2h. Lowest temperature obtained during bypass, Celsius

## Form R800: Supplemental Data Form

HCT_1	C13.2i. HCT, %
BP_CODE_2	C13.1a. Procedure code
BP_CODE_OTH_2	C13.1aa. Specify other Code
BP_MIN_2	C13.1b. Bypass time, minutes
DHCA_2	C13.1c. On DHCA
DHCA_MIN_2	C13.1d. DHCA time, minutes
RCP_2	C13.1e. On RCP
RCP_MIN_2	C13.1f. RCP time, minutes
RCP_FLOW_2	C13.1g. RCP flow, cc/kg/min
BP_TEMP_2	C13.1h. Lowest temperature obtained during bypass, Celsius
HCT_2	C13.1i. HCT, %

C14. Any sternal opening during the Norwood hospitalization? YES .....1  
 NO .....2 (C15)

a. If YES: Number of sternal openings \_\_\_\_ (1 – 5)

	b. Date of Sternal Opening	c. Date of Complete Sternal Closure
1.	__ __ / __ __ / __ __ __ __ M M D D Y Y Y Y	__ __ / __ __ / __ __ __ __ M M D D Y Y Y Y
2.	__ __ / __ __ / __ __ __ __ M M D D Y Y Y Y	__ __ / __ __ / __ __ __ __ M M D D Y Y Y Y
3.	__ __ / __ __ / __ __ __ __ M M D D Y Y Y Y	__ __ / __ __ / __ __ __ __ M M D D Y Y Y Y

STERN_OPEN	C14. Sternal openings during Norwood hospitalization
STERN_NUM	C14a. Number of sterna openings
open_age_0	C14b1. <created var> Age at sternal opening during the Norwood hospitalization, days
clos_age_0	C14c1. <created var> Age at sternal closure during the Norwood hospitalization, days
open_age_1	C14b2. <created var> Age at sternal opening during the Norwood hospitalization, days
clos_age_1	C14c2. <created var> Age at sternal closure during the Norwood hospitalization, days
open_age_2	C14b3. <created var> Age at sternal opening during the Norwood hospitalization, days
clos_age_2	C14c3. <created var> Age at sternal closure during the Norwood hospitalization, days

C15. Was the subject **ever** on methadone and/or clonidine during the Norwood hospitalization? YES .....1  
 NO .....2

METH_CLON	C15. On Methadone and/or clonidine during hospitalization
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C16. Did the subject die during the Norwood hospitalization? YES .....1 (END)  
 NO .....2

NORW_DIED	C16. Died at Norwood
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C17. Was the subject ever discharged **prior** to the Stage II procedure? YES .....1  
 NO .....2 (D3)

STG2_PDIS	C17. Was the subject ever discharged <b>prior</b> to the Stage II procedure
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C18. Feeding method at time of Norwood discharge

- a. Oral YES .....1  
NO .....2
- b. NG tube YES .....1  
NO .....2
- c. NJ tube YES .....1  
NO .....2
- d. G tube YES .....1  
NO .....2
- e. GJ tube YES .....1  
NO .....2
- f. Other YES .....1  
NO .....2

1. If YES, specify: \_\_\_\_\_

FEED_ORAL	C18a. Oral
FEED_NG	C18b. NG tube
FEED_NJ	C18c. NJ tube
FEED_G	C18d. G tube
FEED_GJ	C18e. GJ tube
FEED_OTH	C18f. Other
FEED_OTH_SP	C18f1. Specify

C19. Feeding type at time of Norwood discharge

- a. Formula YES .....1  
NO .....2
- b. Breast milk YES .....1  
NO .....2
- c. Other YES .....1  
NO .....2

1. If YES, specify \_\_\_\_\_

FORMULA	C19a. Formula
BMILK	C19b. Breast milk
TYPE_OTH	C19c. Other
TYPE_OTH_SP	C19c1. Specify

C20. Caloric density of feedings at time of Norwood discharge

- a. Fortified formula YES .....1  
NO .....2
- b. Fortified breast milk YES .....1  
NO .....2

FORT_FORMULA	C20a. Fortified formula
FORT_BMILK	C20b. Fortified breast milk

C21. Weight at time of Norwood discharge

\_\_\_\_\_ . \_\_\_\_\_ kg

a. Date weight was obtained

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

NDIS_WEIGHT	C21. Weight at time of Norwood discharge, kg
ndis_waz_who	<created var> Weight-for-age z score at time of Norwood discharge
ndis_weig_age	C21a.<created var> Age at date weight was obtained, days

**SECTION D: VISIT 2 (STAGE II)**

- D1. Was the subject followed in a weight monitoring program after Norwood discharge? YES .....1  
NO .....2

WEIGHT_MON	D1. Was the subject followed in a weight monitoring program after Norwood discharge?
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- D2. Was the subject followed in an oxygen saturation monitoring program after Norwood discharge? YES .....1  
NO .....2

OXY_MON	D2. Was the subject followed in an oxygen saturation monitoring program after Norwood discharge?
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- D3. Did the subject have the Stage II surgery performed? YES .....1  
NO .....2 (D6)

STG2YN	D3. Did the subject have the Stage II surgery performed?
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- D4. Was the subject on supplemental oxygen at the time of admission for the Stage II procedure? YES .....1  
NO .....2

ADM_OXY	D4. Was the subject on supplemental oxygen at the time of admission for the Stage II procedure?
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D5. Feeding method immediately before Stage II

- a. Oral YES .....1  
NO .....2
- b. NG tube YES .....1  
NO .....2
- c. NJ tube YES .....1



- d. G tube
  - NO .....2
  - YES .....1
  - NO .....2
- e. GJ tube
  - YES .....1
  - NO .....2
- f. Other
  - YES .....1
  - NO .....2

1. If YES, specify \_\_\_\_\_

**END FORM if Stage II WAS performed.**

POSTN_ORAL	D5a. Oral
POSTN_NG	D5b. NG tube
POSTN_NJ	D5c. NJ tube
POSTN_G	D5d. G tube
POSTN_GJ	D5e. GJ tube
POSTN_OTH	D5f. Other
POSTN_OTH_SP	D5f1. Specify

**Questions D6 – D8 are only for subjects who did NOT have a Stage II performed.**

D6. Number of interventional cardiac catheterization procedures after discharge from the Norwood operation up to 12 months of age \_\_\_\_\_ (0 – 5)  
**[If 0, skip to D7]**

**(DO NOT list 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

PN_CATH_N	D6. Number of Catheterization
pn_cath_0	D6a. <created var> Cardiac cath intervention code
pn_cath_age_0	D6a. <created var>Age at interventional catheterization from the Norwood up to 12 months of age
pn_cath_1	D6b. <created var> Cardiac cath intervention code
pn_cath_age_1	D6b. <created var>Age at interventional catheterization from the Norwood up to 12 months of age

D7. Number of other surgical procedures after discharge from the Norwood operation up to 12 months of age \_\_\_\_\_ (0 – 5) **[If 0, END FORM]**

**(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
04	Coarctation repair		
05	Dialysis	17	Thoroцентesis
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

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

PN_OTHER_N	D7. Surgical procedures, number
PN_OTHER_COD_0	D7a. Surgical code
PN_OTHER_SP_0	D7a. Specify other code
PN_OTHER_COD_1	D7b. Surgical code
PN_OTHER_SP_1	D7b. Specify other code
PN_OTHER_COD_2	D7c. Surgical code
PN_OTHER_SP_2	D7c. Specify other code
PN_OTHER_COD_3	D7d. Surgical code
PN_OTHER_SP_3	D7d. Specify other code

D8. Number of above procedures for which subject was placed on cardiopulmonary bypass

(0 – 5)  
[If 0, END FORM]

	a. Procedure code (see Other Surgical Procedure codes above)	b. Bypass minutes	c. DHCA Yes= 1 No = 2	d. DHCA minutes	e. RCP Yes= 1 No = 2	f. RCP minutes	g. RCP flow cc/kg/min	h. Lowest temp in °C during bypass, regardless of location	i. HCT %
1.	___	_____	___	_____	___	_____	_____	____.____	____.____
	a1. If "other" procedure, specify: _____								
2.	___	_____	___	_____	___	_____	_____	____.____	____.____
	a1. f "other" procedure, specify: _____								

## Form R800: Supplemental Data Form

PN_BYPASS_N	D8. Number of above procedures for which subject was placed on cardiopulmonary bypass
PN_CODE_0	d8.1a. Code
PN_CODE_SP_0	d8.1aa. specify other Code
PN_MIN_0	d8.1b. Bypass minutes
PN_DHCA_0	d8.1c. DHCA
PN_DHCA_MIN_0	d8.1d. DHCA minutes
PN_RCP_0	d8.1e. RCP
PN_RCP_MIN_0	d8.1f. RCP minutes
PN_RCP_FLOW_0	d8.1g. RCP flow, cc/kg/min
PN_LOWTEMP_0	d8.1h. Lowest temp obtained during bypass, Celsius
PN_HCT_0	d8.1i. HCT, %