Prehospital **R**esuscitation **O**n **H**elicopter **S**tudy (PROHS)

Manual of Operations

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Chapter 1 Overview

Section 1.1: Contact Information

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1.2 DCC/Site Communication

Monthly Conference Calls
A regularly scheduled monthly meeting will be held on the 2nd Wednesday of each month at 3:00 p.m. central (4:00 p.m. Eastern, 1:00 p.m. Pacific).

Monthly Site Reports
The Houston Coordinating Center will issue a monthly site report which will include enrollment and data completion updates, regulatory updates and any other information which is pertinent to the study enrollment phase.

Weekly Enrollment Updates
During the enrollment period, a weekly update will be sent to the group which will show overall and by site screening and enrollment numbers.

1.3 Study Timeline

1.3.1 Overall Study Timeline

Activities	**Period 1 6/14 – 12/14**	**Period 2 1/15-12/15**	**Period 3 1/16-12/16**	**Period 4 1/17-6/17**
Planning	✔			
Site Training	✔			
IRB approval	✔			
Enrollment		✔	✔	
On-going Data Analysis		✔	✔	✔
Study Close-out				✔

1.3.2 Subject Data Collection Timeline

ASSESSMENTS	**Pre ED**	**ED**	**Inpatient 1st 24 hrs**	**Inpatient Daily Assessment**	**Discharge Information**
Eligibility Criteria	x	x			
Demographics					x
Trauma Activation	x				
EMS Care	x				
Unit arrival information		x	x		
Vital Signs	x	x	x	x	
Glasgow Coma Scale	x	x	x	x	x
Extended Glasgow Outcome Score					x
Mortality	x	x	x	x	x
Life Saving Interventions	x	x	x		
Injury Information	x	x			
Blood Products	x	x	x		
Non-blood Fluids	x	x	x		
Procoagulant Medications	x	x	x		
OR/IR Procedures			x	x	
Lab Results		x	x	x	
Hemostasis Obtained		x	x		
Complications			x	x	x
Injury Severity Score (ISS)					x
Subject Disposition					x
Past Medical History					x

Chapter 2: Recruitment/Screening/Consenting

Purpose: To clarify and standardize the procedures to be utilized to screen and enroll all eligible patients; to provide guidelines for the data collection process on all eligible subjects; and to provide background for waiver of consent.

2.1 Patient Population – the inclusion criteria is divided into two different categories based on the level of direct observation required upon patient's admission to the ED. The first category includes all trauma patients admitted to the participating Level 1 trauma centers via air ambulance (considered the "at risk" population). The second category includes more specific criteria (considered the "highest risk population").

Inclusion Criteria for "at risk" population:

1) Patients with traumatic injuries received directly from the scene via air ambulance to one of the participating Level 1 sites (did not receive lifesaving interventions at an outside hospital or healthcare facility).
2) Estimated age of 15 or older or greater than/equal to 50 kg, if age unknown.

Exclusion Criteria:

1) Prisoners – defined as those admitted directly from a correctional facility.

Inclusion Criteria for "highest risk population": Those who will be followed for direct observation data collection through initial resuscitative period following ED admission.

1) Meet at least one of the following during prehospital care:
    - HR > 120 bpm
    - SBP </= 90 mmHg
    - Penetrating truncal injury
    - Tourniquet application
    - Pelvic binder application
    - Intubation

    OR
2) Received blood products during transport (for facilities with blood products available)

*** Please note that there are no screen failures for this study. Data will be obtained on all patients meeting the "at risk" criteria (15 and older and arrived via helicopter directly from scene) through trauma registry abstraction or direct observation/medical record review.

2.2 Screening Procedures:

The clinical research staff will be in-house and available on a 24/7 basis at each center to screen all subjects who are transported via helicopter directly from the scene. A study ID will be assigned to each patient who meets the eligibility criteria (arrive via helicopter and 15 or older). The clinical research staff will begin real-time data collection on all eligible subjects (those considered "at risk" population in inclusion criteria above.)

At time of initial screening, the research staff will screen if the patient meets the inclusion criteria for "highest risk" population – see inclusion criteria in section 2.2. If the patient meets either one of the

listed criteria (HR, SBP, penetrating truncal injury, tourniquet use, pelvic binder use, or intubation) or has received at least one unit of blood products during transport, they will be followed with direct observation 1) through the initial resuscitation period which includes use of blood products, 2) patient expires, or 3) care determined futile.

For all patients that meet one of the inclusion criteria for the "highest risk" population BUT do not receive any blood products within a three hour time frame from time of ED admission, data collection will cease (complete forms related to the data collected). Additional data for this group will be collected from the participating site's trauma registry. (For example, 34 year old patient arrives at 0200 via air ambulance. In reviewing their prehospital information, it is determined SBP was above 100 mmHg, HR was 98 bpm, crush injury to lower extremities, no tourniquet or pelvic binder in place, and intubated. At 0500, the patient has not received any blood products; data collection stops and all information collected during the 3 hour period will be entered into OpenClinica.)

2.3 Data Collection Process:

For all subjects who met the "highest risk" population criteria, direct observation will continue until initial hemostasis has been achieved or patient expires.

The direct data collection will include:

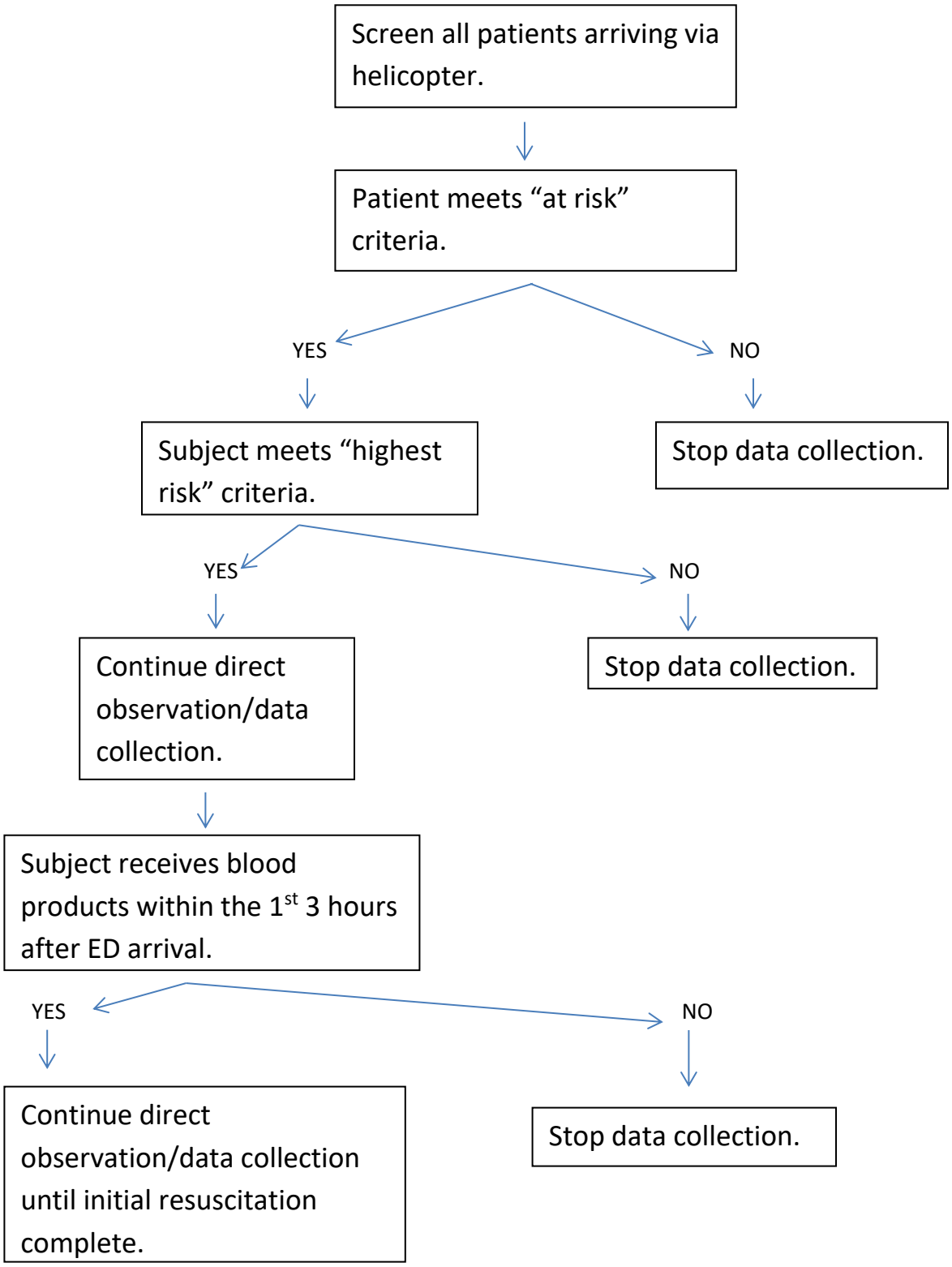
- Prehospital information obtained from the run sheets and/or prehospital clinical staff (transport time, LSIs, blood product usage, fluids, vital signs, hemorrhage control devices, EMT assessment)
- In-hospital information – time to hemostasis, time to active resuscitation stopped, LSIs, vital signs, blood product usage (type, age, amount), fluids types/volumes, routine clinical labs, interventional procedures, hemorrhage control device and procoagulant usage.

The research staff will continue to follow the subjects on a daily basis through the inpatient hospital stay until time of discharge or 30 days (whichever comes first). Daily follow up will include monitoring vital signs, standard clinical labs, procedures and complications following the injury.

It is mandatory for this study to keep a copy of the helicopter "run sheets" for all patients considered "at risk" and "highest risk".

Trauma registry data will be collected on all subjects enrolled in this study.

2.4 PROHS Guidelines for Direct Observation



2.5 Waiver of Consent:

Because this study is comparing two established standard of care methods for resuscitation, we are requesting a waiver of consent for subjects enrolled in this study. There are no study interventions, devices, pharmaceutical agents or randomization involved. The waiver meets the requirements of OHRP 45 CFT 46.116(d) – involves no more than minimal risk, will not adversely affect the welfare and rights of the subjects, cannot be practically carried out without waiver, and whenever appropriate subject will be provided with additional information.

For sites whose local IRB requires consent to be obtained, a copy of the informed consent must be sent to the HCC for review prior to IRB submission.

Chapter 3: Case Report Form Completion:
Purpose: To provide guidance and instruction on how to complete the case report forms.

3.1 General Form Instructions
Study ID Numbers: A study ID # will be assigned to each eligible subject (arrived via helicopter, 15 or older). A linking log will be kept at each site to track the study ID# with the medical record number of the subject.
Dates should be entered in dd/mon/yr format.
Times will be entered based on a 24 hour clock frame (0000 to 2359).

Form Completion:
Forms 1, 2 and 13 will be required for all patients who meet the inclusion criteria (15 or older and admitted directly from the scene via helicopter transport).
Forms 3 – 12 and 14 will also be required for all patients who meet the "Direct Observation Inclusion Criteria". (See note in Section 2.2 for those patients who are considered "highest risk" but do not receive blood products within 3 hours of ED admission.)

All data must be verifiable to a source document and all changes need an audit trail. The PROHS CRF will be considered a source document for data not recorded in the subject's medical record.
Corrections will be made with a single line strikeout with the date of change and initials of person making correction.

If additional forms are needed, number the additional pages as page #.sequential number (i.e. 6.1, 6.2, 6.3).

Please refer to the following guidelines for data entry:

- All blood products will be measured in units
- All crystalloids/colloids will be measured in mls
- Palpable diastolic B/P or HR will be recorded as palpable
- When recording the temperature, check the appropriate box for Fahrenheit or Celsius
- GCS score: The individual scores can be entered (eye movement, verbal and motor) OR the total score can be entered. If the individual scores are entered, the program will calculate the total.
- Not Applicable (NA) will be recorded as -995
- Not Detectable/Not Palpable (ND) will be recorded as -996
- Unknown will be recorded as UNK on paper and -997 in OpenClinica
- Not Recorded/Not Done (NR) will be recorded as -999

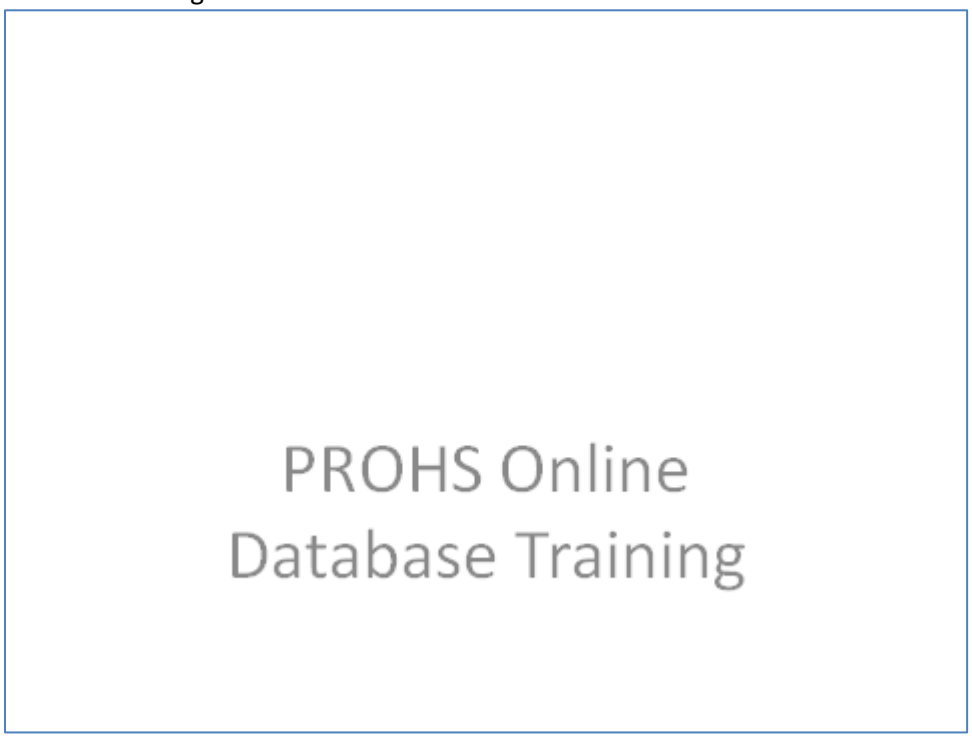
3.2 Timeline for Completion of Forms
For forms 1, 2, 3, 5, 6, and 7 will be completed and data entered within 7 working days of the time of ED admission. Form 4, the blood product and IV fluid form will be submitted as an excel spreadsheet with the majority of the information included. The expiration dates can be submitted within 30 working days.

For forms 8 through 12 and 14 will be completed and data entered within 30 working days of the time of

hospital discharge or day 30 (whichever occurred first).

For form 13 (registry information) – the form will be completed and submitted within 4 months following hospital discharge or day 30 (whichever occurred first).

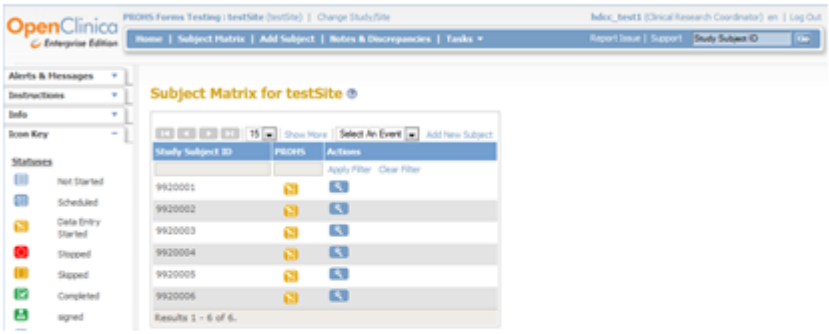
3.3 eCRF training -



PROHS Login Screen

- Access to the PROHS Online Database can be gained through the PROHS SharePoint site, using the **PROHS eCRF Data Entry** link.
- Access can also be gained using a direct link
  - https://hdcc.eclinicalhosting.com/OpenClinica
- Once at the homepage, the user must supply a username and password.
  - Both the username and password are **case sensitive**
- Click the Login button to enter the site.
- If you forget your password, contact the HDCC for password recovery.

Log Out of PROHS Online Database

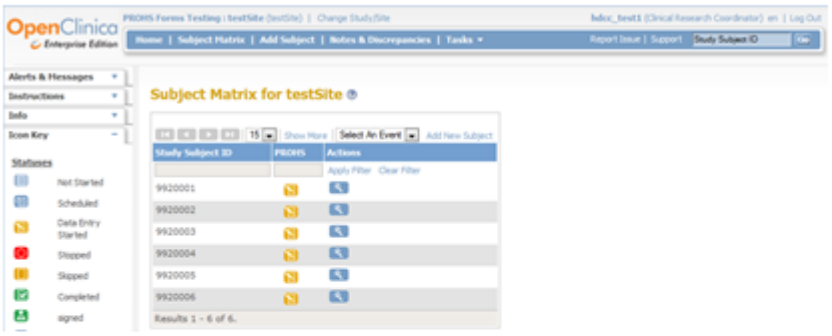


- The Log Out button is located on the right hand corner above the Navigation Bar, on the home page.
- To Log Out, click once on the Log Out button and close your browser

PROHS Online Database

SUBJECT MATRIX

Subject Matrix Overview



- The Subject Matrix is a table with information for all Subjects in a Study.
- You can view, enter, and update information for Subjects in the Study.
- There is one Subject per row, with the Study Subject ID in the first column.
- Each cell contains an icon that identifies the status of a category for the Subject

Subject Matrix Overview

- The CRFs for PROHS can be accessed by clicking once on the icon under the PROHS column.
- You can then click on View/Enter Data, to see the CRFs for this subject

PROHS Online Database

ADD SUBJECT

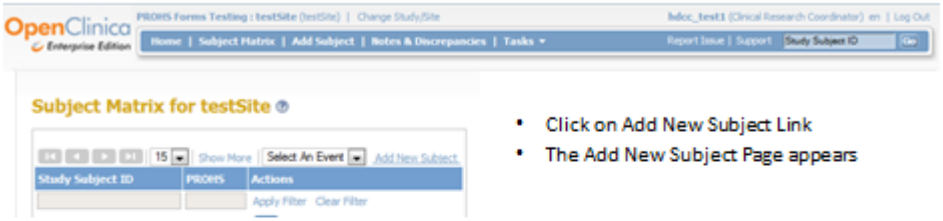
Subject ID format & range for each site

Site ID	Site Name	Subject ID Range
10	UT Houston	1020001 – 1029999
12	Cincinnati	1220001 – 1229999
14	Mayo	1420001 – 1429999
16	Portland	1620001 – 1629999
18	Seattle	1820001 – 1829999
20	Baltimore	2020001 – 2029999
22	USC	2220001 – 2229999
24	Birmingham	2420001 – 2429999
26	Tucson	2620001 – 2629999

- The Subject ID for PROHS is 7 digits long:
- The first 2 digits represent the Site using the ID from the table.
- The remaining five digits represent the Subject.
- The Subject IDs are going to be in sequential order.
- The range of the Subject IDs is:
  - **XX20001 – XX29999**

  where XX(the first 2 digits) represent the Site ID
  - So, for your site, the first two digits will always be your Site ID

Add a Subject



- Click on Add New Subject Link
- The Add New Subject Page appears

- Enter the Study ID and select PROHS from the Study Event
- Click once on the Add button to add the new Subject ID to your site.
- You do not need to enter the Enrollment or Start Dates, these will be prepopulated with the date the Subject is added.

PROHS Online Database

ENTER DATA INTO A eCRF

eCRF Layout

- The layout of an eCRF is:
  - Current Section Tab
  - Other Section Tab
  - Section Drop Down List
  - Title
  - Instructions
  - Body of Current Section
  - Question Headers
  - An asterisk in orange * indicates a required field. You cannot save the eCRF without entering the data for a required field.

eCRF Layout

- Each Item in a section is numbered, i.e. on the Current Section Tab, 0/22 indicates that there are 22 elements that can be completed for this section.
- Once you have completed the elements for the current section, you need to click Save to proceed to the next section.
- PROHS Online Database will automatically load the next section

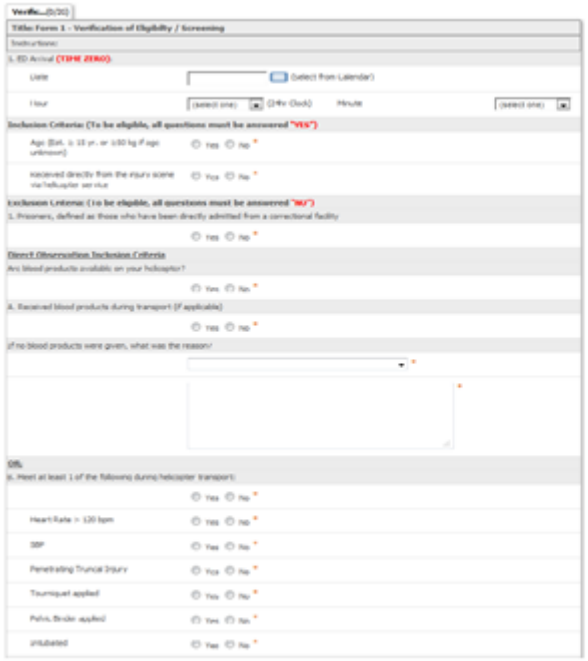
Codes for missing data

	CRF code	eCRF Code
Not Applicable	NA	–995
Not Detectable	ND	–996
Unknown	NK	–997
Not Palpable	NP	–998
Not Recorded/Not Done	NR	–999

- Use these codes for missing data.
- These codes are in the Manual of Instruction for the CRFs and located below the Table of Contents for the CRFs
  - Use the **CRF code** for the paper forms
  - Use the **eCRF code** when entering data in PROHS Online Database
    - Must put a (-)minus sign before numeric value

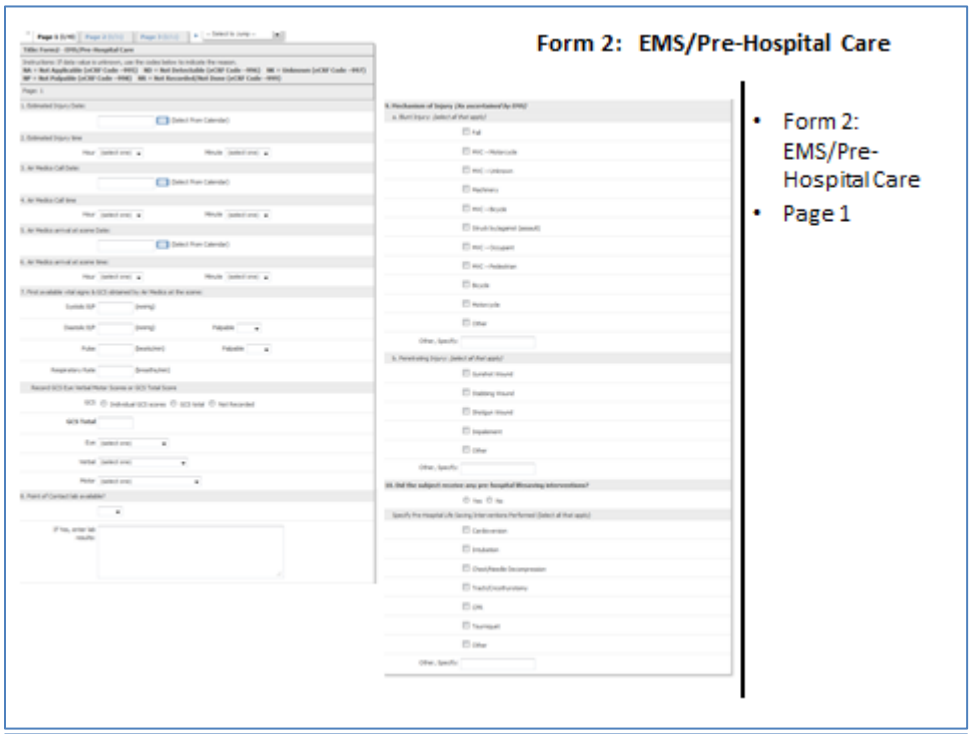
PROHS Online Database

eCRF SCREENSHOTS



Form 1: Screening

- Form 1: Screening


Form 2: EMS/Pre-Hospital Care
• Form 2: EMS/Pre-Hospital Care
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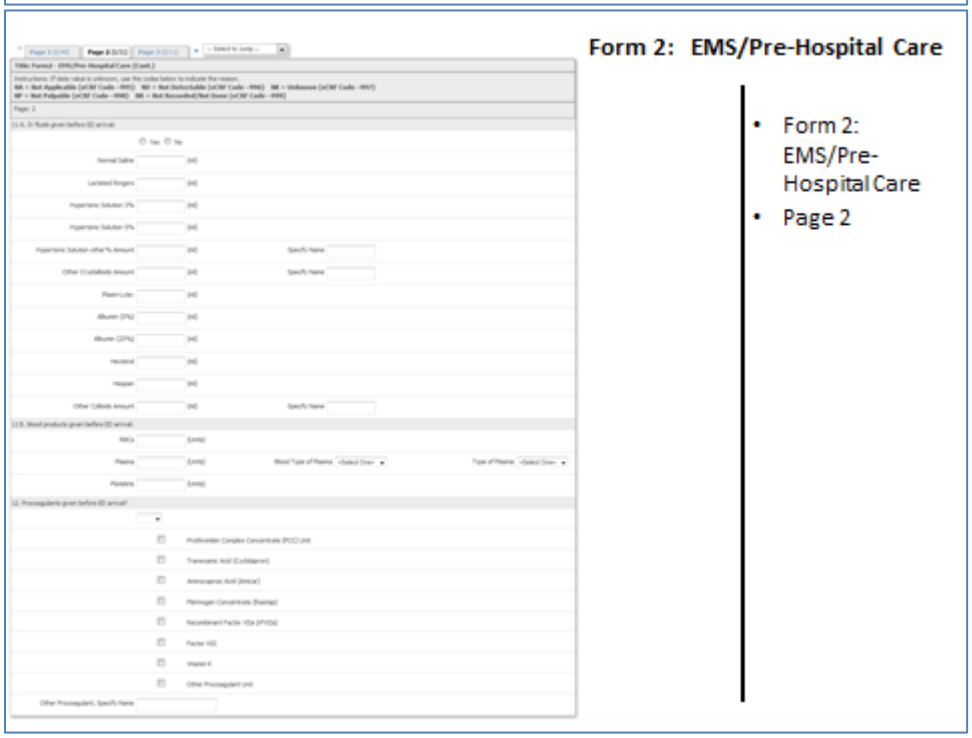
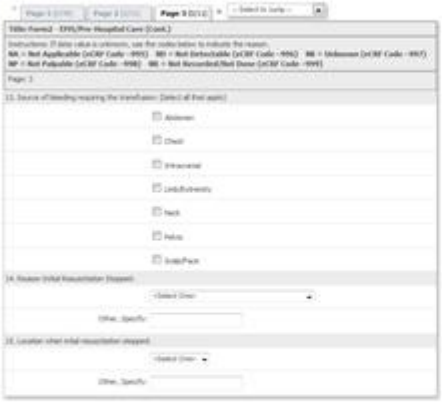

Form 2: EMS/Pre-Hospital Care
• Form 2: EMS/Pre-Hospital Care
• Page 2

Form 2: EMS/Pre-Hospital Care



- Form 2: EMS/Pre-Hospital Care
- Page 3

Form 3: Initial 24 hrs. Vital Signs & GCS

- Form 3: Initial 24 hrs. Vital Signs & GCS
- Vital Signs Admissions
- Page 1

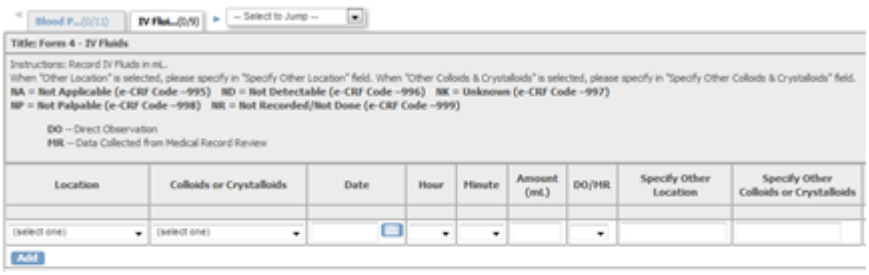
Form 3: Initial 24 hrs. Vital Signs & GCS

- Form 3: Initial 24 hrs. Vital Signs & GCS
- Vital Signs 24 hours
- Page 2

Form 4: IV Fluids & Blood Products

- Form 4: IV Fluids & Blood Products
- Page 1
- Blood Products

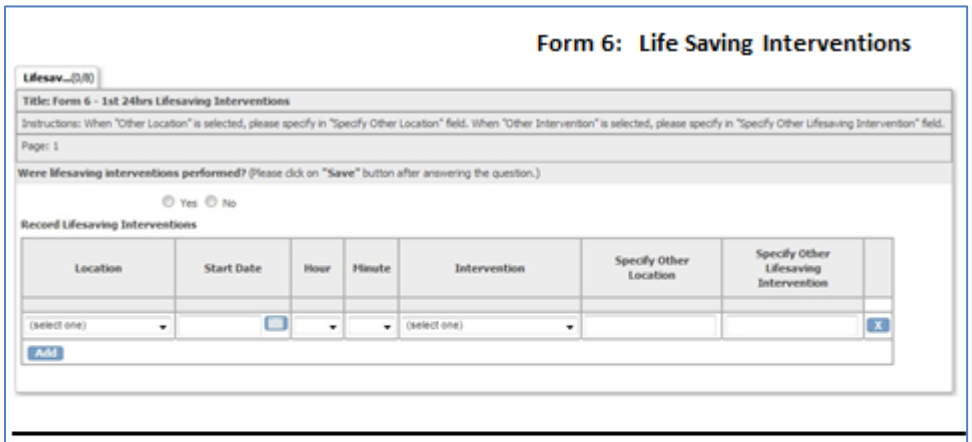
Form 4: IV Fluids & Blood Products



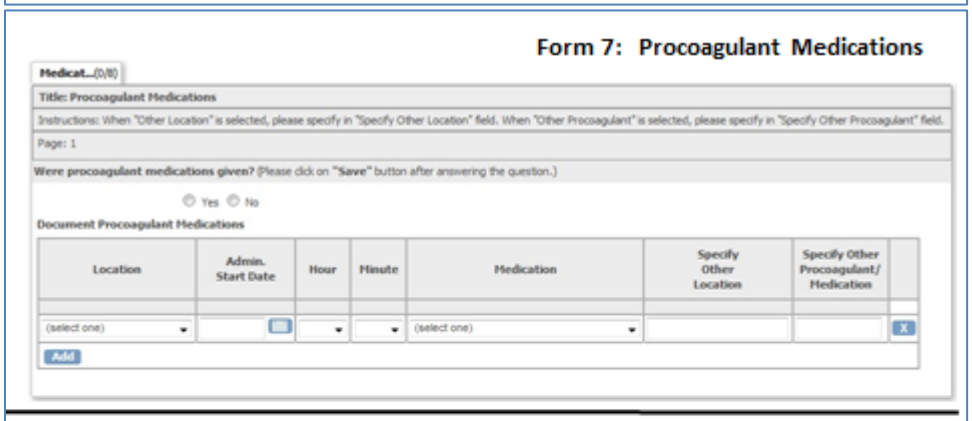
- Form 4: IV Fluids & Blood Products
- Page 2
- IV Fluids

Form 5: End of Resuscitation

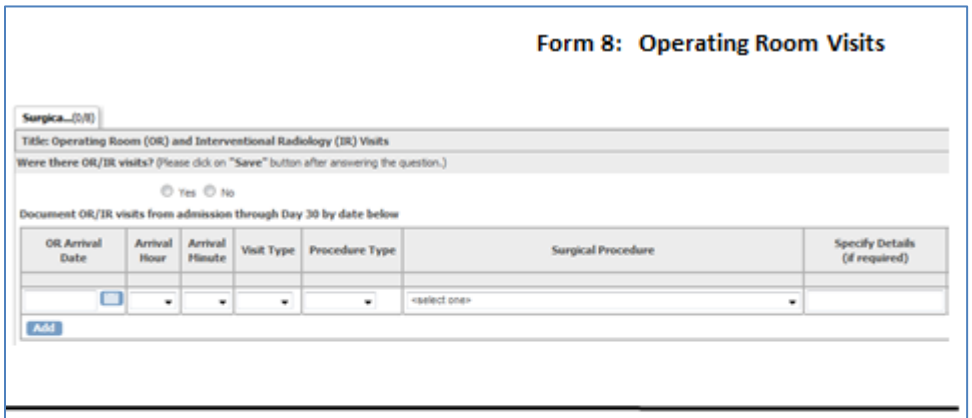
- Form 5: End of Resuscitation



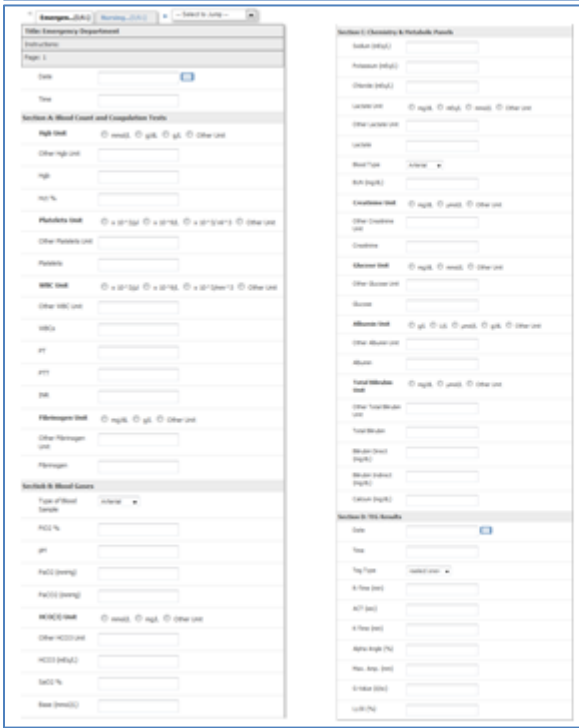
- Form 6: Life Saving Interventions



- Form 7: Procoagulant Medications

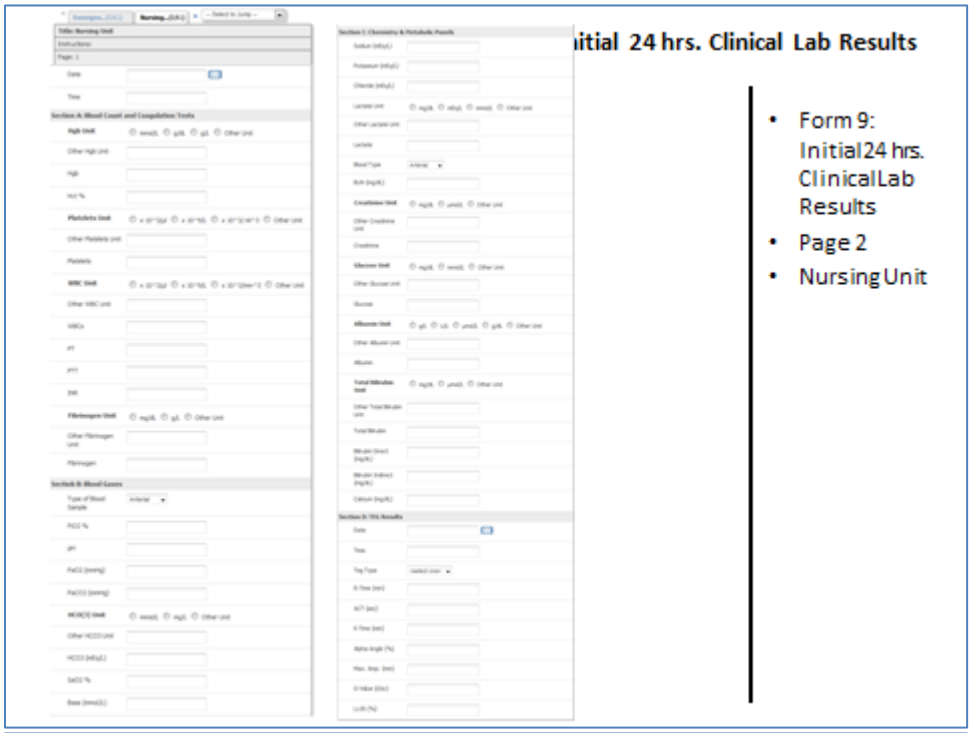


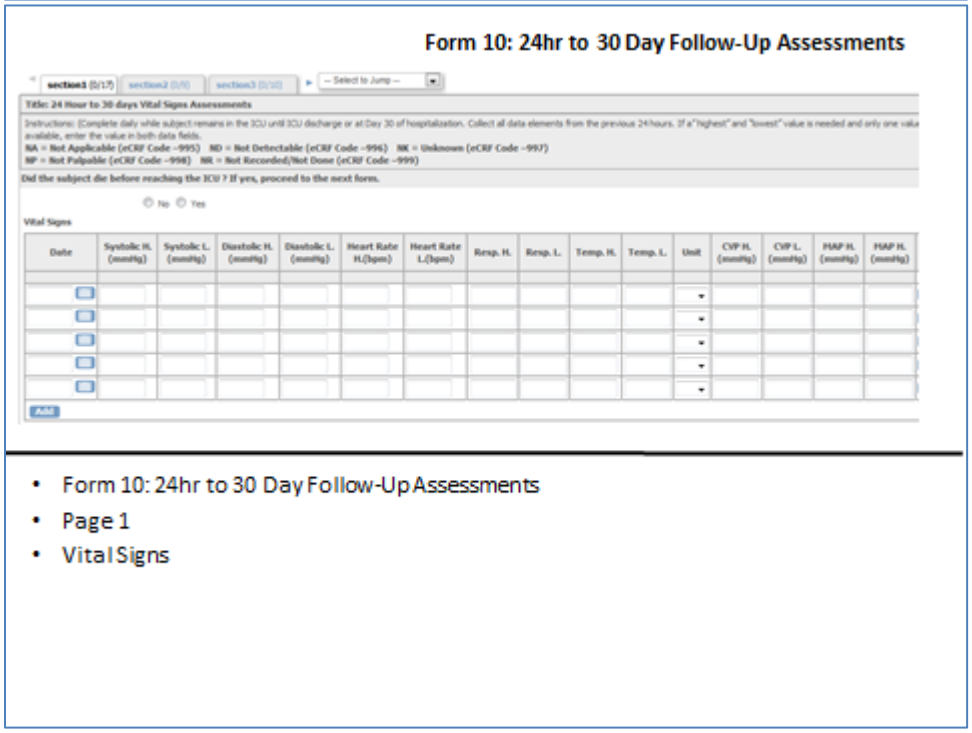
- Form 8: Operating Room Visits



Form 9: Initial 24 hrs. Clinical Lab Results

- Form 9: Initial24 hrs. ClinicalLab Results
- Page 1
- Emergency Department


itial 24 hrs. Clinical Lab Results
• Form 9: Initial24 hrs. ClinicalLab Results
• Page 2
• Nursing Unit


Form 10: 24hr to 30 Day Follow-Up Assessments
• Form 10: 24hr to 30 Day Follow-Up Assessments
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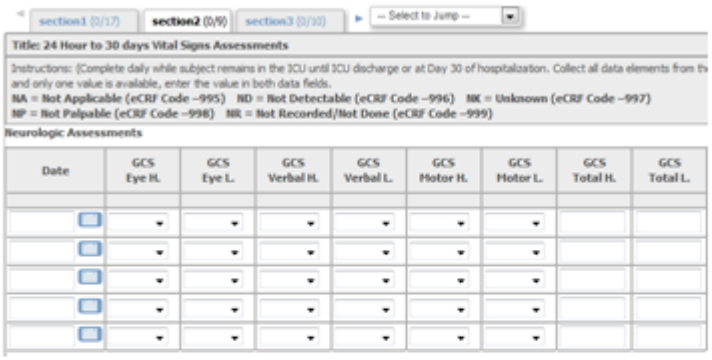
• Vital Signs

Form 10: 24hr to 30 Day Follow-Up Assessments


section1 (0/17) | **section2 (0/9)** | section3 (0/10) | -- Select to Jump --

Title: 24 Hour to 30 days Vital Signs Assessments

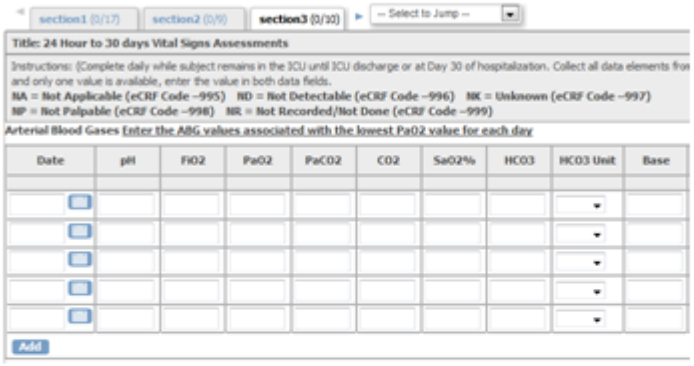
Instructions: (Complete daily while subject remains in the ICU until ICU discharge or at Day 30 of hospitalization. Collect all data elements from th
and only one value is available, enter the value in both data fields.
NA = Not Applicable (eCRF Code –995) ND = Not Detectable (eCRF Code –996) NK = Unknown (eCRF Code –997)
NP = Not Palpable (eCRF Code –998) NR = Not Recorded/Not Done (eCRF Code –999)

Neurologic Assessments

Date	GCS Eye H.	GCS Eye L.	GCS Verbal H.	GCS Verbal L.	GCS Motor H.	GCS Motor L.	GCS Total H.	GCS Total L.

- Form 10: 24hr to 30 Day Follow-Up Assessments
- Page 2
- Neurologic Assessments

Form 10: 24hr to 30 Day Follow-Up Assessments


section1 (0/17) | section2 (0/9) | **section3 (0/10)** | -- Select to Jump --

Title: 24 Hour to 30 days Vital Signs Assessments

Instructions: (Complete daily while subject remains in the ICU until ICU discharge or at Day 30 of hospitalization. Collect all data elements fro
and only one value is available, enter the value in both data fields.
NA = Not Applicable (eCRF Code –995) ND = Not Detectable (eCRF Code –996) NK = Unknown (eCRF Code –997)
NP = Not Palpable (eCRF Code –998) NR = Not Recorded/Not Done (eCRF Code –999)

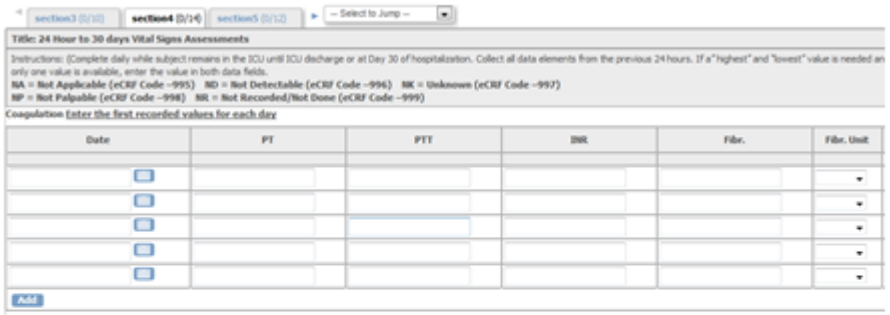
Arterial Blood Gases Enter the ABG values associated with the lowest Pa02 value for each day

Date	pH	FiO2	PaO2	PaCO2	CO2	SaO2%	HCO3	HCO3 Unit	Base

Add

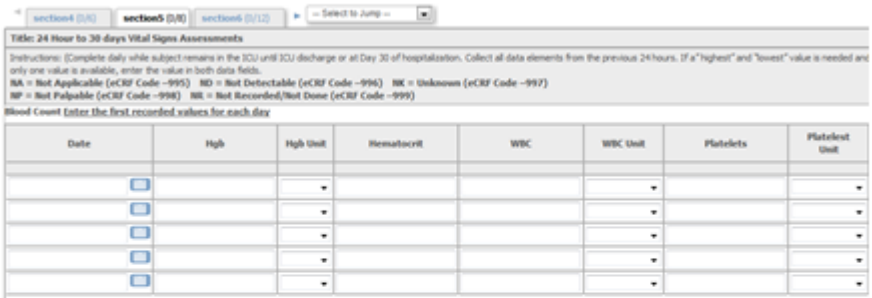
- Form 10: 24hr to 30 Day Follow-Up Assessments
- Page 3
- Arterial Blood Gases

Form 10: 24hr to 30 Day Follow-Up Assessments



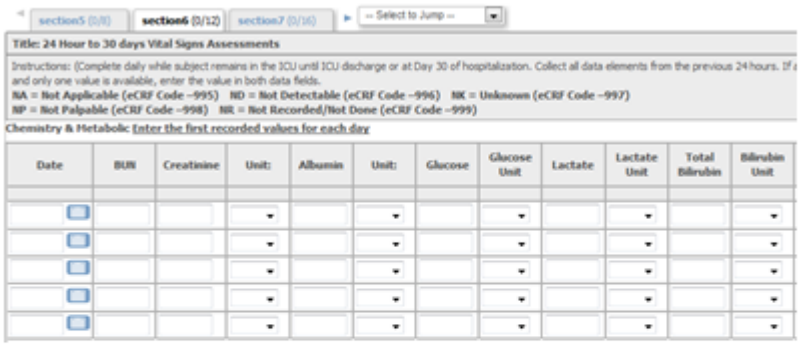
- Form 10: 24hr to 30 Day Follow-Up Assessments
- Page 4
- Coagulation

Form 10: 24hr to 30 Day Follow-Up Assessments



- Form 10: 24hr to 30 Day Follow-Up Assessments
- Page 5
- Blood Count

Form 10: 24hr to 30 Day Follow-Up Assessments



Title: 24 Hour to 30 days Vital Signs Assessments

Instructions: (Complete daily while subject remains in the ICU until ICU discharge or at Day 30 of hospitalization. Collect all data elements from the previous 24 hours. If a and only one value is available, enter the value in both data fields.
NA = Not Applicable (eCRF Code –995) ND = Not Detectable (eCRF Code –996) NK = Unknown (eCRF Code –997)
NP = Not Palpable (eCRF Code –998) NR = Not Recorded/Not Done (eCRF Code –999)

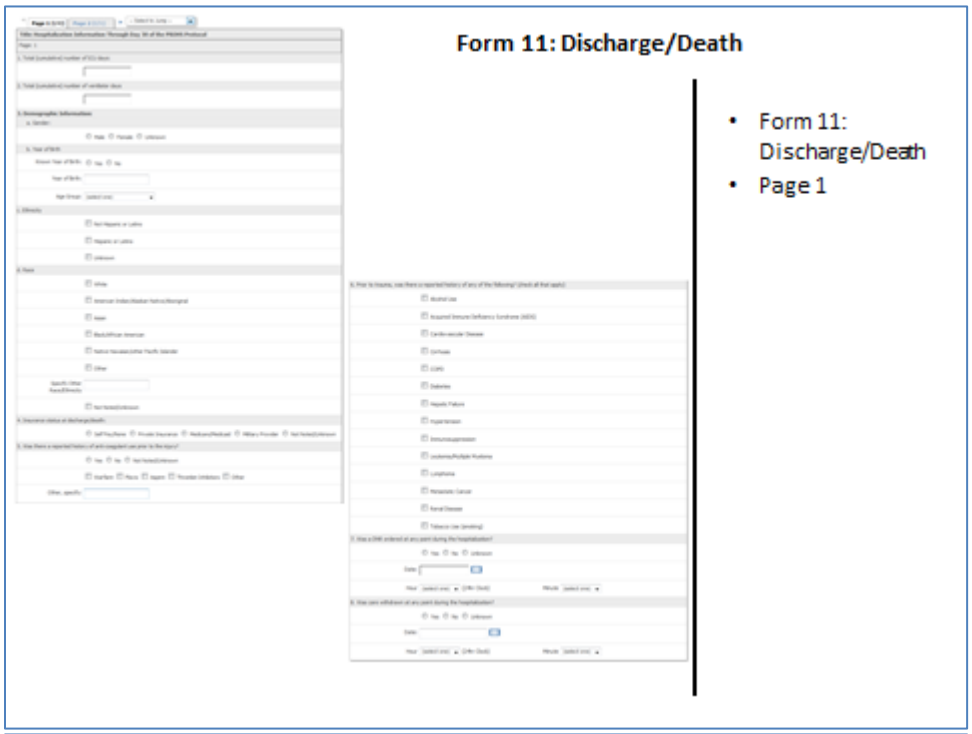
Chemistry & Metabolic Enter the first recorded values for each day

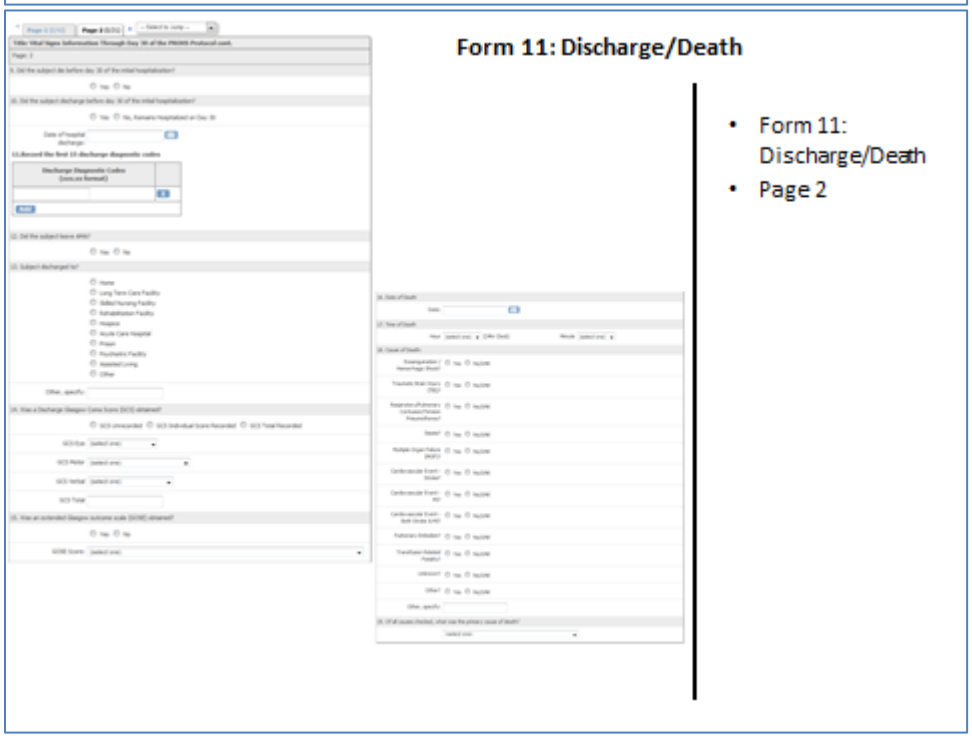
Date	BUN	Creatinine	Unit:	Albumin	Unit:	Glucose	Glucose Unit	Lactate	Lactate Unit	Total Bilirubin	Bilirubin Unit

- Form 10: 24hr to 30 Day Follow-Up Assessments
- Page 6
- Chemistry and Metabolic

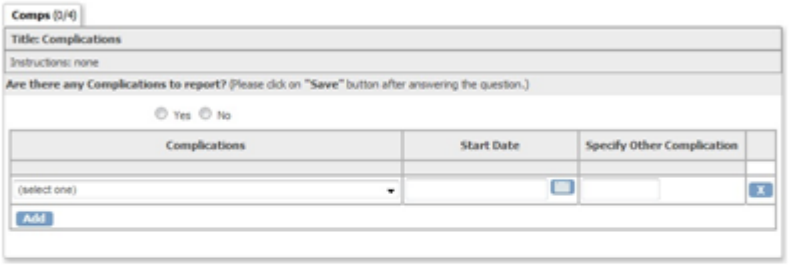
Form 10: 24hr to 30 Day Follow-Up Assessments

- Form 10: 24hr to 30 Day Follow-Up Assessments
- Page 7
- Other Assessments


Form 11: Discharge/Death
• Form 11: Discharge/Death
• Page 1


Form 11: Discharge/Death
• Form 11: Discharge/Death
• Page 2

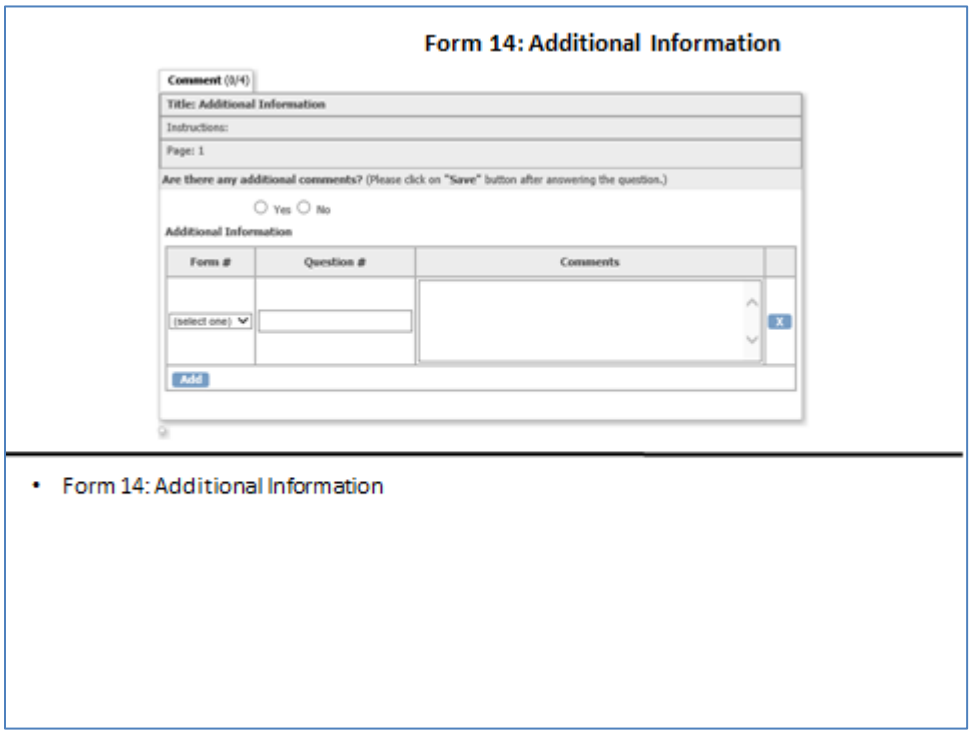
Form 12: Complications



- Form 12: Complications

Form 13: Trauma Registry Data Form

- Form 13: Trauma Registry Data Form



3.4 Individual Case Report Form Instructions

Form 1: Verification of Eligibility/Screening

ED Arrival information – enter the date and time of patient's arrival to the ED.

Inclusion Criteria – check the "yes" or "no" box for #1 and #2. If no is checked, the patient is not eligible for the study – stop data collection.

Exclusion Criteria – check the yes or no box. If yes is checked, patient is not eligible – stop data collection.

Direct Observation Inclusion Criteria

Blood products available on helicopter – yes/no – if yes, complete question A and B; if no, complete question B.

Question A – check yes or no – if yes is checked, check the yes or no box for each criteria (6 in total).

Question B – check yes or no

For the sites with blood products available on the helicopter, complete one of the text boxes with the reason blood products were not given if the patient was eligible. (For example, a reason could be – not enough time during flight, unable to get IV access, etc.)

Form 2: EMS/Pre-Hospital Care

Q1 & 2 – Date and time of injury – this is an estimated date and time.

Q3 & 4 - Date and time the air medic team was called to dispatch to scene.

Q5 & 6 – Date and time of air medic team arrival to the scene.

Q7 – Enter the first available vital signs and GCS following the helicopter crew's arrival to the scene.

Q8 - If point of care blood draws are done as standard of care during transport, check yes and enter the

results in the text box.
Q9 – Check all boxes that apply for both blunt and penetrating. The subject may have more than one cause in blunt, penetrating or both.
Q10 – Check the yes or no box. If the yes box is checked, types of LSIs will appear; check all LSIs which were done.
Q11 – Enter the amount of fluids and blood products given up to time of ED arrival. If you do not have the exact amount, an estimate is acceptable.
11a) Crystalloids and colloids are recorded in mls (ccs).
11b) Blood products are recorded in units.
If the subject received a partial unit, record it as a decimal (1/2 bag = 0.5).
Q12 - Check yes or no if procoagulants were given during transport. If yes is checked, please check the name. If the procoagulant is not listed, check other and add the procoagulant used.
Q13 – Check the boxes for all sources of bleeding identified. More than one box can be checked. **(This question should be answered by the prehospital EMS/flight personnel. This is based on what they think the source of bleeding is – NOT THE ED or TRAUMA PHYSICIAN RESPONDING TO CALL IN ED.)**
Q14 – In the event resuscitation was stopped during the transport or patient arrived to the ED as DOA, please indicate the reason resuscitation was stopped.

Form 3: Initial 24 hour Vital Signs and Glasgow Coma Scale (GCS) Score
******* This form will collect the first available vital signs and GCS score at the **time of ED arrival** and at **time of arrival to the first nursing unit** after admission (i.e. ICU, IMU, other nursing unit). There are 2 tabs at top of page for this form – one for ED admission and one for nursing unit admission.

Do not record the pre-hospital vital signs & GCS score here. The pre-hospital vital signs should be recorded on form 2 only.

If all vital signs and GCS are not collected at the same time, enter the date and time for the 1st recorded vital sign/GCS.

Reminder:
For the temperature box, check the correct box for Fahrenheit or Celsius.
For the GCS, you may either enter in the individual scores for Eye movement, Verbal, and Motor **OR** you can enter the total score. You do not have to enter both the individual scores and the total score.

Form 4: IV Fluids and Blood Products Transfusion Record
IV fluids and blood products will be captured for the 1st 24 hours after ED admission only. There are 2 tabs for this form – the first tab is for blood product administration only and the 2nd tab is for IV fluids. Blood products and IV fluids given prior to ED arrival will be captured on Form 2 only.

For those subjects who are followed with direct observation, the direct observation will continue until initial resuscitation has been achieved. The research staff should continue to monitor the subject's status frequently (every 1 to 2 hours) through the 24 hour period to capture additional fluids/blood products and other interventions.

For those patients who are followed for 3 hours and do NOT receive blood products, check the box, "no

blood products given in 1st 3 hours after ED admission.

For clarification, 1 unit of platelets = 6 pack of platelets; a unit of jumbo plasma = 2 units.

This form will be in an excel spreadsheet format (similar to PROPPR) to avoid any potential delays with entering the data online and also to allow each site to obtain accession #s and expiration date at a later time in the event it can't be obtained real time.

Form 5: End of Resuscitation

Q1a – Indicate ALL areas of bleeding that required resuscitation based on the surgeon's interpretation. More than one box can be checked.

Q1b – Of all the boxes checked in question 1a, select the primary source of bleeding.

Q2a – Indicate the primary reason initial resuscitation was stopped.

The definition for anatomic hemostasis and active resuscitation with blood products stop time is as follows:

Anatomic hemostasis – Surgeon declares hemostasis, based on the following criteria: a) no bleeding requiring intervention in the surgical field or b) in the IR suite, resolution of blush after embolization.

Active resuscitation – Surgeon and/or anesthesiologist agree that patient is adequately resuscitated based on the following criteria, if available: a) stable or increasing blood pressure, b) stable or decreasing heart rate, c) stable or increasing urine output, and/or d) decreasing requirement for pressors to maintain stable blood pressure.

In the event, the reason is not hemostasis achieved, care determined futile or patient expired, check the "other" box and add the reason in the text box. There should be very few reasons for "other".

Q2b – Select the location where initial resuscitation was stopped.

Q3 – Clinically coagulopathic is defined as bleeding from injured surfaces not controlled by sutures or from uninjured sites.

Form 6: Non OR/IR Lifesaving Interventions

All lifesaving interventions will be recorded for the 1st 24 hours after ED admission.
Select the location, date, time and intervention.
**Note that emergency laparotomy and emergency thoracotomy refer to this procedure occurring in the ED or another area in an emergent situation. Intubation is for emergency situations only – not for planned intubation for OR.

Form 7: Procoagulant Medications

Procoagulant medications will be recorded for the 1st 24 hours after ED admission.
Select the location, start date, start time and medication.
If "other" was selected for the medication, please enter information in column labeled "Specify other procoagulant/medication".

Form 8: Operating Room (OR) and Interventional Radiology (IR) Procedures

OR and IR procedures will be recorded through the hospitalization or 30 days, whichever occurs first. A copy of all operative notes should be kept at the site.

Complete a separate line for each OR or IR visit.
Enter date and time of arrival to the OR/IR.
Select the appropriate type of visit depending on location of the procedure (i.e. OR only, IR only, or in a hybrid OR/IR setting).

Select primary or secondary for the procedure and then select the specific code from the detailed list of procedures. For example, subject has an exploratory lap within the 1st 24 hours. The primary type would be checked and procedure code would be #16. During the ex lap, the spleen was removed, type of procedure would be checked as additional and code # 21 would be entered in the procedure code column. In the event the procedure is not listed, select other and enter procedure in text box.

A laminated copy of the OR/IR procedure code numbers will be sent to each site for reference when completing this form.

Form 9: Initial 24 hour Clinical Lab Results
Clinical laboratory results will be recorded from the samples drawn at time of ED arrival and time of arrival to the nursing unit (ICU/IMU, other nursing unit). Only enter the lab values that are collected as standard of care – do NOT collect any samples for research purposes.

There are 2 tabs for this form – tab 1 is for the ED lab results and tab 2 is for the nursing unit lab results. Enter the date/time when the blood was collected. In the event, time of blood collection is not available, enter the date/time of the first recorded results.

For the TEG values, check if the TEG was a Rapid or Kaolin TEG.

Form 10: 24 Hour to 30 Day In-Patient Follow Up Assessment
Daily information will be collected for all "highest risk" subjects who are in the ICU until time of discharge from the ICU or at 30 days after ED admission (whichever occurs first).
The 24 hour period will begin at 0000 and go through 2359 for each daily form.
The first daily form will begin after the first 24 hour after ED admission.
For example, the patient arrives to ED on 11/9/14 at 1500. They are admitted to the ICU at 1800. The first daily form would begin on 11/10/14 at 1501 and would contain information through 11/10/14 at 2359. The second daily form would begin at 11/11/14 at 0000 and go through 11/11/14 at 2359.

Q1 – Enter the date of the 24 hour period of data collection.
Q2 – Enter the highest and lowest vital signs for the designated 24 hour period.
Q3 – Enter the highest and lowest GCS scores for the designated 24 hour period.
Q4 - Lab Assessments – the lab values are divided into 4 sections (ABGs, coagulation, CBC, and chemistry profile).
Arterial Blood Gases – enter the ABG values associated with the LOWEST PaO2 value for the designated 24 hour period.
Coagulation/Blood Count/Chemistry & Metabolic Value Sections – enter the 1st available value for each designated 24 hour period. It is possible to record lab from various timepoints within the 24 hour time period. For example, coagulation values may be collected at a different time than the CBC or chemistry profile.

Q5 – Answer each question in this section.
The PI or Co I will need to make the determination for the last question in this section, "If intubated and displaying mild or moderate hypoxia, does today's CXR/CT demonstrate bilateral infiltrates?"
Q6 – Enter the ventilator setting information that is consistent with the lowest PaO2 value for the specific 24 hour period.
Q7 – Enter the 24 hour total urine output.

Form 11: Discharge/Death
Q1 – Enter the total number of ICU days.
Q2 – Enter the total number of ventilator days.
Q3 – Enter the first recorded Hgb after 24 hours from time of ED admission.
Q4 – Enter the demographic data – gender, year of birth, ethnicity and race.
Q5 – Enter the insurance status of the subject at time of discharge. In the event the subject remains hospitalized at day 30, enter NA.
Q6 – Complete information if available regarding history of anti-coagulation medication prior to injury.
Q7 – Enter all pre-injury significant medical history findings.
Q8 – DNR during hospital – check the yes or no box. If yes, complete date and time for the time DNR was ordered.
Q9 – Care withdrawn – similar to Q7; if yes, complete date and time for the time care withdrawn.
Q10 – If subject expired in hospital, check yes.
Q11 – Enter date subject was discharged from the hospital. If subject remains hospitalized, check box. No further questions need to be answered.
Q12 – Enter the first 15 discharge diagnosis codes from the hospital discharge information.
Q13- Check the appropriate box.
Q14 – Select the location subject was discharged to. If other is selected, please enter location in text box.
Q15 – Enter the GCS if collected at time of discharge.
Q16 – Enter the GOSE score on all patients.
Q 17 to 20- to be completed for subjects who expired in hospital
Q19 – Check all causes of death. Refer to section 5.2 Causes of Death Definitions.
Q20 – Of the causes checked in Q 17, the PI must select the primary cause of death. In the event the PI cannot decide on the primary cause, contact the CCC for assistance.
*** Note: Withdrawal of care is not considered a cause of death.

Form 12: Complications
Record complications which occurred through the hospitalization or up to day 30, whichever comes first. Refer to section 5.1 for the definitions for each complication identified on this form.
At the time of completion of this form, the PI will be required to sign off that they have reviewed the list of complications.

Form 13: Trauma Registry Data Form
Complete the AIS and ISS scores on this form.

Form 14: Additional Information
In the event, there is any additional information for any question on any form, enter the information on

this form. Enter the form # and the question # that the information applies to.

3.5 Data Queries

Multiple range checks for values are imbedded within each of the forms listed to alow for concurrent data entry checks. After data entry on the form has been completed (and indicated by the “marked complete” submission) the form will be integrated into additional checks involving validations across forms, “other” text fields evaluated and missing data. These listings (by subject id and form) will be sent to the coordinators on a weekly basis for correction.

Chapter 4: Trauma Registry Information

Purpose: To provide guidance on accessing data from the trauma registry and instructions on how to submit the data to the HCC.

The trauma registries will be asked to assist with the information routinely entered into the NTDB. Additional information regarding specific data elements to be collected will follow as the study proceeds.

Chapter 5: Safety Monitoring

Purpose: To provide definitions on the complications to be monitored and collected for the study; to provide definitions for the cause of death to be used by the local PI; and to provide instruction on how to complete the death adjudication form and what ancillary documents are required for the adjudication process.

5.1 Complication Definitions

Refer to the following list of complications which will be collected on all "highest risk" subjects during the initial hospitalization or up to 30 days. Document each incidence of the complications on Form 12.

1. Abdominal Compartment Syndrome (ACS)

Elevated intra-abdominal pressure (> 20 cm H2O) requiring the opening of the abdominal cavity with at least one of the following: 1) oliguria (<30cc/hr), 2) diminished cardiac output (< 2.5 L/min/m2), 3) elevated static airway pressures (> 45 cm H2O), or 4) PaO2/FiO2 ratio of less than 200. *(TRDB, 2007)*

2. Abdominal Complications (Open or Closed) after Exploratory Laparotomy

Abdominal complications include:

a. Fistula – abnormal connection between two epithelial-lined organs that normally do not connect.
b. Abscess of other evidence of any infection involving the intra-abdominal or retroperitoneal contents is found on direct examination, during reoperation, or by histopathologic or radiologic examination.
c. Other (please specify)

3. Acute Kidney Injury (AKI) / Acute Renal Failure

Rapid loss of kidney function (within any 48 hours), measured by a rise in creatinine (increase in serum creatinine of either an absolute count of >/= 0.3 mg/dl or 50% increase), decrease in the GFR (> 25%) and/or reduction in urine output defined as <0.5 ml/kg/hr for at least 6 hours.
(Acute Kidney Injury Network, 2007)

4. Acute Respiratory Distress Syndrome (ARDS)-

Lung injury characterized by hypoxemia, pulmonary edema, low lung compliance and capillary leakage. The following criteria must be met:

1. Timing – within 1 week of a known clinical insult or new or worsening respiratory symptoms.
2. Chest Imaging – Bilateral opacities – not fully explained by effusions, lobar/lung collapse or nodules
3. Origin of edema – Respiratory failure not fully explained by cardiac failure or fluid overload. Need objective assess (e.g. echocardiography) to exclude hydrostatic edema if no risk factor present
4. Oxygenation
   A. Mild – 200 mmHg < PaO2/FIO2 </= 300 mmHg with PEEP or CPAP >/= 5 cmH2O[c]
   B. Moderate – 100 mmHg < PaO2/FIO2 </= 200 mmHg with PEEP or CPAP >/= 5 cmH2O[c]
   C. Severe - PaO2/FIO2 < 100 mmHg with PEEP >/= 5 cmH2O[c]

5. Cardiac Arrest

Sudden cessation of cardiac activity (Includes pulseless electrical activity [PEA]).
(TRDB, 2007)

6. Empyema (EMP)

The presence of pus, a positive Gram stain or culture of pleural fluid, or a pleural fluid pH under 7.2 with

normal peripheral blood pH. (*American Journal of Medicine 2006, 119(10): 877-83*)

7. Infections

a. **Bacteremia**

The presence of viable bacteria in the blood with positive blood cultures.
(American College of Chest Physicians/Society of Critical Care Medicine, 1992)

b. **Catheter-Related Bloodstream Infections (CRBSI)**

The presence of bacteremia/fungemia in a patient with a central venous catheter (CVC) in which there is no alternate source for bacteremia/fungemia except the catheter. To diagnose CRBSI, the patient must have clinical manifestations of infection (fever, chills or hypotension); a positive blood culture from a peripheral vein; and some microbiologic evidence the catheter is infected.

Diagnostic criteria (all of 1, 2 and 3 must be met within a 48 hr period):

1. A single positive blood culture from a peripheral vein
2. Clinical manifestations of infection including at least one of a, b, or c
    a) Fever >38.5C
    b) WBC >10,000 or < 3000 per cubic millimeter
    c) Hypotension (SBP < 90) or > 25% drop in systolic blood pressure
3. Microbiologic evidence of catheter infection (at least one of a, b, c, or d)
    a) positive semiquantitative (>15CFU/catheter segment) culture in which the same organisms isolated from the catheter and peripheral blood (**this is the most commonly used technique)**
    b) positive quantitative (>103CFU/catheter segment catheter) culture in which the same organism is isolated from the catheter and peripheral blood
    c) simultaneous quantitative blood cultures with a ≥ 5:1ratio of bacteria (CVC versus peripheral)
    d) differential period of central venous catheter culture versus peripheral blood culture positivity of > 2 hours*(TRDB, 2007)*

c. **Skin Infection (SI)**

Skin infections must meet at least 1 of the following criteria:

1. Patient has purulent drainage, pustules, vesicles, or boils.
2. Patient has at least 2 of the following signs or symptoms with no other recognized cause: pain or tenderness, localized swelling, redness, or heat and at least 1 of the following:

a. organisms cultured from aspirate or drainage from affected site; if organisms are normal skin flora (i.e., diphtheroids [Corynebacterium spp], Bacillus [not B anthracis] spp, Propionibacterium spp, coagulase-negative staphylococci [including S epidermidis], viridans group streptococci, Aerococcus spp, Micrococcus spp), they must be a pure culture

b. organisms cultured from blood

c. positive laboratory test performed on infected tissue or blood (e.g., antigen tests for herpes simplex, varicella zoster, H influenzae, or N meningitidis)

d. multinucleated giant cells seen on microscopic examination of affected tissue

e. diagnostic single antibody titer (IgM) or 4-fold increase in paired sera (IgG) for pathogen.

CDC/NHSN Surveillance Definitions for Specific Types of Infections, January 2014

d. **Soft Tissue Infection (STI)**

Soft tissue infections include necrotizing fascitis, infectious gangrene, necrotizing cellulitis, infectious myositis, lymphadenitis, or lymphangitis and must meet at 1 of the following criteria:

Patient has organisms cultured from tissue or drainage from affected site.

2. Patient has purulent drainage at affected site.
3. Patient has an abscess or other evidence of infection seen during an invasive procedure or histopathologic examination.
4. Patient has at least 2 of the following signs or symptoms at the affected site with no other recognized cause: localized pain or tenderness, redness, swelling, or heat
and at least 1 of the following:
a. organisms cultured from blood
b. positive laboratory test performed on blood or urine (e.g., antigen tests for H influenzae, S pneumoniae, N meningitidis, Group B Streptococcus, or Candida spp)
c. diagnostic single antibody titer (IgM) or 4-fold increase in paired sera (IgG) for pathogen.
CDC/NHSN Surveillance Definitions for Specific Types of Infections, January 2014

e. **Surgical Site Infections (SSI)**

- *Superficial Incisional/Wound Infections*

Infection occurs within 30 days after the operation and infection involves only skin or subcutaneous tissue of the incision **and at least one** of the following:
1. Purulent drainage, with or without laboratory confirmation, from the superficial incision.
2. Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision.
3. At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat and superficial incision is deliberately opened by surgeon, unless incision is culture-negative.
4. Diagnosis of superficial incisional SSI by the surgeon or attending physician.
(TRDB, 2007)

- *Deep Incisional SSI*

Infection occurs within 30 days after the operation and the infection appears to be related to the operation*and* infection involves deep soft tissues (e.g., fascial and muscle layers) of the incision ***and*** at least ***one*** of the following:
1. Purulent drainage from the deep incision, but not from the organ/space component of the surgical site.
2. A deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms: fever (>38ºC), localized pain or tenderness, unless site is culture-negative
3. An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination.
4. Diagnosis of a deep incisional SSI by a surgeon or attending physician.

- *Organ/Space SSI*

Infection occurs within 30 days after the operation and the infection appears to be related to the operation *and* infection involves any part of the anatomy (e.g., organs or spaces), other than the incision, which was opened or manipulated during an operation ***and*** at least ***one*** of the following:
1. Purulent drainage from a drain that is placed through a stab wound into the organ/space (if the area around a stab wound becomes infected, it is not an SSI. It is considered a skin or soft tissue infection, depending on its depth.)
2. Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space.
3. An abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination
4. Diagnosis of an organ/space SSI by a surgeon or attending physician.

(TRDB, 2007)

f. **Urinary Tract Infection (UTI)**

Must meet at least 1 of the following criteria:
At least one of the following signs/symptoms:

- Fever (>38º C)
- Suprapubic tenderness
- Costovertibral angle pain or tenderness

And

A positive urine culture of ≥105 colony-forming units (CFU)/ml with no more than 2 species of microorganisms. Elements of the criterion must occur within a timeframe that does not exceed a gap of 1 calendar day between two adjacent elements.

CDC/NHSN Surveillance Definitions for Specific Types of Infections, January 2014

8. Multiple Organ Failure (MOF)

Multiple organ failure will be defined using the Denver Multiple Organ Failure (MOF) scoring system. This system evaluates four organ systems: pulmonary, hepatic, renal, and cardiac. Organ dysfunction is graded on a scale from 0 to

The pulmonary score is determined by the PaO2/FiO2 (P/F) ratio. P/F >208 receive zero (0) points, ratios of 208-165 receive 1 point, 165-83 receive 2 points, and 83 receive 3 points.

The renal system is graded by serum creatinine level in mg/dL: 0 points for <1.8, 1 point for 1.8-2.5, 2 points for 2.5-5.0, and 3 points for >5.0 mg/dL.

The hepatic score is calculated by total serum bilirubin level in mg/dL: 0 points for bilirubin <2.0, 1 point for 2.0-4.0, 2 points for 4.0-8.0, and 3 points for bilirubin >8.0 mg/dL.

Cardiac dysfunction is graded based on inotropic support and cardiac index (C.I.). No inotropes and cardiac index >3.0 L/min per meter squared yield a score of zero (0), whereas minimal inotropic support or C.I. <3.0 yield a score of 1. Moderate and high dose inotropic receive scores of 2 and 3, respectively.

Scores not recorded are assumed to be normal and calculated as zero (0).

****For multiple organ failure, the MOF score is calculated as the sum of the simultaneously obtained individual organ scores on each hospital day. Single system organ failure is defined as an organ failure grade >0. MOF is defined as a total score of 4 or greater.

9. Pneumonia (PNUI)

Pneumonia must meet at least one of the following:

1. Fever (>38°C or >100.4°F)
2. Leukopenia (<4000 WBC/mm3) or leukocytosis (≥12,000 WBC/mm3)
3. For adults ≥70 years old, altered mental status with no other recognized cause and at least two of the following:

1. New onset of purulent sputum, or change in character of sputum or increased respiratory secretions, or increased suctioning requirements
2. New onset or worsening cough, or dyspnea, or tachypnea
3. Rales or bronchial breath sounds

4. Worsening gas exchange (e.g., O2 desaturations (e.g., PaO2/FiO2 ≤240), increased oxygen requirements, or increased ventilator demand)

CDC/NHSN Surveillance Definitions for Specific Types of Infections, January 2014

10. Sepsis

A systemic response to infection. Two or more of the following three conditions must be present: (1) temperature >38°C or <36°C; (2) heart rate >90 beats per minute; (3) respiratory rate >20 breaths per minute or PaC02<32 mmHg; and white blood cell count >12,000/cu mm,<4,000/cu mm, or> 10% immature (band) forms; AND a known or suspected infection confirmed by culture, CXR, or CT. *(American College of Chest Physicians/Society of Critical Care Medicine, 1992)*

11. Severe Sepsis

Severe sepsis is defined as SIRS plus infection plus acute organ dysfunction. Type of acute organ dysfunction are as follows:

Neurologic: GCS score < 13 on recognition of sepsis or deteriorating GCS score to < 13 during first 24 hours.

Pulmonary: PaO2/FiO2 ratio < 250 (<200 if lung is the primary site of infection) and pulmonary capillary wedge pressure (PCWP) not suggestive of fluid overload

Renal (one of the following): Urine output < 0.5 mL/kg for ≥ 1 hour despite adequate volume resuscitation or increase in serum creatinine ≥ 0.5 mg/dL from baseline (measured with 24 hours of starting sepsis resuscitation). Adequate volume resuscitation is defined as a minimum intravenous fluid infusion of 20 mL/kg/ideal body weight or central venous pressure ≥ 8 mm Hg or PCWP ≥12 mm Hg

Coagulation (one of the following): INR > 1.5, platelet count <80,000 or ≥ 50% decrease in platelets compared with 24 hours after starting sepsis resuscitation in the absence of chronic liver disease

Hypoperfusion: lactate > 4 mmol/L

Journal of Trauma, Volume 70, Number 3, March 2011

12. Septic Shock

Septic shock is defined as SIRS plus infection pluse acute cardiac dysfunction that is defined as:

1. IV fluid challenge ≥ 20 mL/kg/ideal body weight of isotonic crystalloid infusion or CVP ≥ 8 mm Hg or PCWP ≥ 12 mm HG

AND

2. Requirement of vasopressors to increase MAP ≥ 65 mm Hg.

Journal of Trauma, Volume 70, Number 3, March 2011

13. Systemic Inflammatory Response Syndrome (SIRS)

SIRS is a serious condition related to systemic inflammation, organ dysfunction, and organ failure. It is a subset of cytokine storm, in which there is abnormal regulation of various cytokines. Two or more of the following must be present for SIRS (without a positive culture): 1) temperature below 36° C or above 38° C, 2) heart rate > 90 bpm, 3) > 20 breaths per minute or, on blood gas, a PaCO2 less than 32 mmHg, 4) WBC < 4,000 cells/mm3 or > 12,000 cells/mm3. *(American College of Chest Physicians/Society of Critical Care Medicine, 1992)*

14. Thromboembolic complications

a. **Myocardial Infarction (MI)**

Acute, irreversible myocardial injury documented by both of: (1) Abnormal increase in CK-MB ortroponin and (2) New, serial T-wave, S-T segment or Q wave ECG abnormalities. *(TRDB, 2007*

b. **Stroke or Cerebral Infarction.** New neurological deficit not present on admission which is: 1) sudden or rapid in onset, 2)and lasts >24 hours and 3) confirmed as an acute infarction by CT or MRIand 4) that is consistent with the physical exam. *(TRDB, 2007)*

c. **Deep Vein Thrombosis (DVT)** – venous thrombosis confirmed by autopsy, venogram, duplex or other non-invasive vascular evaluation. Document whether the DVT is symptomatic or not

d. **Pulmonary Embolus (PE)** A clinically significant (resulting in hypoxia or tachycardia or hypotension) blood clot lodged in the lumen of a pulmonary artery as diagnosed by CT angiogram, pulmonary angiogram or ventilation perfusion scan. To be differentiated from occult, non-clinically significant PE. *(ROC Hypertonic Resuscitation MOO, 2008)*

e. **Mesenteric Thrombosis** (arterial or venous) Documented on arteriogram, CT angiogram, operative findings or autopsy

f. **Other (not superficial vein thrombi)**

15. Transfusion-Associated Circulatory Overload (TACO)

Infusion volume that cannot be effectively processed by the recipient either due to high rate and/or volume of infusion or an underlying cardiac or pulmonary pathology

Definitive: New onset or exacerbation of 3 or more of the following within 6 hours of cessation of transfusion:

- Acute onset of respiratory distress symptoms (dyspnea, orthopnea, cough),
- Evidence of positive fluid balance,
- Elevated brain natriuretic peptide (BNP),
- Radiographic evidence of pulmonary edema,
- Evidence of left heart failure,
- Elevated central venous pressure (CVP)

Grade 1-Non-Severe: Medical intervention (e.g. symptomatic treatment) is required but lack of such would not result in permanent damage or impairment of a bodily function.

Grade 2-Severe: Inpatient hospitalization or prolongation of hospitalization is directly attributable to the adverse reaction, persistent or significant disability or incapacity of the patient occurs as a result of the reaction, or a medical or surgical intervention is necessary to preclude permanent damage or impairment of a body function.

Grade 3-Life Threatening: Major intervention required following the transfusion (e.g. vasopressors, intubation, transfer to intensive care) to prevent death.

Grade 4-Death: Subject died as a result of the adverse transfusion reaction.

(HNSN, 2011)

16. Transfusion-Related Acute Lung Injury (TRALI)

Acute hypoxemia with PaO2/fraction of inspired oxygen [FIO2] ratio of <300 mmHg combined with chest x-ray showing bilateral infiltrates in the absence of left atrial hypertension (i.e., circulatory overload). Onset of TRALI is abrupt in association with transfusion. Must be discussed with and corroborated with head of the blood bank based on local standard blood bank policy.

Definitive: No evidence of acute lung injury (ALI) prior to transfusion **AND** ALI onset during or within 6 hours of cessation of transfusion **AND** Hypoxemia defined by any of these methods: PaO2 / FiO2< 300 mm Hg; Oxygen saturation less than 90% on room air; other objective evidence **AND** no evidence of left atrial hypertension (i.e. circulatory overload).

Grade 1-Non-Severe: Medical intervention (e.g. symptomatic treatment) is required but lack of such would not result in permanent damage or impairment of a bodily function.

Grade 2-Severe: Inpatient hospitalization or prolongation of hospitalization is directly attributable to the

adverse reaction, persistent or significant disability or incapacity of the patient occurs as a result of the reaction, or a medical or surgical intervention is necessary to preclude permanent damage or impairment of a body function.
Grade 3-Life Threatening: Major intervention required following the transfusion (e.g. vasopressors, intubation, transfer to intensive care) to prevent death.
Grade 4-Death: Subject died as a result of the adverse transfusion reaction.
(HNSN, 2011)

17. Ventilator Associated Pneumonia (VAP)

Pneumonia in patients who have been mechanically ventilated for > 48 hours.
Criteria a-c must be satisfied within a 48 hr period:

a) Radiologic criteria:
   i. New radiographic infiltrate that persists for at least 24 hours not associated with ALI, ARDS, pulmonary contusion, TRALI or TACO.
b) Clinical criteria (one of i or ii)
   i. Tm> 38.5°C or <35.0°C
   ii. WBC> 12,000 or <4000 per cubic millimeter
c) Bacterial confirmation by at least one of:
   i. Quantitative microbiologic cultures obtained by bronchoalveolar lavage yielding≥10^4colony forming units [CFU]/ml or protected specimen brush>10^3 CFU/ml (preferred diagnostic method)
   ii. Histopathologic exam of lung tissue shows one of a or b:
   (a). Abscess formation with intense PMN accumulation in bronchioles &alveoli. (b). Quantitative culture of lung parenchyma that shows $\geq$ 10^4cfu/g tissue.
   iii. Positive blood culture for bacterial pathogen identified in sputum or respiratory culture
   iv. Positive pleural fluid culture with same organism identified in sputum or other respiratory cultures
   v. Positive sputum gram stain with $\geq$3+ of one type of pathogenic bacteria
   vi. Heavy or moderate growth of one type of pathogenic bacteria on semi-quantitativesputum culture

(TRDB, 2007)

5.2 Cause of Death Definitions

This information will be entered on Form 11. There are 2 parts to Question #17 on Form 11 regarding the cause of death. The first question will ask to document ALL causes of death. The second question will ask for the PRIMARY cause of death.

Refer to the following list to document the cause of death.

1) **Exsanguination / Hemorrhagic Shock**

Exsanguination: death caused by uncontrolled bleeding.

Hemorrhagic Shock: shock associated with the sudden and rapid loss of significant amounts of blood. Severe traumatic injuries often cause such blood losses. This results in inadequate perfusion to meet the metabolic demands of cellular function. Hemorrhagic death occurs within a relatively short time (usually during active resuscitation) after admission unless transfusion quickly restores normal blood volume. Occasionally rebleeding may occur, resulting in later deaths.

2) **Traumatic Brain Injury (TBI)**

An injury to the brain caused by penetration of the skull or movement of the brain within the skull. TBI as a cause of death usually occurs with several days of admission. TBI death is directly related to: (1) a TBI deemed non-survivable and documented as such by a faculty physician; (2) rapid deterioration and cardiovascular collapse following hemodynamic changes consistent with herniation, or (3) brain death.

3) **Respiratory/Pulmonary Contusion/Tension Pneumothorax**

Respiratory: any loss of ventilatory capability, usually from a mechanical issue somewhere between the ventilator and the pulmonary parenchyma.

Pulmonary contusion: injury to lung parenchyma, leading to edema and blood collecting in alveolar spaces and loss of normal lung structure & function. This lung injury develops over the course of 24 hours, leading to poor gas exchange, increased pulmonary vascular resistance and decreased lung compliance. Usually death will occur within hours of injury. (MedicineNet.com)

Tension Pneumothorax: The accumulation of air under pressure in the pleural space causing death within minutes. (MedicineNet.com)

4) **Sepsis** – An overwhelming systemic response to documented infection. Patients dying of sepsis usually do so > 72 hours after admission.

5) **MOF** – Altered organ function in at least 2 organ systems. Progressive and profound organ dysfunction that is incompatible with life. Patients dying of MOF usually do so > 48 hours after admission.

6) Stroke

New neurological deficit not present prior to injury which is sudden or rapid in onset, lasts > 24 hours and is confirmed as an infarction by CT or MRI, acutely causing death. (TRDB, 2007)

7) **Myocardial Infarction**

Acute, irreversible myocardial injury documented by both: (1) Abnormal increase in CK-MB or troponin and (2) New, serial T-wave, S-T segment or Q wave ECG abnormalities acutely causing death. (TRDB, 2007)

8) **Pulmonary Embolism** - A blood clot lodged in the lumen of a pulmonary artery acutely causing death, diagnosed by CT angiogram, pulmonary angiogram or ventilation perfusion scan. (TRDB, 2007)

9) **Transfusion Related Fatality** – fatality as a direct result of a complication of blood component transfusion. Refer to the 13 transfusion related complications. (Practice Guidelines for Blood Transfusion) Do we need to keep those in the complication list?

10) **Other (specify)**
11) **Unknown**

5.3 Death Adjudication Process

Similar to PROPPR, it is expected that patients enrolled in PROHS will have a significant mortality rate. It is likely that subjects will have multiple causes of death, especially those that occur after 72 hours. We require that site PI's and study coordinator's discuss each death and use the following categories to assign causality. At the time of death, please place the subject into the death category and describe those proximate clinical issues most likely to have contributed to death.

In the event of a subject death, the local site PI will determine the cause of death using the categories mentioned above in Section 5.2. The cause of death will then be forwarded to the HCC for review. Timing of the withdrawal of care (as applicable) will be noted in the assessment.

Redacted records will be sent to the HCC to facilitate accurate death reconciliation. These records include: 1st 24 hour operative notes, anesthesia records and CT scan reports, admission HX and physical, discharge summary, death summary and autopsy reports and any other important supporting documents from the site PI. Please submit a short paragraph within 2 weeks of the death (from the site PI) summarizing the data supporting the final cause(s) of death.

The HCC PI will review the cause of death assessment and redacted subject records. The HCC PI will then determine cause of death based on the available information. If the HCC PI and the local PI are in agreement of the cause of death, no further action will be necessary. In the event there is a difference in the cause of death, the HCC PI will contact the local PI and further discuss the scenario and ask for additional redacted information as needed.

5.4 Monitored Site Visits

The HCC will monitor the data entered into OpenClinica on a regular basis and will contact the site coordinator via email and/or telephone as needed to address questions. The HCC staff will also be available to go out to the sites as needed if there are issues with the data collection/entry process that require in person monitoring and/or additional training or if the site personnel request an in person site visit.

Chapter 6: Patient and Data Confidentiality
Purpose: To provide information on the responsibilities of maintaining patient confidentiality on all study levels (HCC, site and communication between the HCC & sites).

HCC Responsibilities
All HCC staff handling sensitive PROHS records and data are responsible for adhering to the procedures described herein. The HCC PI, Biostatisticians and programming staff have access to the entire database, including sensitive information. The HCC project manager has restricted access to the database via reports and database views created by the programming staff. The programming and PM teams will work together to ensure that data produced for reports or datasets, had been de-identified and blinded.

Site Responsibilities:
The research staff at each site will follow their local university/institution's HIPPA policies and procedures to ensure all measures are taken to protect the subject's confidentiality.

The HCC will receive only information that has been de-identified.

All PROHS Study Related Personnel (HCC and site)
To ensure all measures are taken to comply with the HIPPA guidelines, refer to the following guidelines:
Sensitive records and data include the following:

- Management information concerning workload, performance, staffing, and similar data.
- Correspondence and documents, which must be protected from unauthorized alteration or disclosure. These types of data include all correspondence, memoranda, and other documents whose release or distribution outside the HDCC needs to be controlled.
- Clinical trial data.
- Payment information that is used to authorize or make cash payments to individuals or organizations.
- Proprietary study related information that has value in and of itself must be protected from unauthorized disclosure.
- Correspondence and documents that are considered highly sensitive and/or critical to an organization and must be protected from unauthorized alteration and/or premature disclosure.
- Records subject to the Privacy Act, which contain information that meets the qualifications for Exemption 6 of the Freedom of Information Act, i.e., for which unauthorized disclosure would constitute a "clearly unwarranted invasion of personal privacy" likely to lead to specific detrimental consequences for the individual in terms of financial, medical, psychological, or social standing.

Computers, Fax Machines and Printers
Computers, fax machines and printers that may be used for confidential data shall be placed in secure areas where access is restricted to only those individuals with permission to access confidential information.

Sensitive electronic data will be stored on a designated secure server. Storing data on workstations will be minimized wherever possible and deleted immediately.

Staff will verify correct fax numbers when sending confidential information, and always use a HDCC fax cover sheet. If an unintended fax that contains confidential information is received, immediately inform the sender and either secure or destroy the information. Staff will stand at public fax machines or printers or have documents containing confidential information retrieved immediately so that unauthorized individuals have no opportunity to see the information.

All faxes need to state the confidential nature of the contents of the communication and contain instructions should the fax be misdirected.

Computer Display
Staff will remove confidential data from screens where it is not required.

Staff will need to be aware of the position of computer screens. Unauthorized individuals should not be able to read screens containing confidential information. Use a monitor visor or hood in service areas.

Staff will need to log off from applications that show confidential data so that no data is accessible after you are finished.

Computers that are used to access confidential data will have screen savers so that unauthorized people cannot read the information if they happen to wander into a restricted area.

Computers that are used to access confidential data will have a time-out feature so that when a staff person steps away from his/her computer for a period of time, the staff person is required to re-enter his or her password.
Computers that are used to access confidential data must be password protected.

Employees should only be given access to those computers and information to which they are entitled. Each employee must use his/her own user name and password to access computers containing confidential data.

Telephone, Internet (email) and Other Communications
References to any subject in the PROHS trial will include only the study ID number. Subject names are considered PHI and should not be used. Staff will not verify a study subject by any identifier other than their study ID.

Conversations (between staff members and/or staff and other individuals) containing confidential information must be restricted to 'private' and non-traffic areas where the conversations cannot be overheard by others. When reasonable, move to a private room, move to a corner of a room, keep voices low, etc.

Staff will not leave voice mail messages containing confidential data. On voice mail boxes that may be accessed by more than one individual, staff will leave instructions on the voice mail that instructs the caller not to leave confidential information as part of their message.

Paper
Staff will remove PHI from supporting event documentation where it is not required.

Paper records and reports containing PHI will not be left in locations where non-PROHS staff (or others without authority to view the information) have access to that information such as printers or unattended on a desktop in open view. Reports which are no longer needed and contain confidential and/or sensitive data must be shredded or stored securely in a locked file cabinet until they can be shredded.

Laptops and PDAs
Laptops or other portable devices (PDA's, etc.) should not be used to store confidential information.

Laptops and other portable equipment (PDAs, travel drives, CD/DVDs, etc.) that contain confidential information must be kept secure and able to be accessed only by authorized individuals. Staff will delete confidential information from laptops and personal devices as soon as it is no longer needed on those devices.

Chapter 7: Site Activity Reports
Purpose: To provide an outline on sending invoices for payments and to provide instruction on the annual reporting requirements.

7.1 Invoicing Requirements

Subcontracts between UTHealth and the participating clinical sites indicate that UTHealth will reimburse each subcontractor for the direct and indirect costs incurred in the performance of tasks outlined in the scope of work found in the subcontract. The total costs cannot exceed the estimated cost that is provided in each subcontract.

All subcontractors should submit invoices at least QUARTERLY to UTHealth at the following address:
POST AWARD FINANCE
The University of Texas Health Science Center at Houston
7000 Fannin, UCT 902
Houston, Texas 77030-1500

Invoices should be submitted:

- using the standard invoice shown at the end of this section
- prepared on institutional letterhead
- certify that all payments requires are for appropriate purposes
- state the period for which reimbursement is being requested
- itemize the costs by the following budget categories:
    - Salaries
    - Employee Benefits
    - Equipment
    - Consultant Costs
    - Travel
    - Other Direct Costs
    - Total Direct Costs
    - Indirect Costs
    - Total
- show current costs and cumulative costs to date
- include subaward number
- signed by Subcontractors authorized representative

Yearly final invoices are due no later than 30 days following termination (i.e., January 31), and it must be signed and marked “Final.” In addition, the final invoice should include the following statement:

> "The Subcontractor assures to the University that all expenditures were incurred in full compliance with OMB Circular A-133 or its own applicable audit regulations. Disallowed costs if found during the retention period of this Subcontract will be promptly refunded to University."

If a finding or questioned cost is found related directly to this Subcontract, then the Subcontractor will promptly notify UTHealth in order to proceed with resolution of such matter, as may be required by UTHealth's prime sponsor or applicable Federal regulations.

The following expenditures require prior approval of the UTHealth Director of Contracts, Sponsored Projects Administration, or designee:

1. A 25% reduction in time devoted to the project by the Principal Investigator or Project Director.
2. Items of general purpose equipment, e.g., office equipment and furnishings, air conditioning, reproduction equipment, automatic data processing equipment, etc.
3. Individual items of equipment costing $5,000 or more. All such items identified in the budget attachment are automatically approved for acquisition.
4. The subaward, transfer or contracting out of any work except for routine purchase of supplies, materials, equipment or general support services.

Even though The University of Washington is not a subcontractor of UTHealth, it is a clinical site. A detailed report of their expenditures should be sent annually to UTHealth.

Sample Invoice

Attachment 6
Sample Invoice

COLLABORATOR:_____ Date: _____

PAYMENT ADDRESS:
_____
_____
_____
_____

INVOICE NO. _____
PRIME AWARD NO. _____
SUBAWARD NO. _____
AWARD AMOUNT $_____

Billing Period:

_____ to _____

Submit invoice to:
Post Award Finance
The University of Texas Health
Science Center at Houston
7000 Fannin, UCT 902
Houston, Texas 77030-1500

Description/Cost Items	Amt Billed for Current Period From: To:	Cumulative Amt from Inception From: To:
Personnel		
Consultant costs		
Equipment		
Materials and Supplies		
Travel		
Other Direct costs		
IDC Exclusions		
Indirect cost		
Total costs		

I certify that this request represents a reimbursement of actual costs incurred during the invoice period and that these costs are appropriate and in accordance with this Subaward. The COLLABORATOR further certifies that payment made by UTHSCH under this Subaward shall not duplicate reimbursement of costs and services that are received from other sources.

Signed: _____
Project Director/designated signatory

Approved for payment: _____
COLLABORATOR/authorized financial official

7.2 Progress Reports

7.2.1 HCC Annual Report

The HCC will submit an annual report which will include all study activity (clinical, regulatory and financial) to ROC by September 1st of each calendar year. This report will serve as internal documentation between the HCC and ROC however the information will be used in preparation of the annual report ROC sends to the NIH.

7.2.2 Clinical Site Reports

Each participating clinical site will submit an annual report to the HCC. The following template is to be utilized to complete the annual report. The deadline for the annual report is August 1st to the HCC. The time period for the annual report is July 1st or previous year to June 30th of current year. The report should be emailed to Donna.A.Grayson@uth.tmc.edu.

Prehospital Resuscitation On Helicopter Study (PROHS) Annual Report TEMPLATE

Clinical Site:
Contractor:
Principal Investigator:
Dates:

Budgetary:
Changes to Personnel since the previous annual report are listed below:
Personnel _____ Role _____
(*Will be listed as necessary. Once personnel is listed as added, they do not need to be listed again, unless their % effort changes or they are removed from the grant funding.)*

Expenditures:
(*Equipment and travel purchases and summaries of other expenditures will be outlined here. Please list actual dollar amounts and ensure they coincide with the invoices sent to UTHouston.)*

Protocol/Enrollment:
(Protocol updates will be listed here. Once the study is enrolling, recruitment will be tracked.)

Presentations/Publications:
(Please cite U01 HL077863-7 on any publication or presentation that is PROHS related. Any such publication, abstract or other presentation should be listed here.)

Communication/Meetings:
(*Indicate the frequency and type of PROHS related communication and meetings that have occurred at your center or at another site.)*

Other Comments/Updates:
(Miscellaneous information will be stated here.)

Chapter 8: Regulatory

Purpose: To inform the study staff of the regulatory requirements for the study, to review the process for institutional approval, maintenance of all regulatory documentation at sites and HCC, and close out procedures.

8.1 IRB Submission Process

8.1.1 Initial IRB Submission

The University of Texas Health Science Center Committee for the Protection of Human Subjects (CPHS) will be responsible for the overall regulatory management for PROHS.

Each site will be responsible for submission of the PROHS protocol, other study documentation, and the UT CPHS approval letter to their local institution's Institutional Review Board for review and approval. Each site is expected to comply with their local regulatory guidelines regarding screening, enrollment, consenting and follow up.

In the event the site is required to obtain consent, the coordinator will forward a copy of the informed consent to be used for review and approval by the HCC prior to IRB submission.

Once the site's IRB has approved the study, the approval letter will be forwarded to the HCC.

8.1.2 Continuing Review Process

The HCC and each site will be responsible for submitting all necessary study documentation in a timely manner to ensure the study remains open at the site until all study procedures and data analysis has been completed.

The HCC will be responsible for providing any updated study documentation including protocol amendments, revised CRFs, overall study enrollment information, and HCC continuing review approval letter.

The sites will be responsible for submission of the continuing review application/paper work prior to the current IRB expiration date to allow for adequate time for the IRB committee to review. The site personnel will forward the updated continuing review approval letter to the HCC.

8.1.3 Other IRB Communication

The site will notify the HCC of any communication with the IRB regarding unanticipated events or subject complications related to the study.

8.2 End of Study Procedures and Record Retention

The site Principle Investigator (PI) or designee is responsible for:

1. Receipt, maintenance, storage, and availability of the regulatory documents binder once the study is underway.
2. Storage of all study records in an appropriately secured location for a period specified by institutional policy, state or federal regulations, or for a minimum of at least two years following FDA notification of study completion.
3. After completion of the study, if on-site record storage is impractical; records may be stored in a

secure off-site facility provided the records are readily accessible in the event of an audit.
4. In the event the PI leaves the clinical site; the PI is responsible for provide the HCCC/HDCC with written notice of the location of study records and the name and phone number of an alternate contact in the event of an audit.
5. The site PI or designee is responsible for ensuring site personnel are trained on this SOP. Such training will be documented on the site training log.

The Houston Coordinating Center (HCC) is responsible for:
1. Collection, organization, and providing regulatory documents to clinical sites at the outset of the study.
2. Establishing and maintaining a tracking system for the timely update of clinical site regulatory documents.
3. Routine communication with clinical sites on regulatory documents with pending expiration dates and collection of updated documents.
4. Providing centers with a date of destruction for clinical research records, if not otherwise specified by local site policies/procedures.
5. The HCC PIs or designee is responsible for ensuring that all appropriate HCCC/HDCC personnel are trained on this SOP. Such training will be documented on a training log.

Procedures
Regulatory Documents
1. The HCC will provide clinical site research coordinators with regulatory documents binder templates.
2. The site research coordinators will ensure that the appropriate documents are placed in the regulatory documents binders on a regular basis and maintained in a secured area with restricted access. The research coordinator will make the binders available for review by the monitor at each site visit.
3. The HCC will work with the research coordinator at each center to ensure documents are complete and current.
4. The HCC will keep electronic copies of all documents received by the centers and will keep any hard copies received in a locked and secured area with restricted access.

Source Documents, Consents, and CRFs
1. The research coordinator or delegate will transcribe the appropriate data from the source documents into each subject's case report form for entry into the eCRF.
2. The research coordinator will ensure that all source documents, consents, and CRFs are stored in a secure location with access limited to research team members, (i.e., monitors from one Sponsor/CRO may not see study documents from another study).
3. The method of clinical documentation at each site (i.e. electronic EMR vs. paper clinical record) may necessitate a separate folder of source documents for completion of the CRF.
4. The HDCC study Monitor will review study document security during regularly scheduled site visits.

Contracts and Financial Records
The research coordinator will store contracts, budgets, and infrastructure documents apart from subject records, in a secure location with access limited only to research team members.

Chapter 9: Training

Purpose: To provide training materials to be used at each site for research and clinical staff to understand subject screening, direct observation, data collection and data entry into the web based database.

9.1 Research Staff

All clinical research staff involved with PROHS must be trained to:

- Screen all eligible patients
- Assess the patients upon ED arrival for eligibility
- Complete direct observation data collection on all eligible "highest risk" subjects
- Communicate with pre-hospital air ambulance staff to obtain pre-hospital information
- Understand the definition of anatomic hemostasis and resuscitation
- Communicate with clinical staff/physicians to obtain hemostasis and resuscitation date & times
- Complete daily assessment information
- Complete data entry into study web based database

9.2 Physicians

All physicians involved in the trauma patient care from ED arrival to hospital unit must be informed of the PROHS study:

- Understand the purpose of this prospective, observational study
- Understand the screening and enrollment criteria
- Understand the definition of anatomic hemostasis and active resuscitation
- Communicate with the research staff regarding hemostasis and resuscitation dates and times.

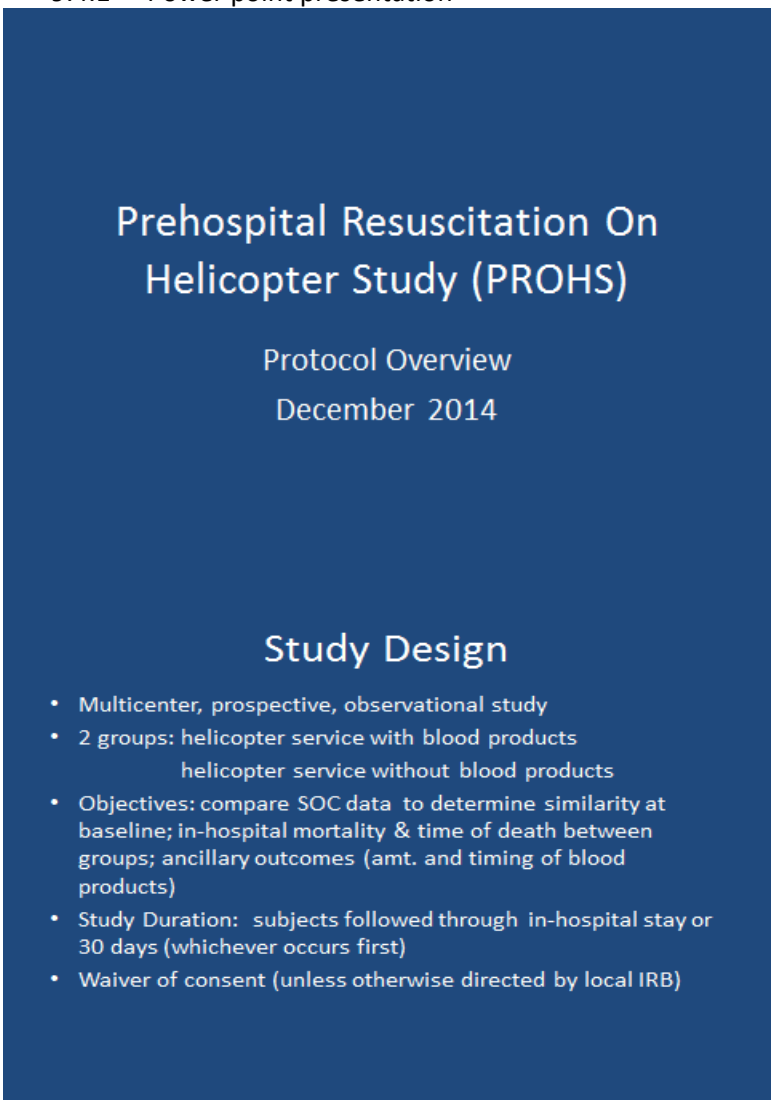
9.3 Clinical Staff (including pre hospital staff)

All clinical staff involved with PROHS will be trained to:

- Understand the purpose of this prospective, observational study
- Understand the screening and enrollment criteria
- Understand the definition of anatomic hemostasis and active resuscitation
- Communicate with the research team regarding times and events throughout direct observation time frame

9.4 Training Materials

9.4.1 Power point presentation



"At Risk" Eligibility Criteria

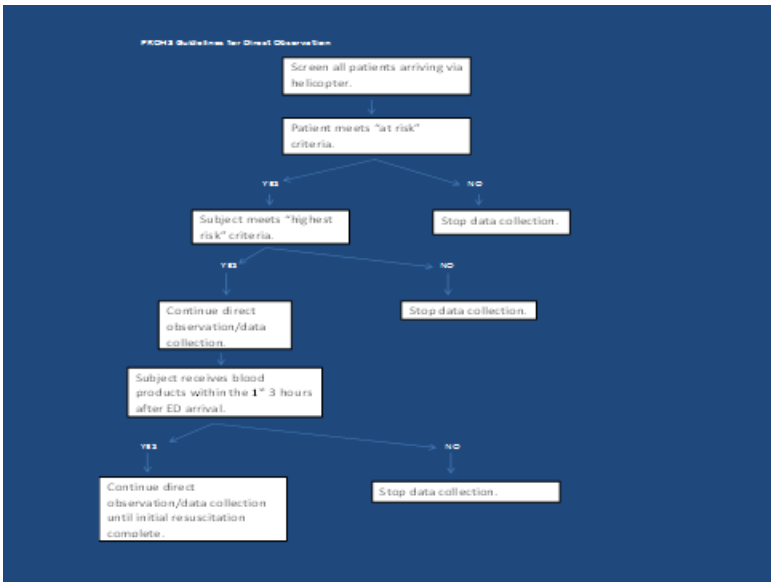
- Trauma injuries transported directly from scene via air ambulance
- ≥ 15 (if age unknown ≥ 50 kg)
- Non-prisoner (prisoner defined as received directly from a correctional facility)

"Highest Risk" Criteria

- Meet at least ONE of the following:
  - HR > 120
  - SBP ≤ 90 mm Hg
  - Penetrating truncal injury
  - Tourniquet application
  - Pelvic binder application
  - Intubation

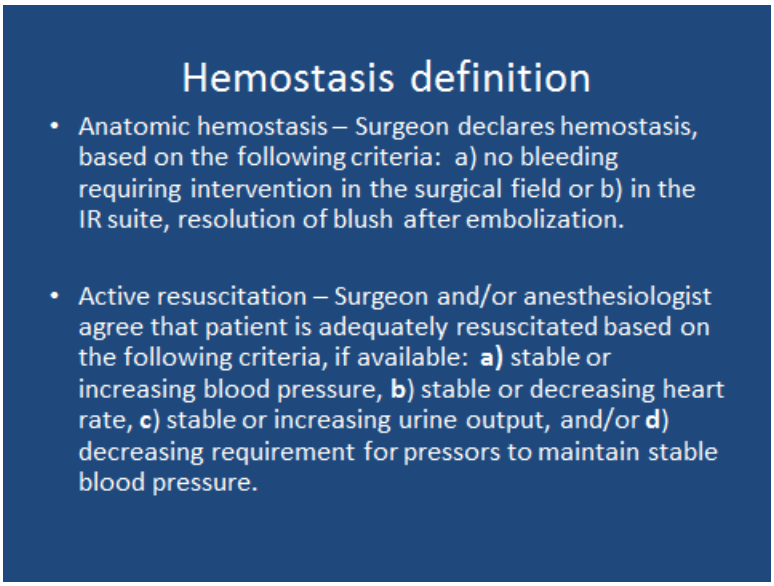
OR

- Received blood products during transport (applicable for sites with blood products available pre-hospital only)



Data Collection

- Direct observation through initial resuscitation complete (hemostasis achieved, care deemed futile or death)
- Indirect observation through hospital discharge or day 30 – research staff round daily to monitor complications and procedures
- Run sheets – copies of the run sheets will be kept on all subjects
- Trauma registry data


Hemostasis definition
• Anatomic hemostasis – Surgeon declares hemostasis, based on the following criteria: a) no bleeding requiring intervention in the surgical field or b) in the IR suite, resolution of blush after embolization.
• Active resuscitation – Surgeon and/or anesthesiologist agree that patient is adequately resuscitated based on the following criteria, if available: a) stable or increasing blood pressure, b) stable or decreasing heart rate, c) stable or increasing urine output, and/or d) decreasing requirement for pressors to maintain stable blood pressure.

9.4.2 One page summary

Prehospital **R**esuscitation **O**n **H**elicopter **S**tudy **(PROHS)**

Study Design: Multicenter, prospective, observational study which includes at least 9 level 1 U.S. trauma centers. The centers will screen patients transported to the Level 1 center via helicopter transport and enroll the highest acuity patients who meet the criteria for resuscitation requiring blood products. The centers will be divided into 2 groups – 1) helicopter service utilizing blood products during transport and 2) helicopter service utilizing crystalloids during transport.

Eligibility Criteria:
Inclusion:
"At risk" population - ≥ 15 years old, received directly from scene via air ambulance service.
"Highest risk" population (to be followed with direct observation) –

- meet at least one of the following: heart rate >120, SBP≤90 mm Hg, penetrating truncal injury, tourniquet application, pelvic binder application or intubation

OR

- received blood product(s) during transport (for those sites with blood product availability)

Exclusion:
Prisoners directly transported from a correctional facility

Screening/Enrollment: Research staff will be available in-house 24/7 to screen all patients transported via helicopter service for "highest risk" eligibility criteria. If the patient meets the "highest risk" eligibility criteria, the research staff will follow the subject with direct observation until initial resuscitation has been achieved or until care is determined futile or subject expires. Indirect data collection will continue through the in-hospital stay up to time of discharge of day 30, whichever occurs first.

Data Collection: Elements to be collected will include injury information, vital signs, standard of care laboratory values, initial resuscitation products and fluids, lifesaving interventions, daily ICU follow up, OR/IR procedures, complications, discharge disposition, and injury severity scores.

Research staff will be asked to round on all directly observed subjects on a daily basis while in hospital to monitor for complication and OR/IR procedures.

Objective: This study will compare the effectiveness of two different existing prehospital resuscitation models in severely injured trauma patients transported by air ambulance.

9.5 Helpful tips

- Recommend frequent and ongoing training prior to and throughout subject enrollment
- Monitor each individual's performance on a regular basis and retrain as needed
- Document attendance at training meetings – use training log to document names, signatures, date of training
- Remember to train new residents and staff at the beginning of each rotation change
- Provide updates to all people involved following the patient's enrollment – let them know the positives and negatives of the process and how to adjust

Chapter 10 – Publication Policy – To be determined at a later date.

Chapter 11 – Protocol