PHN-06

Form A104: Consent

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INSTRUCTIONS: This form must be completed for all potentially eligible trial subjects who have an A104 form expected in ADEPT.

Section A: KEY IDENTIFYING INFORMATION								
A1.	Study Identification Number							
A2.	Study visit	BASELINE0						
	a. What number screening is this?	_						
A3.	Date of form completion	$\frac{1}{M}$ $\frac{1}{M}$ $\frac{1}{D}$ $\frac{1}{D}$ $\frac{1}{Y}$ $\frac{1}{Y}$ $\frac{1}{Y}$ $\frac{1}{Y}$						
A4.	Name of person completing form	PRINT FULL NAME INITIALS						
A5.	Date of visit	$\overline{M} = \overline{M} = $						
	Section B: CONFIRMATION OF MARFAN SYNDROME							
B1.	Eligibility appeal outcome	NOT APPLICABLE1 APPROVED 1 DENIED 2 (D1)						
B2.	Does the subject have a diagnosis of Ma	Does the subject have a diagnosis of Marfan syndrome confirmed by Ghent criteria?						
		YES 1						
		NO2 (D1)						
	If DENIED TO B1 or NO to B2, subject is NOT eligible for the Trial. Skip to D1 and end Baseline Screening.							
	Continu C. CIII	DIFCT CONCENT						
	Section C: Sui	BJECT CONSENT						
C1.	1. Did the subject/parent/legal guardian sign the informed consent document for enrollment?							
		YES						
	a. Date consent signed							

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C2.	Reason for NOT signing Informed Consent Form: (Circle the first applicable choice)						
	SUBJECT/FAMILY UNWILLING TO PARTICIPATE IN RESEARCH STUDY	. 1 (C2a)					
	PRIMARY CARETAKER/PRIMARY CARDIOLOGIST/GENETICIST DID NOT WANT SUBJECT TO PARTICIPATE	.2 (D1)					
	LANGUAGE BARRIER	3 (D1)					
SUBJECT UNWILLING TO BE RANDOMIZED							
	OTHER	` ,					
	i. Specify other reason						
	a. If subject/family is unwilling to participate, specify primary reason:						
	BECAUSE OF TIME COMMITMENT	.1 (D1)					
	BECAUSE OF DISTANCE FROM CENTER	.2 (D1)					
	BECAUSE INSURANCE WILL NOT COVER						
	ECHOCARDIOGRAMS AT A STUDY CENTER	.3 (D1)					
	NO REASON GIVEN	.4 (D1)					
	OTHER	99					
	i. Specify other reason	_					
If no	If no consent, subject is NOT eligible for the Trial. Go to D1 and end Baseline Screening.						
11 110	consent, subject is NOT engine for the That. Go to be and buseline ourcen	mg.					
Section D: CONFIRMATION OF ELIGIBILITY							
D1.	Is the subject eligible to proceed with screening? YES 1 NO	2 (Z1)					
D2.	Does subject require prophylactic drug taper? YES 1 NO	2 (Z1)					
	a. Date prophylactic drug taper begun						
	Section Z: TIME TO COMPLETE FORM AND SIGNATURE						
Z1.	How long did it take to complete this form? minutes						
	Signature of PI: Date:						
	END OF FORM						

Affix Marfan Trial Subject ID: __ - _ _ _ _ _

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