Public Use Dataset
Annotated eCRF

Biomarker Phenotyping of Pediatric Sepsis and Multiple Organ Failure (PHENOMS)
CPCCRN Protocol Number 047

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

PUD Annotated eCRF: Version 1.0
Version Date: December 17, 2018

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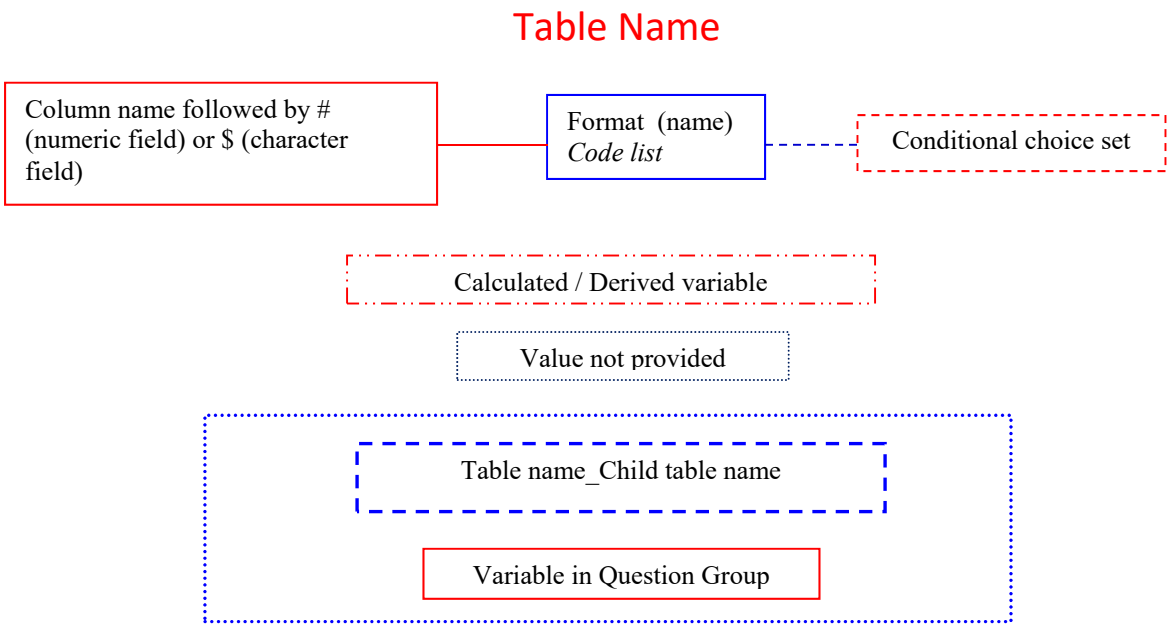
Annotations key



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 date of screening. "Date" in variable names and labels are changed to "Day" throughout. For example, the variable HospDisDate will be called HOSPDISDAY and the label will change from “Hospital discharge date" to “Hospital discharge day (relative to screening date)". No actual dates will be included.

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

Tables describing modifications and/or additions are given after each form, if applicable. A specifications table is also given for the STUDYLABS data set though no form was completed for this data collection.

Table name: Eligibility

PHENOMS Eligibility, Demographics, Permission & Consent v2

PudID # | ItemGroupRepeatKey # | Occurrence #

CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

Inclusi...(0/14) | Exclusi...(0/22) | -- Select to Jump --

Title: Inclusion Criteria

Screening Date: ScreenDay, # * (DD-MMM-YYYY)

Date of onset of sepsis induced organ failure (Day 0): OrganFailureOnsetDay, # * (DD-MMM-YYYY)

Inclusion Criteria

1. Is the subject = 44 weeks gestational age and < 18 years of age?

Inclusion1,# *
YNr
- Yes =1
- No =0

2. Is it anticipated that the subject will have an indwelling arterial or venous catheter for blood sampling for at least one study day?

Inclusion2,# *
YNr
- Yes =1
- No =0

3. Does the subject have at least one organ failure?

Inclusion3,# *
YNr
- Yes =1
- No =0

4. Has the subject met at least 2 of the 4 Systemic Inflammatory Response Syndrome (SIRS) criteria?

Inclusion4,# *
YNr
- Yes =1
- No =0

Indicate SIRS criteria met (select all that apply)
SIRSMet,#
SIRSa
- ☐ Hypothermia (< 36 degrees C) OR Fever (> 38.5 degrees C) =1
- ☐ Leukocytosis (> 12,000 mm3) OR Neutropenia (< 4,000 mm3) OR > 10% immature neutrophils =2
- ☐ Heart rate > 90th percentile for age in absence of stimulation =3
- ☐ Respiratory rate > 90th percentile for age OR Hyperventilation to PaCO2 < 32 torr OR Requirement for mechanical ventilation unrelated to drug administration =4

5. Is the subject suspected to have sepsis / infection?

Inclusion5,# *
YNr
- Yes =1
- No =0

Is the infection considered to be nosocomial by the clinical team?
(Note: infection diagnosed after 48 hours of hospital admission.)

(select one) ConsideredNosocomial,# A "No" response will not exclude subject from study.
YN
1=Yes
0=No

Specify the type of organism for this infection (select all that apply)
OrganismType,#
OrgTyp
- ☐ Bacterial =1
- ☐ Fungal =2
- ☐ Protozoal =3
- ☐ Viral =4

Please note: Inclusion criterion #5 refers to the infection information available at the time of eligibility. If later it is determined that the subject has a documented infection do not change the original information obtained at eligibility. Document the infection information on the Microbiology Results form.

Is the bacterial infection: (select one) BacterialEvidence,# *If documented, upload report to Microbiology Log.*

DocSus
1=Documented
2=Suspected

Is the fungal infection: (select one) FungalEvidence,# *If documented, upload report to Microbiology Log.*

DocSus
1=Documented
2=Suspected

Is the protozoal infection: (select one) ProtoEvidence,# *If documented, upload report to Microbiology Log.*

DocSus
1=Documented
2=Suspected

Is the viral infection: (select one) ViralEvidence,# *If documented, upload report to Microbiology Log.*

DocSus
1=Documented
2=Suspected

Table name: Eligibility

PHENOMS Eligibility, Demographics, Permission & Consent v2

CRF Header Info

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Exit

Inclusi...(0/14) | Exclusi...(0/22) | -- Select to Jump --

Title: Exclusion Criteria

Exclusion Criteria

1. Is there lack of commitment to aggressive intensive care as indicated by do not resuscitate orders and/or other limitations of care?

Exclusion1,# *
YNr
- Yes =1
- No =0

Is subject eligible?

Eligible subjects have all inclusion criteria marked as Yes, and all exclusion criteria marked as No.

Eligible,# *
YNr
- Yes =1
- No =0

Demographics

Date of birth: Birthday, # (DD-MMM-YYYY)

Sex: Sex,#
MFr
- Male =1
- Female =2

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

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

Subject Parental Permission Information

Was a parent / guardian approached for permission for their child to participate in this study?

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

Provide the reason parent / guardian was not approached for parental permission for their child:

(select one) NotApproachPermission,#
NoAprch
1=Attending physician prefers subject not be offered the opportunity to participate in the study
2=Site investigator and/or research coordinator resources inadequate to recruit additional subject
3=Parent / Guardian unavailable to provide parental permission
4=Subject enrollment quota met for seasonal quarter
90=Other

Other (specify): NotApproachPermissionOther,$

Did a parent / guardian give permission for their child to participate in this study?

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

If no, enter reason *if available*: PermissionNotGivenSpecify,$

Note: Permission may be declined without providing a reason.

Parental Permission Date / Time

Date: PermissionDay, # (DD-MMM-YYYY) Time: ConsentTime,$ (HHMM)

Did a parent / guardian give permission for DNA analysis of the subject's blood?

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

If no, enter reason *if available*: PermissionDNANotGivenSpecify,$

Note: Permission may be declined without providing a reason.

Permission for DNA Analysis Date / Time

Date: PermissionDNADay, # (DD-MMM-YYYY) Time: PermissionDNATime,$ (HHMM)

Biological Parent Consent Information

Did a biological parent consent to a one-time blood draw?

(select one) ConsentParent,#
YNNE
1=Yes
0=No
89=Not Eligible

Relationship to subject: (select one) Parent,#
BiolMF
1=biological mother
2=biological father

Consent Date / Time

Date: ConsentParentDay, # (DD-MMM-YYYY) Time: ConsentParentTime,$ (HHMM)

If no, enter reason *if available*: NoConsentParentSpecify,$

Note: Consent may be declined without providing a reason.

Race variable modification in table Eligibility:

Variable	Type	Label
Race3	#	Black or African American
Race5	#	White
Race90	#	Other
Race92	#	Unknown or Not Reported

Table name: BaseClinical

PHENOMS Baseline Clinical Data v1

▼ CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

BaseCli...(0/19)

Title: Baseline Clinical Data

Instructions: The baseline clinical data should reflect the subject's status at time of hospitalization.

Was the subject immunocompromised at the time of hospitalization?

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

Does the subject have any of the following?

Congenital immunodeficiency: (select one) CongenitalImmunodef,#
YN
1=Yes
0=No

Bone marrow or stem cell transplantation: (select one) MarrowTransplant,#
YN
1=Yes
0=No

Graft versus host disease: (select one) GraftHostDisease,#
YN
1=Yes
0=No

Solid organ transplantation: (select one) OrganTransplant,#
YN
1=Yes
0=No

Specify type of transplant: OrganSpecify,$

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

Severe malnutrition: (select one) Malnutrition,#
YN
1=Yes
0=No

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

Specify type of malignancy: MalignancySpecify,$

Chemotherapy or radiotherapy within last 3 months: (select one) Chemotherapy,#
YN
1=Yes
0=No

Human immunodeficiency virus (HIV): (select one) HIV,#
YN
1=Yes
0=No

Rheumatologic disease: (select one) RheumaDisease,#
YN
1=Yes
0=No

Neutropenia (ANC < 1000 cells/ µL): (select one) Neutropenia,#
YN
1=Yes
0=No

Sickle cell disease: (select one) SickleCell,#
YN
1=Yes
0=No

Systemic steroid use (chronic or acute): (select one) SteroidUse,#
YN
1=Yes
0=No

Asplenia or s/p Splenectomy: (select one) Asplenia,#
YN
1=Yes
0=No

Other (select one) OtherImmuno,#

Other OtherImmunoSpecify,$

immunosuppression:	YN 1=Yes 0=No	immunosuppression (specify):	

Table name: Diagnoses

PHENOMS ICU Admission Diagnoses v1

CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

Diagnos...(0/18)

Title: ICU Admission Diagnoses

Instructions: Record the primary diagnosis and all secondary diagnoses determined at ICU admission. In addition, a yes / no response must be provided for the specific conditions listed below.

Location of ICU care: (select one) ICULocation,#
ICU
1=PICU
2=CICU

Was the subject healthy prior to this hospitalization?

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

Diagnosis Information

Primary Diagnosis at ICU Admission: PrimaryDx,$

Does this subject have any secondary diagnoses upon ICU admission?

(select one) SecondDxYN,# If yes, provide diagnoses in the table below.
YN
1=Yes
0=No

Table name: Diagnoses_SecondDx

Secondary Diagnoses at ICU Admission	
SecondDx,$	X
Add	

Does the subject have any of the following conditions listed below?

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

Hemolytic anemia: (select one) HemoAnemia,#
YN
1=Yes
0=No

Rheumatologic disease: (select one) RheumaDisease,#
YN
1=Yes
0=No

Inflammatory bowel disease: (select one) IBD,#
YN
1=Yes
0=No

Immunologic renal disease: (select one) RenalDisease,#
YN
1=Yes
0=No

Chromosomal abnormality (not hereditary condition): (select one) ChromAbnormal,#
YN
1=Yes
0=No

Metabolic disease: (select one) MetabolicDisease,#
YN

1=Yes
0=No

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

Cardiovascular disease (congenital): (select one) CardiovascularDisease,#
YN
1=Yes
0=No

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

Short gut syndrome: (select one) ShortGut,#
YN
1=Yes
0=No

Post-operative / surgery: (select one) PostOp,#
YN
1=Yes
0=No

Liver disease: (select one) LiverDisease,#
YN
1=Yes
0=No

Table name: PRISM

PHENOMS PRISM III v1

▼ CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

PRISMIII (0/38)

Title: Pediatric Risk of Mortality Index, Version III

Instructions: Record the worst physiologic values obtained during the following 6 hour timeframe: 2 hours prior to ICU admission through 4 hours post ICU admission. If the timeframe spans 2 calendar days, enter the first date.

Date of PRISM III: PRISMDay, # (DD-MMM-YYYY)

Cardiovascular / Neurologic Vital Signs

Lowest Systolic Blood Pressure (SBP): PRISMLowSBP,# (mmHg)

Highest Heart Rate: PRISMHighHeartRate,# (beats/min)

Lowest Temperature: PRISMLowTemp,# (°C)

Highest Temperature: PRISMHighTemp,# (°C)

How many pupils were > 3 mm and fixed? (select one) PRISMPupilReflex,#
PR
0=0
1=1
2=2

PRISMPupilReflexND,#
PRND
☐ Pupillary reflexes unable to be assessed due to edema or eye patch =Indicated

Glasgow Coma Scale
Record the *worst* (lowest) GCS score obtained during the following 6 hour timeframe: 2 hours prior to ICU admission through 4 hours post ICU admission. Note: The responses for the 3 variables must be obtained from the same assessment.

For infants under 2 years of age, use the descriptions provided in parentheses ().

Eye Response: (select one) PRISMGCSEye,#
GCSEye
1=1 - No eye opening
2=2 - Eye opening in response to pain stimulus
3=3 - Eye opening to speech (shout)
4=4 - Eyes open spontaneously

Verbal Response: (select one) PRISMGCSVerbal,#
GCSVerb
1=1 - No verbal response
2=2 - Incomprehensible sounds (moans to pain)
3=3 - Inappropriate words (cries to pain)
4=4 - Confused (irritable,cries)
5=5 - Oriented (coos, babbles)

Motor Response: (select one) PRISMGCSMotor,#
GCSMot
1=1 - No response to pain
2=2 - Extension to pain (decerebrate)
3=3 - Flexion to pain (decorticate)
4=4 - Withdrawal to pain
5=5 - Localized pain
6=6 - Obeys commands (spontaneous)

At the time of this GCS assessment, was the subject intubated? (select one) PRISMIntubate,#
YN
1=Yes
0=No

PRISMGCSND,#
GCSND
☐ GCS not done =Indicated

Acid-Base / Blood Gases

Lowest pH: PRISMLowpH,# (#.##)

Highest pH: PRISMHighpH,# (#.##)

PRISMpHND,#
ND
☐ Not done =Indicated

Lowest PaO2: PRISMLowPaO2,# (mmHg)

PRISMPaO2ND,#
ND
☐ Not done =Indicated

Highest PCO2: PRISMHighPCO2,# (mmHg)

PRISMPCO2ND,#
ND
☐ Not done =Indicated

Chemistry Tests

Lowest Total CO2: PRISMLowTotalCO2,# (mmol/L)

Highest Total CO2: PRISMHighTotalCO2,# (mmol/L)

PRISMTotalCO2ND,INT
ND
☐ Not done =Indicated

Highest Serum Glucose: PRISMHighGlucose,# (mg/dL)

PRISMGlucoseND,#
ND
☐ Not done =Indicated

Highest Serum Potassium: PRISMHighPotassium,# (mmol/L)

PRISMPotassiumND,#
ND
☐ Not done =Indicated

Highest Creatinine: PRISMHighCreatinine,# (mg/dL)

PRISMCreatinineND,#
ND
☐ Not done =Indicated

Highest BUN: PRISMHighBUN,# (mmol/L)

PRISMBUNND,#
ND
☐ Not done =Indicated

Hematology Tests

Lowest WBC: PRISMLowWBC,# (10^3/µL)

PRISMWBCND,#
ND
☐ Not done =Indicated

Lowest Platelets: PRISMLowPlatelet,# (10^3/µL)

PRISMPlateletND,#
ND
☐ Not done

=Indicated

Highest PT: [redacted] PRISMHighPT,# (seconds)

PRISMPTND,#
ND
☐ Not done =Indicated

Highest PTT: [redacted] PRISMHighPTT,# (seconds)

PRISMPTTND,#
ND
☐ Not done =Indicated

Table name: Assent

PHENOMS Subject Assent v1

▼ CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

Assent (0/11)

Title: Subject Assent

Assent for Study Participation

Was the subject approached for assent to participate in this study?

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

Provide the reason subject not approached for assent:

(select one) NotApproachAssent,#
NoAsnt
1=Too young
2=Not mentally competent to provide assent
90=Other

Other (specify): NotApproachAssentOther,$

Did the subject assent to participate in this study?

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

If no, enter reason *if available*: NoAssentReason,$ Note: Assent may be declined without providing a reason.

Assent date and time

Assent Date: AssentDay, # (DD-MMM-YYYY) Assent Time: AssentTime,$ (HHMM)

Assent for DNA Analysis

Did subject assent for DNA analysis?

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

If no, enter reason *if available*: AssentDNANotGivenSpecify,$ Note: Assent may be declined without providing a reason.

Assent for DNA Analysis Date / Time

Date: AssentDNADay, # (DD-MMM-YYYY) Time: AssentDNATime,$ (HHMM)

Table name: Dates

PHENOMS Hospitalization Summary v3

▼ CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

Dates (0/23)

Title: Hospitalization Summary

Transfer Subject

Was this subject transferred from another hospital?

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

Previous Study Enrollment

Was this subject enrolled in the PHENOMS study during a previous hospitalization?

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

Enter the OpenClinica Subject ID from the Original enrollment: OriginalStudySubjectID,$

Hospital Admission Date and Time

Date: HospAdmitDay, # (DD-MMM-YYYY) Time: HospAdmitTime,$ (HHMM)

ICU Admission Date and Time

Date: ICUAdmitDay, # (DD-MMM-YYYY) Time: ICUAdmitTime,$ (HHMM)

ICU Discharge Information

Date: ICUDisDay, # (DD-MMM-YYYY) Time: ICUDisTime,$ (HHMM)

Vital Status at ICU Discharge: (select one) ICUVitalStatus,#
VitStat
1=Alive
0=Dead

Was an autopsy obtained?

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

Upload Full Autopsy Report: Click to upload file

Hospital Discharge Information

Date: HospDisDay, # (DD-MMM-YYYY) Time: HospDisTime,$ (HHMM)

Vital Status at Hospital Discharge: (select one) HospVitalStatus,#
VitStat
1=Alive
0=Dead

Was an autopsy obtained?

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

Upload Full Autopsy Report: Click to upload file

Vital Status at Day 28

Did subject die in hospital prior to study day 28?

(select one) Day28PriorHospDeath,#
YN
1=Yes
0=No

Vital status at Day 28: (select one) VitalStatusDay28,#

VitStatU
1=Alive
0=Dead
92=Unknown

Date Vital Status Assessed: VitalStatusDay28Day, # (DD-MMM-YYYY)

Date Subject Last Known to be Alive: LastKnownAliveDay, # Note: Complete if Vital Status at Day 28 is Dead or Unknown.

This is the **last** date the subject was known to, or is documented as being alive. (DD-MMM-YYYY)

Was an autopsy obtained?

(select one) VitalStatusDay28AutopsyObtain,#

YN
1=Yes
0=No

Upload Full Autopsy Report: Click to upload file

Table name: OrganFail

PHENOMS Organ Failure v1

▼ CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

OrganFa...(0/8)

Title: Organ Failure

Instructions: Specify which of the following organ systems failed today. Organ systems are assessed for the entire study day and need not occur at the same time.

Organ failure definitions:
Cardiovascular: Inotrope OR vasopressor infusion requirement
Pulmonary: PaO2/FiO2 ratio of < 300 mm Hg AND mechanical ventilator requirement
Hepatic: ALT > 100 U/L AND either bilirubin > 1.0 mg/dL OR INR >1.5
Renal: Creatinine > 1 mg/dL with Oliguria (urine output < 0.5 mL/kg/hr)
Hematologic: Platelet count < 100,000 cells/µL AND INR >1.5
Central Nervous System: Glasgow coma score < 12 in absence of sedatives

Study day definitions
Study Day 0 (zero): Date of onset of sepsis induced organ failure 0000 to 2359
All other study days: 0000 to 2359
Discharge prior to day 28: 0000 to ICU discharge

Date: OFIDay, # (DD-MMM-YYYY) Study day: (select one) StudyDay,#

StDay
0=0
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

Cardiovascular:

(select one) OFICardio,#

YN
1=Yes
0=No

Pulmonary:

(select one) OFIPulm,#

YN
1=Yes
0=No

Hepatic:

(select one) OFIHepatic,#

YN
1=Yes
0=No

Renal:

(select one) OFIRenal,#

YN
1=Yes

0=No

Hematologic:

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

Central Nervous System:

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

Table name: Intervent

PHENOMS Interventions, Clinical & Physical Findings v1

CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

Interve...(0/12) | Suspici...(0/11) | -- Select to Jump --

Title: ICU Interventions and Clinical Findings

Instructions: Enter the ICU interventions and clinical findings that occurred at any time on this study day.

Study day definitions
Study Day 0 (zero): Date of onset of sepsis induced organ failure 0000 to 2359
All other study days: 0000 to 2359
Discharge prior to day 28: 0000 to ICU discharge

Date: ICUIntervenDay, # (DD-MMM-YYYY)

Study day: (select one) StudyDay,#
StDay
0=0
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

ICU Interventions and Clinical Findings

On this study day, did any of the following occur at any time?

Infectious nidus removed: (select one) InfectiousNidus,#
YNNAU
1=Yes
0=No
96=Not applicable
92=Unknown

Inflammation source effectively removed: (select one) InflammSource,#
YNNAU
1=Yes
0=No
96=Not applicable
92=Unknown

Mechanical ventilation (invasive or non-invasive): (select one) MechVent,#
YN
1=Yes
0=No

Extracorporeal support (ECMO): (select one) ECMO,#
YN
1=Yes
0=No

Nitric oxide received: (select one) NitricOxide,#
YN
1=Yes

0=No

Continuous renal replacement therapy (CRRT): (select one) CRRT,#
YN
1=Yes
0=No

Immune suppressant tapered by 50%: (select one) ImmuneSuppress,#
YN
1=Yes
0=No

Plasma exchange therapy: (select one) PlasmaExchange,#
YN
1=Yes
0=No

Transfusion, PRBCs: (select one) PRBCTransfusion,#
YN
1=Yes
0=No

Transfusion, Platelets: (select one) PlateletTransfusion,#
YN
1=Yes
0=No

Table name: Intervent

PHENOMS Interventions, Clinical & Physical Findings v1

CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

Interve...(0/12) | Suspici...(0/11) | -- Select to Jump --

Title: Clinical Team Suspicions and Physical Findings

Instructions: Enter the clinical team suspicions and physical findings that occurred at any time on this study day.

Study day definitions
Study Day 0 (zero): Date of onset of sepsis induced organ failure 0000 to 2359
All other study days: 0000 to 2359
Discharge prior to day 28: 0000 to ICU discharge

Clinical Team Suspicions and Physical Findings

Does the clinical team suspect this subject may have?

Thrombocytopenia associated multiple organ failure (TAMOF): (select one) SuspectedTAMOF,#
YN
1=Yes
0=No

Sequential multiple organ failure (SMOF): (select one) SuspectedSMOF,#
YN
1=Yes
0=No

Macrophage activation syndrome/ secondary HLH: (select one) SuspectedMAS,#
YN
1=Yes
0=No

Primary HLH: (select one) SuspectedPrimaryHLH,#
YN
1=Yes
0=No

Post transplant lymphoproliferative disease: (select one) SuspectedLPD,#
YN
1=Yes
0=No

Organ rejection: (select one) SuspectedOrganRejection,#
YN
1=Yes
0=No

Graft versus host disease: (select one) SuspectedGraftHost,#
YN
1=Yes
0=No

Pancreatitis: (select one) SuspectedPancreatitis,#
YN
1=Yes
0=No

Hepatomegaly: (select one) SuspectedHepatomegaly,#
YNU
1=Yes
0=No
92=Unknown

Splenomegaly: (select one) SuspectedSplenomegaly,#
YNNAU
1=Yes
0=No
96=Not applicable
92=Unknown

Are all known infections covered by sensitive antibiotics on this day?

(select one) KnownInfectionsCovered,#

```
YN
1=Yes
0=No
```

Table name: Labs

PHENOMS Laboratory Values v1

▼ CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

SingleV...(0/28)

Title: Daily Labs: SINGLE VALUE ONLY

Instructions: Enter the lowest / highest result for each lab indicated below obtained at any time on this study day.

Study day definitions
Study Day 0 (zero): Date of onset of sepsis induced organ failure 0000 to 2359
All other study days: 0000 to 2359
Discharge prior to day 28: 0000 to ICU discharge

Date: LabDay, # (DD-MMM-YYYY)

Study day: (select one) StudyDay,#
StDay
0=0
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

LOWEST VALUES

Absolute lymphocyte count (ALC): LowLymphocyte,# (10^3/µL)
LymphocyteND,#
ND
Not done =Indicated

Absolute neutrophil count (ANC): LowNeutrophil,# (10^3/µL)
NeutrophilND,#
ND
Not done =Indicated

Hemoglobin: LowHemoglobin,# (g/dL)
HemoglobinND,#
ND
Not done =Indicated

Platelet Count: LowPlatelet,# (10^3/µL)
PlateletND,#
ND
Not done =Indicated

HIGHEST VALUES

INR: HighINR,#
INRND,#
ND
Not done =Indicated

PT: HighPT,# (seconds)
PTND,#
ND
Not done =Indicated

Creatinine: HighCreatinine,# (mg/dL)
CreatinineND,#
ND
Not done =Indicated

Total bilirubin:	HighBilirubin,# (mg/dL)	BilirubinND,# ND Not done =Indicated
Amylase:	HighAmylase,# (IU/L)	AmylaseND,# ND Not done =Indicated
Lipase:	HighLipase,# (IU/L)	LipaseND,# ND Not done =Indicated
ALT:	HighALT,# (IU/L)	ALTND,# ND Not done =Indicated
LDH:	HighLDH,# (IU/L)	LDHND,# ND Not done =Indicated
Triglycerides:	HighTriglycerides,# (mg/dL)	TriglyceridesND,# ND Not done =Indicated

PHENOMS Microbiology Results v1

CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

Microbi...(0/6)

Title: Microbiology Results

Instructions: Enter *all* microbiology results obtained from Day 0 through Day 28 or ICU discharge, whichever occurs first. In addition, microbiology results *prior to* Day 0 (date of onset of sepsis induced organ failure) should be included if relevant to the current episode of infection.

Study day definitions
Study Day 0 (zero): Date of onset of sepsis induced organ failure 0000 to 2359
All other study days: 0000 to 2359
Discharge prior to day 28: 0000 to ICU discharge

Table name: Microbiology_Microbiology

Date Specimen Collected (DD-MMM-YYYY)	Time Specimen Collected (HHMM)	Sample Site	Test Type	Test Result	If test result is positive or contaminant upload test report (including sensitivities)	
MicroDay, #	MicroTime,$	(select one) SampleSite,# Site 1=Abscess 2=Blood 3=Bronchial brush 4=Bronchoalveolar lavage 5=Nasopharyngeal 6=Pleural fluid 7=Peritoneal fluid 8=Skin 9=Spinal fluid 10=Sputum 11=Stool / Rectal 12=Surgical site 13=Urine 14=Vascular catheter 15=Wound (non-surgical) 90=Other	(select one) TestType,# Type 1=Culture 2=PCR 90=Other	(select one) TestResult,# Result 1=Positive 0=Negative 2=Contaminant	Click to upload file	X

Add

Table name: AtypicalLabs

PHENOMS Atypical Labs v1

CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

Atypica...(0/9)

Title: Atypical Labs: ALL VALUES AVAILABLE

Instructions: Enter ALL results for the labs listed below.

C-Reactive Protein (CRP), Ferritin or Free Hemoglobin

Were any results for CRP, Ferritin, or Free Hemoglobin obtained during the study?

(select one) AllLabsYN,#

YN
1=Yes
0=No

Table name: AtypicalLabs_CRP

Date (DD-MMM-YYYY)	Time (HHMM)	Test Type	Results	
AllLabsDay, #	AllLabsTime,$	(select one) AllLabsType,#	AllLabsResult,#	X

CRPFF
1=C-Reactive Protein (CRP) (mg/dL)
2=Ferritin (ng/mL)
3=Free Hemoglobin (mg/dL)

Add

Bone Marrow, Genotyping, Natural Killer Cells or sCD25

Were any results for Bone Marrow, Genotyping, Natural Killer Cells or sCD25 obtained during the study?

(select one) RareLabsYN,#

YN
1=Yes
0=No

Note: Bone marrow, genotyping, natural killer cells and sCD25 tests should NOT be drawn for the purposes of this study.

Table name: AtypicalLabs_Geno

Date (DD-MMM-YYYY)	Test Type	Upload Results	
RareLabsDay, #	(select one) RareTestType,#	Click to upload file	X

Geno
1=Bone Marrow
2=Genotyping
3=Natural Killer Cells
4=sCD25

Add

Table name: STUDYLABS

Variable	Type	Label
CRPH	#	C-reactive protein high-sensitivity (mg/dL)
CollectionDay	#	Day of sample collection (relative to screening date)
Ferritin	#	Ferritin (ng/mL)
ICUIntervenDay	#	Day for ICU interventions and clinical findings (collected daily) (relative to screening date)
SFASLigand	#	sFas Ligand (pg/mL)
TNFAlpha	Char	Blood endotoxin-stimulated TNF-alpha (pg/mL)

Table name: ImmuneMeds

PHENOMS Immune Medication Administration v1

▼ CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

ImmuneM...(0/5)

Title: Immune Medications

Instructions: For Day 0 through Day 28 or ICU discharge, whichever occurs first, enter steroids, immunosuppressive drugs, chemotherapy, and immune-modulating drugs (e.g., systemic corticosteroids, hydrocortisone, methylprednisolone, dexamethasone, primary HLH directed chemotherapy, G-CSF, GM-CSF, IVIG, etoposide, Rituximab, Tocilizumab, Infliximab, Anakinra, Dacilizumab, Basilixumab). If the subject is discharged on the medication, or still receiving it after day 28, check "Continued at Day 28/Discharge."

Study day definitions
Study Day 0 (zero): Date of onset of sepsis induced organ failure 0000 to 2359
All other study days: 0000 to 2359
Discharge prior to day 28: 0000 to ICU discharge

Were any immune medications taken during the study?

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

Table name: ImmuneMeds_ImmuneMeds

Name of Immune Medication	Start Date (DD-MMM-YYYY)	Stop Date (DD-MMM-YYYY)		
ImmuneMed,$	ImmuneStartDay, #	ImmuneStopDay, #	ImmuneContinue,# Contin ☐ Continued at Day 28/Discharge =Indicated	X

Add

The following items were appended to ImmuneMeds_ImmuneMeds:

Column Name	Data type	Description
Status	varchar	Status of coding
ImmuneMedCoded	varchar	Coded Immune Medication*

* RXNorm version 11/05/2018 was used to provide coded medication names.

PHENOMS Antimicrobial Medication Administration v1

▼ CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

Antimic...(0/4)

Title: Antimicrobial Medication Administration

Instructions: For Day 0 through Day 28 or ICU discharge, whichever occurs first, enter *only* systemic antibiotic, antifungal and antiviral medications. Topical agents to skin, eye, wounds, etc. should not be entered. If the subject is discharged on the medication, or still receiving it after Day 28, check "Continued at Day 28/Discharge."

Study day definitions
Study Day 0 (zero): Date of onset of sepsis induced organ failure 0000 to 2359
All other study days: 0000 to 2359
Discharge prior to day 28: 0000 to ICU discharge

Table name: AntimicroMeds_Antimicrobial

Name of Antimicrobial Medication	Start Date (DD-MMM-YYYY)	Stop Date (DD-MMM-YYYY)		
MicrobMed,$	MicrobStartDay, #	MicrobStopDay, #	MicrobContinue,# Contin ☐ Continued at Day 28/Discharge =Indicated	X

Add

The following items were appended to AntimicroMeds_Antimicrobial:

Column Name	Data type	Description
Status	varchar	Status of coding
MicrobMedCoded	varchar	Coded Antimicrobial Medication *

* RXNorm version 11/05/2018 was used to provide coded medication names.

Table name: Biosampling

PHENOMS Biosampling Log v3

▼ CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

◄ **Blood** (0/8) | SiRD (0/15) ► -- Select to Jump --

Title: Biosampling Log

Instructions: Enter the subject's CRISMA Lab ID# and the collection date and time of each blood sample drawn. If the biological parent consents to the one-time blood draw, enter the date and time this sample is drawn.

Note: Additional lab data will be entered into the CRISMA EDC system.

CRISMA EDC link: https://crisma.upmc.com/Apps/home/

CRISMA Lab ID#:

Subject Blood Samples

Table name: Biosampling_BloodDraw

Date of Blood Sample (DD-MMM-YYYY)	Time of Blood Sample (HHMM)	
BloodSampleDay, #	BloodSampleTime,$	X
Add		

Did the subject miss any blood draws due to site-specific IRB blood limit?

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

If yes, date of last blood draw: BloodSampleLimitDay, #

Biological Parent Blood Sample

Was a sample collected from a biological parent?

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

Date of blood sample: ParentSampleDay # (DD-MMM-YYYY)

Time of blood sample: ParentSampleTime,$ (HHMM)

Table name: ContinuedConsent

PHENOMS Subject Continued Participation Consent v1

▼ CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

Cont Co...(0/11)

Title: Subject Continued Participation Consent

Instructions: Complete for subjects that turn 18 years old during study participation.

Consent for Continued Participation

Was the subject approached for consent for continued participation in this study?

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

Provide the reason subject not approached for continued consent:

(select one) NotApproachContConsent,#
NoApprch
1=Not mentally competent to provide consent
90=Other

Other (specify): NotApproachContConsentOther,$

Did the subject consent to continued participation in this study?

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

Reason continued consent not given: ContConsentNotGiven,$

Note: Consent may be declined without providing a reason.

Continued consent date and time

Continued Consent Date: ContConsentDay, # (DD-MMM-YYYY)

Continued Consent Time: ContConsentTime,$ (HHMM)

Consent for DNA Analysis

Did the subject consent for DNA analysis?

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

If no, enter reason *if available*: ContConsentDNANotGivenSpecify,$

Note: Consent may be declined without providing a reason.

Consent for DNA Analysis Date / Time

Date: ContConsentDNADay, # (DD-MMM-YYYY)

Time: ContConsentDNATime,$ (HHMM)

Table name: WithdrawalOfConsent

PHENOMS Withdrawal from Study Participation v1

▼ CRF Header Info

Click the flag icon next to an input to enter/view discrepancy notes. Please note that you can only save the notes if CRF data entry has already started.

Exit

WoC (0/5)

Title: Withdrawal from Study Participation

Date and Time of Withdrawal

Date permission withdrawn: SubjectWithdrawnDay, # (DD-MMM-YYYY)

Time permission withdrawn: SubjectWithdrawnTime,$ (HHMM)

Subject withdrew from:

(Check all that apply)

WDfromBloodDraw,#
WoCdraw
☐ Further blood draws
=Indicated

WDfromDataCollection,#
WoCdata
☐ All further data collection
=Indicated

Reason for subject withdrawal:

WDReason,$