DATA SHOWN INCLUDES REPLACEMENT WITH F01A DATA AS APPROPRIATE

Section A: KEY IDENTIFYING INFORMATION

A1. Study Identification Number ___ ___ - ___ ___ ___ ___ ___ - ___

Replaced by blinded subject ID

subj_id	Blinded subject ID

Blinded site ID <created var>

site_id	Blinded site ID

A2. Acrostic Identifier ___ ___ ___ ___ ___

Removed to protect privacy

A3. Patient date of birth ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

Removed to protect privacy

A4. Patient gender MALE .....1 FEMALE 2

GENDER	A4. Patient gender

A5. Name of person completing form _____ ___ ___ ___
PRINT FULL NAME INITIALS

Removed to protect privacy

A6. Date of form completion ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

Replaced by age

f001_age	<created var> Age at Screening (years)

f001_6to19	<created var> Age at screening is [6,19) years?

Section B: PATIENT INFORMATION

B1. Patient 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	B1. Patient race

MORESPEC	B1a. Specify more than one race

OTHRSPEC	B1b. Specify other

B2. Is patient of Hispanic or Latino origin? YES ..... 1 NO ..... 2 UNKNOWN ..... -8

HISPANIC	B2. Is patient of Hispanic or Latino origin

B3. Patient residential zip/postal code ___ ___ ___ ___ ___ ___
(For U.S. residents, leave the last space blank)

Removed to protect privacy

Section C: ANATOMY AND FONTAN PROCEDURES

INSTRUCTIONS: If the patient had more than one Fontan procedure, report information related to only the most recent Fontan procedure for questions in Section C.

Anatomic Diagnosis Reclassified using form F01A

F01A_COMP_AGE	<created var> (Form1A:A1) Age (yrs) of the subject when the form F01A was completed

<F01A> REASON FOR RECLASSIFICATION:

Diagnosis category did not exist on original Code List 1
Additional levels added to diagnosis category 2
Additional choices added to category level 3
Revision and expansion of category code assignments 4
OTHER 99

A. SPECIFY _____

NONE, NOT RECLASSIFIED .....-1

RECLASS	(Form 1A: C1) Reason for Pre-Fontan diagnosis reclassification

WKSHCOMP	(Form 1A: C2) Pre-Fontan Anatomic Diagnosis Worksheet completed

ANASPEC	(Form 1A: B3a) Specify (if anatomic dx code is A1.02.03 or A1.06.03)

C1. Patient anatomic diagnosis providing indication for Fontan procedure

Anatomic Diagnosis Code
(**See Code List A**)
[code required for data entry]

a. Level 1 ___ ___

b. Level 2 ___ ___

c. Level 3 ___ ___

d. Level 4 ___ ___

e. Level 5 ___ ___

Anatomic Diagnosis Name Worksheet

Final, updated Anatomic Diagnosis <created variable>

A1.01.xx.xx.xx: Single ventricle, double inlet left ventricle
A1.02.xx.xx.xx: Single ventricle, double inlet right ventricle
A1.03.xx.xx.xx: Single ventricle, mitral atresia
A1.04.xx.xx.xx: Single ventricle, tricuspid atresia
A1.05.xx.xx.xx: Single ventricle, unbalanced AV canal defect
A1.06.xx.xx.xx: Single ventricle, heterotaxia syndrome
A1.07.xx.xx.xx: Other single ventricle
A2.xx.xx.xx.xx: Hypoplastic left heart syndrome
A3.xx.xx.xx.xx: Other functional SV not fitting any other categories
A4.xx.xx.xx.xx: Other

dx1	<created var> Final (corrected) Pre-Fontan anatomic diagnosis, level 1

dx2	<created var> Final (corrected) Pre-Fontan anatomic diagnosis, level 2

dx3	<created var> Final (corrected) Pre-Fontan anatomic diagnosis, level 3

dx4	<created var> Final (corrected) Pre-Fontan anatomic diagnosis, level 4

dx5	<created var> Final (corrected) Pre-Fontan anatomic diagnosis, level 5

f001_dx	<created var> Final (corrected) Pre-Fontan dx, per Screener (code list A)

f001_dxcat	<created var> Final (corrected) Pre-Fontan dx, categorical (code list A)

vent_type	<created var> Final Core Lab adjudicated ventricular type

lloop	<created var> L-loop configuration

twovent	<created var> Functionally SV hearts with 2 ventricles (A1.06,A3.05-A3.07)

reclassified	<created var> Pre-Fontan Diagnosis Reclassified

C2. Date of most recent Fontan completion ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

Replaced by the age of subject

FONTAN_AGE	<created var> C2. Age (yrs) of the subject when the most recent Fontan was completed

fontan_prior	<created var> Number of months since Fontan surgery was performed

fontan_gt6	<created var> Last Fontan surgery >6 months prior to form completion

C3. Type of most recent Fontan procedure

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

a. Level 1 ___ ___

b. Level 2 ___ ___

c. Level 3 ___ ___

d. Level 4 ___ ___

Surgical Procedure Name Worksheet

Type of most recent Fontan procedure <created variable>

B2.02.01.xx: Atriopulmonary connection
B2.02.02.xx: Atrioventricular connection (Bjork)
B2.02.03.xx : TCPC intracardiac lateral tunnel
B2.02.04.xx : TCPC extracardiac lateral tunnel
B2.02.05.xx : TCPC extracardiac conduit
B2.02.06.xx : Intraatrial conduit
B2.02.07.xx : Other Fontan

Collapsed Categories <created var>

fontancat	<created var> Type of most recent Fontan (collapsed categories)

All Categories <created var>

fontan	<created var> Type of most recent Fontan (concatenation of all 4 levels)

FONPROL1	C3a. Type of most recent Fontan procedure level 1

FONPROL2	C3b. Type of most recent Fontan procedure level 2

FONPROL3	C3c. Type of most recent Fontan procedure level 3

FONPROL4	C3d. Type of most recent Fontan procedure level 4

C4. Number of ancillary surgical procedures completed with the most recent Fontan procedure

___ (0-5) (**IF 0, SKIP TO C5**)

CONPRO_N	C4. Number of procedures concurrent with most recent procedure

conpro	<created var> All ancillary surgical procedure codes

Ancillary Surgical Procedure Code (See codes below)

a. ___ ___
b. ___ ___
c. ___ ___
d. ___ ___
e. ___ ___

1. If code=99 (Other), specify: _____

Ancillary Surgical Procedures			
Code	**Procedure Name**	**Code**	**Procedure Name**
01	Patch repair of pulmonary artery stenosis	07	Atrio-ventricular valve oversewn
02	Repair of atrio-ventricular valve for regurgitation	08	Atrio-ventricular valve replacement
03	Atrial septectomy	09	Semilunar valve replacement
04	Revision of Superior Vena Cava connection	10	Aortic arch repair
05	Ligation of main pulmonary artery	11	Pacemaker insertion
06	Division of main pulmonary artery	99	Other

CONPRO1_0	C4. Ancillary surgical procedure code (0)

CONPRO1_1	C4. Ancillary surgical procedure code (1)

CONPRO1_2	C4. Ancillary surgical procedure code (2)

CONPRO1_3	C4. Ancillary surgical procedure code (3)

CONPRO1_4	C4. Ancillary surgical procedure code (4)

CONPRO1S_0	C4. Specify ancillary surgical procedure code (0)

CONPRO1S_1	C4. Specify ancillary surgical procedure code (1)

CONPRO1S_2	C4. Specify ancillary surgical procedure code (2)

CONPRO1S_3	C4. Specify ancillary surgical procedure code (3)

CONPRO1S_4	C4. Specify ancillary surgical procedure code (4)

C5. Fontan revision performed

YES.....1 NO..... 2 (**C6**) UNKNOWN.....-8 (**C6**)

FONTANRV	C5. Fontan revision performed

a. Date of most recent Fontan revision ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

Replaced by the age of subject

FONTANRV_AGE	<created var> C5a. Age (yrs) of the subject when the most recent Fontan revision was done

fontanrv_prior	<created var> # Number of months since Fontan revision

fontanrv_gt6	<created var> Last Fontan revision >6 months prior to form completion

C6. Does patient receive ongoing cardiac care at a PHN site?

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

IF NO, STOP - FORM COMPLETE

PHNCARE	C6. Does patient receive ongoing cardiac care at a PHN center

Section D: POST-FONTAN FOLLOW-UP

D1. Is patient currently on an ACE inhibitor?

YES.....1 NO.....2 (**D2**) UNKNOWN.....-8 (**D2**)

ACEINHIB	D1. Is patient currently on a ACE inhibitor

a. Code number of ACE inhibitor (**See codes below**) ___ ___ . ___ ___

1. If code=13.99 (Other converting enzyme inhibitor), specify: _____

ACE inhibitors			
Code	**Generic (Trade) Name**	**Code**	**Generic (Trade) Name**
13.00	Converting enzyme inhibitor (unspecified)	13.07	Lisinopril (Prinivil, Zestril)
13.01	Benzapril	13.08	Pentopril
13.02	Captopril (Capoten)	13.09	Perindopril (Aceon)
13.03	Cilarapril (Primaxin)	13.10	Quinapril (Accupril)
13.04	Enalapril (Vasotec)	13.11	Ramipril (Altace)
13.05	Enalaprilat (Vasotec)	13.12	Trandolapril (Mavik)
13.06	Fosinopril (Monopril)	13.99	Other converting enzyme inhibitor

ACE_NAME	D1a. Code for ACE inhibitor

ACE_SP	D1a1. Name of ACE inhibitor

D2. Date of last visit to PHN site for any reason ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

Replaced by the age of subject

LASTVIS_AGE	<created var> D2. Age (yrs) of the subject when he/she had the last visit to PHN site

lastvisit_prior	<created var> # of months prior to form completion of last visit to center

lastvisit_gt6	<created var> Last visit to PHN site >6 months prior to form completion

Section E: PATIENT OUTCOMES

E1. Echocardiographic evidence of decreased systolic ventricular function on **most recent** echocardiogram

YES 1
NO 2
UNKNOWN..... -8

DEPRESVF	E1. Echocardiographic evidence of depressed ventricular function

E2. History of developmental delay

YES 1
NO 2
UNKNOWN..... -8

DEVDELAY	E2. History of developmental delay

E3. Current diagnosis of learning disability

YES 1
NO 2
POSSIBLE 3
UNKNOWN..... -8

LEARNDIS	E3. Current diagnosis of learning disability

E4. History of atrial tachyarrhythmia requiring therapy

YES 1
NO 2
UNKNOWN..... -8

ATRIALTA	E4. History of atrial tachyarrhythmia requiring therapy

E5. History of ventricular tachyarrhythmia requiring therapy

YES 1
NO 2
UNKNOWN..... -8

VENTTACH	E5. History of ventricular tachyarrhythmia requiring therapy

E6. Permanent pacemaker

CURRENT 1
PAST 2
NEVER 3
UNKNOWN..... -8

PACEMAKER	E6. Permanent pacemaker

E7. History of thrombosis

YES 1
NO 2

THROMBOS	E7. History of thrombosis

E8. History of stroke

YES 1
NO 2
POSSIBLE 3
UNKNOWN..... -8

STROKE	E8. History of stroke

E9. Current evidence of specific neurological deficit

YES 1
NO 2
UNKNOWN..... -8

NEURODEF	E9. Current evidence of specific neurological deficit

E10. History of protein-losing enteropathy

YES 1
NO 2
POSSIBLE 3
UNKNOWN..... -8

ENTEROPA	E10. History of protein-losing enteropathy

E11. Interventional cardiac catheterization or cardiovascular surgical intervention within the last 6 months

YES 1
NO 2
UNKNOWN..... -8

INTERVT6	E11. Interventional cardiac catheterization within last 6 months

a. Date of most recent interventional cardiac catheterization or cardiovascular surgical intervention

___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

Replaced by the age of subject

INTERV_AGE	<created var> E11a. Age (yrs) of the subject when he/she had the most recent cath or surgical intervention

interv_prior	<created var> # of months prior to form completion of last cardiac intervention

interv_gt6	<created var> Last interventional cardiac cath/surg >6 mos prior to form comp. date

Section F: DETERMINATION OF POTENTIAL ELIGIBILITY FOR ENROLLMENT IN THE FONTAN CROSS-SECTIONAL STUDY

All 4 of the criteria below must be met to be potentially eligible:

a. Current age of patient is at least 6 years and less than 19 years; AND

b. All Fontan surgery and revision dates > 6 months prior to form completion date; AND

c. Most recent interventional cardiac catheterization or cardiovascular surgical intervention > 6 months prior to form completion date; AND

d. Current care at PHN study site.

F1. Is patient potentially eligible for enrollment?

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

ELIGIBLE	F1. Is patient potentially eligible for enrollment

FORMSTAT_ID	Unique form/subject ID

FORM_ID	4 letter code for the form

VER_ID	1 letter code added to form code to make unique form/version

DESTATUS	Form completion