

Public Use Dataset Annotated eCRF

**Pediatric ECMO and Cefepime
(PEACE)
CPCCRN
Protocol Number 059**

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

Protocol Version 1.06
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Annotations key:

Table name

▼ CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only

Exit

Informa...(0/16) CCC (0/12) -- Select to Jump --

Title: Patient Information

Date of registration:

RegistrDate,DATE * DD-MMM-YYYY COLUMN NAME, DATA_TYPE

Post IVH secondary to prematurity

Is the etiology of this patient's hydrocephalus post IVH secondary to prematurity?

(select one) BaselineIVH,INT * If "No", skip to Patient History

YN
1=Yes
0=No

Single-select
RESPONSE_LABEL
RESPONSE_VALUES = RESPONSE_OPTIONS_TEXT

Has the patient had any previous ventricular acc

(select one) If "Yes", provide the date(s) of previous reservoirs

Table name: Registration_PrevRes

Date(s) of previous reservoirs DD-MMM-YYYY	
<input type="text"/> ResDate,DATE	X

Add

Hispanic or Latino =1 Ethnicity,INT,ethnic *
 Not Hispanic or Latino =0
 Unknown or Not reported =92

Radio Buttons
COLUMN NAME, DATA_TYPE, RESPONSE_LABEL
RESPONSE_OPTIONS_TEXT= RESPONSE_VALUES

American Indian or Alaska Native =1 Race,INT
Race
 Asian =2
 Black or African American =3
 Native Hawaiian or Other Pacific Islander =4
 White =5
 Unknown or Not Reported =92

Checkbox
COLUMN NAME, DATA_TYPE, RESPONSE_LABEL
RESPONSE_OPTIONS_TEXT= RESPONSE_VALUES

Data Types (length):

ST – character string (3999 characters)
 INT – integer
 REAL – real number
 DATE – Date DD-MMM-YYYY (8)
 PDATE – Partial Date
 FILE – URL to a file (10 MB)

Notes

The population for the public use dataset is the 17 consented subjects.


- The datasets are primarily based on raw datasets (i.e., as captured in study database with minimal modifications). Selected derived data elements are also included.
- A masked identifier, PUDID, is present in all datasets to facilitate merging. For datasets with multiple records per subject, PUDID and ItemGroupRepeatKey uniquely identify records.
- Open text fields and other variables have been reviewed for sensitive or identifying information and modified as needed.
- All date variables are recoded to be number of days since consent date.

Table name: PKDemog

PEACE Subject Demographics v1

Demog (0/5)

Title: Demographics

Date of birth: value not provided  * (DD-MMM-YYYY) Sex: Sex,INT *
MFr
Male =1
Female =2

Ethnicity: Ethnicity,INT
Ethnic
Hispanic or Latino =1
Not Hispanic or Latino =2
Unknown or Not Reported =92

Race: RacePUD,INT
RacePUD
(select all that apply)
American Indian or Alaska Native =3
Asian =3
Black or African American =2
Native Hawaiian or Other Pacific Islander =3
White =1
Unknown or Not Reported =3

Length / Height: Height,REAL (cm) Multiple races selected = 3

Variable	Format	Type	Label	Algorithm / Notes
AgeYears	N/A	REAL	Age in years	(Consentdate – Birthdate)/365.24 rounded to one decimal place

Table name: Diagnoses

PEACE Diagnoses v1

Diagnos...(0/5)

Title: Diagnoses

Primary Diagnosis: (select one)

PrimaryDx,INT

Other (specify):

value not provided

PrimDx

1=Airway/tracheal abnormality, obstruction, surgery

2=Asthma

3=Cancer

4=Cardiac arrest

5=Cardiovascular disease - acquired

6=Cardiovascular disease - arrhythmia

7=Cardiovascular disease - congenital

8=Central nervous system infection

9=Congenital anomaly or chromosomal defect

10=Diabetes (non-DKA)

11=Diabetic ketoacidosis (DKA)

12=Drowning / asphyxia / hanging

13=Gastrointestinal disorder

14=Hematologic disorder

15=HIV infection

16=Hypoxic ischemic encephalopathy

17=Ingestion (drug or toxin)

18=Medical device malfunction

19=Musculoskeletal condition

20=Neurological miscellaneous

21=Neurological - cords, bones

22=Neurological - vascular malformations

23=Neurological CSF related (hydrocephalus / Chiari / fenestrations / arachnoid cysts)

24=Pertussis

25=Pneumonia / bronchiolitis

26=Renal failure

27=Respiratory distress / failure

28=Scoliosis / spine surgery

29=Seizures

30=Sepsis / SIRS / septic shock

31=Shock (non-septic)

32=Stroke / cerebral ischemia / cerebral infarction

33=Suicide attempt

34=Transplant

35=Trauma

90=Other

Does the subject have any chronic diagnoses?

(select one)

ChronicDxYN,INT If yes, provide diagnoses below.

YN

1=Yes

0=No

Table name: Diagnoses_ChronicDx

Chronic Diagnoses	Other (specify)
(select one) ChronicDx,INT	

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 (BPD, CF)

8=Congenital anomaly or chromosomal defect

9=Diabetes

10=Musculoskeletal

11=Neurologic - static encephalopathy

12=Neurologic - other chronic condition

13=Neurologic - chronic seizures

14=Transplant

90=Other

ChronicDxOther,ST

Table name: PKSample
PEACE Antibiotic and PK Sampling v3

Completed: 2020 1/25/2020 2/26/2020 Select to Jump

Title: Set PK Sampling Period ***If PK samples were not obtained for a set sampling period, leave this tab blank.

Subject Information for Set PK Sampling Period

Date of Administration: (DD-MMM-YYYY) Time of Administration: (HH:MM)

Date Completed: (DD-MMM-YYYY) Time Completed: (HH:MM)

Total Administration Doses: (1)

Set PK Sampling Period

Date subject started sampling: (DD-MMM-YYYY)

What is the dosing interval desired for the set PK sampling period?

(select one)

0=Freq
1=Every 6 hours
2=Every 8 hours
3=Every 12 hours
4=Every 18 hours
5=Every 24 hours

Dosing Weight: (kg)

Table name: PKSample_One

Sample #	PK Dose/Timepoint	GOAL Date (DD-MMM-YYYY)	GOAL Time (HH:MM)	ACTUAL Date (DD-MMM-YYYY)	ACTUAL Time (HH:MM)	Sample Drawn From	Other Sample Draw Site	Total Volume Collected (mL)	Temperature (°C)
(select one) <input type="text" value="PK1SampleNumber_INT"/>	(select one) <input type="text" value="PK1Timepoint_INT"/>								
PK1Dose	PK1Time								
1=01	1=Pre-dose								
2=02	2=15 minute								
3=03	3=30 minute								
4=04	4=60 minute								
5=05	5=2 hours								
6=06	6=4 hours								
7=07	7=8 hours								
8=08	8=12 hours								
9=09	9=18 hours								
10=10	10=24 hours								
11=Stop sample	11=Stop sample								
12=Stop trough sample	12=Stop trough sample								
	13=Not applicable								

What is the reason PK sampling is incomplete?

(select one)

YN
1=Yes
0=No

Other (specify):

Provide the reason PK sampling is incomplete:

1=Parent(s) or guardian(s) withdrew consent for further PK sampling
2=Subject needed massive blood product transfusion for hemorrhage
3=Subject requiring therapeutic plasma exchange
4=Subject's ECMO run terminated prior to finishing PK sampling period
5=ECMO circuit changed-out
6=ECMO circuit changed-out
7=Subject's ECMO run terminated prior to finishing PK sampling period
8=Subject's ECMO circuit changed-out
9=Subject's ECMO circuit changed-out
10=Other

Was the dosing interval shortened during this PK sampling period?

(select one)

YN
1=Yes
0=No

What was the dosing interval changed to?

(select one)

0=Freq
1=Every 6 hours
2=Every 8 hours
3=Every 12 hours
4=Every 18 hours
5=Every 24 hours

Upload Worksheet for Set PK Sampling Period

value not provided

Blood Product Transfusions For Set PK Sampling Period

Did this subject have a blood product transfusion during this PK sampling period?

(select one)

YN
1=Yes
0=No

Table name: PKSample_BloodOne

Date Transfusion Started (DD-MMM-YYYY)	Time Transfusion Started (HH:MM)	Blood Product Type	Amount Administered (mL)
<input type="text" value="PK1TRANSSTARTDAY_INT"/>	<input type="text" value="PK1TransStartTime_ST"/>	(select one) <input type="text" value="PK1BloodProduct_INT"/>	<input type="text" value="PK1BloodAmount_REAL"/>
		1=Whole blood 2=Fresh red blood cells (RBC) 3=Fresh frozen plasma (FFP) 4=Platelets 5=Cryoprecipitate	

Table name: PKSample

PEACE Antibiotic and PK Sampling v3

Title: 2nd PK Sampling Period
Antibiotic Administration for 2nd PK Sampling Period

Date of Administration: (DD-MMM-YYYY) Time of Administration: (HHMM)
 Date Completed: (DD-MMM-YYYY) Time Completed: (HHMM)
 Total Administered Dose: (mg)

2nd PK Sampling Period
 Date subject started this period: (DD-MMM-YYYY)

What is the order being entered for the 2nd PK sampling period?
 (select one)
 0=Freq
 1=Every 6 hours
 2=Every 8 hours
 3=Every 12 hours
 4=Every 18 hours
 5=Every 24 hours

Dosing Weight: (kg)

Table name: PKSample_Two

Sample #	PK Dose Therapeutic	GOAL Date (DD-MMM-YYYY)	GOAL Time (HHMM)	ACTUAL Date (DD-MMM-YYYY)	ACTUAL Time (HHMM)	Sample Drawn From	Other Sample Draw Site	Total Volume Collected (mL)	Temperature °C
<input type="text" value="PK2SampleNumber_INT"/>	<input type="text" value="PK2Timepoint_INT"/>	<input type="text" value="PK2GOALDAY_INT"/>	<input type="text" value="PK2GoalTime_ST"/>	<input type="text" value="PK2ACTUALDAY_INT"/>	<input type="text" value="PK2ActualTime_ST"/>	<input type="text" value="PK2SampleSite_INT"/>	<input type="text" value="PK2SampleSiteOther_ST"/>	<input type="text" value="PK2TotalVolume_REAL"/>	<input type="text" value="PK2Temperature_REAL"/>
<input type="text" value="PK2Qtymb"/>	<input type="text" value="PK2Timepoint_INT"/>					<input type="text" value="PK2Draw"/>			
1-01	1=10-minute dose					1=Arterial catheter			
2-01	2=15 minute					2=Venous catheter (not site of antibiotic administration)			
3-01	3=30 minute					3=ECMO circuit (not site of antibiotic administration)			
4-01	4=60 minute					0=Other			
5-01	5=1 hour								
6-01	6=2 hour								
7-01	7=3 hour								
8-01	8=4 hour								
9-01	9=6 hour								
10-01	10=8 hour								
11-01	11=12 hour								
12-01	12=18 hour								
13-01	13=24 hour								
14-01	14=Not applicable								

(select one)
 1=Yes
 0=No

Provide the reason PK sampling was not completed: Other (specify):

(select one)
 1=Parent(s) or guardian(s) withdrew consent for further PK sampling
 2=Subject needed massive blood product transfusion for hemorrhage
 3=Subject removed from continuous renal replacement therapy
 4=Subject requiring therapeutic plasma exchange
 5=Subject's ICU stay terminated prior to finalizing PK sampling period
 6=ECMO circuit changed-out
 7=Oxygenator changed-out in ECMO circuit
 8=Dosing interval changed
 9=Subject died
 0=Other

(select one)
 1=Yes
 0=No

What was the dosing interval changed to? (select one)
 0=Freq
 1=Every 6 hours
 2=Every 8 hours
 3=Every 12 hours
 4=Every 18 hours
 5=Every 24 hours

Upload Worksheet for 2nd PK Sampling:

Blood Product Transfusions For 2nd PK Sampling Period
 Did this subject have a blood product transfusion during the 2nd PK sampling period?
 (select one)
 1=Yes
 0=No

Table name: PKSample_BloodTwo

Date Transfusion Started (DD-MMM-YYYY)	Time Transfusion Started (HHMM)	Blood Product Type	Amount Administered (mL)
<input type="text" value="PK2TRANSSTARTDAY_INT"/>	<input type="text" value="PK2TransStartTime_ST"/>	<input type="text" value="PK2BloodProduct_INT"/>	<input type="text" value="PK2BloodAmount_REAL"/>
		<input type="text" value="PK2Typ"/> (select one) 1=Whole blood 2=Packed red blood cells (PRBC) 3=Fresh frozen plasma (FFP) 4=Platelets 5=Cryoprecipitate	

HMVY bUa Y. D?Gla dY

PEACE Antibiotic and PK Sampling v3

CompAnt... (0/7) 1stPKSa... (0/29) 2ndPKSa... (0/29) -- Select to Jump --

Title: Comprehensive Cefepime Administration

Table name: PKSample_Antibiotic

Date of Administration (DD-MM-YYYY)	Time of Administration (HH:MM)	Total Administered Dose (mg)	Evaluated for PK Sampling?	If evaluated, was dose used for PK Sampling?	If not used for PK sampling, why?	Other reason not used
ANTIBIOTICADMINDAY,INT	AntibioticAdminTime,ST	TotalDose,REAL	(select one) EvaluateForPKs,INT 1=Yes 0=No	(select one) PKSamp 1=Yes, 1st PK sampling 2=Yes, 2nd PK sampling 0=No, not used for PK sampling	(select one) NotUsed 1= Parent(s) or guardian(s) withdrew consent for PK sampling 2= Subject's ECMO run terminated prior to beginning PK sampling 3= Subject no longer receiving cefepime 4= Subject needed massive blood product transfusion for hemorrhage 10= Subject removed from continuous renal replacement therapy 5= Subject receiving therapeutic plasma exchange 7= Entire ECMO circuit changed-out 8= Oxygenator changed-out in ECMO circuit 9= Subject died 90= Other (specify)	(select one) WhyNotUsedForPKs,INT WhyNotUsedForPKsOther,ST

Add

Table name: PKSample
 PEACE Antibiotic and PK Sampling v2

Title: Let PK Sampling Period *If PK samples were not obtained for a 1st sampling period, leave this tab blank.**

Antibiotic Information for 1st PK Sampling Period

Date of Administration: (DD-MMM-YYYY) Time of Administration: (HHMM)

Date Completed: (DD-MMM-YYYY) Time Completed: (HHMM)

Total Administration Dose: (mg)

1st PK Sampling Period

Date subject started on sample: (DD-MMM-YYYY)

What is the initial dosing interval for this 1st PK sampling period?

(select one)

0=never
 1=Every 6 hours
 2=Every 8 hours
 3=Every 12 hours
 4=Every 18 hours
 5=Every 24 hours

Dosing Weight: (kg)

Table name: PKSample_One

Sample #	PK Dose Timepoint	GOAL Date (DD-MMM-YYYY)	GOAL Time (HHMM)	ACTUAL Date (DD-MMM-YYYY)	ACTUAL Time (HHMM)	Sample Drawn From	Other Sample Draw Site	Total Volume Collected (mL)	Temperature °C
(select one) <input type="text" value="PK1SampleNumber_INT"/> <input type="button" value="PK1SampleNumber_INT"/>	(select one) <input type="text" value="PK1Timepoint_INT"/> <input type="button" value="PK1Timepoint_INT"/>					(select one) <input type="text" value="PK1SampleSite_INT"/> <input type="button" value="PK1SampleSite_INT"/>	<input type="text" value="PK1SampleSiteOther_ST"/>	<input type="text" value="PK1TotalVolume_REAL"/>	<input type="text" value="PK1Temperature_REAL"/>
<input type="radio"/> PK1Umbd <input type="radio"/> 1=11 <input type="radio"/> 2=02 <input type="radio"/> 3=03 <input type="radio"/> 4=04 <input type="radio"/> 5=05 <input type="radio"/> 6=06 <input type="radio"/> 7=07 <input type="radio"/> 8=08 <input type="radio"/> 9=09 <input type="radio"/> 10=10 <input type="radio"/> 11=Stop sample <input type="radio"/> 12=Stop trough sample	<input type="radio"/> PK1Time <input type="radio"/> 1=Pre-dose <input type="radio"/> 2=15 minute <input type="radio"/> 3=30 minute <input type="radio"/> 4=45 minute <input type="radio"/> 5=1 hour <input type="radio"/> 6=2 hour <input type="radio"/> 7=3 hour <input type="radio"/> 8=4 hour <input type="radio"/> 9=5 hour <input type="radio"/> 10=6 hour <input type="radio"/> 11=8 hour <input type="radio"/> 12=10 hour <input type="radio"/> 13=12 hour <input type="radio"/> 14=18 hour <input type="radio"/> 15=24 hour <input type="radio"/> 16=Not applicable	<input type="text" value="PK1GOALDAY_INT"/>	<input type="text" value="PK1GoalTime_ST"/>	<input type="text" value="PK1ACTUALDAY_INT"/>	<input type="text" value="PK1ActualTime_ST"/>	<input type="radio"/> V02w <input type="radio"/> 1=Internal catheter (not site of antibiotic administration) <input type="radio"/> 2=External catheter (not site of antibiotic administration) <input type="radio"/> 3=ECHO circuit (not site of antibiotic administration) <input type="radio"/> 90=Other	<input type="text" value="PK1SampleSiteOther_ST"/>	<input type="text" value="PK1TotalVolume_REAL"/>	<input type="text" value="PK1Temperature_REAL"/>

How many samples obtained for this 1st PK sampling period? (Enter 0 if there should be a total of 03 samples)

(select one)

YN
 1=Yes
 0=No

Provide the reason PK sampling was **Not Comp**

(select one) Other (specify):

1=Parent(s) or guardian(s) withdrew consent for further PK sampling
 2=Subject needed massive blood product transfusion for hemorrhage
 3=Subject placed on continuous renal replacement therapy
 4=Subject requiring therapeutic plasma exchange
 5=Subject's ECHO run terminated prior to finishing PK sampling period
 6=Enteric ECHO circuit chipped out
 7=Oxygenator changed-out in ECHO circuit
 8=Dosing interval changed
 9=Subject died
 90=Other

Was the dosing interval shortened during this PK sampling period?

(select one)

YN
 1=Yes
 0=No

What was the dosing interval changed to?

(select one)

0=never
 1=Every 6 hours
 2=Every 8 hours
 3=Every 12 hours
 4=Every 18 hours
 5=Every 24 hours

Upload bloodbank for 1st PK Sampling Period:

Blood Product Transfusion for 1st PK Sampling Period

Did this subject have a blood product transfusion during the 1st PK sampling period?

(select one)

YN
 1=Yes
 0=No

Table name: PKSample_BloodOne

Date Transfusion Started (DD-MMM-YYYY)	Time Transfusion Started (HHMM)	Blood Product Type	Amount Administered (mL)
<input type="text" value="PK1TRANSSTARTDAY_INT"/>	<input type="text" value="PK1TransStartTime_ST"/>	(select one) <input type="text" value="PK1BloodProduct_INT"/> <input type="button" value="PK1BloodProduct_INT"/>	<input type="text" value="PK1BloodAmount_REAL"/>
		<input type="radio"/> 0=Typ <input type="radio"/> 1=Whole blood <input type="radio"/> 2=Packed red blood cells (PRBC) <input type="radio"/> 3=Plasma from plasma (FP) <input type="radio"/> 4=Platelets <input type="radio"/> 5=Cryoprecipitate	

Table name: PKSample

PEACE Antibiotic and PK Sampling v2

Title: 2nd PK Sampling Period												
Date of Administration:		PK2ANTIBIOTICADMINDAY_INT <input type="checkbox"/> (DD-MM-YYYY)			Time of Administration:						PK2AntibioticAdminTime_ST (HHMM)	
Date Completed:		PK2ANTIBIOTICSTOPDAY_INT <input type="checkbox"/> (DD-MM-YYYY)			Time Completed:						PK2AntibioticStopTime_ST (HHMM)	
Total Administration Date:		PK2Dose_REAL (mg)										
2nd PK Sampling Period												
Date subject started on current regimen:		PK2OXYGENATORSTARTDAY_INT <input type="checkbox"/> (DD-MM-YYYY)										
What is the initial dosing interval for the 2nd PK sampling period?												
Dosing Reg:		PK2InitalDoseInterval_INT <input type="checkbox"/> Pre-dose <input type="checkbox"/> Every 6 hours <input type="checkbox"/> Every 8 hours <input type="checkbox"/> Every 12 hours <input type="checkbox"/> Every 18 hours <input type="checkbox"/> Every 24 hours										
Dosing Weight (kg):		PK2DosingWeight_REAL										
Table name: PKSample_Two												
Sample #	PK Dose Timestamp	GOAL Date (DD-MM-YYYY)	GOAL Time (HHMM)	ACTUAL Date (DD-MM-YYYY)	ACTUAL Time (HHMM)	Sample Drawn From	Other Sample Draw Site	Total Volume Collected (mL)	Temperature °C			
(select one) PK2SampleNumber_INT 1=01 2=02 3=03 4=04 5=05 6=06 7=07 8=08 9=09 10=10 11=Stop sample 12=Stop trough sample	(select one) PK2Timepoint_INT 1=Pre-dose 2=15 minute 3=30 minute 4=45 minute 5=90 minute 6=1-3 hour 7=3-6 hour 8=6-12 hour 9=12-18 hour 10=18-24 hour 96=Not applicable	PK2GOALDAY_INT <input type="checkbox"/>	PK2GOALTime_ST	PK2ACTUALDAY_INT <input type="checkbox"/>	PK2ACTUALTime_ST <input type="checkbox"/> Draw <input type="checkbox"/> Arterial catheter <input type="checkbox"/> Stopper catheter (not site of antibiotic administration) <input type="checkbox"/> ECHO circuit (not site of antibiotic administration) <input type="checkbox"/> Other	PK2SampleSite_INT	PK2SampleSiteOther_ST	PK2TotalVolume_REAL	PK2Temperature_REAL			
[Back]												
This question MUST be answered for ALL subjects enrolled in PEACE for whom a 2nd sampling period was started. You will sample obtained for the 2nd PK sampling period? (Note: there should be a total of 12 samples)												
YN 1=Yes 0=No		PK2Complete_INT										
Provide the reason PK sampling for completed:		PK2NotComplete_INT			Other (specify): PK2NotCompleteOther_ST							
NotComp 1=Subject(s) or guardian(s) withdrew consent for further PK sampling 2=Subject needed massive blood product transfusion for hemorrhage 3=Subject placed on continuous renal replacement therapy 4=Subject requiring therapeutic plasma exchange 5=Subject's ECHO run terminated prior to finishing PK sampling period 6=ECMO circuit changed-out 7=Dryweight changed-out in ECHO circuit 8=Dosing interval changed 9=Subject died 96=Other												
Was the dosing interval shortened during this PK sampling period?												
YN 1=Yes 0=No		PK2DoseIntervalChange_INT										
What was the dosing interval changed to?		PK2ChangedToInterval_INT <input type="checkbox"/> Pre-dose <input type="checkbox"/> Every 6 hours <input type="checkbox"/> Every 8 hours <input type="checkbox"/> Every 12 hours <input type="checkbox"/> Every 18 hours <input type="checkbox"/> Every 24 hours										
USUAL Structure for 2nd PK Sampling Period:		value not provided										
Blood Product Transfusion for 2nd PK Sampling Period												
Did this subject have a blood product transfusion during this PK sampling period?		PK2BloodTransfusion_INT # y/n, complete the table below: <input type="checkbox"/> Yes <input type="checkbox"/> No										
Table name: PKSample_BloodTwo												
Date Transfusion Started (DD-MM-YYYY)	Time Transfusion Started (HHMM)	Blood Product Type	Amount Administered (mL)									
PK2TRNSSTARTDAY_INT <input type="checkbox"/>	PK2TransStartTime_ST	(select one) PK2BloodProduct_INT 1=Whole Blood 2=Packed red blood cells (PRBC) 3=Fresh frozen plasma (FFP) 4=Platelets 5=Cryoprecipitate	PK2BloodAmount_REAL									
[Back]												

HLVY bLa Y. D?GLa dY

PEACE Antibiotic and PK Sampling v2

1stPKSa... (0/25) 2ndPKSa... (0/25) -- Select to Jump --


Title: Comprehensive Cepipime Administration
Table name: PKSample_Antibiotic

Date of Administration (DD-MM-YYYY)	Time of Administration (HHMM)	Total Administered Dose (mg)	Evaluated for PK Sampling?	If evaluated, was dose used for PK Sampling?	If not used for PK sampling, why?	Other reason not used
ANTIBIOTICADMINDAY_INT	AntibioticAdminTime_ST	TotalDose_REAL	<small>(select one)</small> EvaluateForPKs_INT 1=Yes 0=No	<small>(select one)</small> UsedForPKs_INT PK Samp 1=Yes, 1st PK sampling 2=Yes, 2nd PK sampling 0=No, not used for PK sampling	<small>(select one)</small> WhyNotUsedForPKs_INT NotUsed 1=1 - Parent(s) or guardian(s) withdrew consent for PK sampling 2=2 - Subject's ECMO run terminated prior to beginning PK sampling 3=3 - Subject no longer receiving cefepime 4=4 - Subject needed massive blood product transfusion for hemorrhage 5=5 - Subject placed on continuous renal replacement therapy 6=6 - Subject receiving therapeutic plasma exchange 7=7 - Entire ECMO circuit changed-out 8=8 - Oxygenator changed-out in ECMO circuit 9=9 - Subject died 0=10 - Other (specify)	WhyNotUsedForPKsOther_ST

Add

HUV'Y'buJa Y. 'D?97AC

PEACE ECMO Information v3

ECMO (0/20)			
Title: ECMO Information			
ECMO Initiation			
Date of ECMO Initiation: (start of flow)	ECMOSTARTDAY,INT  (DD-MMM-YYYY)	Time of ECMO Initiation:	ECMOStartTime,ST (HHMM)
Mode of ECMO			
(select one)	ModeECMO,INT	Other (specify):	ModeECMOOther,ST
Mode 1=VA 2=VA + V 3=VA-VV 4=VV 5=VV-VA 6=VVA 7=VVDL 8=VVDL + V 90=Other			
Pump			
Is the pump type centrifugal?			
(select one)	CentrifugePump,INT	Pump ID: (from ELSO registry)	CentrifugePumpID,INT
YN 1=Yes 0=No			
Is the pump type roller head?			
(select one)	RollerPump,INT	Pump ID: (from ELSO registry)	RollerPumpID,INT
YN 1=Yes 0=No			
Oxygenator			
Is the oxygenator coated?			
(select one)	OxygenCoating,INT		
YN 1=Yes 0=No			
Type: (select one)	OxygenCoatingType,INT	Other (specify):	OxygenCoatingTypeOther,ST
Coat 1=Bioline 2=Carmeda 3=Safeline 90=Other			
Is the oxygenator a silicone lung?			
YN 1=Yes 0=No	(select one) SiliconeLung,INT	Size of oxygenator:	OxygenatorSize,REAL (m2)

Is the oxygenator hollow fiber?

(select one)

HollowFiber,INT

Vendor: (select one)

HollowFiberVendor,INT

Other (specify):

HollowFiberVendorOther,ST

YN
1=Yes
0=NoHFiber
1=Infinity
2=Lilliput
3=Medos
4=Medtronic
5=Medtronic minimax
6=Quadrox
7=Quadrox-D
8=Quadrox-iD
9=Terumo
90=Other**Tubing**

Is the circuit tubing coated?

(select one)

TubingCoating,INT

Type: (select one)

TubingCoatingType,INT

Other (specify):

TubingCoatingTypeOther,ST

YN
1=Yes
0=NoCoat
1=Bioline
2=Carmeda
3=Safeline
90=Other**Circuit Priming**Total priming volume:
(both non-blood &
blood products)

CircuitPrimeVolume,REAL (mL)

Table name: PKECMO

PEACE ECMO Information v2

ECMO (0/19)			
Title: ECMO Information			
ECMO Initiation			
Date of ECMO Initiation: (start of flow)	ECMOSTARTDAY,INT <input type="text" value="DD-MMM-YYYY"/>	Time of ECMO Initiation:	ECMOSTartTime,ST (HHMM)
Mode of ECMO			
(select one) Mode 1=VA 2=VA + V 3=VA-VV 4=VV 5=VV-VA 6=VVA 7=VVDL 8=VVDL + V 90=Other	ModeECMO,INT	Other (specify):	ModeECMOOther,ST
Pump			
Is the pump type centrifugal?			
(select one) YN 1=Yes 0=No	CentrifugePump,INT	Pump ID: (from ELSO registry)	CentrifugePumpID,INT
Is the pump type roller head?			
(select one) YN 1=Yes 0=No	RollerPump,INT	Pump ID: (from ELSO registry)	RollerPumpID,INT
Oxygenator			
Is the oxygenator coated?			
(select one) YN 1=Yes 0=No	OxygenCoating,INT		
Type: (select one) Coat 1=Bioline 2=Carmeda 3=Safeline 90=Other	OxygenCoatingType,INT	Other (specify):	OxygenCoatingTypeOther,ST
Is the oxygenator a silicone lung?			
(select one) YN 1=Yes 0=No	SiliconeLung,INT	Size of oxygenator:	OxygenatorSize,REAL (m2)

Is the oxygenator hollow fiber?

(select one) **HollowFiber,INT**
YN
1=Yes
0=No

Vendor: (select one) **HollowFiberVendor,INT**
HFiber
1=Infinity
2=Lilliput
3=Medos
4=Medtronic
5=Medtronic minimax
6=Quadrox
7=Quadrox-D
8=Quadrox-iD
9=Terumo
90=Other

Other (specify): **HollowFiberVendorOther,ST**

Tubing

Is the circuit tubing coated?

(select one) **TubingCoating,INT**
YN
1=Yes
0=No

Type: (select one) **TubingCoatingType,INT**
Coat
1=Bioline
2=Carmeda
3=Safeline
90=Other

Other (specify): **TubingCoatingTypeOther,ST**

Table name: PKECMO

PEACE ECMO Information v1



ECMO (0/20)			
Title: ECMO Information			
ECMO Initiation			
Date of ECMO Initiation: (start of flow)	ECMOSTARTDAY,INT (DD-MMM-YYYY)	Time of ECMO Initiation:	ECMOStartTime,ST (HHMM)
Mode of ECMO			
(select one) Mode 1=VA 2=VA + V 3=VA-VV 4=VV 5=VV-VA 6=VVA 7=VVDL 8=VVDL + V 90=Other	ModeECMO,INT	Other (specify):	ModeECMOOther,ST
Pump			
Is the pump type centrifugal?			
(select one) YN 1=Yes 0=No	CentrifugePump,INT	Pump ID: (from ELSO registry)	CentrifugePumpID,INT
Is the pump type roller head?			
(select one) YN 1=Yes 0=No	RollerPump,INT	Pump ID: (from ELSO registry)	RollerPumpID,INT
Oxygenator			
Date subject started on current oxygenator:	OXYGENATORSTARTDAY,INT (DD-MMM-YYYY)		
Is the oxygenator coated?			
(select one) YN 1=Yes 0=No	OxygenCoating,INT		
Type: (select one) Coat 1=Bioline 2=Carmeda 3=Safeline 90=Other	OxygenCoatingType,INT	Other (specify):	OxygenCoatingTypeOther,ST
Is the oxygenator a silicone lung?			

(select one) SiliconeLung,INT

Size of oxygenator:

OxygenatorSize,REAL (m2)

YN
1=Yes
0=No

Is the oxygenator hollow fiber?

(select one) HollowFiber,INT

Vendor: (select one)

HollowFiberVendor,INT

Other (specify):

HollowFiberVendorOther,ST

YN
1=Yes
0=NoHFiber
1=Infinity
2=Lilliput
3=Medos
4=Medtronic
5=Medtronic minimax
6=Quadrox
7=Quadrox-D
8=Quadrox-iD
9=Terumo
90=Other**Tubing**

Is the circuit tubing coated?

(select one) TubingCoating,INT

Type: (select one)

TubingCoatingType,INT

Other (specify):

TubingCoatingTypeOther,ST

YN
1=Yes
0=NoCoat
1=Bioline
2=Carmeda
3=Safeline
90=Other

PEACE Renal Replacement Therapy v1

Table name: PKRRT_RRTLog

RRT (0/6)

Title: Renal Replacement Therapy

Instructions: For renal replacement therapy, record the initial type, all start and stop dates, and any changes to the type of RRT from the time consent was obtained through the end of the calendar day on which the last PK sample from the 2nd sampling period is drawn.

Start Date (DD-MMM-YYYY)	Start Time (HHMM)	Stop Date (DD-MMM-YYYY)	Stop Time (HHMM)	Type of RRT	Other Type of RRT
RRTSTARTDAY,INT	RRTStartTime,ST	RRTSTOPDAY,INT	RRTStopTime,ST	(select one) RRTType,INT RRT 1=CWHD 2=CWHD 3=CWHD 4=UF (SCUF) 90=Other	RRTTypeSpecify,ST

Add

PEACE Fluid Balance v1





FluidBa...(0/5)

Title: Fluid Balance

Instructions: Record all I's & O's beginning the calendar day prior to the 1st PK sampling period through the end of the calendar day on which the last PK sample from the 2nd sampling period is drawn. Only one total per day will be documented. Under "Total Urinary Output," document the portion of total output that is urine for that day.

Total Daily Intake



Table name: PKFluid_Intake

Date (DD-MMM-YYYY)	Total Intake (mL)	
INTAKEDAY,INT 	TotalIntake,REAL	

Add

Total Daily Output

Table name: PKFluid_Output

Date (DD-MMM-YYYY)	Total Output (mL)	Total Urinary Output (mL)	
OUTPUTDAY,INT 	TotalOutput,REAL	UrinaryOutput,REAL	

Add

PEACE Renal and Hepatic Function Labs v1

Table name: PKLabs_Labs

Labs (0/7)

Title: Renal and Hepatic Function Labs

Instructions: Record all labs drawn as standard of care beginning the calendar day prior to the 1st PK sampling period through the end of the calendar day on which the last PK sample from the 2nd sampling period is drawn.

Date (DD-MMM-YYYY)	Time (HHMM)	BUN (mg/dL)	Creatinine (mg/dL)	Total Bilirubin (mg/dL)	ALT (IU/L)	AST (IU/L)	
PKLABSDAY,INT <input type="text"/>	PKLabsTime,ST	BUNmg,REAL	Creatinine,REAL	TotalBilirubin,REAL	ALT,REAL	AST,REAL	<input type="text"/>

Add

PEACE Concomitant Medications v1

Table name: PKConMeds_ConMeds

ConMeds (0/5)

Title: Concomitant Medications

Instructions: Document each medication *administered* to the subject for all time periods specified in the table below and record a response for all columns. Please note, the PK sampling period could span more than one day.

Calendar Day Prior to 1st PK: 0000-2359 the day prior to the 1st PK sampling period *pre-dose* sample.
Day of AND During 1st PK sampling period: Begins at 0000 on the day of the 1st PK sampling period *pre-dose* sample, and ends at the time the last sample of the 1st PK sampling period is drawn.
Calendar Day Prior to 2nd PK: 0000-2359 the day prior to the 2nd PK sampling period *pre-dose* sample.
Day of AND During 2nd PK sampling period: Begins at 0000 on the day of the 2nd PK sampling period *pre-dose* sample, and ends at the time the last sample of the 2nd PK sampling period is drawn.

Name of Medication	Calendar Day PRIOR to 1st PK	Day of AND During 1st PK Period	Calendar Day PRIOR to 2nd PK	Day of AND During 2nd PK Period	
MedName,ST	(select one) PK1PriorDay,INT YN 1=Yes 0=No	(select one) PK1SampleDay,INT YN 1=Yes 0=No	(select one) PK2PriorDay,INT YN 1=Yes 0=No	(select one) PK2SampleDay,INT YN 1=Yes 0=No	<input type="button" value="X"/>
<input type="button" value="Add"/>					




PEACE Shipping Information v1

Table name: PKShip_Ship

Shippin...(0/4)

Title: Shipping Log

Enter the total number of samples shipped to CHOP. Enter multiple shipments, if applicable.

Date Shipped	Tracking Number	Number of PK Samples Shipped	Date Received
<p>SHIPPEDDAY,INT </p>	<p>value not provided</p>	<p>(select one) PKSamplesShipped,INT NumShip 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</p>	<p>RECEIVEDDAY,INT  </p>




Table name: PK
Cefepime pharmacokinetic results

Variable	Type	Label	Algorithm / Notes
PUDID	#	Subject ID	Randomly generated ID number that uniquely identifies a subject across datasets
Period	#	Period	Sampling Period. Takes values 1 or 2.
Sample	\$	Sample	Sample Number. Takes values 1 through 10. There is also one occurrence of the value "Stop Sample", indicating early discontinuation of sampling period.
Cefepime	\$	Cefepime (ng/mL)	"<LLOQ" indicates less than the lower limit of quantitation

Table name: CEFEPIMEINDICATION**Indication for Cefepime**

Variable	Type	Label	Algorithm / Notes
PUDID	#	Subject ID	Randomly generated ID number that uniquely identifies a subject across datasets
CefepimeIndication	\$	Indication for Cefepime	