INSTRUCTIONS: Complete this form each time any of the following events occur:

1. **Non-drug related adverse or serious adverse event;**
2. **Study drug-related adverse or serious adverse event.**

The Clinical Center Principal Investigator (PI) must review and sign this form.

Section A: KEY IDENTIFYING INFORMATION

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

Replaced by blinded ID

blind_id	Blinded ID

A2. Acrostic Identifier ___ ___ ___ ___ ___

Removed to protect privacy

A3. Date of onset of adverse event ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

Replaced by age at onset of adverse event

ae_age	A3. <created var>Age at onset of adverse event, days

A4. Time event started/was diagnosed ___ ___ : ___ ___

a. AM .....1 PM.....2 24-Hour 3

AE_T	A4. Time event started/was diagnosed
AETIME_TU	A4a. Time: units
aetime24	<created var> Time event started/was diagnosed (24-hour time)

A5. Date form initiated ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

Replaced by age at form initiation

frmini_age	[Version A Only] A5. <created var>Age at form initiation, days
comp_age	A5. <created var>Age at form initiation, days

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

Removed to protect privacy

A7. Patient is enrolled in both ISV & SVR Trials

YES ..... 1 NO..... 2

SVRISV_YN	[Added Version D]A7. Patient is enrolled in both ISV & SVR Trials

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)**

RELATED	[Added Version D]B1. Is this AE related to a separately reported AE that occur

a. Identify the event code: ___ ___ ___ ___ ___ ___ ___ ___

PRIOREVTCD	[Added Version D]B1a. Identify the event code:

b. Identify the AE event name/ specify other: _____

PRIORAENM	[Added Version D]B1b. Identify the AE event name other:

c. Onset date: ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

Replaced by age at onset

prioron_age	B1c. <created var>Age at onset, days

B2. Adverse event occurrence INPATIENT..... 1 **(B3)** OUTPATIENT..... 2

AEOCCUR	B2. Adverse event occurrence

a. Was patient hospitalized because of this event? YES ..... 1 NO 2

AEHOSP	B2a. Was the patient hospitalized because of this event?

B3. Briefly describe the event from start to resolution: _____

_____

_____

_____

_____

Removed to protect privacy

B4. Event code **(See CTCAE-MedDRA Code List)** ___ ___ ___ ___ ___ ___ ___ ___

EVTCODE	[Added Version D]B4. Event code (See CTCAE-MedDRA Code List)
AE_SPEC_P	B4a. CTCAE-MedDRA shortname/ specify other

a. CTCAE-MedDRA short name/ specify other _____

AE_SPEC	[Versions A B C only] B4a. CTCAE-MedDRA shortname/ specify other
AE_SPEC_P	B4a. CTCAE-MedDRA shortname/ specify other
AECODE	[Versions A B C only] Event code

B5. Primary body system (circle only one)

CARDIOVASCULAR.....1
NEUROLOGICAL 2
GASTROINTESTINAL 3
RENAL.....4
FLUIDS/ELECTROLYTES/NUTRITION.....5
INFECTIOUS/INFLAMMATORY 6
HEMATOLOGIC 7
SKIN 8
SURGICAL 9
PULMONARY 10
MISCELLANEOUS 99

BODSYS	B5. Primary body system

B6. Was medication administered to treat this event? **(See Code List D)** YES..... 1 NO.....2 **(B7)**

MED_ADM	B6. Was medication administered to treat this event

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

aemedcd_0 - aemedcd_30	B6a-B6ee <created var> Medication given for this event (Code List D)
AEMEDNAM_0 - AEMEDNAM_30	B6a-ee. Medication name for this event

B7. Was patient placed on extracorporeal membrane oxygenation (ECMO) in relation to this event?

YES	NO
1	2

ECMO	[Added Version C] B7. Was patient placed on ECMO?

B8. Was patient intubated or placed on mechanical ventilation in relation to this event?

YES	NO
1	2

INTUBATED	[Added Version D]B8. Was patient intubated or placed on mechanical ventilation

B9. Did patient receive cardiopulmonary resuscitation in relation to this event?

YES	NO
1	2

CPR	[Added Version D]B9. Did patient receive cardiopulmonary resuscitation.

YES	NO
1	2 **(B11)**

B10. Was another treatment administered or intervention performed for this event?

OTHERTX	B10. Was another treatment administered or intervention performed

[Do not list medications recorded in B6a-j or the interventions named above]

a. Specify _____

_____

_____

_____

_____

_____

OTHTX_S	B10a. Specify

B11. Concomitant medications?
(In the 24 hours prior to the event)
(See Code List D)

YES .....1 NO.....2 **(B12)**

CONCMEDS	B11. Concomitant medications

	Medication Code [Code required for data entry]
1.	___ ___ . ___ ___
	a. Name
2.	___ ___ . ___ ___
	a. Name
3.	___ ___ . ___ ___
	a. Name
4.	___ ___ . ___ ___
	a. Name
5.	___ ___ . ___ ___
	a. Name
6.	___ ___ . ___ ___
	a. Name
7.	___ ___ . ___ ___
	a. Name

concmcd_0 - concmcd_23	<created var, Versions A,B Only> Concomitant medication (Code List D) (0-23)
CONCMNAM_0 - CONCMNAM_23	[Versions A,B Only] B11a. Specify other concomitant med #1-23
medcode0 - medcode23	[Added Version C] <created var>B11.1-B11.24. Concomitant medication code
MEDNAM_0 - MEDNAM_23	[Added Version C] B11.1a-B11.24a. Concomitant medication name
cncsrt_age_0 - cncsrt_age_23	[Versions A, B, C only] <created var>Age at start of concomitant medication #1-24, days
cncstp_age_0 - cncstp_age_23	[Versions A, B, C only] <created var>Age at stop of concomitant medication #1-24, days

B12. Date last dose of study drug taken ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

Replaced by age when last dose of study drug taken

aedose_age	B12. <created var>Age when last dose of study drug taken, days

a. Time last dose taken ___ ___ : ___ ___

1. Units AM..... 1 PM..... 2 24-Hour..... 3

AEDOSE_T	[Added Version C] B12a. Time last dose of study drug taken
AEDOSE_TU	[Added Version C] B12a1. Time last dose of study drug taken: units

b. Last dose <u>prescribed</u> ___ . ___ ___ ___ mg/kg/dose

AEDOSERX	[Added Version C] B12b. Last dose prescribed, mg/kg/dose

c. Last dose administered ___ . ___ ___ mg bid

AEDOSADM	[Added Version C] B12c. Last dose administered, mg bid

B13. Was this event related to the **study drug**? NOT RELATED .....1 **(B14)**
POSSIBLY RELATED 2
PROBABLY RELATED 3

DRUGREL	[Versions A,B Only] B13. Was this event related to the Study Drug
FDRUGREL	[Added Version C] B13. Was this event related to the Study Drug

a. Did the event signs and symptoms decrease after the study drug was stopped or the dose reduced?

YES	NO	N/A
1	2	-1

DECREASE	[Versions A,B Only] B13a. Did event symptoms decrease after drug was stopped
FDECREAS	[Added Version C] B13a. Did event symptoms decrease after drug was stopped

b. Did the event signs and symptoms reappear after the study drug was reintroduced?

YES	NO	N/A
1	2	-1

REAPPEAR	[Versions A,B Only] B13b. Did event symptoms reappear after drug was reintroduced
FREAPEAR	[Added Version C] B13b. Did event symptoms reappear after drug was reintroduced

B14. Was this event related to a **non-study medication**?

NOT RELATED .....1 **(B15)**
POSSIBLY RELATED 2
PROBABLY RELATED.....3

NONSTMED	B14. Was this event related to a non-study medication

a. Specify medication **Medication Code** ___ ___ . ___ ___ **Medication Name**

nsmedcd	B14a. <created var>Medication code: event related to a non-study med (Code List D)
NSMEDNAM	B14.a. Medication Name

b. Did the event signs and symptoms decrease after the non-study medication was stopped or the dose reduced?

YES	NO	N/A
1	2	-1

B7SIGNDE	B14b. Did the event signs decrease after non-study drug stopped

c. Did the event signs and symptoms reappear after the non-study medication was reintroduced?

YES	NO	N/A
1	2	-1

B7SIGNRE	B14c. Did event signs reappear after non-study drug reintroduced

B15. Was this event associated with a **study test**? NOT ASSOCIATED .....1 **(B16)**
POSSIBLY ASSOCIATED.....2
PROBABLY ASSOCIATED 3

TESTREL	B15. Was this event associated with a study test

a. Specify test
ECHOCARDIOGRAM 1
NEURODEVELOPMENTAL.....3
VENIPUNCTURE.....4

TEST_S	B15a. Specify test

B16. In the investigator's judgment, was this event **expected**, i.e., is it known to occur in the infant single ventricle population or is it a known side effect of the study drug? YES .....1 NO.....2

EXPECTED	B16. Based on prior condition, was this event expected

B17. Seriousness of event

NOT SERIOUS..... 1 **(B18)**
MODERATELY SERIOUS..... 2 **(B18)**
Physician narrative required ◄ SERIOUS ..... 3 **(B18)**
Physician narrative required ◄ DEATH 4

SERIOUS	B17. Seriousness of event

a. Date of death ___ ___ / ___ ___ / ___ ___ ___ ___ (M M D D Y Y Y Y) **(C8)**

Replaced by age at death

death_age	B17a. Age at death, days

B18. Event resolved at this time YES ..... 1 NO ..... 2 **(C1)**

RESOLVED	B18. Event resolved at this time

a. If YES, date event resolved ___ ___ / ___ ___ / ___ ___ ___ ___ (M M D D Y Y Y Y) **(C8)**

Replaced by age event resolved

resolv_age	B18a. Age event resolved, days

- ***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 or Patient DEATH:

1. Contact the AE Monitor within **24 hours** of the PI's notification of the event.
2. Fax this form to the AE Monitor within **72 hours** of notification of the event.
3. Fax the required physician narrative and any supporting documentation with this form.

If NOT SERIOUS or MODERATELY SERIOUS:

1. Contact the AE Monitor within **3 days** of the PI's notification of the event.
2. Fax this form to the AE Monitor within **10 days** of notification of the event.

Fax all forms to: N. SALLA BA, MD - AE MONITOR
PHN DATA COORDINATING CENTER
FAX NUMBER: 617-923-4176

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

Initial Report: _____ _____
Signature of Clinical Center PI (Signature NOT entered into ADEPT) Date

Initial date faxed to PHN DCC ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

Signature, date of signature, and date faxed to PHN DCC removed to protect privacy

Section C: RESOLUTION OF ADVERSE EVENT

C1. Study Identification Number ___ ___ - ___ ___ ___ ___ ___ - ___

This field is a repeat of A1 and has been removed

C2. Acrostic Identifier ___ ___ ___ ___ ___

This field is a repeat of A2 and has been removed

C3. Final Event Code **(See CTCAE-MedDRA Code List)** ___ ___ ___ ___ ___ ___ ___ ___

RES_AECODE	[Added Version D] C3. Final Event Code (See CTCAE-MedDRA Code List)

C4. Final CTCAE-MedDRA Short Name/ specify other _____

_____

RES_NAME	[Added Version D]C4. Final CTCAE-MedDRA Short Name/ specify other

C5. AE Onset Date ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

Replaced by age at onset of adverse event

res_onset_age	C5. <created var>Age at onset of adverse event, days

C6. AE resolved Date ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

This is a repeat of field B18a

a. Did this AE result in death? YES .....1 NO 2

RES_DEATH	[Added Version D]C6a. Did this AE result in death?

C7. Brief description of adverse event status: _____

Removed to protect privacy

C8. Date form finalized ___ ___ / ___ ___ / ___ ___ ___ ___
M M D D Y Y Y Y

C9. Date faxed to PHN ___ ___ / ___ ___ / ___ ___ ___ ___ **(END)**
M M D D Y Y Y Y

Final Report: _____ _____
Signature of Clinical Center PI (Signature NOT entered into ADEPT) Date

Information removed to protect privacy