

**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. Date of enrollment visit \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

*Replaced by age*

enroll_age	<created var> A3. Age (yrs) at enrollment: enrollment date (F02B, A3) - DOB (F02A, A3)
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A4. Date of form completion \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

*Replaced by age*

COMP_AGE	<created var> A4. Age (yrs) when form was completed
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A5. Name of person completing form \_\_\_\_\_ PRINT FULL NAME \_\_\_\_\_ INITIALS \_\_\_\_\_

*Removed to protect privacy***Section B: INFORMED CONSENT**

B1. Is the patient old enough to consent to study participation without informed consent by a parent or legal guardian?

YES ..... 1

NO ..... 2 (B2)

OFAGE	<Added Form Version B> B1. Is patient old enough to consent to study
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a. Did the patient sign the informed consent document?

YES ..... 1 (B3)

NO ..... 2 (B4)

PTCONSNT	<Added Form Version B> B1a. Did patient sign the informed consent
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B2. Did the patient's parent or legal guardian sign the informed consent document?

YES ..... 1

NO ..... 2 (B4)

## Form F02B: Fontan Patient Enrollment Visit Form

CONSENT	B2. Did parent/guardian sign informed consent document
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a. Did the patient sign the age-appropriate assent or consent document?

YES ..... 1

NO ..... 2 (B4)

NOT APPLICABLE.....- 1

ASSNTDOC	B2a. Did the patient sign the age-appropriate assent
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B3. Date of first completed or scheduled study test (or questionnaire)

__	M	__	M	/	__	D	__	D	/	__	Y	__	Y	__	Y	__	Y
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**STOP - FORM COMPLETE**

TEST1_AGE	<created var> B3. Age (yrs) at first completed or scheduled test (or questionnaire)
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B4. Reason consent (or assent) form not signed

UNWILLING TO PARTICIPATE BECAUSE OF TIME  
COMMITMENT..... 1

UNWILLING TO PARTICIPATE BECAUSE OF DISTANCE.. 2

NO SHOW FOR SCHEDULED VISIT ..... 3

OTHER ..... 99

a. Specify \_\_\_\_\_

NOCNST_R	B4. Reason consent (or assent) not signed
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NOCNST_O	B4a. Specify
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B5. Did the parent/legal guardian agree to complete the Child Health Questionnaire - Parent Report?

YES ..... 1

**GIVE FORM F007 TO  
PARENT/GUARDIAN**

NO ..... 2

CHQAGR2B	<Added Form Version C> B5. Did parent/guardian agree to complete CHQ
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consented	<created var> Consent to Full Study
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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