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.   Date start inclusion/exclusion screening ___ ___ / ___ ___ / ___ ___ ___ ___
                                                  M   M   D   D   Y   Y   Y   Y

screen_age	A3. <created var>Age at date start screening, days

A4.   Name of person completing form   _____ ___ ___ ___
                                                PRINT FULL NAME   INITIALS

Removed to protect privacy

Section B: PATIENT INFORMATION

B1.   Date of birth   ___ ___ / ___ ___ / ___ ___ ___ ___
                              M   M   D   D   Y   Y   Y   Y

 Removed to protect privacy

B2.   Gender   MALE 1   FEMALE 2

GENDER	B2. Patient gender

B3.   Race   WHITE 1
               BLACK OR AFRICAN AMERICAN 2
               ASIAN 3
               AMERICAN INDIAN OR ALASKAN NATIVE 4
               NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER................................ 5
               MORE THAN ONE RACE 6
                   a. Specify _____
               OTHER .... .99
                   b. Specify _____
                UNKNOWN .... -8

RACE	B3. Race
RACEMR_S	B3a. More than one race: specify
RACEOT_S	B3b. Other: specify

B4.   Is patient of Hispanic or Latino origin?   YES................1   NO 2   UNKNOWN.. -8

HISPANIC	B4. Is patient of Hispanic or Latino origin?

B5.   Birth weight   ___ ___ ___ ___ g

BWT	B5. Birth weight, g
lowbwt	<created var> Birth weight <2500g, 1=Yes 2=No

B6.   Gestational age   ___ ___ weeks   (enter –3 if only "full term" is noted in medical record)

GESTAGE	B6. Gestational age, weeks
preterm	<created var>Gestational age <37 weeks, 1=Yew 2=No
bwtgrp	<created var> 1: BWT <=30th percentile for gestational age (GA) 2: BWT >30th and <=70th percentile for GA, 3: >70th percentile for GA

Section C: DIAGNOSIS

C1.   Prenatal diagnosis of congenital heart disease   YES...........1   NO ....2 **(C3)**   UNKNOWN......-8 **(C3)**
   a.   Fetal age at prenatal diagnosis   ___ ___ weeks

PRENATDX	C1. Prenatal diagnosis of congenital heart disease
PNDXAGE	C1a. Fetal age at prenatal diagnosis, weeks

C2.   Fetal intervention (atrial septostomy, aortic valve dilatation)   YES.......1 **(C4)**   NO ....2 **(C4)**

FETALINT	C2. Fetal intervention

C3.   If diagnosed after birth, age at diagnosis of congenital heart disease   ___ ___ hours   **OR**   ___ ___ days

Answer if <24 hours. Round partial hrs up.   Answer if ≥24 hours. Round partial days up.

AGEDXHR	C3a. Age at diagnosis of congenital heat: Hours
AGEDXDAY	C3b. Age at diagnosis of congenital heat: Days

C4.   Most recent anatomic diagnosis

Anatomic Diagnosis Code (**See Code List O**) [code required for data entry]	**Anatomic Diagnosis** **Name Worksheet**
	If coding = O6 you **must** specify here:
a. Level 1 ___ ___	a1.
b. Level 2 ___ ___	b1.
c. Level 3 ___ ___	c1.
d. Level 4 ___ ___	d1.

adx	C4. <created var>Anatomic Diagnosis Code (Code List O)
ANATDX1	C4a. Level 1
ANATDX2	C4b. Level 2
ANATDX3	C4c. Level 3
ANATDX4	C4d. Level 4
ANDX_S	C4a1. Level 1:specify

C5.   Any associated anatomic diagnoses?   YES 1   NO .... 2 **(D1)**

ANDX

Code associated anatomic diagnoses (See Code List I)

a) ___ - ___ ___ ___   If Other, specify _____

b) ___ - ___ ___ ___   If Other, specify _____

c) ___ - ___ ___ ___   If Other, specify _____

d) ___ - ___ ___ ___   If Other, specify _____

e) ___ - ___ ___ ___   If Other, specify _____

ASSOCDX	C5. Any associated anatomic diagnoses?
asso_adx	<created var> Concatenation of all associate anatomic diagnosis codes
ASDXCODE_0	C5a. Code associated anatomic diagnoses
ASDXCODE_1	C5b. Code associated anatomic diagnoses
ASDXCODE_2	C5c. Code associated anatomic diagnoses
ASDXCODE_3	C5d. Code associated anatomic diagnoses
ASDXCODE_4	C5e. Code associated anatomic diagnoses
ASDX_S_0	C5a. 'Specify other' associated anatomic diagnoses
ASDX_S_1	C5b. 'Specify other' associated anatomic diagnoses
ASDX_S_2	C5c. 'Specify other' associated anatomic diagnoses
ASDX_S_3	C5d. 'Specify other' associated anatomic diagnoses
ASDX_S_4	C5e. 'Specify other' associated anatomic diagnoses

Section D: STRATIFICATION

D1.   Does patient have aortic atresia?   YES.........1   NO.........2

ATRESIA	D1. Does patient have aortic atresia?

D2.   Does patient have obstructed pulmonary venous return?
(Definition: use of intervention, including balloon septostomy, open atrial
septectomy or urgent Norwood procedure.)   YES.........1   NO.........2

BSTRUCT	D2. Does patient have obstructed pulmonary venous return?

D3.   Surgeon ID (Enter -1 for surgeon ID if patient will not be randomized)   ___ ___ - ___ ___
Removed to protect privacy

Section E: INCLUSION and EXCLUSION CRITERIA

Does the patient meet the following criteria?

E1.   Does patient have HLHS or related single, morphologic <u>right</u> ventricle
anomaly?   YES...1   NO...2

HLHS	E1. Does patient have hypoplastic left heart syndrome

E2.   Is a Norwood procedure part of the treatment plan for this patient?   YES...1   NO...2

NORWPLAN	E2. Is a Norwood procedure part of the treatment plan

E3.   Does patient have a single, morphologic left ventricle anomaly?   YES...1   NO...2

LFVANOM	D1. Does patient have aortic atresia?

E4.   Does patient have any major congenital abnormality or acquired extra-
cardiac disorder that could **independently** affect the likelihood of the   YES...1   NO...2 **(E5)**
subject meeting the primary endpoint?

	a. Congenital diaphragmatic hernia	YES...1 NO...2
	b. Tracheoesophageal fistula	YES...1 NO...2
	c. Need for high frequency ventilation	YES...1 NO...2
	d. Renal failure requiring dialysis	YES...1 NO...2
	e. Trisomy 13	YES...1 NO...2
	f. Trisomy 18	YES...1 NO...2
	g. Other	YES...1 NO...2

            1. Specify:

NHRi

CONGENTL	E4. Does patient have any major congenital abnormality
HERNIA	E4a. Congenital diaphragmatic hernia
FISTULA	E4b. Tracheoesophageal fistula
NEEDVANT	E4c. Need for high frequency ventilation
RENAL	E4d. Renal failure requiring dialysis
TRISOM13	E4e. Trisomy 13
TRISOM18	E4f. Trisomy 18
CONGOTH	E4g. Congenital: Other
CONOTH_S	E4g1. Congenital : Other: Specify

E5. Is there any **preoperative** anatomic evidence that in the opinion of the surgeon renders either a MBTS or RV-to-PA shunt technically impossible?   YES...1   NO...2 **(E6)**

    a. Aberrant right subclavian artery   YES...1   NO...2

    b. Significant conal coronary artery in proposed shunt area   YES...1   NO...2

    c. Other   YES...1   NO...2

       1. Specify:

NOSHUNT	E5. Any preoperative anatomic evidence
SUBCLAV	E5a. Aberrant right subclavian artery
CORONARY	E5b. Significant conal coronary artery in proposed shunt area
NOSHNOTH	E5c. Evidence: Other
NOSHNT_S	E5d. Evidence: Other: specify

E6. Did patient die before screening could be completed?   YES...1   NO...2 **(F1)**

    a. Date of death: ___ ___ / ___ ___ / ___ ___ ___ ___
                    M   M   D   D   Y   Y   Y   Y

Replaced by age at death, days

DIED	E2. Is a Norwood procedure part of the treatment plan
DIED_Age	E5a. <created var> Age at date of death, days

Added version D

E7. Patient **not approached** to obtain Informed Consent   YES...1   NO...2 **(F1)**

OCENTFAR	[Added version D]E7. Patient not approached to obtain Informed Consent?

Added version D

E8.   Reason patient was not approached:

      a. Patient from outside of North America   YES...1   NO...2

      b. Language barrier preventing informed consent   YES...1   NO...2

      c. Outside referring physician objection   YES...1   NO...2

      d. Other   YES...1   NO...2 **(F1)**

           1. Specify:

REASON_PT_NA	[Added version D]E8a. Patient from outside of North America
REASON_PT_LB	[Added version D]E8b. Language barrier preventing informed consent
REASON_PT_PO	[Added version D]E8c. Outside referring physician objection
REASON_PT_O	[Added version D]E8d. Other
REASON_PT_OS	[Added version D]E8d1. Patient not approached: Other: specify

Patient is NOT ELIGIBLE if E1 or E2 = NO or if any of E3-E6 = YES.

Section F: TRIAL ELIGIBILITY

F1.   Date completed inclusion/exclusion screening   __ __ / __ __ / __ __ __ __
                                                            M   M   D   D   Y   Y   Y   Y

Replaced by age when completed inclusion/exclusion screening, days

comp_age	F1. <created var>Age at date completed screening, days

F2.   Is patient eligible for the trial?   YES.................. 1   NO .... 2 **(END)**

ELIGIBLE	F2. Is patient eligible for trial?

Section G: PATIENT CONSENT

G1.   Did the parent/legal guardian sign the informed consent document?   YES.................. 1   NO .... 2 **(G2)**

CONSENT	G1. Did parent/guardian sign the informed consent document?
main549cohort	<created var>In the SVR main analysis cohort: 1=yes, 2=No

      a.   Date consent signed   __ __ / __ __ / __ __ __ __ **(END)**
                                                           M   M   D   D   Y   Y   Y   Y

consent_age	G1a. <created var>Age at date consent signed, days

rand_age	<created var>Age at randomization, days

G2. Reason for NOT signing Informed Consent Form: (Circle the **first** applicable choice)

UNWILLING TO BE RANDOMIZED TO SPECIFIC SURGERY .... 1 **(END)**
FAMILY UNWILLING TO PARTICIPATE IN RESEARCH STUDY 2
LANGUAGE BARRIER .... 3 **(END)**
OTHER 99
1.   Other, specify: _____ **(END)**

    a.   If family is unwilling to participate, specify primary reason:

BECAUSE OF TIME COMMITTMENT 1

BECAUSE OF DISTANCE FROM CENTER 2

NO REASON GIVEN 3

OTHER 99

1.   Other, specify: _____

NOCNST	G2. Reason for NOT signing Informed Consent Form:
NOCNST_S	G2i. No consent: Other: specify
NOFAM	G2a. If family is unwilling to participate, specify reason:
NOFAM_S	G2ai. Family unwilling: Other: specify