INSTRUCTIONS: Complete this form each time an adverse event occurs.
Extension Study: Complete for an adverse event which occurs during or within 24 hours after a study test of intervention only. The Study PI or Clinical Center PI must review and sign this form.

Section A: KEY IDENTIFYING INFORMATION

A1. Study Identification Number ___ ___ - ___ ___ ___ ___ ___ - ___

A2. Acrostic Identifier ___ ___ ___ ___ ____

A3. Event number (assigned sequentially by DMS) ___ ___

A4. Date of onset of adverse event ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

A5. Date form completed ___ ___ / ___ ___ / ___ ___ ___ ____
M M D D Y Y Y Y

A6. Name of person completing form _____ ___ ___ ___
PRINT FULL NAME INITIALS

Section B: DESCRIPTION OF ADVERSE EVENT

B1. Is this AE related to a separately reported AE that occurred prior to this one?

YES 1
NO ..... 2 **(B2)**

a. Prior Event number ___ ___

B2. Seriousness of event: **(See definitions in QxQ)**

NOT SERIOUS ..... 1 **(B5)**
SERIOUS (**PHYSICIAN NARRATIVE REQUIRED**) 3

B3. Indicate why the event was classified as serious: (Use the code list below.)

a. _____
b. _____
c. _____
d. _____

Code	Definitions for classification of event as an SAE
1	Is fatal
2	Is life-threatening (the subject was, in the view of the Principal Investigator, in immediate danger of death from the event as it occurred)
3	Is severely or permanently disabling
4	Necessitates significant intervention, such as major surgery, to prevent permanent impairment of a body function or permanent damage to a body structure
5	Necessitates or prolongs hospital admission
6	Increases the level of care
7	Involves a drug overdose
8	The Principal Investigator, medical monitor, or DSMB considers it to be a serious adverse event

B4. Was a treatment administered or intervention performed for this event?

YES.....1

NO.....2 **(B5)**

a.	ECMO	YES 1	NO 2
b.	Intubation and mechanical ventilation	YES 1	NO 2
c.	Pacemaker placement	YES 1	NO 2
d.	Surgery	YES 1	NO 2
e.	Catheterization	YES 1	NO 2
f.	Cardiopulmonary resuscitation	YES 1	NO 2
g.	Listing for transplant	YES 1	NO 2
h.	Other (except medication)	YES…… ….1	NO……2

1. Specify OTHER _____

B5. Briefly describe the event: _____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

B6. Event code (From CTCAE-MedDRA Code List) ___ ___ ___ ___ ___ ___ ___ ___

a. Specify (Short Name from CTCAE-MedDRA Code List) _____

_____

B7. Was medication administered to treat this event? **(See Code List D)** YES..... 1 NO.....2 **(B8)**

	Medication Code	Medication Name Worksheet
a.	___ ___ . ___ ___	
b.	___ ___ . ___ ___	
c.	___ ___ . ___ ___	
d.	___ ___ . ___ ___	
e.	___ ___ . ___ ___	
f.	___ ___ . ___ ___	
g.	___ ___ . ___ ___	
h.	___ ___ . ___ ___	
i.	___ ___ . ___ ___	
j.	___ ___ . ___ ___	

B8. Was this event related to the **shunt that the patient received**?

NOT RELATED 1
POSSIBLY RELATED 2
PROBABLY RELATED 3

B9. Was this event associated with a **study test or procedure**?

NOT ASSOCIATED..... 1 **(B10)**
POSSIBLY ASSOCIATED..... .2
PROBABLY ASSOCIATED 3

a. Specify test ECHOCARDIOGRAM.....1
NEURODEVELOPMENTAL.....2
24 HR. ECG HOLTER……...3

B10. In the investigator's judgment, based on the list of expected events for these patients as outlined in the protocol, was this event **expected**?

YES..... 1
NO 2

B11. Date faxed to PHN DCC ___ ___ / ___ ___ / ___ ___ ___ ___ (M M D D Y Y Y Y)

Initial Report: _____ _____
Signature of Clinical Center PI Date

COMPLETE FORM R201 WHEN THE EVENT IS RESOLVED

- ***Please review this form with the Clinical Center Principal Investigator (PI) prior to data entry and submission to the Data Coordinating Center (DCC).***
- ***The Clinical Center PI must sign this form.***

SUBMISSION INSTRUCTIONS:

If SEROUS ADVERSE EVENT (trial and study) or Patient DEATH (in trial only):
Contact the DCC within 24 hours of the PI's notification of the event.
Fax R200 within 72 hours of notification of the event to, SVR DCC AE Lead.
Fax the required physician narrative and any supporting documentation with this form.

If NOT SERIOUS:
Contact the DCC within 3 days of the PI's notification of the event.
Fax R200 to the DCC within 10 days of notification of the event in the trial and Quarterly for Extension Study.

Fax all forms to: DCC AE Lead
PHN Data Coordinating Center
FAX NUMBER: **617-926-7090**

DATA ENTRY INSTRUCTIONS:
This form must be entered into ADEPT within 3 days of being faxed to the DCC.