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

Replaced by age

COMP_AGE	<created var> Age (yrs) of the subject at A3. Date form completed

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

Removed to protect privacy

Section B: PRE-FONTAN ASSESSMENT (continued)

Pre-Fontan Cardiac Catheterization

[Note: Responses to questions B1 through B9 should be based on findings on the last cardiac catheterization the patient had prior to the most recent Fontan]

B1. Date of last cardiac catheterization prior to Fontan procedure ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

Replaced by age

PRCATH_AGE	<created var> Age (yrs) of the subject at B1. Date of last cardiac catheterization prior to Fontan

B2. Mean pulmonary artery pressure ___ ___ ___ mmHg

PAPRES S	B2. Mean pulmonary artery pressure (mmHg)

B3. Systemic ventricular end diastolic pressure ___ ___ mmHg

EDP	B3. Systemic ventricular end diastolic pressure (mmHg)

B4. Systemic oxygen saturation ___ ___ ___ %

O2SAT	B4. Systemic oxygen saturation (%)

a. Status of patient at time of measurement

BREATHING ROOM AIR 1
ON SUPPLEMENTAL OXYGEN 2

O2SATSTS	B4a. Status of patient at time of measurement

Section B: Pre-Fontan Assessment (continued)

Pre-Fontan Cardiac Catheterization (continued)

B5. Superior vena cava (SVC) anatomy

Anatomic Diagnosis Code (See Code List G) [code required for data entry]	**SVC Anatomy Name Worksheet**
a. Level 1 ___ ___	a.
b. Level 2 ___ ___	b.
c. Level 3 ___ ___	c.
d. Level 4 ___ ___	d.

preop_svc	<created var> Pre-Fontan superior vena cava anatomy (code list G)
SVCDX1	B5a. SVC anatomy - Level 1
SVCDX2	B5b. SVC anatomy - Level 2
SVCDX3	B5c. SVC anatomy - Level 3
SVCDX4	B5d. SVC anatomy - Level 4

B6. Are there SVC abnormalities? YES .....1 NO ..... 2 (**B7**) UNKNOWN..... -8 (**B7**)

SVCSTEN	B6. Are there SVC abnormalities?

Abnormality	**1.Present**		If YES, **2. Origin**		If YES, **3. Side**		
	YES	**NO**	**CONGENITAL**	**ACQUIRED**	**RIGHT**	**LEFT**	**BOTH**
a. SVC stenosis	1	2	1	2	1	2	3
b. SVC occlusion	1	2	1	2	1	2	3
c. Retro-aortic innominate vein	1	2					
d. Levoatrial-cardinal vein	1	2					
e. CS ostial atresia or stenosis	1	2					

f. Other	1	2					
	If Other=YES, specify: _____						

svcsum	<created var> Number of SVC abnormalities (0-6)
SVCSTEN1	B6a1. SVC stenosis - present?
SVCSTEN2	B6a2. SVC stenosis - Origin
SVCSTEN3	B6a3. SVC stenosis - Side
SVCOCCL1	B6b1. SVC occlusion - present?
SVCOCCL2	B6b2. SVC occlusion - Origin
SVCOCCL3	B6b3. SVC occlusion - Side
RAIVEIN	B6c1. Retro-aortic innominate vein - present?
LEVCVEIN	B6d1. Levoatrial-cardinal vein
CSOASTEN	B6e1. CS ostial atresia or stenosis
SVCOTHER	B6f1. Other
SVCOTSPC	B6f1.1. Specify:

Section B: Pre-Fontan Assessment (continued)

Pre-Fontan Cardiac Catheterization (continued)

B7. Inferior vena cava (IVC) anatomy

Anatomic Diagnosis Code (See Code List G) [code required for data entry]	**IVC Anatomy Name Worksheet**
a. Level 1 ___ ___	a.
b. Level 2 ___ ___	b.
c. Level 3 ___ ___	c.
d. Level 4 ___ ___	d.

preop_ivc	<created var> Pre-Fontan inferior vena cava anatomy (code list G)
IVCDX1	B7a. IVC Anatomy - Level 1
IVCDX2	B7b. IVC anatomy - Level 2
IVCDX3	B7c. IVC anatomy - Level 3
IVCDX4	B7d. IVC anatomy - Level 4

B8. Are there IVC abnormalities? YES .....1 NO ..... 2 (**B9**) UNKNOWN..... -8 (**B9**)

IVCSTEN	B8. Are there IVC abnormalities?	

Abnormality	**1.Present**		If YES, **2. Origin**	
	YES	**NO**	**CONGENITAL**	**ACQUIRED**
a. IVC stenosis	1	2	1	2
b. IVC occlusion	1	2	1	2
c. Cor triatriatum Dexter	1	2		
d. Other	1	2		
	If Other=YES, specify: _____ _____			

ivcsum	<created var> Number of IVC abnormalities (0-4)
IVCSTEN1	B8a1. IVC stenosis - Present?
IVCSTEN2	B8a2. IVC stenosis- Origin
IVCOCCL1	B8b1. IVC occlusion - Present?
IVCOCCL2	B8b2. IVC occlusion - Origin
CORTRDEX	B8c1. Cor triatriatum Dexter
IVCOTHER	B8d1. Other
IVCOTSPC	B8d1.1. Specify:

Section B: Pre-Fontan Assessment (continued)

Pre-Fontan Cardiac Catheterization (continued)

B9. Pulmonary artery abnormality YES .....1 NO ..... 2 (**C1**) UNKNOWN ..... -8 (**C1**)

PA_ABN	B9. Pulmonary artery abnormality	

a. Number of pulmonary artery abnormalities ___ ___ (1-15)

NUMPA_AB	B9a. Number of pumonary artery abnormalities

	Pre-Fontan Pulmonary Artery Abnormality Code (See Code List H) [code required for data entry]				
	a. Level 1	**b. Level 2**	**c. Level 3**	**d. Level 4**	**Pulmonary Artery Abnormality Name Worksheet**
1.	___ ___- ___ ___- ___ ___- ___ ___				1.
2.	___ ___- ___ ___- ___ ___- ___ ___				2.
3.	___ ___- ___ ___- ___ ___- ___ ___				3.
4.	___ ___- ___ ___- ___ ___- ___ ___				4.
5.	___ ___- ___ ___- ___ ___- ___ ___				5.
6.	___ ___- ___ ___- ___ ___- ___ ___				6.
7.	___ ___- ___ ___- ___ ___- ___ ___				7.
8.	___ ___- ___ ___- ___ ___- ___ ___				8.

If patient had more than 8 PA abnormalities pre-Fontan, please use and attach Form F04B, Question B9 Supplement to record information about these additional abnormalities.

main_paab	<created var> Number of Main PA Abnormalities
right_paab	<created var> Number of Right PA Abnormalities
left_paab	<created var> Number of Left PA Abnormalities
lobar_paab	<created var> Number of Lobar PA Abnormalities
all_preop_paab	<created var> All Pre-Fontan PA Abnormalities (code list H)
preop_paab0	<created var> Pre-Fontan PA abnormality (code list H) (0)
preop_paab1	<created var> Pre-Fontan PA abnormality (code list H) (1)
preop_paab2	<created var> Pre-Fontan PA abnormality (code list H) (2)
preop_paab3	<created var> Pre-Fontan PA abnormality (code list H) (3)
PAAB_A_0	B9a1a. Pre-Fontan PA abnormality: Level 1 (0)
PAAB_A_1	B9a1a. Pre-Fontan PA abnormality: Level 1 (1)
PAAB_A_2	B9a1a. Pre-Fontan PA abnormality: Level 1 (2)
PAAB_A_3	B9a1a. Pre-Fontan PA abnormality: Level 1 (3)
PAAB_B_0	B9a1b. Pre-Fontan PA abnormality: Level 2 (0)
PAAB_B_1	B9a1b. Pre-Fontan PA abnormality: Level 2 (1)
PAAB_B_2	B9a1b. Pre-Fontan PA abnormality: Level 2 (2)
PAAB_B_3	B9a1b. Pre-Fontan PA abnormality: Level 2 (3)
PAAB_C_0	B9a1c. Pre-Fontan PA abnormality: Level 3 (0)
PAAB_C_1	B9a1c. Pre-Fontan PA abnormality: Level 3 (1)
PAAB_C_2	B9a1c. Pre-Fontan PA abnormality: Level 3 (2)
PAAB_C_3	B9a1c. Pre-Fontan PA abnormality: Level 3 (3)
PAAB_D_0	B9a1d. Pre-Fontan PA abnormality: Level 4 (0)
PAAB_D_1	B9a1d. Pre-Fontan PA abnormality: Level 4 (1)
PAAB_D_2	B9a1d. Pre-Fontan PA abnormality: Level 4 (2)
PAAB_D_3	B9a1d. Pre-Fontan PA abnormality: Level 4 (3)
PAAB_E_0	B9a1e. Pre-Fontan PA abnormality: name worksheet (0)
PAAB_E_1	B9a1e. Pre-Fontan PA abnormality: name worksheet (1)
PAAB_E_2	B9a1e. Pre-Fontan PA abnormality: name worksheet (2)
PAAB_E_3	B9a1e. Pre-Fontan PA abnormality: name worksheet (3)

Section C: FONTAN PROCEDURE

C1. Date of most recent Fontan procedure ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

Replaced by age

FONTAN_AGE	<created var> Age (yrs) of the subject at C1. Date of most recent Fontan procedure

C2. Height at Fontan ___ ___ ___ . ___ cm

FONTANHT	C2. Height at Fontan (cm)

C3. Weight at Fontan ___ ___ ___ . ___ kg

FONTANWT	C3. Weight at Fontan (kg)

C4. Confirm type of Fontan procedure

Fontan 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
a.
b.
c.
d.

fontan_sg	<created var> Fontan surgical procedure code (code list B)
fontan_sgcat	<created var> Confirm type of most recent Fontan (collapsed categories)
FONTNCD1	C4a. Type of Fontan procedure - Level 1
FONTNCD2	C4b. Type of Fontan procedure - Level 2
FONTNCD3	C4c. Type of Fontan procedure - Level 3
FONTNCD4	C4d. Type of Fontan procedure - Level 4
FONTNOTH	C4c1. Specify:

C5. Type of material used in Fontan construction

GORTEX 1
AUTOLOGOUS PERICARDIUM.....2
HOMOGRAFT 3
XENOGRAFT PERICARDIUM.....4
OTHER..... 99
a. If OTHER, specify: _____
UNKNOWN..... ....-8

MATERIAL	C5. Type of material used in Fontan construction
MATRLOTH	C5a. Specify:

C6. Fenestration performed YES.....1 NO 2

FENESTRN	C6. Fenestration performed:

C7. Duration of total cardiopulmonary bypass ___ ___ ___ minutes
[**Enter 0 if no bypass**]

CARDPULB	C7. Duration of total cardiopulmonary bypass (minutes)

Section C: Fontan Procedure (continued)

C8. Surgical procedures concurrent with most recent Fontan procedure YES.....1 NO.....2 (**C9**)

CONCPROC	C8. Surgical procedures concurrent with most recent Fontan

a. Number of procedures ___ (1-5)

NUMPROCS	C8a. Number of procedures	

Surgical Procedure Code (See codes below)

1. ___ ___
2. ___ ___
3. ___ ___
4. ___ ___
5. ___ ___

a. 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

concurrent_sg	<created var> All concurrent surgical procedures
PXCODE_0	C8a1. Concurrent surgical procedure code (0)
PXCODE_1	C8a1. Concurrent surgical procedure code (1)
PXCODE_2	C8a1. Concurrent surgical procedure code (2)
PXCODE_3	C8a1. Concurrent surgical procedure code (3)
PXCODE_4	C8a1. Concurrent surgical procedure code (4)
concurrent_sgsp	<created var> All 'other' concurrent surgical procedures
PXOTHER_0	C8a1. Concurrent surgical procedure code: specify other (0)
PXOTHER_1	C8a1. Concurrent surgical procedure code: specify other (1)
PXOTHER_2	C8a1. Concurrent surgical procedure code: specify other (2)
PXOTHER_3	C8a1. Concurrent surgical procedure code: specify other (3)
PXOTHER_4	C8a1. Concurrent surgical procedure code: specify other (4)

Section C: Fontan Procedure (continued)

C9. Post-operative complications YES.....1 NO.....2 (**C10**)

POSTCOMP	C9. Post-operative complications	

a. Number of complications ___ (1-15)

NUMCOMPS	C9a. Number of complications	

Complication Code (See Code List C) [code required for data entry]	**Complication Name Worksheet**
1. ___ - ___ ___ ___ ___	1.
2. ___ - ___ ___ ___ ___	2.
3. ___ - ___ ___ ___ ___	3.
4. ___ - ___ ___ ___ ___	4.
5. ___ - ___ ___ ___ ___	5.
6. ___ - ___ ___ ___ ___	6.
7. ___ - ___ ___ ___ ___	7.
8. ___ - ___ ___ ___ ___	8.
9. ___ - ___ ___ ___ ___	9.
10. ___ - ___ ___ ___ ___	10.
11. ___ - ___ ___ ___ ___	11.
12. ___ - ___ ___ ___ ___	12.
13. ___ - ___ ___ ___ ___	13.
14. ___ - ___ ___ ___ ___	14.
15. ___ - ___ ___ ___ ___	15.

POSTCOMP	C9. Post-operative complications

peri_eff	<created var> Number of Pericardial Effusion Complications
plural_eff	<created var> Number of Pleural Effusion Complications
sp_comp	<created var> Number of 'Other Significant' Complications
allother_comp	<created var> Number of All Remaining Complications
postop_comp	<created var> All Post-Op complications (code list C)
COMPCD_0	C9a1. Post-op complication code (code list C) (0)
COMPCD_1	C9a1. Post-op complication code (code list C) (1)
COMPCD_2	C9a1. Post-op complication code (code list C) (2)
COMPCD_3	C9a1. Post-op complication code (code list C) (3)
COMPCD_4	C9a1. Post-op complication code (code list C) (4)
COMPCD_5	C9a1. Post-op complication code (code list C) (5)
COMPCD_6	C9a1. Post-op complication code (code list C) (6)
COMPCD_7	C9a1. Post-op complication code (code list C) (7)
COMPCD_8	C9a1. Post-op complication code (code list C) (8)
COMPCD_9	C9a1. Post-op complication code (code list C) (9)
COMPCD_10	C9a1. Post-op complication code (code list C) (10)
COMPCD_11	C9a1. Post-op complication code (code list C) (11)
COMPCD_12	C9a1. Post-op complication code (code list C) (12)
COMPCD_13	C9a1. Post-op complication code (code list C) (13)
postop_compsp	<created var> All 'other' Post-Op complications (code list C)
COMPOT_0	C9a1. Post-op complication: name worksheet (0)
COMPOT_1	C9a1. Post-op complication: name worksheet (1)
COMPOT_2	C9a1. Post-op complication: name worksheet (2)
COMPOT_3	C9a1. Post-op complication: name worksheet (3)
COMPOT_4	C9a1. Post-op complication: name worksheet (4)
COMPOT_5	C9a1. Post-op complication: name worksheet (5)
COMPOT_6	C9a1. Post-op complication: name worksheet (6)
COMPOT_7	C9a1. Post-op complication: name worksheet (7)
COMPOT_8	C9a1. Post-op complication: name worksheet (8)
COMPOT_9	C9a1. Post-op complication: name worksheet (9)
COMPOT_10	C9a1. Post-op complication: name worksheet (10)
COMPOT_11	C9a1. Post-op complication: name worksheet (11)
COMPOT_12	C9a1. Post-op complication: name worksheet (12)
COMPOT_13	C9a1. Post-op complication: name worksheet (13)

C10. Date of hospital discharge for most recent Fontan completion

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

Replaced by age

HOSPDC_AGE	<created var> Age (yrs) of the subject at C10. Date of hospital discharge for most recent Fontan completion

Section C: Fontan Procedure (continued)

C11. Evidence of significant decreased systolic ventricular function at time of discharge

YES..... 1 NO..... 2 (**C12**)

VNTDYS4B	C11. Decreased systolic ventricular function at discharge	

a. Basis of diagnosis

	YES	NO
1. Clinical history and physical exam	1	2
2. Echocardiography	1	2
3. Magnetic resonance imaging	1	2
4. Cardiac catheterization	1	2
5. Other	1	2

a. If Other=YES, specify: _____

_____

VDYSHX4B	C11a1. Clinical history and physical exam
VDECHO4B	C11a2. Echocardiography
VDMRI4B	C11a3. Magnetic resonance imaging
VDCATH4B	C11a4. Cardiac catheterization
VDOTHR4B	C11a5. Other
VDSPEC4B	C11a5a. Specify:

C12. Number of medications prescribed at time of hospital discharge ___ (0-9)
(**IF 0, GO TO FORM F04C**)

NUMMEDS	C12. Number of medications prescribed at time of discharge:

Medication Code (See Code List D) **[Code required for data entry]**	**Medication Name Worksheet**
a. ___ ___ . ___ ___	a.
b. ___ ___ . ___ ___	b.
c. ___ ___ . ___ ___	c.
d. ___ ___ . ___ ___	d.

e. ___ ___ . ___ ___

f. ___ ___ . ___ ___

g. ___ ___ . ___ ___

h. ___ ___ . ___ ___

i. ___ ___ . ___ ___

e.
f.
g.
h.
i.

PROCEED TO FORM F04C:
Fontan Medical Record Review Form (Part III)

postop_meds	<created var> All medications prescribed at discharge (List D)
medcd_0	<created var> Hospital discharge medication code (0)
medcd_1	<created var> Hospital discharge medication code (1)
medcd_2	<created var> Hospital discharge medication code (2)
medcd_3	<created var> Hospital discharge medication code (3)
medcd_4	<created var> Hospital discharge medication code (4)
medcd_5	<created var> Hospital discharge medication code (5)
medcd_6	<created var> Hospital discharge medication code (6)
medcd_7	<created var> Hospital discharge medication code (7)
medcd_8	<created var> Hospital discharge medication code (8)
MEDCD1_0	C12a. Hospital discharge medication code (digits 1-2) (0)
MEDCD1_1	C12a. Hospital discharge medication code (digits 1-2) (1)
MEDCD1_2	C12a. Hospital discharge medication code (digits 1-2) (2)
MEDCD1_3	C12a. Hospital discharge medication code (digits 1-2) (3)
MEDCD1_4	C12a. Hospital discharge medication code (digits 1-2) (4)
MEDCD1_5	C12a. Hospital discharge medication code (digits 1-2) (5)
MEDCD1_6	C12a. Hospital discharge medication code (digits 1-2) (6)
MEDCD1_7	C12a. Hospital discharge medication code (digits 1-2) (7)
MEDCD1_8	C12a. Hospital discharge medication code (digits 1-2) (8)
MEDCD2_0	C12a. Hospital discharge medication code (digits 3-4) (0)
MEDCD2_1	C12a. Hospital discharge medication code (digits 3-4) (1)
MEDCD2_2	C12a. Hospital discharge medication code (digits 3-4) (2)
MEDCD2_3	C12a. Hospital discharge medication code (digits 3-4) (3)
MEDCD2_4	C12a. Hospital discharge medication code (digits 3-4) (4)
MEDCD2_5	C12a. Hospital discharge medication code (digits 3-4) (5)
MEDCD2_6	C12a. Hospital discharge medication code (digits 3-4) (6)
MEDCD2_7	C12a. Hospital discharge medication code (digits 3-4) (7)
MEDCD2_8	C12a. Hospital discharge medication code (digits 3-4) (8)
MEDNM_0	C12a. Hospital discharge medication code: name worksheet (0)
MEDNM_1	C12a. Hospital discharge medication code: name worksheet (1)
MEDNM_2	C12a. Hospital discharge medication code: name worksheet (2)

MEDNM_3	C12a. Hospital discharge medication code: name worksheet (3)
MEDNM_4	C12a. Hospital discharge medication code: name worksheet (4)
MEDNM_5	C12a. Hospital discharge medication code: name worksheet (5)
MEDNM_6	C12a. Hospital discharge medication code: name worksheet (6)
MEDNM_7	C12a. Hospital discharge medication code: name worksheet (7)
MEDNM_8	C12a. Hospital discharge medication code: name worksheet (8)

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