Pediatric Heart Network: Trial of BB vs. ARB in Marfan Syndrome

251

Form A190: Re-Consent

INSTRUCTIONS: This form is addable in the Baseline Event in ADEPT and must be data entered for subjects who were greater than or equal to 15 years of age and less than 18 years of age at the time of randomization.

PHN-06

	Section A: KEY IDENTIFYING INFORMATION				
A1.	Study Identification Number		-		
A2.	Study visit	BASELINE 0			
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			
	Section B: MARFAN TRIAL	RE-CONSENT INFORMATION			
B1.	Did the subject provide informed consent fo	r himself/herself on the original trial consent fo	rm?		
		YES	1)		
B2.	Did the subject re-consent to be in the trial?	YES 1 NO 2 <b>(B</b>	13)		
		SUBJECT IS NOT CAPABLE TO RE-CONSENT3 (C	;1)		
	a. Date consent signed	/(C	:1)		
B3.	Reason for NOT re-consenting to be in the	trial: (Circle the <b>primary</b> reason)			
	SUBJECT UNWILLING TO	CONTINUE IN RESEARCH STUDY1 (I	В3а)		
		PRIMARY CARDIOLOGIST/GENETICIST T TO CONTINUE 2 (0	<b>C1</b> )		
	LANGUAGE BARRIER	3 (0	<b>31)</b>		
	OTHER	99			
	i. Specify other reason	(0	<b>C1</b> )		

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		Tom Aros. No consent		
	a. If subject is unwilling to co	ontinue, specify primary reason:		
	BECAUSE O	F TIME COMMITMENT	1	(C1)
	BECAUSE O	F DISTANCE FROM CENTER	2	(C1)
		ISURANCE WILL NOT COVER IOGRAMS AT A STUDY CENTER	3	(C1)
	NO REASON	I GIVEN	4	(C1)
	OTHER		99	)
	i. Specify	other reason		
stud	y drug and Trial. Please comp	stion B2=2 'NO'), then subject must be withdrav blete and data enter into ADEPT Forms A212 (Pe d A216 (Permanent Withdrawal From Trial).		
	Section C: MUSCULO	SKELETAL ANCILLARY STUDY RE-CONSENT		
C1.	Is the subject participating in the	e Musculoskeletal Ancillary Study?		
		YES	1	(C2)
		NO	2	(Z1)
C2.	Did the subject provide informed consent form?	d consent for himself/herself on the original ancillar	y stud	ly
		YES	1	(Z1)
		NO	2	

C3. Did the subject re-consent to be in the ancillary study?

a. Date consent signed

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YES...... 1

SUBJECT IS NOT CAPABLE

NO......2 (C4)

TO RE-CONSENT...... 3 (Z1)

 $\frac{1}{M} \frac{1}{M} \frac{1}{M} \frac{1}{D} \frac{1}{D} \frac{1}{N} \frac{1}{N} \frac{1}{N} \frac{1}{N} \frac{1}{N} \frac{1}{N} \frac{1}{N} \frac{1}{N}$  (Z1)

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4. Reason for I	NOT re-consenting to be in the ancillary study: (Circle the <b>primary</b> reason)		
	SUBJECT UNWILLING TO CONTINUE IN ANCILLARY STUDY 1	(C4a	
	SUBJECT DID NOT RE-CONSENT TO MARFAN TRIAL	•	
	PRIMARY CARETAKER/PRIMARY CARDIOLOGIST/GENETICIST DID NOT WANT SUBJECT TO CONTINUE IN ANCILLARY STUDY 3	(Z1)	
	LANGUAGE BARRIER4	(Z1)	
	OTHER		
	i. Specify other reason	(Z1)	
a. If subje	ct is unwilling to continue in the ancillary study, specify the primary reason:		
	BECAUSE OF TIME COMMITMENT1	(Z1)	
	BECAUSE OF DISTANCE FROM CENTER	(Z1)	
	BECAUSE OF PHYSICAL DEMANDS OF ANCILLARY STUDY 3	(Z1)	
	NO REASON GIVEN4	(Z1)	
	OTHER		
	i. Specify other reason		

complete and data enter into ADEPT Form A416 (Withdrawal from Ancillary Study).

Z1.	How long did it take to complete this form? minutes				
END OF FORM					

Section Z: TIME TO COMPLETE FORM

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