

**Public Use Dataset
Annotated eCRF**

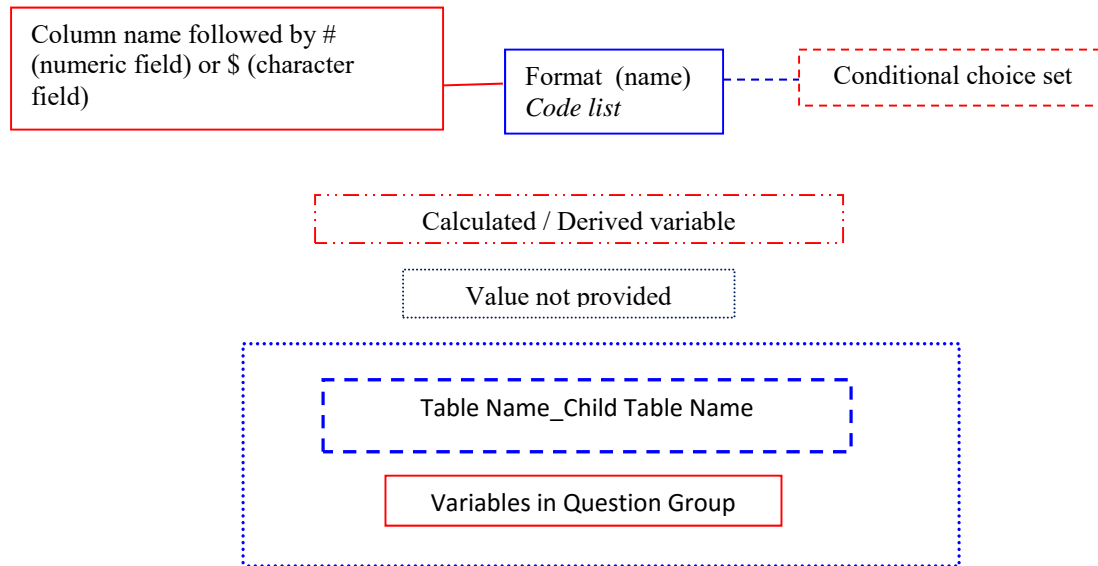
**Inhaled Nitric Oxide Use in Pediatric Intensive Care
(Nitric Oxide)
CPCCRN Protocol Number 054**

Collaborative Pediatric Critical Care Research Network
Eunice Kennedy Shriver National Institute for Child
Health and Human Development (NICHD)

PUD Annotated eCRF Version 1
Version Date: September 4, 2018

Annotations key

Table Name



Notes

StudySubjectID was replaced by PudID which uniquely identifies a subject across datasets.

Occurrence and ItemGroupRepeatKey are also unique data identifiers and appear where applicable.

All date variables are recoded to be number of days since iNO initiation. Variable names and labels are changed as well. For example, the variable ICUDischargeDate will be called ICUDischargeDay and the label will change from "Date of ICU Discharge" to "Day of ICU Discharge (relative to iNO initiation)". No actual dates will be included.

Open text fields and other variables have been reviewed for sensitive or identifying information and modified as needed.

Table name: Eligibility

iNO Eligibility

PudID #



◀ Inclusion...(0/4) Exclusion...(0/7) ▶ -- Select to Jump --

Title: Inclusion Criteria

Screening Date: * (DD-MMM-YYYY)

Inclusion Criteria

1. Is the subject < 18 years of age?

Inclusion1,# *

YNr

Yes =1

No =0

2. Is the subject mechanically ventilated?

Inclusion2,# *

YNr

Yes =1

No =0

3. Is the subject receiving inhaled nitric oxide (iNO) in the PICU or CICU?

Inclusion3,# *

YNr

Yes =1 If the subject does not meet inclusion criteria, do not save this information to OpenClinica.

No =0

Table name: Eligibility

iNO Eligibility

PudID #



Inclusi...(0/4) Exclusi...(0/7) -- Select to Jump --

Title: Exclusion Criteria

Exclusion Criteria

1. Is the subject a newborn with congenital diaphragmatic hernia (CDH)?

Exclusion1,# *
YNr
Yes = 1
No = 0

2. Is the subject a newborn with meconium aspiration syndrome (MAS)?

Exclusion2,# *
YNr
Yes = 1
No = 0

3. Is the subject a newborn with persistent pulmonary hypertension of the newborn (PPHN)?

Exclusion3,# *
YNr
Yes = 1
No = 0

4. Was the subject started on iNO at an outside institution?

Exclusion4,# *
YNr
Yes = 1
No = 0

5. Has this subject previously been enrolled in the iNO study during this hospitalization?

Exclusion5,# *
YNr
Yes = 1
No = 0

Subject Eligibility

Is subject eligible?
Eligible subjects have all inclusion criteria marked as Yes, and all exclusion criteria marked as No.

Eligible,# *
YNr
Yes = 1 If "No", save this page and do not continue. You have completed data entry for this subject.
No = 0

If subject was started on iNO prior to intubation, was there < 48 hours between iNO initiation and intubation?

(select one) iNO48Hour,#
YNNA
1=Yes
0=No
96=Not applicable
If "No", save this page and do not continue. You have completed data entry for this subject.

Table name: Demographics

iNO Demographics

PudID #

Demog (0/4)

Title: Demographics

Date of birth: **Birthday, #** (DD-MMM-YYYY) Sex: **Sex, #**
Male = 1
Female = 2

Ethnicity: **Ethnicity, INT** Race: (select all that apply)
Ethnic
Hispanic or Latino = 1
Not Hispanic or Latino = 2
Unknown or Not Reported = 92

American Indian or Alaska Native
Asian
Black or African American
Native Hawaiian or Other Pacific Islander
White
Unknown or Not Reported

Additional / derived variables included in the DEMOGRAPHIC dataset:

Variable	Type	Label	Algorithm / Notes
RACE2	#	Asian	1 = Yes, 0 = No
RACE3	#	Black or African American	1 = Yes, 0 = No
RACE5	#	White	1 = Yes, 0 = No
RACE92	#	Unknown or Not Reported	1 = Yes, 0 = No

Table name: Diagnosis

iNO Acute Diagnoses

PudID #

ItemGroupRepeatKey #

Diagnos...(0/16)

Title: Acute Diagnosis Information			
Acute Diagnosis Information			
Which is the primary organ system dysfunction leading to iNO initiation?			
	(select one)	AcuteOrganSystem,#	
		Organ 1=Cardiac 2=Respiratory	
Primary Cardiac Dysfunction:	(select one)	CardiacDysfunction,#	
		CDiag 1=Cardiomyopathy 2=Cardiomyopathy s/p ECMO or VAD placement 3=Congenital heart disease 4=Heart transplant - postoperative 5=Pulmonary hypertension – preexisting 6=Pulmonary hypertension	
Primary Respiratory Dysfunction:	(select one)	RespiratoryDysfunction,#	
		RespDiag 1=Acute lung injury / ARDS non pulmonary etiology 2=Acute lung injury - sepsis 3=Asthma 4=Bronchiolitis - not RSV 5=Pneumonia - aspiration 6=Pneumonia - bacterial 7=Pneumonia - viral other than RSV 8=Pertussis 9=RSV - pneumonia/bronchiolitis/pneumonitis	
Does the subject have a pre-hospitalization diagnosis of chronic pulmonary hypertension?			
	(select one)	ChronicPHTNDx,#	
		YN 1=Yes 0=No	
Is the subject receiving treatment for pulmonary hypertension at home?	(select one)	HomeTreatPHTNYN,#	
		YN 1=Yes 0=No	
Home treatment (select all that apply):		HomeTreatPHTN,# Treat	Specify:
		Ambrisentan =1 Beraprost =2 Bosentan =3 Epoprostenol =4 Iloprost =5 Macitentan =6 Riociguat =7 Sildenafil =8 Sitaxentan =9 Tadalafil =10	HomeTreatPHTNSpecify, \$

Trespostinil =11
Other =90

Chronic Diagnosis Information

Does the subject have any chronic diagnoses?

(select one) **ChronicDxYN,#** If yes, select all applicable diagnoses below.
 YN
 1=Yes
 0=No

Table name: **Diagnosis_ChronicDx**

Chronic Diagnoses	Specify
(select one) ChronicDx,# ChronDx 1=Asthma 2=Cancer 3=Cardiovascular disease - acquired 4=Cardiovascular disease - arrhythmia 5=Cardiovascular disease - congenital 6=Chronic renal failure 7=Chronic lung disease of Infancy (BPD) 8=Chronic lung disease other (e.g. CF) 9=Chromosomal defect 10=Connective tissue disease 11=Diabetes 12=HIV 13=Hypercoaguable disorder 14=Liver disease 15=Musculoskeletal 16=Neurologic - static encephalopathy 17=Neurologic - other chronic condition 18=Neurologic - chronic seizures 19=Obesity, morbid 20=Obstructive sleep apnea 21=Prematurity 22=Sickle cell disease 23=Transplant, solid organ 24=Transplant, bone marrow 90=Other (specify)	ChronicDxSpecify, \$
<input type="button" value="Add"/>	

Congenital Heart Disease Information

Does the subject have congenital heart disease?

(select one) **CHDDxYN,#** If yes, select all applicable diagnoses below.
 YN
 1=Yes
 0=No

Table name: **Diagnosis_CHDDx**

Type of Congenital Heart Disease	Specify
(select one) CHDDx,# CHDDx 1=Anomalous coronary artery 2=Anomalous pulmonary venous return - partial 3=Anomalous pulmonary venous return - total 4=Aortic insufficiency 5=Aortic stenosis - atresia 6=Atrioventricular canal defect	

- 7=Atrial septal defect - primum
- 8=Atrial septal defect - secundum
- 9=Coarctation of the aorta
- 10=Cor triatriatum
- 11=Double outlet right ventricle
- 12=Ebstein's anomaly
- 13=Hypoplastic aortic arch
- 14=Hypoplastic left heart syndrome
- 15=Interrupted aortic arch
- 16=Mitral insufficiency
- 17=Mitral stenosis
- 18=Patent ductus arteriosus
- 19=Pulmonary atresia
- 20=Pulmonary valve or artery stenosis
- 21=Pulmonary vein stenosis
- 22=Single ventricle - not hypoplastic left heart syndrome
- 23=Tetralogy of Fallot
- 24=Transposition of the great vessels
- 25=Tricuspid stenosis/atresia
- 26=Truncus arteriosus
- 27=Ventricular septal defect
- 90=Other cyanotic heart disease (specify)
- 100=Other non-cyanotic heart disease (specify)

CHDDxSpecify, \$

X

Add

Acquired Heart Disease Information

Does the subject have acquired heart disease?

(select one) AHDxYN,# If yes, select all applicable diagnoses below.

- YN
- 1=Yes
- 0=No

Table name: **Diagnosis_AHDx**

Type of Acquired Heart Disease	Specify	
(select one) AHDx,# AHDx 1=Arrhythmia 2=Cardiac arrest 3=Cardiomyopathy 4=Congestive heart failure 5=Kawasaki's disease 6=Myocarditis 7=Overdose with cardiac affects 8=Rheumatic fever 9=Transplant rejection 10=Tumor 11=Vasculitis 90=Other (specify)	AHDxSpecify, \$	X
<p>Add</p>		

Additional / derived variables included in the DIAGNOSIS dataset:

Variable	Type	Label	Algorithm / Notes
HomeTreatPHTN1	#	Ambrisentan	1 = Yes, 0 = No
HomeTreatPHTN2	#	Beraprost	1 = Yes, 0 = No
HomeTreatPHTN3	#	Bosentan	1 = Yes, 0 = No
HomeTreatPHTN4	#	Epoprostenol	1 = Yes, 0 = No
HomeTreatPHTN5	#	Iloprost	1 = Yes, 0 = No
HomeTreatPHTN6	#	Macitentan	1 = Yes, 0 = No
HomeTreatPHTN7	#	Riociguat	1 = Yes, 0 = No
HomeTreatPHTN8	#	Sildenafil	1 = Yes, 0 = No
HomeTreatPHTN9	#	Sitaxentan	1 = Yes, 0 = No
HomeTreatPHTN10	#	Tadalafil	1 = Yes, 0 = No
HomeTreatPHTN11	#	Trespostinil	1 = Yes, 0 = No
HomeTreatPHTN90	#	Other	1 = Yes, 0 = No

Table name: FSS

iNO Baseline Functional Assessments

PudID #

FSS (0/7)

Title: Functional Status Scale	
Instructions: These assessments should reflect the subject's status at the time of ICU admission.	
Date of FSS:	FSSDay,#  (DD-MMM-YYYY)
Mental Status Classification:	FSSMental,# Normal =1 Mild dysfunction =2 Moderate dysfunction =3 Severe dysfunction =4 Very severe dysfunction =5
Sensory Classification:	FSSSensory,# Normal =1 Mild dysfunction =2 Moderate dysfunction =3 Severe dysfunction =4 Very severe dysfunction =5
Communication Classification:	FSSCommun,# Normal =1 Mild dysfunction =2 Moderate dysfunction =3 Severe dysfunction =4 Very severe dysfunction =5
Motor Function Classification:	FSSMotor,# Normal =1 Mild dysfunction =2 Moderate dysfunction =3 Severe dysfunction =4 Very severe dysfunction =5
Feeding Classification:	FSSFeeding,# Normal =1 Mild dysfunction =2 Moderate dysfunction =3 Severe dysfunction =4 Very severe dysfunction =5
Respiratory Classification:	FSSResp,# Normal =1 Mild dysfunction =2 Moderate dysfunction =3 Severe dysfunction =4 Very severe dysfunction =5

Table name: TechDepend

PuID #

iNO Technology Dependence



TechDep... (0/4)







Title: Technology Dependence		
Indicate, with a yes or no response, what technology the subject was dependent on prior to this hospitalization:		
Oxygen?	(select one)	Oxygen,#
	YesNo 1=Yes 0=No	
Tracheostomy?	(select one)	Tracheostomy,#
	YesNo 1=Yes 0=No	
Home / chronic ventilator?	(select one)	HomeVent,#
	YesNo 1=Yes 0=No	
Chronic vascular access?	(select one)	VascularAccess,#
	YesNo 1=Yes 0=No	

Table name: HospSummary

iNO Hospitalization Summary

PudID #

Summary (0/18)

Title: Hospitalization Summary			
Hospital Admission Information			
Hospital Admission Date:	HospAdmitDay, #	 (DD-MMM-YYYY)	Hospital Admission Time: HospAdmitTime,\$ (HHMM)
ICU Admission Information			
ICU Admission Date:	ICUAdmitDay, #	 (DD-MMM-YYYY)	ICU Admission Time: ICUAdmitTime,\$ (HHMM)
ICU Admission Type:	(select one) ICUAdmissionType, # ICUAdm 1=Medical 2=Surgical 3=Cardiac 90=Other		
Does the subject have a history of prematurity (< 37 weeks gestation at birth)?			
	(select one) HxPrematurity, # YN 1=Yes 0=No		
Birthweight:	BirthWeight, # (g)	Estimated Gestational Age:	GestationAge, # (weeks)
Mechanical Ventilation			
Date Mechanical Ventilation Initiated:	MechVentStartDay, #	 (DD-MMM-YYYY)	Time Mechanical Ventilation Initiated: MechVentStartTime,\$ (HHMM)
ICU Discharge Information			
ICU Discharge Date:	ICUDisDay, #	 (DD-MMM-YYYY)	ICU Discharge Time: ICUDisTime,\$ (HHMM)
Vital Status at ICU Discharge:	(select one) ICUVitalStatus, # VitStat 1=Alive 0=Dead		
Vital Status on Study Day 28:	(select one) Day28VitalStatus, # Day28Vit 1=Alive 0=Dead 2=Discharged prior to study day 28		
Hospital Discharge Information			
Hospital Discharge Date:	HospDisDay, #	 (DD-MMM-YYYY)	
Vital Status at Hospital Discharge:	(select one) HospVitalStatus, # VitStat 1=Alive 0=Dead		
Death Information			
Date of Death:	DeathDay, #	 (DD-MMM-YYYY)	Time of Death: DeathTime,\$ (HHMM)

iNO Intubations & Extubations

PudID #

ItemGroupRepeatKey #

Table Name: MechVent



MechVent (0/6)

Title: Intubation & Extubation

Instructions: Document *every occurrence* the subject is intubated and extubated while participating in the iNO study. The first entry should be the same as the date and time of mechanical ventilation initiation noted on the hospitalization summary form. The last entry should be the date and time of final extubation and separation from mechanical ventilation.

Is the subject chronically ventilated?

(select one) **ChronicVentYN,#**

YN
1=Yes
0=No

If yes, what date did the subject return to their ventilator settings used at home in absence of iNO OR ventilator settings discharged home on? **PreiNOVentSettingsDays,#** (DD-MMM-YYYY)

Table name: MechVent_MechVentLog

Date Intubated (DD-MMM-YYYY)	Time Intubated (HHMM)	Date Extubated (HHMM)	Time Extubated (HHMM)
MechStartDay,#	MechStartTime,\$	MechStopDay,#	MechStopTime,\$

Add

Table name: Initiation

iNO Initiation

PudID #

Initiat... (0/25)

Title: Nitric Oxide Initiation Information

Instructions:

Study day 0 (zero): iNO initiation until 2359

All other study days: 0000 to 2359

Discharged prior to day 28: 0000 to time of ICU discharge

Date of iNO Initiation: iNOStartDay,# (DD-MMM-YYYY) Time of iNO Initiation: iNOStartTime,\$ (HHMM)

Location of iNO Initiation: (select one) InitiationLocation,# Initial Dose of iNO: InitialiNODose,# (ppm)

Loc
1=PICU
2=CICU
3=Cardiac OR
4=Other OR
5=Catheterization Lab
6=Emergency Room

Primary Indication for iNO Initiation: (select one) PrimaryIndication,# Specify: PrimaryIndicationSpecify,\$

iNO
1=Acute hypoxemic respiratory failure without elevated PA pressure
2=Acute hypoxemic respiratory failure with documented elevated PA pressure
3=Postoperative cardiac surgery pulmonary hypertension
4=Pre-existing chronic pulmonary hypertension
90=Other

Was invasive measurement of pulmonary artery pressure performed in the 12 hours prior to iNO initiation?

(select one) InvasivePAMeasure,#

YN
1=Yes
0=No

Record *SIMULTANEOUSLY OCCURRING* pulmonary artery and systemic pressures.

PA Systolic BP: PASystolicBP,# (mmHg) Systemic Systolic BP: SBP,# (mmHg)

PA Diastolic BP: PADiastolicBP,# (mmHg) Systemic Diastolic BP: DBP,# (mmHg)

PA Mean BP: PAMeanBP,# (mmHg) Systemic Mean BP: MeanBP,# (mmHg)

Did the subject have a cardiac arrest in the 12 hours prior to iNO initiation?

(select one) CardiacArrest,#

YN
1=Yes
0=No

At the time of iNO initiation, was the subject on:

CVVH/dialysis? (select one) CVVH,#

1=Yes
0=No

ECMO? (select one) ECMO, #
YN
1=Yes
0=No

Was a cardiac surgery performed prior to iNO initiation?

(select one) CardiacSurgery, #
YN
1=Yes
0=No

Were any of the following surgeries performed:

Bidirectional Glenn procedure or Hemi-Fontan? (select one) HemiFontan, #
YN
1=Yes
0=No

Fontan? (select one) Fontan, #
YN
1=Yes
0=No

Heart transplant? (select one) HeartTransplant, #
YN
1=Yes
0=No

Ventricular assist device placement (LVAD, RVAD, single ventricle)? (select one) VADPlacement, #
YN
1=Yes
0=No

Was a cardiac catheterization performed prior to iNO initiation?

(select one) Catheterization, # If yes, upload a report for each catheterization performed prior to Day 0.
YN
1=Yes
0=No

Upload Cardiac Cath Report	Value not provided	
		X
Add		

Was an echocardiogram obtained in the 12 hours prior to iNO initiation?

(select one) EchoObtained, INT If yes, upload a report for each echo performed prior to Day 0.
YN
1=Yes
0=No

Upload Echo	Value not provided	
--------------------	--------------------	--

Report	
	<input type="button" value="X"/>
<input type="button" value="Add"/>	

Table name: Day0

iNO Day 0

PudID #

Day0 (0/14)

Title: iNO Day 0 Data	
Instructions: For all questions listed below, provide the response based on what transpired with the subject throughout the entire study day (i.e. occurred anytime on this study day).	
Study day definitions Study day 0 (zero): iNO initiation until 2359 All other study days: 0000 to 2359 Discharged prior to day 28: 0000 to time of ICU discharge	
Study Day 0 Date:	Day0Day,# <input type="text"/> (DD-MMM-YYYY)
On study day 0, was the subject:	
Continuously on iNO therapy?	(select one) iNOContinuous,# YN 1=Yes 0=No
Discontinued from iNO therapy?	(select one) iNODiscontinue,# YN 1=Yes 0=No
Restarted on iNO therapy?	(select one) iNORestart,# YN 1=Yes 0=No
On mechanical ventilation?	(select one) MechanicalVent,# YN 1=Yes 0=No
On ECMO?	(select one) ECMOInitiated,# YN 1=Yes 0=No
On HFOV?	(select one) HFOVInitiated,# YN 1=Yes 0=No
On CVVH/dialysis?	(select one) CVVHInitiated,# YN 1=Yes 0=No
Did the subject receive sildenafil or tadalafil on study day 0?	
	(select one) Sildenafil,# YN 1=Yes 0=No
Did the subject have a cardiac arrest on study day 0?	
	(select one) CardiacArrest,# YN 1=Yes 0=No
Was a cardiac catheterization performed on Day 0?	
	(select one) Day0Catheterization,# If yes, upload a report for each catheterization performed on Day 0. YN 1=Yes 0=No

iNO Arterial Blood Gases & Respiratory Data

PudID #

Item Group Repeat Key #

ABG (0/6) PulseOx (0/4) Vent (0/20) -- Select to Jump --

Title: Arterial Blood Gases						
Instructions: Record ABG values from the draw just <i>prior</i> to iNO initiation. After iNO is initiated all ABG data will be recorded through the first 48 hours of study participation.						
Table name: Respiratory_ABGLog						
Date (DD-MMM-YYYY)	Time (HHMM)	pH (#.##)	paO ₂ (mmHg)	paCO ₂ (mmHg)	CO-oximeter saturation (%)	
ABGDay,#	ABGTime,\$	ABGpH,#	paO2,#	paCO2,#	CoOx,#	X
<input type="button" value="Add"/>						

iNO Arterial Blood Gases & Respiratory Data

PudID #

ItemGroupRepeatKey #



ABG (0/6) PulseOx (0/4) Vent (0/20) -- Select to Jump --

Title: Pulse Ox & End Tidal CO2

Instructions: Pulse oximeter saturation will be recorded closest to the top of every hour for the first 48 hours of study participation, and if available, ETCO₂ will also be recorded during this same timeframe.

Table name: Respiratory_PulseLog




Date (DD-MMM-YYYY)	Time (HHMM)	Pulse Oximetry (SpO ₂) (%)	ETCO ₂ (mmHg)	
PulseOxDay,# 	PulseOxTime,\$	SPO2,#	ETCO2,#	
				

Table Name: Respiratory

PudID #

Item Group Repeat Key #

Title: Respiratory Parameters

Instructions: Record the ventilator settings, conventional or high frequency oscillatory ventilation (HFOV), just prior to HD initiation. After HD is initiated all ventilator changes will be recorded through the first 48 hours of study participation.

Enter date of ventilation support for the subject (optional):

Please complete the appropriate table below depending on the response to this question.

1=Conventional
 2=HFOV

Conventional Ventilation

Table name: Respiratory_VentLog

Date (DD-MM-YYYY)	Time (HH:MM)	Mode <input type="text" value="ConMode_#"/>	Other Mode	Respiratory Rate (bpm)	Exhaled VT (mL/kg)	MAP (cmH ₂ O)	PEEP (cmH ₂ O)	PEEP (cmH ₂ O)	FiO ₂ (% # #) (must be a decimal)	Pulse Oximetry (SpO ₂) (%)	EtCO ₂ (mmHg)
<input type="text" value="ConDay_#"/>	<input type="text" value="ConTime_#"/>	<input type="text" value="ConMode_#"/> <small> 1=Pressure control 2=PCV 3=Volume control 90=Other </small>	<input type="text" value="ConModeSpecify_#"/>	<input type="text" value="ConRespRate_#"/>	<input type="text" value="ConExhaleVT_#"/>	<input type="text" value="ConMAP_#"/>	<input type="text" value="ConPEEP_#"/>	<input type="text" value="ConPEEP_#"/>	<input type="text" value="ConFiO2_#"/>	<input type="text" value="ConSpO2_#"/>	<input type="text" value="ConEtCO2_#"/>

High Frequency Oscillatory Ventilation

Table name: Respiratory_HFOVLog

Date (DD-MM-YYYY)	Time (HH:MM)	MAP (cmH ₂ O)	HFOV Frequency (Hz)	HFOV Amplitude (cmH ₂ O)	FiO ₂ (% # #) (must be a decimal)	Pulse Oximetry (SpO ₂) (%)
<input type="text" value="HFOVDay_#"/>	<input type="text" value="HFOVTime_#"/>	<input type="text" value="HFOVMAP_#"/>	<input type="text" value="HFOVfreq_#"/>	<input type="text" value="HFOVamp_#"/>	<input type="text" value="HFOVFiO2_#"/>	<input type="text" value="HFOVSpO2_#"/>

iNO Nitric Oxide Data



PudID #

ItemGroupRepeatKey #



iNO (0/4)

Title: Inhaled Nitric Oxide Dosage Information				
Instructions: Record all iNO dose changes through 48 hours of study participation.				
Table name: NitricOxide_iNOLog				
Date of Dose Change (DD-MMM-YYYY)	Time of Dose Change (HHMM)	FiO ₂ prior to iNO Dose Change (###) (must be a decimal)	Dose of iNO (ppm)	
iNODay,#	iNOTime,\$	FiO2BeforeChange,#	iNODose,#	
<input type="button" value="Add"/>				

Table name: Daily

iNO Daily Data

PudID #

Occurrence #

Daily (0/15)

Title: iNO Daily Data


Instructions: For all questions listed below, provide the response based on what transpired with the subject throughout the entire study day (i.e. occurred anytime on this study day). These data will be collected everyday up to a maximum of 28 days or ICU discharge, whichever occurs first.

Study day definitions

Study day 0 (zero): iNO initiation until 2359

All other study days: 0000 to 2359

Discharged prior to day 28: 0000 to time of ICU discharge

Study Day Date:	DailyDataDay, #	 (DD-MMM-YYYY)	Study day:	(select one)	StudyDay, #
				StDay	
				1=1	
				2=2	
				3=3	
				4=4	
				5=5	
				6=6	
				7=7	
				8=8	
				9=9	
				10=10	
				11=11	
				12=12	
				13=13	
				14=14	
				15=15	
				16=16	
				17=17	
				18=18	
				19=19	
				20=20	
				21=21	
				22=22	
				23=23	
				24=24	
				25=25	
				26=26	
				27=27	
				28=28	

On this study day, was the subject:

Continuously on iNO therapy? (select one) **iNOContinuous, #**
YN
1=Yes
0=No

Discontinued from iNO therapy? (select one) **iNODiscontinue, #**
YN
1=Yes
0=No

Restarted on iNO therapy? (select one) **iNORestart, #**
YN
1=Yes
0=No

On mechanical ventilation? (select one) **MechanicalVent, #**
YN
1=Yes
0=No

On ECMO? (select one) **ECMOInitiated, #**
YN
1=Yes
0=No

On HFOV? (select one) **HFOVInitiated,#**
 YN
 1=Yes
 0=No

On CVVH/dialysis? (select one) **CVVHInitiated,#**
 YN
 1=Yes
 0=No

Did the subject receive sildenafil or tadalafil on this study day?

(select one) **Sildenafil,#**
 YN
 1=Yes
 0=No

On this study day, did the subject have a cardiac arrest?

(select one) **CardiacArrest,#**
 YN
 1=Yes
 0=No

Was a cardiac catheterization performed on this study day?

(select one) **Catheterization,#** If yes, upload a report for each catheterization performed on this study day.
 YN
 1=Yes
 0=No

Upload Cardiac Cath Report	Value not provided	
		X
Add		

Was an echocardiogram obtained on this study day?

(select one) **EchoObtained,#** If yes, upload a report for each echo performed on this study day.
 YN
 1=Yes
 0=No

Upload Echo Report	Value not provided	
		X
Add		

Table name: Day28FSS

iNO ICU Discharge Functional Assessments v1

PudID #

FSS (0/8)


Title: Day 28 / ICU Discharge Functional Status Scale (FSS)	
Instructions: Record scores that reflect the subject's status on study day 28 or at ICU discharge, whichever occurs first.	
Date of FSS Assessment:	FSSDay,#  (DD-MMM-YYYY) FSSCompleted,\$ Day 28 ICU discharge
Mental Status Classification:	FSSMental,# Normal =1 Mild dysfunction =2 Moderate dysfunction =3 Severe dysfunction =4 Very severe dysfunction =5
Sensory Classification:	FSSSensory,# Normal =1 Mild dysfunction =2 Moderate dysfunction =3 Severe dysfunction =4 Very severe dysfunction =5
Communication Classification:	FSSCommun,# Normal =1 Mild dysfunction =2 Moderate dysfunction =3 Severe dysfunction =4 Very severe dysfunction =5
Motor Function Classification:	FSSMotor,# Normal =1 Mild dysfunction =2 Moderate dysfunction =3 Severe dysfunction =4 Very severe dysfunction =5
Feeding Classification:	FSSFeeding,# Normal =1 Mild dysfunction =2 Moderate dysfunction =3 Severe dysfunction =4 Very severe dysfunction =5
Respiratory Classification:	FSSResp,# Normal =1 Mild dysfunction =2 Moderate dysfunction =3 Severe dysfunction =4 Very severe dysfunction =5

Table name: RESPONSIVENESS

Variable name	Label	Format
SufficientInform	Sufficient site diagnosis	YN. 0 = No 1 = Yes
FundamentDiag	Fundamental cardiac diagnosis	Char
CongenitalHeart	Congenital heart disease	YN. 0 = No 1 = Yes

Table name: FUNDAMENTALCARDIACDX

Variable name	Label	Format
AcuteOrganSystem	Acute primary organ dysfunction leading to iNO initiation	ORGAN. 1 = Cardiac 2 = Respiratory
CR	Clinician response	oxy. (der) 0 = No 1 = Yes 93 = Unable to determine
CRAdj	Adjudication needed for clinician responsiveness question	cr. (der) 0=Clinician did not respond 1=Clinician responded but not in timely manner 2=Clinician responded in timely manner 93=Unable to determine
CRReviewer1	Clinician response (reviewer 1)	oxy.
CRReviewer2	Clinician response (reviewer 2)	cr.
ImprovedOxy	Oxygenation improvement	YN. 0 = No 1 = Yes
ImprovedOxyAdj	Adjudication needed for oxygenation improvement question	YN. 0 = No 1 = Yes
ImprovedOxyReviewer1	Oxygenation improvement (reviewer 1)	oxy.
ImprovedOxyReviewer2	Oxygenation improvement (reviewer 2)	cr.