

Public Use Dataset  
Annotated eCRF

**Translating an Adult Ventilator Computer Protocol  
To Pediatric Critical Care  
(Vent CDS R21)  
CPCCRN Protocol Number 011**

---

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

Protocol Version 1.00

Version Date: April 29, 2011

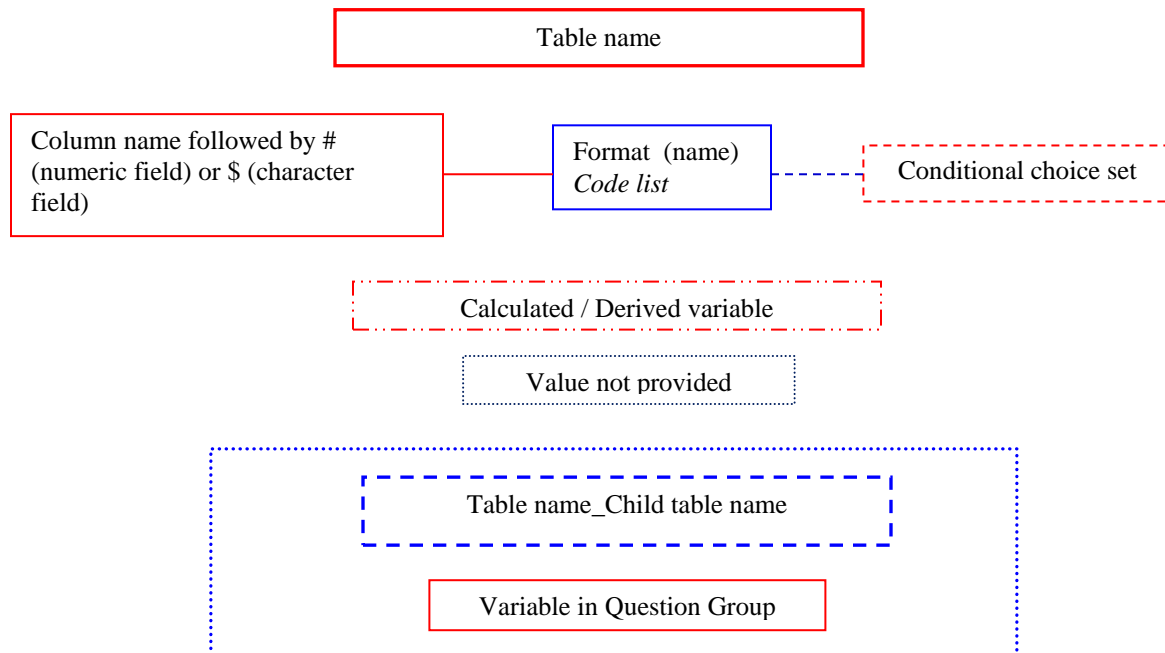
Annotated eCRF Version 2.0

Version Date: April 19, 2017

# Table of Contents

<b>Annotations key:</b> .....	3
<b>Notes</b> .....	3
<b>R21 Eligibility v1.0:</b> .....	4
<b>R21 Blood Gases and Ventilator Information v1.0:</b> .....	5
<b>R21 Blood Gases and Ventilator Information v1.0:</b> .....	6
<b>R21 Lab and Radiology Information v1.0:</b> .....	7
<b>R21 Additional Data Elements v1.0:</b> .....	8
<b>Ventilator Settings Log Joined with SPO2 and Blood Gases Log</b> .....	9
<b>Subject-level Derived Variables</b> .....	12

## Annotations key:



## Notes

StudySubjectID was replaced by SubjectID, sequential integers, that uniquely identifies a patient across datasets, it does not contain information about original site or medical record number. ItemGroupRepeatKey is also a unique subject identifier.

Sensitive and/or identifying information entered in free text fields have been removed from the public use datasets.

'Date' variables are replaced with 'day' variables. Day variables are populated with the number of days since the reference date, the date of the first ventilator reading. The date of the first ventilator reading is coded as 0 (Day 0) and all other dates will be recoded as number of days after Day 0 (if any dates occur before the first ventilator reading day, these dates will have a negative value).

# Eligibility (1 of 1)

## R21 Eligibility v1.0:

SubjectID #

ScreenDay #

Inclusion (0/4) Exclusion (0/5) Demog (0/12) -- Select to Jump --

**Title: Patient Demographics**

Age: Value not provided Age unit: (select one)

Sex: (select one) Sex, # Gender  
 1 = Male  
 2 = Female

Ethnicity:
 ☐ Hispanic or Latino  
☐ Not Hispanic or Latino  
☐ Unknown or Not Reported
 Ethnicity, #

Ethnic  
 1 = Hispanic or Latino  
 2 = Not Hispanic or Latino  
 92 = Unknown or Not Reported

Race: (select all that apply)
 ☐ American Indian or Alaska Native  
☐ Asian  
☐ Black or African American  
☐ Native Hawaiian or Other Pacific Islander  
☐ White  
☐ Unknown or Not Reported
 \*Race, #

Primary Diagnosis: PrimaryDiagnosis, \$

Is this patient chronically ventilated?
 ☐ Yes ☐ No
 ChronicVent, #

Height: Height, # (cm)

Weight: Weight, # (kg)

Ulna length: (if available) UlnaLength, # (cm) NOTE: If your site does not collect these data, please leave blank.

Make & Model of ventilator: VentilatorMake, \$

Make & Model of oximeter: OximeterMake, \$

YesNo  
 1=Yes  
 0=No

Race  
 3=Black or African American  
 5=White  
 92 =Other/Unknown

\*Recoded values 1 (American Indian or Alaska Native), 2 (Asian), and 4 (Native Hawaiian or Other Pacific Islander) as 95 (Other/Unknown).

# ABGVent (1 of 2)

## R21 Blood Gases and Ventilator Information v1.0:

SubjectID #

ItemGroupRepeatKey #

SPO2End...(0/4) | BloodGas (0/8) | Ventila...(0/24) | -- Select to Jump --

**Title: SPO2 and End Tidal CO2 Log**

Instructions: Please record *ALL* available SPO2 and End Tidal CO2 values during this patient's ventilation data collection time period (up to 168 hours, or extubation or death, whichever comes first).

Date (DD-MMM-YYYY)	Time (HHMM)	SPO2 (pulse oximeter) (%)	End Tidal CO2 (mmHg)
SPO2Day, #	SPO2Time, \$	SPO2, #	EndTidalCO2, #

ADD | ABGVent\_SPO2

SPO2End...(0/4) | **BloodGas (0/8)** | Ventila...(0/24) | -- Select to Jump --

**Title: Blood Gases Log**

Instructions: Please record *ALL* available arterial and capillary blood gases during this patient's ventilation data collection time period (up to 168 hours, or extubation or death, whichever comes first). You have an option to upload a file with these data, instead of entering data in OpenClinica, if your site is capable of pulling blood gas data from the medical record and has received approval from the DCC to do this.

Date (DD-MMM-YYYY)	Time (HHMM)	Source of Blood	pH (#.##)	PCO2 (mmHg)	PO2 (mmHg)	HCO3 (mEq/L)
		(select one)				

ADD

BloodGasLabDay, # | BloodGasLabTime, \$ | pH, # | PaCO2, # | PaO2, # | HCO3, #

ABGVent\_BloodGas | Upload file | BloodGasSource, #

Blood  
 1 = Arterial  
 2 = Capillary  
 92 = Unknown

# ABGVent (2 of 2)

## R21 Blood Gases and Ventilator Information v1.0:

SubjectID #

ItemGroupRepeatKey #

SP02End...(0/4) BloodGas(0/8) Ventila...(0/24) -- Select to Jump --

**Title: Ventilator Settings Log**

Instructions: Please record ALL ventilator settings during this patient's data collection time period (up to 168 hours, or extubation or death, whichever comes first). At a minimum, ventilator settings should be recorded 4 times/day.

Record date and time patient was started on the ventilator

Date:  (DD-MMM-YYYY) **VentStartDay, #**

Time:  (HHMM) **VentStartTime, \$**

Record the date and time patient was removed from the ventilator

Date:  (DD-MMM-YYYY) **Value not provided**

Time:  (HHMM) **Value not provided**

**Ventilator Settings**

Date (DD-MMM-YYYY)	Time (HHMM)	Ventilator Mode	Ventilator Rate (bpm)	Spontaneous respirations?	Tidal Volume Exhaled (mL/kg)	PIP (cmH2O)
<b>VentDay, #</b>	<b>VentTime, \$</b>	<b>VentMode, #</b> (select one)	<b>VentilatorRate, #</b>	<b>SpontaneousResp, #</b>	<b>VTExhaled, #</b>	<b>PIP, #</b>
<div> <div>ADD</div> <div>ABGVent_Vent</div> </div>						

**VentMode**  
 1 = Pressure Control  
 2 = PRVC  
 3 = HFOV  
 4 = Volume Control

**YesNoS**  
 1=Yes  
 0=No

Pressure Support (cmH2O)	Mean Airway Pressure (cmH2O)	PEEP (cmH2O)	ETT Leak (%)	HFOV Frequency	HFOV Amplitude
<b>PS, #</b>	<b>MAP, #</b>	<b>PEEP, #</b>	<b>ETTLeak, #</b>	<b>HFOVFrequency, #</b>	<b>HFOVAmplitude, #</b>
<div> <div>ADD</div> <div>ABGVent_Vent</div> </div>					

FiO2 (###) *MUST be a decimal*	Primary reason for FiO2 change	Other FiO2 change (specify)	Primary reason for ventilator change	Other ventilator change (specify)	Extubation readiness test performed?	Notes
<b>FiO2, #</b>	<b>FiO2ReasonFor Change, #</b>	<b>FiO2OthReasonFor Change, \$</b>	<b>VentReasonFor Change, #</b>	<b>VentOthReason ForChange, \$</b>	<b>Extubation, #</b> (select one)	<b>VentNote, \$</b>
<div> <div>ADD</div> <div>ABGVent_Vent</div> </div>						

**FiO2Chng**  
 1 = PO2 or SPO2 too high  
 2 = PO2 or SPO2 too low  
 90 = Other  
 3 = No change made  
 4 = Not Reported

**VentChng**  
 1 = PCO2 too high  
 2 = PCO2 too low  
 3 = pH too high  
 4 = pH too low  
 5 = End Tidal CO2 too high  
 6 = End Tidal CO2 too low  
 7 = VT too high  
 8 = VT too low  
 90 = Other  
 9 = No change made  
 10 = Not Reported

**YesNoS**  
 1=Yes  
 0=No

## R21 Lab and Radiology Information v1.0:

SubjectID #

ItemGroupRepeatKey #

Lab (0/3) Radiolo... (0/11) -- Select to Jump --

**Title: Hemoglobin Lab Results**

Instructions: Please record a daily hemoglobin value if obtained as standard of care. If more than one hemoglobin value per day is available, record the value that is closest to one of the ventilator data capture points.

Date (DD-MMM-YYYY)	Time (HHMM)	Hgb (g/dL)
HemLabDay, #	HemLabTime, \$	Hemoglobin, #

ADD LabRad\_HemLabs

Lab (0/3) Radiolo... (0/11) -- Select to Jump --

**Title: Radiology Information**

Instructions: Please record a daily chest x-ray if obtained as standard of care.

Record if the following were reported/seen for each chest x-ray (CXR)

Date (DD-MMM-YYYY)	Lung volume (inflation)	Atelectasis?	Pneumothorax?	Pneumomediastinum?	Subcutaneous emphysema?
CXRDay, #	CXRLungVolume, #	CxrAtelectasis, #	CxrPneumothorax, #	CxrPneumomedia, #	CxrSubqEmphysema, #

ADD LabRad\_CXR

LungVol  
1 = Normal  
2 = Hyperinflation  
3 = Low (under) inflation  
99= Not reported

YesNoNR  
1=Yes  
0=No  
99 = Not Reported

Pneumoperitoneum?	Cardiomegaly?	Infiltrates?	Pulmonary Edema?	Number of quadrants?
CxrPneumoperit, #	CxrCardiomegaly, #	CxrInfiltrates, #	CxrPulmonaryEdema, #	CxrQuadrants, #

LabRad\_CXR

Infilt  
91 = None  
1 = Unilateral  
2 = Bilateral  
99= Not reported

Quad  
0 = 0  
1 = 1  
2 = 2  
3 = 3  
4 = 4  
99= Not reported

AddData (1 of 1)

## R21 Additional Data Elements v1.0:

SubjectID #

**Data (0/6)**

**Title: Additional Data Elements**

**Demographics**

Date of birth:

**Date and time patient was removed from the ventilator**

Date:   Time:   ☐ Discharged from hospital on mechanical ventilation

**Vital Status**

Vital Status at ICU Discharge:

Vital Status at Hospital Discharge:

YesNo  
1 = Yes



## Ventilator Settings Log Joined with SPO2 and Blood Gases Log

This dataset is based on the ABGVent\_Vent dataset with some observations excluded:

- If the time of the ventilator setting is missing, then the observation is excluded.
- If multiple observations with identical date and time exist for the same subject, the observation with the largest ItemGroupRepeatKey is kept.

Variables that come from the ABGVent\_SPO2 and ABGVent\_BloodGas datasets are joined to the observations from the ABGVent\_Vent dataset in the following manner. The value for each of these variables comes from the last observation (most recent) in the relevant dataset that has a date and time equal to or less than the date and time of the ventilator setting. For cases when the most recent observation is more than 4 hours before the date and time of the ventilator setting, the value of the variable is set to missing. Additionally, for variables that come from the ABGVent\_BloodGas dataset, only observations where BloodGasSource is Arterial or Capillary are considered.

Variable	Format	Type	Label	Algorithm / Notes
SubjectID		#	Subject ID	Randomly generated ID number that uniquely identifies an eligible subject across datasets
itemgrouprepeatkey		#	ItemGroupRepeatKey	= ItemGroupRepeatKey from ABGVent_Vent dataset. SubjectID + ItemGroupRepeatKey uniquely identifies records in this dataset
VentDay		#	Day of ventilator reading (relative to the date of the first ventilator reading)	= VentDay from ABGVent_Vent dataset
VentTime		#	Time of ventilator reading	= VentTime from ABGVent_Vent dataset
TotalTimeMin		#	Minutes since first ventilator reading	= Time, in minutes, since the time of the first ventilator reading
VentMode	VentMode 1 = Pressure Control 2 = PRVC 3 = HFOV 4 = Volume Control	#	Ventilator Mode	= VentMode from ABGVent_Vent dataset

VentChanges (2 of 3)

Variable	Format	Type	Label	Algorithm / Notes
VentilatorRate		#	Ventilator Rate (bpm)	= VentilatorRate from ABGVent_Vent dataset
SpontaneousResp	YesNoS 1=Yes 0=No	#	Spontaneous Respiration	= SpontaneousResp from ABGVent_Vent dataset
VTExhaled		#	VT exhaled (mL/kg)	= VTExhaled from ABGVent_Vent dataset
PIP		#	PIP (cmH20)	= PIP from ABGVent_Vent dataset
PS		#	pressure support (cmH20)	= PS from ABGVent_Vent dataset
MAP		#	mean airway pressure (cmH20)	= MAP from ABGVent_Vent dataset
PEEP		#	PEEP (cmH20)	= PEEP from ABGVent_Vent dataset
ETTleak		#	ET tube leak (%)	= ETTleak from ABGVent_Vent dataset
HFOVFrequency		#	HFOV frequency	= HFOVFrequency from ABGVent_Vent dataset
HFOVAmplitude		#	HFOV amplitude	= HFOVAmplitude from ABGVent_Vent dataset
FiO2		#	FiO2	= FiO2 from ABGVent_Vent dataset
SPO2Day		#	SPO2/End Tidal Day (relative to the date of the first ventilator reading)	= SPO2Day from ABGVent_SPO2 dataset
SPO2Time		#	SPO2/End Tidal Time	= SPO2Time from ABGVent_SPO2 dataset
SPO2		#	SPO2 pulse oximetry O2sat (%)	= SPO2from ABGVent_SPO2 dataset
EndTidalCO2		#	End tidal CO2 (mmHg)	= EndTidalCO2from ABGVent_SPO2 dataset
BloodGasLabDay		#	Day of Blood Gas Lab (relative to the date of the first ventilator reading)	= BloodGasLabDay from ABGVent_BloodGas dataset
BloodGasLabTime		#	Time of Blood Gas Lab	= SPO2Time from ABGVent_BloodGas dataset

VentChanges (3 of 3)

Variable	Format	Type	Label	Algorithm / Notes
BloodGasSource	Blood 1 = Arterial 2 = Capillary 92 = Unknown	#	Source of Drawn Blood	= SPO2Time from ABGVent_ BloodGas dataset
pH		#	pH (##.##)	= pH from ABGVent_ BloodGas dataset
PaCO2		#	PaCO2 (mmHg)	= PaCO2from ABGVent_ BloodGas dataset
PaO2		#	PaO2 (mmHg)	= PaO2from ABGVent_ BloodGas dataset
HCO3		#	HCO3 bicarb (mEq/L)	= HCO3from ABGVent_ BloodGas dataset
OXYGEN_INDEX		#	Oxygenation Index	= NULL if PaO2 = NULL = 0 else if PaO2 = 0 = (FiO2 x 100 x MAP)/PaO2 otherwise
oxygen_sat_index		#	Oxygen Saturation Index	= NULL if SPO2 = NULL = NULL else if SPO2 > 97 = 0 else if SPO2 = 0 = (FiO2 x 100 x MAP)/SPO2 otherwise
SF_RATIO		#	S/F Ratio	= NULL if FiO2 = NULL = 0 if FiO2 = 0 = NULL else if SPO2 > 97 = SPO2/FiO2 otherwise
PF_RATIO		#	P/F Ratio	= NULL if FiO2 = NULL = 0 if FiO2 = 0 = PaO2/FiO2 otherwise

## Subject-level Derived Variables

Variable	Format	Type	Label	Algorithm / Notes
SubjectID		#	Subject ID	Randomly generated ID number that uniquely identifies an eligible subject across datasets
VentFreeDays		#	28 Day ventilator-free days	= NULL if Hospital Vital Status is Dead AND time from ventilator start to ventilator stop is < 28 days = 0 else if subject was discharged from hospital on mechanical ventilation = 0 else if time from ventilator start to ventilator stop is >= 28 days = 28 – (time from ventilator start to ventilator stop) otherwise
PredictedWeight		#	Predicted Weight (kg)	For subjects with available height, weight, and gender recorded, predicted body weight calculated using a calculator (Relcore, Inc., Los Angeles, CA)
FirstPFRatio		#	First available PF Ratio	Patient's first non-missing value for PF Ratio as defined in the VentChanges dataset.
FirstPFRatioHours		#	Time of first available PF Ratio (hours after time of first recorded ventilator settings)	Number of hours from first recorded ventilator setting to the time of the ventilator setting associated with the first available PF Ratio.
FirstSFRatio		#	First available SF Ratio	Patient's first non-missing value for SF Ratio as defined in the VentChanges dataset.
FirstSFRatioHours		#	Time of first available SF Ratio (hours after time of first recorded ventilator settings)	Number of hours from first recorded ventilator setting to the time of the ventilator setting associated with the first available SF Ratio.

SubjectLevelDerived (2 of 3)

Variable	Format	Type	Label	Algorithm / Notes
FirstOI		#	First available Oxygenation Index	Patient's first non-missing value for Oxygenation Index as defined in the VentChanges dataset.
FirstOIHours		#	Time of first available Oxygenation Index (hours after time of first recorded ventilator settings)	Number of hours from first recorded ventilator setting to the time of the ventilator setting associated with the first available Oxygenation Index.
FirstOSI		#	First available Oxygen Saturation Index	Patient's first non-missing value for Oxygen Saturation Index as defined in the VentChanges dataset.
FirstOSIHours		#	Time of first Oxygen Saturation Index (hours after time of first recorded ventilator settings)	Number of hours from first recorded ventilator setting to the time of the ventilator setting associated with the first available Oxygen Saturation Index.
PFRatio24		#	PF Ratio closest to 24 (+/- 9) hours after time of first recorded ventilator settings	Patient's PF Ratio, as defined in the VentChanges dataset, that is closest to 24 hours after the time of the first recorded ventilator setting. Only values that were between 15 and 33 hours after the time of the first recorded ventilator setting are considered.
PFRatio24Hours		#	Time (hours) of PF ratio closest to 24 (+/- 9) hours	Number of hours from first recorded ventilator setting to the time of the ventilator setting associated with the PF Ratio closest to 24 hours.
SFRatio24		#	SF Ratio closest to 24 (+/- 9) hours after time of first recorded ventilator settings	Patient's PS Ratio, as defined in the VentChanges dataset, that is closest to 24 hours after the time of the first recorded ventilator setting. Only values that were between 15 and 33 hours after the time of the first recorded ventilator setting are considered.
SFRatio24Hours		#	Time (hours) of SF ratio closest to 24 (+/- 9) hours	Number of hours from first recorded ventilator setting to the time of the ventilator setting associated with the SF Ratio closest to 24 hours.

SubjectLevelDerived (3 of 3)

Variable	Format	Type	Label	Algorithm / Notes
OI24		#	Oxygenation Index closest to 24 (+/- 9) hours after time of first recorded ventilator settings	Patient's Oxygenation Index, as defined in the VentChanges dataset, that is closest to 24 hours after the time of the first recorded ventilator setting. Only values that were between 15 and 33 hours after the time of the first recorded ventilator setting are considered.
OI24Hours		#	Time (hours) of Oxygenation Index closest to 24 (+/- 9) hours	Number of hours from first recorded ventilator setting to the time of the ventilator setting associated with the Oxygenation Index closest to 24 hours.
OSI24		#	Oxygen Saturation Index closest to 24 (+/- 9) hours after time of first recorded ventilator settings	Patient's Oxygen Saturation Index, as defined in the VentChanges dataset, that is closest to 24 hours after the time of the first recorded ventilator setting. Only values that were between 15 and 33 hours after the time of the first recorded ventilator setting are considered.
OSI24Hours		#	Time (hours) of Oxygen Saturation Index closest to 24 (+/- 9) hours	Number of hours from first recorded ventilator setting to the time of the ventilator setting associated with the Oxygen Saturation Index closest to 24 hours.
BilateralInfiltrates	YESNO 1 = Yes 0 = No	#	Bilateral Infiltrates	= Yes if CXRInfiltrates (from LabRad_CXR dataset) is Bilateral for at least one record = No otherwise
QuadrantInfiltrates	YESNO	#	Quadrant Infiltrates	= Yes if CXRQuadrants (from LabRad_CXR dataset) is 1 or 2 or 3 or 4 for at least one record = No otherwise