University of Pennsylvania
Office of Regulatory Affairs
3624 Market St., Suite 301 S
Philadelphia, PA 19104-6006
Ph: 215-573-2540/ Fax: 215-573-9438
INSTITUTIONAL REVIEW BOARD
(Federalwide Assurance # 00004028)

22-Nov-2016

Mark Seamon
Mark.Seamon@uphs.upenn.edu
Attn: Jennifer Leonard
Jennifer.Leonard@uphs.upenn.edu

PRINCIPAL INVESTIGATOR	: Mark Seamon
TITLE	: Prospective Observational Study of Temporary Intravascular Shunts in Trauma
SPONSORING AGENCY	: NO SPONSOR NUMBER
PROTOCOL #	: 826367
REVIEW BOARD	: IRB #7

Dear Dr. Seamon:

The above referenced protocol was reviewed and approved using the expedited procedure set forth in 45 CFR 46.110, category 5, on 21-Nov-2016. This study will be due for continuing review on or before 20-Nov-2017.

Approval by the IRB does not necessarily constitute authorization to initiate the conduct of a human subject research study. Principal investigators are responsible for assuring final approval from other applicable school, department, center or institute review committee(s) or boards has been obtained. If any of these committees require changes to the IRB-approved protocol and informed consent/assent document(s), the changes must be submitted to and approved by the IRB prior to beginning the research study.

If this protocol involves cancer research with human subjects, biospecimens, or data, you may not begin the research until you have obtained approval or proof of exemption from the Cancer Center's Clinical Trials Review and Monitoring Committee.

The waiver of informed consent and HIPAA waiver of authorization were reviewed as authorized by 45 CRF 46.116 (d) and 45 CFR 164.512 (i), respectively, and approved on 21-Nov-2016.

An expedited review procedure was used for the HIPAA authorization waiver because the research involves no more than minimal risk to the privacy of the individuals who are the subject of the protected health information for which use or disclosure is being sought.

The protected health information for which use or access has been determined to be necessary is as follows:

Direct identifiers:
-Used/collected:
---Names
---Medical record numbers

-Disclosed:
---No direct identifiers will be disclosed

Indirect identifiers:
-Used/collected:
---No indirect identifiers are being used/collected.

-Disclosed:
---No indirect identifiers will be disclosed

The following documents were included in this review:
-HS-ERA Initial Application Submission, confirmation code: ccdidfda, submitted 11-17-16
-Request for Waiver of HIPAA Authorization, uploaded 11-15-16
-Data Collection Tool, uploaded 11-15-16

NOTE: In the next modification please make the following administrative update to the online application bio page under Medical Information Disclosure: please select yes and select the option request for HIPAA waiver.

The review of the research has determined the following:

- An adequate plan has been presented to protect the identifiers from improper use and disclosure;
- An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research exists, unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law; and,
- An adequate written assurance has been provided that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted under the law.
- That the research cannot practicably be conducted without the waiver to access and use of the protected health information.

If you have any questions about the information in this letter, please contact the IRB administrative staff. Contact information is available at our website: http://www.upenn.edu/IRB/directory.

Thank you for your cooperation.

Sincerely,

Benjamin Hernberg

Digitally signed by Benjamin Hernberg
Reason: I attest to the accuracy and integrity of this document
Date: 2016.11.22 15:36:48 -05'00'

IRB Administrator

EAST MULTICENTER STUDY
DATA DICTIONARY

Temporary Intravascular Shunt Study – Data Dictionary

Data Entry Points and appropriate definitions / clarifications:

Entry space	Definition / Instructions
1. Specific Artery Shunted	Select single answer for the anatomic name of artery shunted
2. Was more than one artery shunted?	Select yes if more than one artery was shunted (please fill out additional entry sheet with separate study ID # for each artery shunted).
3. Was there an associated venous injury?	Select yes if there was an associated major venous injury. Otherwise select no.
4. Which vein was injured	Free Text for name of vein injured
5. How was the venous injury managed?	Venorrhaphy – Select if vein was primarily repaired Patch – Select if vein was repaired using a patch Ligation – Select if vein was ligated Shunt placement – Select if an intravenous shunt was used (not necessary to fill out an additional study form for shunted venous injuries)
Patient Demographics	
6. Age	Select patient age in years
7. Sex	Select patients biologic sex (Male or Female)
Past Medical History	Select yes if patient has each characteristic, no if patient does not, unknown if the information is not obtainable.
8. Diabetes	Select yes if patient has diagnosis of diabetes
9. Warfarin Use	Select yes if patient is currently on warfarin
10. Direct Oral Anticoagulant Use	Select yes if patient is currently on a direct oral anticoagulant medication
11. Aspirin Use	Select yes if patient is currently on aspirin
12. Plavix Use	Select yes if patient is currently on Plavix
13. Chronic Kidney disease	Select yes if patient has a diagnosis of chronic kidney disease

14. Congestive Heart Failure	Select yes if patient has a diagnosis of congestive heart failure
Prehospital Care	
15. Method of prehospital transport	Select the response corresponding to the method of prehospital transport.
16. Prehospital CPR	Select yes if patient had a cardiac arrest requiring prehospital CPR. Otherwise select no.
17. Was a tourniquet placed prehospital or in the emergency room?	Select yes if a tourniquet was placed either prehospital or in the emergency room.
18. Total tourniquet time	Enter the total tourniquet time in minutes.
Injury Characteristics	
19. ISS	Numerical value for calculated Injury Severity Score
20. AIS	Numerical value for AIS (Acute injury Score)
21. Type of injury mechanism	Single choice for best description of type of injury mechanism. Options include: Blunt, penetrating, mixed
22. Mechanism of Injury	Single choice for best description of injury mechanism. Options include: GSW (Gunshot wound), Shotgun (Shotgun wound), Stab (Stab Wound), (MVC) motor vehicle collision, (MCC) motorcycle collision, fall, assault, (HMA) heavy machinery accident, other
Initial Emergency Room Physiology	Patients physiology upon presentation to the emergency room (ED) or earliest recorded time point after arrival to the hospital
23. Heart Rate	Numerical value for heart rate on presentation to the ED
24. Systolic Blood Pressure	Numerical value for systolic blood pressure (SBP) on presentation to the ED
25. GCS	Numerical value for Glasgow Coma Scale (GCS) on presentation to the ED
Initial Laboratory Studies	Patients initial laboratory values upon presentation to the emergency department
26. INR	Numerical value for international normalized ratio (INR)
27. aPTT	Numerical value for activated partial thromboplastin (aPTT) time in seconds
28. Lactic Acid	Numerical value for lactic acid (mmol/L)
29. Hemoglobin	Numerical value for Hemoglobin (g/dL)
30. Platelets	Numerical value for Platelet count (thousand/µl)
31. WBC	Numerical Value for white blood cell (WBC) count (thousand/µl)

Transfusion Requirements	In the first 24 hours following admission, how many units of each of the following did the patient receive?
32. RBC	Numerical value for units of red blood cells (RBC) transfused in the first 24 hours
33. FFP	Numerical value for units of fresh frozen plasma (FFP) transfused in the first 24 hours
34. Platelets	Numerical value for units of platelets transfused in the first 24 hours
35. Did patient receive TXA?	Answer yes if patient received Transexemic Acid (TXA). Otherwise select no.
36. Did patient receive Factor VIIa?	Answer yes if patient received recombinant factor VIIa. Otherwise select no.
37. Did patient receive PCC?	Answer yes if patient received prothrombin complex concentrate (PCC). Otherwise select no.
Initial Physical Exam	Initial ED/trauma bay physical exam findings.
38. Hard Signs of Vascular Injury	Were there hard signs of vascular injury present on initial physical exam. The following are hard signs of vascular injury: • Absent distal pulses. • Signs of distal ischemia. Pain, pallor, paresthesia, paralysis, poikilothermia. • Audible bruit or palpable thrill at injury site. • Active pulsatile hem. • Large expanding hematoma. • Pulsatile hematoma.
39. Compartment Syndrome	Was compartment syndrome present on initial presentation? See the following article for definition and diagnosis of compartment syndrome. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3535085/
40. Arterial Pressure Index	Numerical value for arterial pressure index (API) for vascular injuries to the extremities. Arterial Pressure Index = (SBP injured) / (SBP uninjured)
41. MESS Score	If an extremity vessel was shunted, what was the mangled extremity severity score (MESS) of that extremity? The following may be used to calculate MESS score http://www.mdcalc.com/mangled-extremity-severity-score-mess-score/
Initial Operative/Shunting Procedure	
42. Specialty of initial operating surgeon	Choose specialty of initial operative surgeon. Choices include: Trauma/Acute Care, Vascular, General Surgery, Trauma Surgeon with vascular consultation.
43. Was a tourniquet used intraoperatively?	Select yes if a tourniquet was used during the initial operative procedure. Otherwise select no.
44. Total tourniquet time	What was the total tourniquet time including any time from prehospital or ED placed tourniquets in minutes?
45. Indication for Shunt Placement	Choose from the listed options the indication for shunt placement

46. If shunt used for damage control, what was the indication for damage control technique?	Choose from the listed options the rational for damage control technique.
47. Time from injury to shunt placement	Numerical value for time from injury to shunt placement in minutes Start time of shunt placement is defined as the moment vascular continuity is re-established with the shunt.
48. Were fasciotomies perfomed?	Select yes if fasciotomies were performed. Otherwise select no.
49. Was an embolectomy performed?	Select yes if embolectomy performed. Otherwise select no.
50. What type of shunt was used?	Select from the listed choices the type of shunt used.
51. Systemic anticoagulation intraoperatively	Select yes if systemic anticoagulation was given intraoperatively. Otherwise select no.
52. What type of anticoagulation was used	Select from the given options the type of anticoagulation given intraoperatively.
53. Total heparin dose if used	Numerical value for the total heparin dose given intraoperatively in units of heparin. Select 0 if none was given.
54. Were there any recognized technical errors during shunt placement?	Select yes if there were recognized technical errors during shunt placement. Otherwise select no.
55. If shunted vessel was associated with a fracture, how was the fracture initially stabilized?	Choose from the listed choices how fractures associated with vascular injury were initially stabilized.
56. Were there any associated nerve injuries?	Choose yes if there were associated injuries to major nerves. Otherwise select no.
57. Was an on table angiogram performed following shunting	Choose yes if an on table angiogram performed following shunting. Otherwise select no.
58. If angiogram performed, were vessels patient?	Choose yes if angiogram showed patient vessels, no if vessels were not patent.
Shunt Dwell Period	
59. Was there hypotension (SBP <90 mmHg) during shunt dwell period?	Select yes if hypotension was present during shunt dwell period. Otherwise select no.
60. Were vasopressors used during shunt dwell period?	Select yes if vasopressors were used during shunt dwell period. Otherwise select no.
61. Was CPR required at any point prior to definitive vascular repair?	Select yes if CPR was required during shunt dwell period. Otherwise select no.
62. Did compartment syndrome develop at any time during shunt dwell period?	Select yes if compartment syndrome developed during shunt dwell period. Otherwise select no.
63. Was anticoagulation used during shunt dwell period?	Select yes if systemic anticoagulation was given during shunt dwell period. Otherwise select no.
64. What type of systemic anticoagulation was used	Select type of systemic anticoagulation given
Definitive Repair	
65. Time from shunt placement to definitive vascular repair	Numerical value for time from shunt placement to definitive vascular repair in hours. The beginning of the shunt dwell period is defined as the time when vascular continuity was re-established with the shunt at the index operation. The end of the shunt dwell period is defined as the time

	when vascular continuity was re-established by definitive vascular repair.
66. Specialty of the surgeon performing definitive vascular repair	Choose specialty of initial operative surgeon. Choices include: Trauma/Acute Care, Vascular, General Surgery, Trauma Surgeon with vascular consultation.
67. Method of definitive repair	Choose from the listed options the method of definitive vascular repair
68. Was embolectomy performed during definitive repair	Select yes if embolectomy was performed during the definitive vascular repair. Otherwise select no.
69. Was systemic anticoagulation used during shunt dwell period?	Select yes if systemic anticoagulation was used during the shunt dwell period. Otherwise select no.
70. What type of anticoagulation was used?	Select type of systemic anticoagulation given
71. Was completion angiography performed following definitive repair?	Select yes if completion angiography was performed following definitive repair. Otherwise select no.
72. Were fasciotomies performed following definitive repair?	Select yes if fasciotomies were performed following definitive repair. Otherwise select no.
Shunt related Complications	Select yes for each of the listed complications if they were noted during shunt dwell period. Select no if they complication did not occur.
73. Shunt Dislodgement	Select yes if shunt dislodgement occurred during shunt dwell period. Otherwise select no.
74. Shunt Thrombosis	Select yes if shunt thrombosis occurred during shunt dwell period. Otherwise select no.
75. Distal Ischemia	Select yes if distal ischemia occurred during shunt dwell period. Otherwise select no. Distal ischemia is defined as distal tissue injury caused by prolonged poor perfusion diagnosed by clinical exam or imaging.
76. If Distal ischemia was noted, which organs/tissues were involved	Free Text field. List organs/tissues involved by distal ischemia if present.
Post-definitive repair and outcomes	
77. Was systemic anticoagulation used post definitive repair?	Select yes if systemic anticoagulation was used after definitive vascular repair
78. What type of anticoagulation was used post definitive repair?	Select type of systemic anticoagulation given
79. Was follow up imaging obtained?	Select yes if follow up imaging was obtained. Otherwise select no.
80. How long after definitive vascular repair was follow up imaging obtained?	Numerical value for number of days following definitive repair that follow up imaging was obtained.
81. What type of imaging was obtained?	Select type of imaging obtained.
82. Was vascular repair patent on follow up imaging?	Select yes if follow up imaging showed a patent vascular repair. Otherwise select no.
83. Total ICU length of stay	Numerical value for total length of ICU stay in days
84. Total hospital length of stay	Numerical value for total length of hospital stay in days
85. Total ventilator days	Numerical value for total number of ventilator days
86. Hospital Disposition	Select from the given options

Study ID # _____

Institution _____

1. **Specific Artery Shunted:**

Torso:

__Innominate Artery

__Subclavian Artery

__Intra-Thoracic Common Carotid Artery

__Descending Thoracic Aorta

__Abdominal Aorta

__Common Iliac Artery

__External Iliac Artery

__Internal Iliac Artery

__Common Hepatic Artery

__Celiac Artery

__Superior Mesenteric Artery

__Renal Artery

Extremity:

__Brachial Artery

__Axillary Artery

__Common Femoral Artery

__Superficial Femoral Artery

__Deep Femoral Artery

__Popliteal Artery

Cervical:

__Common Carotid Artery (extra-thoracic)

__Internal carotid

__External Carotid

2. Was more than one artery shunted? ____Yes _____No

**If more than one vessel shunted, submit an additional datasheet for each vessel shunted.

3. Was there a venous injury associated with the shunted artery? ____Yes _____No

4. Which vein(s) were injured?

_____

_____

5. How was the venous injury managed during the initial procedure?

Venorrhaphy_____ Patch_____ Ligation ____ Shunt placement _____

Patient Demographics:

6. Age (years) _____

7. Gender: Male ____ Female ____

Past Medical History:

8. Diabetes _____

9. Warfarin Use _____

10. Direct Oral Anticoagulant Use _____

11. Aspirin Use _____

12. Plavix Use _____

13. Chronic Kidney Disease _____

14. Heart Failure _____

Prehospital Care:

15. Method of Transport

ALS_____

BLS_____

Police Transfer_____

Private Vehicle _____

Unknown _____

16. Prehospital CPR? Yes _____ No _____

17. Was a Tourniquet Placed Prehospital?

Yes_____ No_____

18. Total Prehospital Tourniquet Time _____Minutes

Injury Characteristics:

19. ISS _____

20. AIS: Head:_____ Abdomen:_____

Chest: _____ Extremity:_____

21. Type of Injury mechanism

Blunt _____

Penetrating _____

Mixed _____

22. Mechanism of Injury -specific

Motor vehicle Collision_____

Motorcycle Collision _____

Gun Shot Wound _____

Shot Gun Wound _____

Stabbing _____

Fall _____

Machinery Accident _____

Assault _____

Other _____

Initial ED Physiology:

23. Heart Rate _____ (bpm)

24. Systolic Blood Pressure _____ (mmHg)

25. GCS _____

Initial ED Laboratory Studies

26. INR _____

27. aPTT _____

28. Lactate_____

29. Hemoglobin _____

30. Platelets _____

31. White Blood Cell Count _____

Transfusion Requirements

In first 24 hours of admission how much of each of the following did the patient receive?

32. RBC _____ (units)

33. FFP _____

34. Platelets _____

35. Did Patient receive TXA? Yes / No

36. Did Patient Receive Factor IIVa? Yes / No

37. Did Patient Receive PCC (prothrombin complex concentrate)? Yes / No

Initial ED Physical Exam

38. Hard Signs of Vascular Injury?

Yes _____ No _____

39. Was compartment syndrome present?

Yes _____ No _____

40. Arterial Pressure Index (for vascular injuries of extremities) _____

41. If extremity vessel was shunted what was the MESS score of the involved extremity?

_____ (points)

Initial Operative/Shunting Procedure:

42. What was the specialty of the initial operating surgeon?

Trauma/Acute Care _____

Vascular _____

General Surgery _____

Trauma w/ Vascular Consultation _____

43. Was a tourniquet used intraoperatively? _____yes _____no

44. If a Tourniquet was used, what was the total tourniquet time (including prehopsital, ED and intraoperative)?

_____ minutes

45. What was the indication for shunt placement?

_____Damage Control Procedure

_____Maintain perfusion during orthopedic fixation

_____Maintain perfusion during vein harvest

_____Maintain perfusion awaiting specialist consultation

_____Other (Please Specify) _____

46. If Damage Control was the indication for shunt placement, what was the rational for use of damage control techniques?

Hemodynamic Instability _____

Traumatic Coagulopathy_____

Other Life Threatening Injuries _____

Not Applicable _____

47. Time from injury to shunt placement _____ minutes

*Start time of shunt placement is defined as the moment vascular continuity is re-established with the shunt.

48. If vascular injury requiring shunt was in an extremity vessel, were fasciotomies performed at index operation?

___Yes ___No

49. Was an embolectomy performed prior to shunt placement? _____yes _____no

50. What type of shunt was used?

Argyle ____ Size _____Fr

Javid ____ Size_____Fr

Sundt _____ Size_____Fr

Other: _____ Size _____Fr

51. Was systemic anticoagulation given intraoperatively? _____yes _____no

52. What type of anticoagulation was used?

_____Heparin Bolus

_____Heparin infusion

_____N/A

53. Total heparin dose if used _____ units.

54. Were there any recognized technical errors during shunt placement? _____yes _____no

55. If shunted vessel was associated with a fracture, how was the fracture initially stabilized?

_____ External fixation during shunt procedure

_____Formal repair during shunt procedure

_____Other

56. Were there any associated nerve injuries? _____yes _____no

57. Was an on table angiogram performed following shunting _____yes _____no

58. If angiogram performed, were vessels patient?

_____yes

_____no

_____N/A

Shunt Dwell Period:

59. Was there hypotension (SBP <90 mmHg) during shunt dwell period? _____yes _____no

60. Were vasopressors used during shunt dwell period? _____yes _____no

61. Was CPR required at any point prior to definitive vascular repair? _____yes _____no

62. Did compartment syndrome develop at anytime during shunt dwell period? _____yes _____no

63. Was anticoagulation used during shunt dwell period? _____yes _____no

64. What type of anticoagulation was used?

_____Heparin _____Aspirin

_____Plavix _____N/A

Definitive Repair:

65. Time from shunt placement to definitive vascular repair _____ hours

**The beginning of the shunt dwell period is defined as the time when vascular continuity was re-established with the shunt at the index operation. The end of the shunt dwell period is defined as the time when vascular continuity was re-established by definitive vascular repair.

66. What was the specialty of the surgeon performing definitive vascular repair?

Trauma/Acute Care _____

Vascular _____

General Surgery _____

Trauma w/ Vascular Consultation _____

67. Method of definitive repair:

Primary _____

Autologous venous bypass graft _____

Prosthetic bypass graft _____

Ligation _____

Other _____

68. Was embolectomy performed during definitive repair? ____yes _____no

69. Was systemic anticoagulation used during definitive repair? _____yes _____no

70. What type of anticoagulation was used?

_____Heparin _____Aspirin

_____Plavix _____N/A

71. Was completion angiography performed following definitive repair? _____yes _____no

72. Were fasciotomies performed following definitive repair? _____yes _____no

Shunt Related Complications:

Did any of the following shunt related complications occur during the shunt dwell period?

73. Shunt Dislodgement _____yes _____no

74. Shunt Thrombosis _____yes _____no

75. Distal ischemia _____ yes _____no

76. If distal ischemia was noted, which organs/tissues were involved? _____

*Distal ischemia is defined as distal tissue injury caused by prolonged poor perfusion diagnosed by clinical exam or imaging.

Post-definitive repair and outcomes:

77. Was anticoagulation used post definitive repair? _____yes _____no

78. What type of anticoagulation was used post definitive repair?

_____Aspirin

_____Plavix

_____Prophylactic dose heparin or lovenox

_____Theraputic dose anticoagulation

_____ None

79. Was follow up imaging obtained? _____yes _____no

80. How long after definitive repair was follow up imaging obtained? _____ (Days)

81. What type of imaging was obtained?

_____CT scan

_____MRI

_____Ultrasound

_____ None

82. Was vascular repair patent on follow up imaging? _____yes _____no

83. Total ICU length of stay _____days

84. Total hospital length of stay _____days

85. Total ventilator days _____days

86. Hospital Disposition

Home _____

Acute Rehablitation Center _____

Skilled Nursing Facility _____

Death _____

Other _____