

Section A: KEY IDENTIFYING INFORMATION

A1. Study Identification Number _____ - _____ - _____

Replaced by blinded subject ID

subj_id	Blinded subject ID
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Blinded site ID <created var>

site_id	Blinded site ID
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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. 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 A4. Date Form Completed
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A5. Name of person completing form _____
PRINT FULL NAME INITIALS*Removed to protect privacy***Section B: ASSESSMENT OF COMPLETION OF STUDY REQUIREMENTS**

B1. Primary caregiver completed Child Health Questionnaire – Parent Report (Form F007)

YES..... 1 (B2) NO 2

COMPPCHQ	B1. Primary caregiver completed CHQ-PF50
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a. Reason not completed

PRIMARY CAREGIVER REFUSED 1

PRIMARY CAREGIVER DID NOT SHOW UP FOR
SCHEDULED VISIT OR MAIL QUESTIONNAIRE TO SITE 2

FAMILY LOST TO FOLLOW-UP 3

OTHER 99

1. If OTHER, specify: _____

NOPCHQ_R	B1a. Reason not completed (CHQ-PF50)
NOPCHQ_S	B1a1. Reason not complete: CHQ-PF50:Specify

Form F011: Fontan Study Summary Form

B2. Patient completed echocardiogram

YES..... 1 (**B3**) NO2

COMPECHO	B2. Patient completed echocardiogram
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a. Reason not completed

PRIMARY CAREGIVER OR PATIENT REFUSED..... 1

PATIENT DID NOT SHOW UP FOR SCHEDULED VISIT2

PATIENT LOST TO FOLLOW-UP3

OTHER 99

1. If OTHER, specify: _____

NOECHO_R	B2a. Reason not completed: ECHO
NOECHO_S	B2a1. Reason not complete: ECHO: Specify

Form F011: Fontan Study Summary Form

B3. Patient had blood drawn for Serology Core Lab

YES..... 1 (**B4**) NO 2

COMPSERO	B3. Patient had blood drawn for Serology Core Lab
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a. Reason blood not drawn

PRIMARY CAREGIVER OR PATIENT REFUSED.....1
 PATIENT DID NOT SHOW UP FOR SCHEDULED VISIT2
 PATIENT LOST TO FOLLOW-UP3
 MEDICAL PERSONNEL UNABLE TO OBTAIN SPECIMEN4
 OTHER 99

1. If OTHER, specify: _____

NOSERO_R	B3a. Reason not completed: Serology
NOSERO_S	B3a1. Reason not complete: Serology : Specify

B4. Patient completed 12-lead electrocardiogram

YES..... 1 (**B5**) NO 2

COMP12LD	B4. Patient completed 12-lead electrocardiogram
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a. Reason not completed

PRIMARY CAREGIVER OR PATIENT REFUSED.....1
 PATIENT DID NOT SHOW UP FOR SCHEDULED VISIT2
 PATIENT LOST TO FOLLOW-UP3
 OTHER 99

1. If OTHER, specify: _____

N012LDRS	B4a. Reason not completed: 12-lead electrocardiogram
N012LDOT	B4a1. Reason not complete: Electrocardiogram: Specify

B5. Patient completed exercise testing

YES..... 1 (**B6**) NO 2

COMPEXER	B5. Patient completed exercise testing
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a. Reason not completed

PRIMARY CAREGIVER OR PATIENT REFUSED.....1
 PATIENT DID NOT SHOW UP FOR SCHEDULED VISIT2
 PATIENT LOST TO FOLLOW-UP3

Form F011: Fontan Study Summary Form

PATIENT UNABLE TO COOPERATE/UNDERSTAND INSTRUCTIONS...4
PATIENT DID NOT MEET HEIGHT REQUIREMENT5
PATIENT HAS MEDICAL CONDITION WHICH PRECLUDES
EXERCISE TESTING.....6
PATIENT HAD ADVERSE EVENT DURING TESTING7
OTHER 99

1. If OTHER, specify: _____

NOEXER_R	B5a. Reason not completed: Exercise
NOEXER_S	B5a1. Reason not complete: Exercise : Specify

Form F011: Fontan Study Summary Form

B6. Patient completed cardiac MRI

YES..... 1 (**B7**) NO 2

COMPMRI	B6. Patient completed MRI
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a. Reason not completed

PRIMARY CAREGIVER OR PATIENT REFUSED.....1
 PATIENT DID NOT SHOW UP FOR SCHEDULED VISIT2
 PATIENT LOST TO FOLLOW-UP3
 PATIENT UNABLE TO COMPLETE STUDY WITHOUT SEDATION4
 PATIENT HAS MEDICAL CONDITION WHICH PRECLUDES
 PERFORMANCE OF MRI5
 PATIENT HAD ADVERSE EVENT DURING PROCEDURE6
 OTHER 99

1. If OTHER, specify: _____

NOMRI_R	B6a. Reason not completed: MRI
NOMRI_S	B6a1. Reason not complete: MRI: Specify

QUESTIONS B7 AND B8 TO BE COMPLETED FOR PATIENTS \geq 10 YEARS OF AGE ONLY

B7. Patient completed Child Health Questionnaire – Self-Report Form (Form F008)

YES..... 1 (**B8**) NO 2

COMPCCHQ	B7. Patient completed CHQ-CF87
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a. Reason not completed

PRIMARY CAREGIVER OR PATIENT REFUSED.....1
 PATIENT DID NOT SHOW UP FOR SCHEDULED
 VISIT OR MAIL QUESTIONNAIRE TO SITE2
 PATIENT LOST TO FOLLOW-UP3
 PATIENT IS UNABLE TO READ ENGLISH OR SPANISH.....4
 OTHER 99

1. If OTHER, specify: _____

NOCCHQ_R	B7a. Reason not completed: CCHQ
NOCCHQ_S	B7a1. Reason not complete: CCHQ: Specify

B8. Patient completed Congenital Heart Adolescent and Teenager (CHAT) Questionnaire (Form F009)

YES..... 1 (**B9**) NO 2

COMPCHAT	B8. Patient completed CHAT
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Form F011: Fontan Study Summary Form

a. Reason not completed

PRIMARY CAREGIVER OR PATIENT REFUSED 1
 PATIENT DID NOT SHOW UP FOR SCHEDULED
 VISIT OR MAIL QUESTIONNAIRE TO SITE 2
 PATIENT LOST TO FOLLOW-UP 3
 PATIENT IS UNABLE TO READ ENGLISH OR SPANISH 4
 OTHER 99

1. If OTHER, specify:

NOCHAT_R	B8a. Reason not completed: CHAT
NOCHAT_S	B8a1. Reason not complete: CHAT: Specify

QUESTION B9 TO BE COMPLETED FOR ALL PATIENTS

B9. Did patient or primary caregiver complete at least one of the study tests?

YES 1

NO 2

STOP – FORM COMPLETE

COMPTST	B9. Patient completed at least one of the study tests
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a. Date first study test/questionnaire completed

__	__	/	__	__	/	__	__	__	__
M	M		D	D		Y	Y	Y	Y

Replaced by age

FIRST_AGE	<created var> Age (yrs) of the subject at B9a. Date of first test completed
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b. Date last study test/questionnaire completed

__	__	/	__	__	/	__	__	__	__
M	M		D	D		Y	Y	Y	Y

Replaced by age

LAST_AGE	<created var> Age (yrs) of the subject at B9b. Date of last test completed
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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