Section A: KEY IDENTIFYING INFORMATION
TO BE COMPLETED BY THE STUDY COORDINATOR

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

Replaced by age

FONTAN_AGE	<created var> A5. Age (yrs) of the subject when the most recent Fontan was completed

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

Replaced by age

COMP_AGE	<created var> A6. Age (yrs) of the subject when the form was completed

A7. Name of person completing form _____ ___ ___ ___
                                            PRINT FULL NAME   INITIALS

Removed to protect privacy

Section B: MEDICAL RECORD ABSTRACTION AND INTERVIEW STATUS
TO BE COMPLETED BY STUDY COORDINATOR

Questions B1 through B4 must be answered for <u>all</u> patients listed on the Fontan Screening Log (Form F000) who were randomly selected for potential participation by the DCC.

B1.   Did the patient have a cardiac surgical procedure within the last 6 months?

YES 1

NO 2

UNKNOWN.... -8

NEWFN6MO	B1. Cardiac surgical procedure in last 6 months

B2.   Did the patient have an interventional cardiac catheterization within the last 6 months?

YES 1

NO 2

UNKNOWN.... -8

CATH6MO	B2. Interventional cardiac cath in last 6 months

B3.   Is the patient receiving ongoing cardiac care at the study site?

YES 1

NO 2

CARDCARE	B3. Is patient receiving ongoing cardiac care at the study site?

B4.   Is the patient alive?

YES 1

NO 2

PTALIVE	B4. Is the patient alive?

If B1=(YES or UNKNOWN) or B2=(YES or UNKNOWN) or B3=NO or B4=NO, SKIP TO SECTION D

B5.   Was the patient's parent/primary caregiver able to be contacted?

YES................1

NO 2   **SKIP TO SECTION D**

PRIMCARE	B5. Was the patient's primary caregiver able to be contacted?

B6.   Did the patient's parent/primary caregiver agree to be interviewed?

YES 1

NO 2   **SKIP TO SECTION D**

PRIMINTW	B6. Did patient's primary caregiver agree to be interviewed?

a. Date of interview   ___ ___ / ___ ___ / ___ ___ ___ ___
                          M   M   D   D   Y   Y   Y   Y

Replaced by age

INTRVW_AGE	<created var> B6a. Age (yrs) of the subject when she/he had the interview

b. How was interview conducted?   BY TELEPHONE 1

IN PERSON 2

INTRVCON	B6b. How was the interview conducted?

Section C: INTERVIEW SECTION: TO BE OBTAINED FROM THE CAREGIVER

THE INTERVIEW CAN BE CONDUCTED BY TELEPHONE OR IN PERSON. HOWEVER, THE <u>PERSON INTERVIEWED MUST BE A PRIMARY CAREGIVER OF THE PATIENT</u>.

**READ ALL LOWERCASE TEXT TO THE PARENT/PRIMARY CAREGIVER
TO BE INTERVIEWED**

We would like to ask you some questions to help us determine if [PATIENT] would be able to participate in a study of children who have had Fontan surgery and if you are interested in scheduling a visit to enroll [PATIENT] in the study. There will be no charge to you for any of the tests associated with the study. Before we begin, let me remind you that all information is strictly confidential and that your name and [PATIENT'S] name will not be used in any reports.

Please answer each question as accurately as you can. This interview is completely voluntary and will not affect [PATIENT'S] medical care. You may stop the interview at any time. If there is a question that you cannot or do not wish to answer, please tell me and I will go on to the next question.

If you have any questions or concerns about this interview, you may call [DOCTOR] at [SITE]. If you have any questions about your rights as a research subject, you may call [IRB CHAIR], who is the Chair of the Institutional Review Board at [SITE], at [TELEPHONE NUMBER].

C1.   What is your relationship to [PATIENT]?

MOTHER 1
FATHER 2
OTHER 99
   a. If OTHER, specify: _____

PTRELAT	C1. What is your relationship to [PATIENT]?
SPECRELT	C1a. What is your relationship to [PATIENT]?: specify

C2.　Are you able to read English or Spanish well enough to complete a written questionnaire in one of these languages?

YES, ENGLISH 1

YES, SPANISH 2

YES, ENGLISH AND SPANISH 3

NO 4

ENGSPAN	C2. Read English or Spanish enough to complete questionnaire?

C3.　Is [PATIENT] at least 6 years old and less than 19 years old?

YES................ 1

NO 2

AGE6TO19	C3. Is [PATIENT] at least 6 years old and less than 19 years old

C4.　Will you permit [PATIENT] to have an echocardiogram performed at [SITE] as part of the study?

YES................ 1

NO 2

PRMTECHO	C4. Will you permit [PATIENT]to have echocardiogram

C5.　Will you permit [PATIENT] to have blood drawn once at [SITE] as part of the study?

YES................ 1

NO 2

PRMBLOOD	C5. Will you permit [PATIENT] to have blood drawn

C6.　Are you willing to complete a written health status questionnaire about [PATIENT] in either English or Spanish?

YES................ 1

NO 2

HLTHQUST	C6. Willing to complete written health quest. about [PATIENT]

C7.　Does [PATIENT] have any other medical (non-cardiac) or psychiatric condition that may make it difficult for [HIM/HER] to have an echocardiogram or blood drawn or may affect interpretation of study results?

YES................ 1

NO 2

REFUSED...... -7

OTHERCON	C7. Does [PATIENT] have any other medical/psychiatric condition

C8.　Is [PATIENT] participating in or planning to participate in another research study that would prevent completion of study testing or affect interpretation of study results?

YES................ 1

NO 2

OTHRSTUD	C8. Is [PATIENT] participating in another research study

C9 FOR FEMALE PATIENTS ONLY:

C9. For completeness and accuracy, I am required to ask the following question with regard to all potential female study participants. Is [PATIENT] currently pregnant or planning to get pregnant in the next six months?

YES............... 1

NO 2

REFUSED...... -7

UNKNOWN.... -8

| PREGNANT | C9. Is [PATIENT] currently pregnant or planning in next 6 months |

Thank you for answering these questions.

- INFORM RESPONDENT ABOUT PATIENT'S ELIGIBILITY STATUS FOR PARTICIPATION IN THE FONTAN CROSS-SECTIONAL STUDY. NOTE THAT, IF A RESPONSE ON A GRAY-SHADED LINE IS CIRCLED FOR ANY QUESTION IN SECTION B OR C, THE PATIENT IS <u>NOT</u> ELIGIBLE FOR PARTICIPATION IN THE STUDY.

- IF PATIENT IS ELIGIBLE, AND RESPONSES TO C4 <u>AND</u> C5 ARE 'YES', ENLIST PARTICIPATION FOR <u>FULL</u> STUDY:
  - o DESCRIBE STUDY AND TESTS TO BE PERFORMED;
  - o ADDRESS ALL QUESTIONS;
  - o SCHEDULE ENROLLMENT VISIT IF RESPONDENT AGREES TO PARTICIPATE IN THE FULL STUDY.

- IF PATIENT IS ELIGIBLE BUT RESPONSE TO C4 AND/OR C5 IS 'NO',
  - o ASK RESPONDENT IF HE/SHE IS WILLING TO COMPLETE THE CHILD HEALTH QUESTIONNAIRE – PARENT REPORT BY MAIL

END OF INTERVIEW

Section D: DETERMINATION OF STUDY ELIGIBILITY BY STUDY COORDINATOR

**QUESTIONS D1 THROUGH D3 TO BE COMPLETED BY STUDY COORDINATOR
AFTER DETERMINING ELIGIBILITY OF PATIENT AND
ENLISTING PARTICIPATION IN STUDY IF PATIENT IS ELIGIBLE**

All of the following criteria must be met to be eligible for participation in the study:

1) Patient is currently at least 6 years of age and less than 19 years of age (C3=YES); AND

2) All cardiac surgery dates are $\geq$ 6 months prior to the interview date (B1=NO); AND

3) The most recent interventional cardiac catheterization is $\geq$ 6 months prior to the interview date (B2=NO); AND

4) Patient receives current care at PHN study site (B3=YES); AND

5) Patient does not have a non-cardiac medical or psychiatric disorder that would invalidate results of the study or prevent completion of study tests (C7=NO); AND

6) Patient is not participating in or planning to participate in another research study that would prevent completion of study or confound test results (C8=NO); AND

7) If female, the patient is not currently pregnant or planning to get pregnant in the next six months (C9=NO); AND

8) Primary caregiver has reading fluency in English or Spanish (C2=YES, ENGLISH; YES, SPANISH; or YES, ENGLISH AND SPANISH).

D1.   Is the patient eligible for participation in the Fontan Cross-Sectional Study?

YES 1

NO 2   **STOP – FORM COMPLETE**

The patient is eligible for participation in the <u>full</u> study if the primary caregiver agreed to

1) Complete a written health questionnaire (C6=YES); AND

2) Permit the child to have an echocardiogram (C4=YES) and blood draw (C5=YES).

FXSELIG	D1. Is the patient eligible for participation in Fontan study

D2.   Did the patient's parent/legal guardian agree to participate in the full study (i.e., complete the Child Health Questionnaire - Parent Report and permit the patient to have an echocardiogram and blood drawn)?

YES 1

NO 2 (**D3**)

PRTAGREE	D2. Did patient parent agree to participation in the full study?

a. Was an enrollment visit scheduled?

YES 1

NO 2 (**D2.c**)

VISTSCHD	D2a. Was an enrollment visit scheduled

b. Date of scheduled visit   ___ ___ / ___ ___ / ___ ___ ___ ___
                                              M   M   D   D   Y   Y   Y   Y

STOP – FORM COMPLETE

VISIT_AGE	<created var> D2b. Age (yrs) of the subject when she/he had the scheduled visit

c. Reason visit not scheduled   _____

                                                 _____

                                               _____

STOP – FORM COMPLETE

D3.   Did the parent/legal guardian agree to complete the Child Health Questionnaire - Parent Report by mail?

YES 1   **MAIL FORM F007 TO PARENT/GUARDIAN**

NO 2

CHQAGREE	D3. Did parent agree to complete the CHQ-Parent report by mail

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