

A serious adverse event is defined as any event which:

1. Is fatal; or
2. Is life-threatening (the patient was, in the view of the Principal Investigator, in immediate danger of death from the event as it occurred); or
3. Is severely or permanently disabling; or
4. Necessitates significant intervention, such as major surgery, to prevent permanent impairment of a body function or permanent damage to a body structure; or
5. Requires hospital admission; or
6. The Principal Investigator considers to be a serious adverse event.

### 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 serious adverse event \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

M M D D Y Y Y Y

*Replaced by age*

AEDATE_AGE	<created var> Age (yrs) of the subject at A3. Date of serious adverse event
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A4. Date PHN Site PI notified about event \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

M M D D Y Y Y Y

*Replaced by age*

NOTIF_AGE	<created var> Age (yrs) of the subject at A4. Date PHN Site PI notified about the serious adverse event
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A5. 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 A5. Date form completed
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A6. Name of person completing form \_\_\_\_\_

PRINT FULL NAME INITIALS

*Removed to protect privacy*

**Section B: DESCRIPTION OF SERIOUS ADVERSE EVENT (SAE)**

B1. Specify event \_\_\_\_\_

SPECEVNT	B1. Specify the serious adverse event
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B2. Was event associated with a study test?

NOT ASSOCIATED ..... 1 (B3)

POSSIBLY ASSOCIATED ..... 2

PROBABLY ASSOCIATED ..... 3

ASSOTEST	B2. Was the serious adverse event associated with a study test?	
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a. Specify test

ECHOCARDIOGRAM ..... 1

CARDIAC MRI ..... 2

ELECTROCARDIOGRAM..... 3

EXERCISE TEST ..... 4

VENIPUNCTURE ..... 5

OTHER ..... 99

1. If OTHER, specify: \_\_\_\_\_

\_\_\_\_\_

ASSOSPEC	B2a. Specify test
ASSOTHER	B2a1. If other, specify:

B3. Treatment administered for event YES..... 1 NO .....2

AETRMNT	B3. Treatment administered for the serious adverse vent	
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a. If YES, specify: \_\_\_\_\_

\_\_\_\_\_

AETXSPEC	B3a. If yes, specify:
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B4. Event resolved YES..... 1 NO .....2

AERESOLV	B4. Serious adverse event resolved:
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a. If YES, date event resolved

___	___	/	___	___	/	___	___	___	___
M	M		D	D		Y	Y	Y	Y

*Replaced by age*

AERES_AGE	<created var> Age (yrs) of the subject at B4a. Date of serious adverse event
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## Form F06B: Fontan Serious Adverse Event Notification Form

B5. Comments

AECOMMNT	B5. Comments on the serious adverse event
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FAX COMPLETED FORM WITHIN 24 HOURS OF THE PRINCIPAL INVESTIGATOR'S NOTIFICATION  
THAT THE EVENT OCCURRED TO:

**DIANNE GALLAGHER****PHN DATA COORDINATING CENTER****FAX NUMBER: 617-923-4176**

A NARRATIVE FROM THE SITE PI AND SUPPORTING DOCUMENTATION DESCRIBING THE SAE  
MUST ACCOMPANY THIS FORM.

B6. Date form faxed to PHN DCC

<u>  </u>	<u>  </u>	/	<u>  </u>	<u>  </u>	/	<u>  </u>	<u>  </u>	<u>  </u>	<u>  </u>
M	M		D	D		Y	Y	Y	Y

*Replaced by age*

AEFAX_AGE	<created var> Age (yrs) of the subject at B6. Date form faxed to PHN DCC:
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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