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IRB_00081463 **Created:** 3/11/2015 1:23 PM

PI: Raminder Nirula MD/Assistant Professor of Surgery **Submitted:** 3/10/2015

Title: Development of a Prediction Model for Patients With Chest Trauma: A Multi-institutional study of the AAST

1. Contacts and Title

1. Principal Investigator:

Raminder Nirula

Email	Training	CoI Date
r.nirula@hsc.utah.edu	12/12/2011 MN	4/21/2015

a. Position of Principal Investigator:

- (●) **Faculty**
- ( ) Student
- ( ) Staff
- ( ) Resident/Fellow
- ( ) Other

If Other, describe:

b. Will the Principal Investigator consent participants? ( ) Yes (●) **No**

2. Contact Person(s) (if different from the PI):

Name	Email	Training
Lara Senekjian	lara.senekjian@hsc.utah.edu	10/10/2013 SM

3. Internal Staff and Sub-Investigator(s) (Within the University of Utah):

Name	Email	Training	Obtaining Consent	CoI Date

There are no items to display

4. External Sub-Investigator(s) (Investigators outside the University of Utah):

Last Name	First Name	Affiliation
Cocanour	Christine	University California Davis
Combria	Raul	University California San Diego
Demetriades	Demetrios	USC Department of Surgery
Galante	Joseph	University California Davis
Jurkovich	Jerry	University of Washington School of Medicine
Malhotra	Ajai	Virginia Commonwealth University School of Medicine
Park	Pauline	University of Michigan
Peitzman	Andrew	University of Pittsburg Medical Center
Scalea	Thomas	University of Maryland
Sperry	Jason	University of Pittsburg Medical Center

5. Faculty Sponsor (if needed):

6. Guests:

Last Name	First Name	E-Mail

There are no items to display

7. What type of application is being submitted?

New Study Application (or Amendment/Continuing Review)

8. Title Of Study:

Development of a Prediction Model for Patients With Chest Trauma: A Multi-institutional study of the AAST

9. Study Purposes and Objectives:

Purpose: This study is to create a prediction model for patient that have sustained chest trauma causing multiple rib fractures. Currently patients admitted with rib fractures have increased risk of pneumonia, increased length of stay, and prolonged ventilator times. It is unclear which patients will have these worsened outcomes at the time of admission. The goal of this study is to identify admission (within 24 hours) criteria that have negative impact on patient outcome. This study will generate prediction model using admission factors and chest CT scan to determine if there is a patient population that has increased risk of worse outcome.

10. Background and Introduction:

Significance

Chest trauma has significant burden on the trauma population. In drivers over the age of 64 who died in a frontal crash, 47% sustained fatal chest injury.[8] Rib fractures are seen in 39% of patients with blunt chest trauma.[4] Of the roughly 100,000 trauma deaths 25% are the result of chest trauma.[9] Pulmonary contusion can be seen in 30-70% of blunt thoracic trauma, however worse outcomes are seen in patients that have both contusion and rib fracture.[1] It appears that the increase in number of ribs fractured causes worse outcomes with pneumonia occurring in 3-5.2% of patients with 1-5 ribs fractured and 6.8-8.4% with 6 or more ribs fractured.[10] According to Dehghan et al, severe chest trauma (flail or any patient with AIS 3 or greater) leads to decreased lung volumes, atelectasis, chest tightness, dyspnea and chronic pain.[4] These factors are amplified in the elderly, but it is unclear to what degree, or if another population may be affected more than the general population. There has been suggestion that mortality can reach 12% in patients with rib fractures with 33% having severe pulmonary complications.[11] In the population 65 and greater there is an increased risk of pneumonia 31% vs 17% in those less than 65. Thoracic trauma also has impact on the population level. It has been reported that only 43% of patients with severe chest wall injury return to previous full time employment.[4] The average patient has a 70±41 lost days of work.[12] At post trauma day 30, 70% of patients with rib fracture are still using narcotics.[12] There is a significant indication that patients with blunt chest trauma have complications, however which patients have the highest possibility of these complications has not been fully elucidated.

Reference:

1. Kent R, Woods W, Bostrom O. Fatality risk and the presence of rib fractures. *Ann Adv Automot Med*. 2008;52:73–82.

2. Dehghan N, de Mestral C, McKee MD, Schemitsch EH, Nathens A. Flail chest injuries: a review of outcomes and treatment practices from the National Trauma Data Bank. *J Trauma Acute Care Surg*. 2014;76(2):462–468. doi:10.1097/TA.0000000000000086.

3. Shorr RM, Crittenden M, Indeck M, Hartunian SL, Rodriguez A. Blunt thoracic trauma. Analysis of 515 patients. *Ann Surg*. 1987;206(2):200–205.

4. Simon B, Ebert J, Bokhari F, et al. Management of pulmonary contusion and flail chest: an Eastern Association for the Surgery of Trauma practice management guideline. *J Trauma Acute Care Surg*. 2012;73(5 Suppl 4):S351–61. doi:10.1097/TA.0b013e31827019fd.

5. Flagel BT, Luchette FA, Reed RL, et al. Half-a-dozen ribs: the breakpoint for mortality. *Surgery*. 2005;138(4):717–23– discussion 723–5. doi:10.1016/j.surg.2005.07.022.

6. Bulger EM, Arneson MA, Mock CN, Jurkovich GJ. Rib fractures in the elderly. *J Trauma*. 2000;48(6):1040–6– discussion 1046–7.

7. Kerr-Valentic MA, Arthur M, Mullins RJ, Pearson TE, Mayberry JC. Rib fracture pain and disability: can we do better? *J Trauma*. 2003;54(6):1058–63– discussion 1063–4. doi:10.1097/01.TA.0000060262.76267.EF.

8. Nirula R, Diaz JJ, Trunkey DD, Mayberry JC. Rib fracture repair: indications, technical issues, and future directions. *World J Surg*. 2009;33(1):14–22. doi:10.1007/s00268-008-9770-y.

9. Tanaka H, Yukioka T, Yamaguti Y, et al. Surgical stabilization of internal pneumatic stabilization? A prospective randomized study of management of severe flail chest patients. *J Trauma*. 2002;52(4):727–32– discussion 732.

10. Battle CE, Hutchings H, Lovett S, et al. Predicting outcomes after blunt chest wall trauma: development and external validation of a new prognostic model. *Crit Care*. 2014;18(3):R98. doi:10.1186/cc13873.

11. Pressley CM, Fry WR, Philp AS, Berry SD, Smith RS. Predicting outcome of patients with chest wall injury. *Am J Surg*. 2012;204(6):910–3– discussion 913–4. doi:10.1016/j.amjsurg.2012.05.015.

12. Trupka A, Waydhas C, Hallfeldt KK, Nast-Kolb D, Pfeifer KJ, Schweiberer L. Value of thoracic computed tomography in the first assessment of severely injured patients with blunt chest trauma: results of a prospective study. *J Trauma*. 1997;43(3):405–11– discussion 411–2.

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2. Study Location and Sponsors

1. **Department:**
SURGERY RESEARCH

2. **Location of Study:**

University of Utah's Covered Entity (Health sciences, hospitals, and clinics)

3.

Is this a Multicenter Study (i.e., the study involves other sites with other PIs):

◉ **Yes** ○ No

a. If yes, are you the lead investigator of this study, or is this the central location for the study?

◉ **Yes** ○ No

4. Indicate other locations that are participating in the study for which you, as the PI, are responsible:

Site Name	Other Site	Site Investigator	Investigator/Main Contact
View Other	University California Davis Health System	yes	Joseph Galante
View Other	University California Davis Health System	yes	Christine Cocanour
View Other	University California San Diego	yes	Raul Combria
View Other	University of Maryland	yes	Thomas Scalea
View Other	University of Michigan	yes	Pauline Park
View Other	University of Pittsburg Medical Center	yes	Jason Sperry
View Other	University of Pittsburg Medical Center	yes	Andrew Peitzman
View Other	University of Washington School of Medicine	yes	Jerry Jurkovich
View Other	University Southern California Department of Surgery	yes	Demetrios Demetriades
View Other	Virginia Commonwealth University School of Medicine	yes	Ajai Malhotra

a. How will adverse events, unanticipated problems, interim results, and changes to the research be communicated between the participating sites and the Principal Investigator?
This is retrospective collection of data, therefore no adverse events will take place. Any changes to research will be directly communicated to other site investigators via email or phone call.

5. Indicate the source(s) of funding obtained or applied for to support this study.

Sponsor	Sponsor Type	Sponsor Contact Information

There are no items to display

6. Does this study have functions assigned to a Contract Research Organization (CRO)?
○ Yes ◉ **No**

If yes, CRO Contact Information:

7. Does this study involve use of the Utah Population Database (UPDB)?
○ Yes ◉ **No**

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3. Participants

1. Ages of Participants:
18 and older (Consent form needed)

2. Specific age range of participants (e.g., 7-12 years old, 60+, etc.):
greater than 18 years - obtained by chart review

3. Indicate any vulnerable participant groups (other than children) included:

None

If "Other", please specify:

If "None" and no children are involved, answer the following question.
Has the participant selection process overprotected potential subjects who are considered vulnerable so that they are denied opportunities to participate in research?
○ Yes ◉ **No**

4. Number of participants to be enrolled during the entire study:

At Utah: 500

All Centers: 4000

5. Characteristics of Participants/Inclusion Criteria:

Inclusion Criteria

Inclusion criteria will be all patients greater than or equal to 18 years old at admission who sustained blunt chest trauma causing at least two rib fractures based on chest CT scan. Patients will have survived at least 48 hours. Patients must have chest CT completed within 24 hours of admission.

6. Participant Exclusion Criteria:

Exclusion Criteria

Exclusion criteria include any patients less than 18 years old at time of admission. Patients incurring penetrating injury to the chest and patients without chest CT scan within 24 hours will also be excluded. Patients with "devastating head injury deemed non-survivable at admission" as well as patients with ICP monitoring greater than 3 days or receiving emergency craniotomy within 24 hours will be excluded.

7. **Is a substantial percentage of the participant population anticipated to be non-English speaking?**

○ Yes ◉ **No**

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4. Study Information

1. **Design of Study (select all that apply):**
   Retrospective Chart Review
   If Other, describe:

2. **Does your study involve the use of any placebo?**
   ○ Yes ◉ **No**

3. **Length of entire study, from initiation through closeout:** 18 months projected with data analysis

4. **How will participants be recruited or identified for inclusion in the study?**

   a. **Select all methods that will be used:**
   Written or electronic record review

   Patients will be identified via chart review based on methods at each participating center. A list of applicable patients will be generated based on pre-specified ICD.9 codes that will give them diagnosis of flail chest. The final list of those included for analysis will meet the above stated inclusion and exclusion criteria.

   b. **Describe the recruitment/participant identification process in detail (e.g. who will review charts or records, who can refer participants to the study, where will flyers be posted, how often will recruitment letters be sent, when will follow-up phone calls be made, etc.):**

   no prospective recruitment required

5. **How will consent be obtained?**
   Waiver or Alteration of Informed Consent

6. **Describe all the procedures chronologically, from screening/enrollment through study closeout, which will be completed in the research project.**

   Time Frame:

   January - March 2015: IRB approval and modification at each participating center

   April - June 2015: Acquire data from participating center and submission to PI

   July - December 2015: Data and scan analysis

   January - June 2016: Draft and revise manuscript

7. **Are all procedures for research purposes only (non-standard or non-standard of care procedures)?**
   ◉ **Yes** ○ No

   If no, list the procedures that are performed for research purposes only (non-standard or non-standard of care procedures):

8. **Is there a safety monitoring plan for this study?**
   ○ Yes ◉ **No**

9. **Provide a summary of the statistical methods, data analysis, or data interpretation planned for this study. Factors for determining the proposed sample size (e.g., power) should be stated.**

   Methods: Retrospective chart review will occur based on those patients that fit the above inclusion/exclusion criteria. Patients that fit within the above criteria will be analyzed for eight primary outcome variables.

   Primary outcome variables:

   Pneumonia: defined by CDC guidelines of pneumonia[17] (http://www.cdc.gov/Features/Pneumonia/)

   Radiologic findings:

Two or more serial chest radiographs with at least one of the following:

- New or progressive and persistent infiltrate
- Consolidation
- Cavitation

Signs/Symptoms/Lab:

At least one of the following:

- Fever (>38°C or >100.4°F)
- Leukopenia (<4000 WBC/mm3) or leukocytosis (≥12,000 WBC/mm3)
- For adults ≥70 years old, altered mental status with no other recognized cause

And at least two of the following:

- New onset of purulent sputum, or change in character of sputum, or increased respiratory secretions, or increased suctioning requirements
- New onset or worsening cough, or dyspnea, or tachypnea
- Rales or bronchial breath sounds
- Worsening gas exchange (e.g., O2 desaturations (e.g., PaO2/FiO2 ≤240), increased oxygen requirements, or increased ventilator demand)

Mortality: during hospitalization or within 30 days of initial discharge

Pleural effusion: fluid identified surrounding lung tissue, seen on chest x-ray or chest CT scan without septations or evidence of pus at time of drainage

Empyema: pus around lung tissue, dictated by provider diagnosis in chart, including positive fluid culture

Tracheostomy: in hospital tracheostomy or within 30 days of initial discharge

Hospital Length of Stay: collected in hours

Ventilator Time: collected in hours

Patient admission data (including first 24 hours of hospital stay) will be collected for inclusion in possible model. Candidate variables are identified in appendix I. Data collected is described fully for admission variables in Appendix I. The objective of this model is to identify data at time of admission that would indicate poor outcomes and possibly indicate patients with higher risk of complications.

Sample Size: In order for the model to have adequate sensitivity and specificity with narrow 95% confidence intervals, it will require 300 patients for analysis. It has been shown that of the outcomes (pneumonia, mortality, pleural effusion, empyema and tracheostomy) empyema and tracheostomy are routinely the least common with a 2.9-10% occurrence.[18] Using STATA to calculate confidence interval a sample size of 300 would give CI, 0.0021- 0.0290 which is adequately narrow. However we intend to include roughly 20 predictor terms in the regression model, where the number of indicator terms needed for the categorical variables is included in the sum of 20. To avoid "overfitting" then, where unreliable correlation is introduced by violating the n=10 events for every predictor term, we will collect a sample size of n= 4000.[19] Level 1 trauma centers that routinely admit patients with the above criteria will be included in the creation of the model. One extra trauma center will be withheld from the initial model in order to validate the final model.

Mortality, pneumonia, pleural effusion, empyema and tracheostomy will be analyzed as binary outcomes. Regarding ICU length of stay, hospital length of stay and ventilator days will be with linear regression modeling.

Candidate variables have been identified. These variables were chosen as predictor variables as they may have impact on hospital course and can be collected for each patient at the time of admission or within 24 hours. Previous models have suggested candidate variables, which will be considered, however clear methodology was not explained in previous methods.[14,15]

For each outcome a logistic regression model will be created. Candidate predictors will all be included in initial prediction model.[20,21] This will then be reduced in stepwise fashion by manually removing variables one at a time. Variables that improve the ROC area by at least 1 point will be retained in the final model, as the goal is discrimination rather than statistical significance.

One of the selected centers will be held from initial evaluation. The model will then be externally validated using this hospital. Internal validation using bootstrapping will also be used.

Deriving a prognostic score will be done by weighing the regression coefficients.

14. Battle CE, Hutchings H, Lovett S, et al. Predicting outcomes after blunt chest wall trauma: development and external validation of a new prognostic model. Crit Care 2014;18(3):R98.

15. Pressley CM, Fry WR, Philp AS, Berry SD, Smith RS. Predicting outcome of patients with chest wall injury. Am J Surg 2012;204 (6):910-3-discussion913-4.

1. Simon B, Ebert J, Bokhari F, et al. Management of pulmonary contusion and flail chest: an Eastern Association for the Surgery of Trauma practice management guideline. J Trauma Acute Care Surg. 2012;73(5 Suppl 4):S351-61.

2. Hyllienmark P, Brattström O, Larsson E, Martling C-R, Petersson J, Oldner A. High incidence of post-injury pneumonia in intensive care-treated trauma patients. Acta Anaesthesiol Scand 2013;57(7):848-54.

3. Gannon CJ, Pasquale M, Tracy JK, McCarter RJ, Napolitano LM. Male gender is associated with increased risk for postinjury pneumonia. Shock 2004;21(5):410-4.

4. Dehghan N, de Mestral C, McKee MD, Schemitsch EH, Nathens A. Flail chest injuries: a review of outcomes and treatment practices from the National Trauma Data Bank. J Trauma Acute Care Surg 2014;76(2):462-8.

5. Tanaka H, Yukioka T, Yamaguti Y, et al. Surgical stabilization of internal pneumatic stabilization? A prospective randomized study of management of severe flail chest patients. J Trauma 2002;52(4):727-32-discussion732.

6. Balci AE, Eren S, Cakir O, Eren MN. Open fixation in flail chest: review of 64 patients. Asian Cardiovasc Thorac Ann 2004;12 (1):11-5.

7. Mayberry JC, Ham LB, Schipper PH, Ellis TJ, Mullins RJ. Surveyed opinion of American trauma, orthopedic, and thoracic surgeons on rib and sternal fracture repair. J Trauma 2009;66(3):875-9.

8. Kent R, Woods W, Bostrom O. Fatality risk and the presence of rib fractures. Ann Adv Automot Med 2008;52:73-82.

9. Shorr RM, Crittenden M, Indeck M, Hartunian SL, Rodriguez A. Blunt thoracic trauma. Analysis of 515 patients. Ann Surg 1987;206(2):200-5.

10. Flagel BT, Luchette FA, Reed RL, et al. Half-a-dozen ribs: the breakpoint for mortality. Surgery 2005;138(4):717-23 -discussion723-5.

11. Bulger EM, Arneson MA, Mock CN, Jurkovich GJ. Rib fractures in the elderly. J Trauma 2000;48(6):1040-6-discussion1046-7.

12. Kerr-Valentic MA, Arthur M, Mullins RJ, Pearson TE, Mayberry JC. Rib fracture pain and disability: can we do better? J Trauma 2003;54(6):1058-63-discussion1063-4.

13. Nirula R, Diaz JJ, Trunkey DD, Mayberry JC. Rib fracture repair: indications, technical issues, and future directions. World J Surg 2009;33(1):14-22.

14. Battle CE, Hutchings H, Lovett S, et al. Predicting outcomes after blunt chest wall trauma: development and external validation of a new prognostic model. Crit Care 2014;18(3):R98.

15. Pressley CM, Fry WR, Philp AS, Berry SD, Smith RS. Predicting outcome of patients with chest wall injury. Am J Surg 2012;204 (6):910-3-discussion913-4.

16. Trupka A, Waydhas C, Hallfeldt KK, Nast-Kolb D, Pfeifer KJ, Schweiberer L. Value of thoracic computed tomography in the first assessment of severely injured patients with blunt chest trauma: results of a prospective study. J Trauma 1997;43(3):405-11 -discussion411-2.

17. CDC/NHSN Surveillance Definitions for Specific Types of Infections. httpwww.cdc.govnhsnPDFspscManualpscNosInfDefcurrent.pdf. 2014;

18. Chen J, Jeremitsky E, Philp F, Fry W, Smith RS. A chest trauma scoring system to predict outcomes. Surgery 2914;156(4):988 -94.

19. Harrell FE, Lee KL, Mark DB. Tutorial in Biostatistics: Multivariable prognostic models: issues in developing models, evaluating assumptions and adequacy, and measuring and reducing errors. Stat Med 1996;15:361-87.

20. Kalkman CJ, Visser K, Moen J, Bonsel GJ, Grobbee DE, Moons KGM. Preoperative prediction of severe postoperative pain. Pain 2003;105(3):415-23.

21. Janssen KJM, Moons KGM, Kalkman CJ, Grobbee DE, Vergouwe Y. Updating methods improved the performance of a clinical prediction model in new patients. J Clin Epidemiol 2008;61(1):76-86.

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Request for Waiver or Alteration of Consent

Requested Waivers

Date Created	Type of Request	Purpose of Waiver Request
View 1/12/2015	Waiver of Informed Consent	Chart Review/Data Collection

5. Data Monitoring Plan

1. **Privacy Protections:** Privacy refers to persons and to their interest in controlling access of others to themselves. Privacy can be defined in terms of having control over the extent, timing and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. **What precautions will be used to ensure subject privacy is protected?**

   Select all that apply:
   The collection of information about participants is limited to the amount necessary to achieve the aims of the research, so that no unneeded information is being collected

   Other or additional details (specify):

2. **Confidentiality Precautions:** Confidentiality is an extension of the concept of privacy; it refers to the subject's understanding of, and agreement to, the ways identifiable information will be stored and shared. Identifiable information can be printed information, electronic information or visual information such as photographs. **What precautions will be used to maintain the confidentiality of identifiable information?**

   Select all that apply:
   Storing research data on password protected computers or in locked cabinets or offices
   All data that will be transferred or transported outside of the institution will be encrypted

   Other or additional details (specify):

3. **Will photos, audio recordings, or video recordings, or medical images of participants be made during the study?**
   ◉ Yes ○ No

   If yes, describe the recording/images and what will become of them after creation (e.g., shown at scientific meetings, stored in the medical/research record, transcribed, erased, etc.):
   Inclusion criteria requires that patients have CT scan of the chest completed to participate. Two independent reviewers at the University of Utah will review each scan. The results of each scan will be documented for statistical analysis only and will be erased when analysis is complete.

4. **How will study data and documentation be monitored throughout the study?**

   Select all that apply:
   Confirmation that all appropriate information has been reported to the sponsor, oversight agencies (such as the FDA), and/or IRB

   Other additional details (specify):

5. **Who will be the primary monitor of the study data and documentation?**

   Select all that apply:
   Principal Investigator

   Other or additional details (specify):

6. **How often is study data and documentation monitoring planned (e.g., monthly, twice a year, annually, after N participants are enrolled, etc.)?**
   Data will be reviewed periodically for completeness after each 1000 participant's data is incorporated into the AAST database. Again will be evaluated prior to submission of any presentations or manuscripts.

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6. Risks and Benefits

1.

Describe the reasonable foreseeable risks or discomforts to the participants:

No direct patient intervention will take place, however there will be risk to loss of patient confidentiality of participant information.

2. **Describe the potential benefits to society AND to participants (do not include compensation):**

This study will help practitioners predict outcomes in trauma patients that sustain multiple rib fractures. Notoriously a significant portion of these patients have poor outcomes, however which patient will have the morbidity is unclear. By identifying patients at time of admission who have increased risk of poor outcome, practitioners could admit the patient to higher state of care or transfer to specialized hospital as needed. Thus decreasing re-admissions and poor outcomes. Participants will have no potential benefit as they have already been treated for the disease described.

3. **Are there any costs to the participants from participation in research?**

○ Yes ◉ **No**

If yes, specify:

4. **Is there any compensation to the participants?**

○ Yes ◉ **No**

a. **If yes, answer the following:**
Specify overall amount:

b. **Specify when participants will be paid (e.g. at each visit, at end of study, etc.):**

c. **If applicable, please specify payment by visit or other time interval (e.g. $10 per visit, etc.):**

d. **If applicable, explain plan for prorating payments if participant does not complete the study:**

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7. HIPAA and the Covered Entity

1. **Does this study involve Protected Health Information (PHI) or de-identified health information?**

◉ **Yes** ○ No

a. **If yes, select the method(s) of authorization that will be used:**
De-identified

If needed, select De-Identification Form: Safe Harbor De-Identification

b. **If yes, will PHI be disclosed outside the Covered Entity?**
○ Yes ◉ **No**

If so, to whom?

And for what purposes?

2. **Does this study involve any of the following:**

a. **The investigational use of a drug?**
○ Yes ◉ **No**

b. **The investigational use of a medical device?**
○ Yes ◉ **No**

c. **Is this an investigator-initiated drug or device trial lead by the Principal Investigator?**
○ Yes ◉ **No**

d. **Exposure to radioisotopes or ionizing radiation?**
○ Yes ◉ **No**

e. **Does the study involve cancer patients and/or address a cancer question?**
○ Yes ◉ **No**

f. **Obtaining data or information from the UUHSC Enterprise Data Warehouse (EDW) in a query outside of the Utah Population Database (UPDB)?**
○ Yes ◉ **No**

g. Any component of the Center for Clinical and Translational Science (CCTS)?
○Yes ◉**No**

The Clinical Services Core (CSC)?
○Yes ○No

h. A Humanitarian Device Exemption (HDE)?
○Yes ◉**No**

i. Creating or sending samples to a tissue bank/repository?
○Yes ◉**No**

j. The use of human subjects and biological agents (e.g., staphylococcus aureus, adenovirus), or the deliberate transfer of recombinant DNA vectors/plasmids (recombinant DNA, or DNA or RNA derived from recombinant DNA) or synthetic DNA into human research participants?
○Yes ◉**No**

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Safe Harbor De-Identification

1. This declaration applies to the following part(s) of this study:

A. ☐ All of the information used or disclosed in this study.

B. ☑ The information received or collected from these sources: all external sites listed

C. ☑ The information shared with or disclosed to these groups: all external sites listed

2. As the principal investigator for this study, I declare the following:

A. To the best of my knowledge, the information could not be used (alone or with other information) to identify an individual who is a subject of the information, and

B. None of the following types of information, regarding subjects or relatives, employers, or household members of subjects, are used or disclosed in the part of this study indicated above:

1. Names;
2. All geographic identifiers except state or the first three digits of a zip code (however, all data from the following 17 3-digit zips are combined together under "000": 036, 059, 063, 102, 203, 556, 692, 790, 821, 823, 830, 831, 878, 879, 884, 890, and 893)
3. The month and day (the year can be kept) from all dates directly related to an individual, including birth date, admission date, discharge date, date of death. Ages over 89 are combined in a single category of "Age 90 and older."
4. Telephone numbers;
5. Fax numbers;
6. Electronic mail addresses;
7. Social security numbers;
8. Medical record numbers;
9. Health plan beneficiary numbers;
10. Account numbers;
11. Certificate/license numbers;
12. Vehicle identifiers and serial numbers, including license plate numbers;
13. Device identifiers and serial numbers;
14. Web Universal Resource Locators (URLs);
15. Internet Protocol (IP) address numbers;
16. Biometric identifiers, including finger and voice prints;
17. Full face photographic images and any comparable images; and,
18. Any other unique identifying number, characteristic, or code, except as permitted for re-identification.

3. If I assign a code or other means of record identification to allow de-identified information to be re-identified,

A. The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual, and

B. I will not use or disclose the code or other means of record identification for any purpose other than re-identification, and I will not disclose the mechanism for re-identification.

4. Before I allow a code to be used to re-identify this information,

A. If the purpose of the re-identification is within the scope of the original protocol, I will obtain approval of an amendment from the IRB and comply with the requirements of HIPAA; or

B. If the purpose of the re-identification is outside the scope of the original protocol, I will submit a full New Study Application, obtain IRB approval, and comply with the requirements of HIPAA.

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8. Resources and Responsibilities

1. **State and justify the qualifications of the study staff:**

   Medical decision making is not required in this study. Data will be collected, collated from other sites and analyzed by sub-investigator. She will ensure the completeness and accuracy of the data from Utah as well as other sites. She will independently review CT scans with the assistance of the PI for verification of accuracy of analysis. As as general surgery resident she is qualified to analyze these images. The PI has participated in multiple studies including chart reviews and clinical trials. He will closely monitor the sub-investigator.

   External investigators will gather data at their respective sites and submit de-identified data to University of Utah. IRB approval will take place at each site as appropriate.

2. **Describe the training that study staff and investigators will receive in order to be informed about the protocol and understand their research-related duties and functions:**

   PI and sub-investigator created the protocol and understand all responsibility required for the study.

3. **Describe the facilities to be used for the research activities (e.g. hospitals, clinics, laboratories, classrooms/schools, offices, tissue banks, etc.):**
   Single research office with password protected encrypted computers for all data analysis. We will oversee all participating sites and ensure IRB approval is obtained at each site. We will keep records of the IRB approval. Research will not be permitted to start until IRB approval has been completed.

4. **Describe the medical or psychological resources available at this site (and other participating sites, if applicable) that participants might require as a consequence of the research. If not applicable, please state.**
   N/A participants have been treated and require no further resources

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Documents and Attachments

If any of your documents (such as investigational brochures, sponsor protocols, advertisements, etc.) are not available in an electronic format, please scan and save them as PDF files or contact our office for assistance.

Naming Documents: Please use the title field to clearly indicate the content of each form. The name you enter will be listed on your approval letter. Use names that will differentiate from earlier versions.

Examples:
Consent Document Control Group 04/14/05
Consent Document Treatment Group 4/14/05
Sponsor Protocol 04/14/05 Version 2
Assent Document (Highlighted Changes)

Apple/Macintosh Users: MS Word documents must have a .doc file extension. See ERICA home page for instructions.

Print View: IRB Draft Protocol Summary

eProtocol Summary:

Name	Version	Date Created	Date Modified
There are no items to display			

Consent Documents, Consent Cover Letters, Consent Information Sheets, Consent Scripts, etc.:

Name	Version	Date Created	Date Modified
There are no items to display			

Parental Permission Documents:

Name	Version	Date Created	Date Modified
There are no items to display			

Assent Documents:

Name	Version	Date Created	Date Modified
There are no items to display			

VA Consent Documents:

Name	Version	Date Created	Date Modified
There are no items to display			

Surveys, Questionnaires, Interview Scripts, etc.:

Name	Version	Date Created	Date Modified
There are no items to display			

Full Protocol (company protocol, sponsor protocol, investigator-initiated protocol, etc.):

Name	Version	Date Created	Date Modified
There are no items to display			

Investigational Brochure (IB) for Investigational Drug or Drug/Device Package Insert:

Name	Version	Date Created	Date Modified
There are no items to display			

Grant Application:

Name	Version	Date Created	Date Modified
There are no items to display			

Literature Cited/References:

Name	Version	Date Created	Date Modified
There are no items to display			

Principal Investigator's Scholarly Record (CV/Resume):

Name	Version	Date Created	Date Modified
NirulaCV12-05-2014.pdf	0.01	12/5/2014 2:35 PM	12/5/2014 2:35 PM

Faculty Sponsor's Scholarly Record (CV/Resume):

Name	Version	Date Created	Date Modified
There are no items to display			

Other Stamped Documents:

Only attach documents here as directed by the IRB, such as the Data/Information Request Form for UUHSC EDW.

Name	Version	Date Created	Date Modified
There are no items to display			

Recruitment Materials, Advertisements, etc.:

Name	Version	Date Created	Date Modified
There are no items to display			

Other Documents:

Name	Version	Date Created	Date Modified
There are no items to display			

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Finish Instructions

Finish Instructions

1. **To view errors, select the "Hide/Show Errors" option at the top or bottom of the page. If you have errors on your application, you won't be able to submit it to the IRB.**
2. **Selecting the Finish button will NOT submit the application to the IRB. You MUST select the "Submit" option on the workspace once you've selected the "Finish" button.**
3. **If your study has a faculty sponsor: Once the PI submits the application, it will be sent to the faculty sponsor for final approval. The IRB cannot review the study until the faculty sponsor submits the application to the IRB.**

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Addition of a Site

a. **Site Name:**
Other

If Other, provide full site name: University California Davis Health System

b. **Site address:**
2221 Stockton BLVD
Sacramento CA 95817

c. **Site phone number:** 916-734-8298

d. **Does this site have an investigator?**
◉ **Yes** ○ No

Enter the investigator's or main contact's name:
Joseph Galante

e. **Select the study procedures that will be conducted at this site:**

Data collection

If Other, describe:

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Addition of a Site

a. **Site Name:**
Other

If Other, provide full site name: University California Davis Health System

b. **Site address:**
2315 Stockton Blvd
Sacramento CA 95817

c. **Site phone number:** 916-734-8298

d. **Does this site have an investigator?**
◉ **Yes** ○ No

Enter the investigator's or main contact's name:
Christine Cocanour

e. **Select the study procedures that will be conducted at this site:**

Data collection

If Other, describe:

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Addition of a Site

a. **Site Name:**
Other

If Other, provide full site name: University California San Diego

b. **Site address:**
200 West Arbor Drive #8896
Sand Diego, CA 92103

c. **Site phone number:** 619-543-7200

d. **Does this site have an investigator?**
◉ **Yes** ○ No

Enter the investigator's or main contact's name:
Raul Combria

e. **Select the study procedures that will be conducted at this site:**

Data collection

If Other, describe:

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Addition of a Site

a. **Site Name:**
Other

If Other, provide full site name: University of Maryland

b.

Site address:
22 S Greene St
Baltimore MD 21201

c. **Site phone number:** 410-328-8976

d. **Does this site have an investigator?**
◉ **Yes** ○ No

Enter the investigator's or main contact's name:
Thomas Scalea

e. **Select the study procedures that will be conducted at this site:**

Data collection

If Other, describe:

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Addition of a Site

a. **Site Name:**
Other

If Other, provide full site name: University of Michigan

b. **Site address:**
1C421 University Hospital
1500 East Medical Center Dr
Ann Arbor MI 48109

c. **Site phone number:** 734-936-9690

d. **Does this site have an investigator?**
◉ **Yes** ○ No

Enter the investigator's or main contact's name:
Pauline Park

e. **Select the study procedures that will be conducted at this site:**

Data collection

If Other, describe:

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Addition of a Site

a. **Site Name:**
Other

If Other, provide full site name: University of Pittsburg Medical Center

b. **Site address:**
200 Lothrop St
Pittsburgh PA 15213

c. **Site phone number:** 866-629-8077

d. **Does this site have an investigator?**
◉ **Yes** ○ No

Enter the investigator's or main contact's name:
Jason Sperry

e. **Select the study procedures that will be conducted at this site:**

Data collection

If Other, describe:

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a. **Site Name:**
Other

If Other, provide full site name: University of Pittsburg Medical Center

b. **Site address:**
200 Lothrop St
Pittsburgh PA 15213

c. **Site phone number:** 866-629-8077

d. **Does this site have an investigator?**
◉ **Yes** ○ No

Enter the investigator's or main contact's name:
Andrew Peitzman

e. **Select the study procedures that will be conducted at this site:**

Data collection

If Other, describe:

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Addition of a Site

a. **Site Name:**
Other

If Other, provide full site name: University of Washington School of Medicine

b. **Site address:**
Department of Surgery 359796
Harborview Medical Center
325 Ninth Avenue
Seattle WA 98104

c. **Site phone number:** 206-744-3406

d. **Does this site have an investigator?**
◉ **Yes** ○ No

Enter the investigator's or main contact's name:
Jerry Jurkovich

e. **Select the study procedures that will be conducted at this site:**

Data collection

If Other, describe:

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Addition of a Site

a. **Site Name:**
Other

If Other, provide full site name: University Southern California Department of Surgery

b. **Site address:**
2051 Marengo St IPT C5L 100
Los Angeles, CA 90033

c. **Site phone number:** 323-409-7716

d. **Does this site have an investigator?**
◉ **Yes** ○ No

Enter the investigator's or main contact's name:
Demetrios Demetriades

e. **Select the study procedures that will be conducted at this site:**

Data collection

If Other, describe:

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Addition of a Site

a. **Site Name:**
Other

If Other, provide full site name: Virginia Commonwealth University School of Medicine

b. **Site address:**
West Hospital 15th Floor East Wing
1200 E Broad St
Richmond VA 23298

c. **Site phone number:** 804-282-7748

d. **Does this site have an investigator?**
◉ **Yes** ○ No

Enter the investigator's or main contact's name:
Ajai Malhotra

e. **Select the study procedures that will be conducted at this site:**

Data collection

If Other, describe:

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Request for Waiver or Alteration of Consent

1. **Purpose of the Waiver Request:**
   Chart Review/Data Collection
2. **Type of Request:**
   Waiver of Informed Consent

   a. **Will deception be used?** ○ Yes ◉ **No**

   If yes, provide the rationale and describe the debriefing procedures:
3. **List the identifying information you plan to collect or keep a link to (e.g. names, dates, or identification numbers such as social security numbers or medical record numbers, etc.).**
   Identifying information will only be patient age and medical record number. Patient data will be uploaded to a password protected and encrypted database with de-identified number assigned by random at each institution. At each site all data will be stored on password protected and encrypted computer, including the University of Utah data.
4. **Explain why the research could not practicably be conducted without the waiver or alteration. For example, complete the following sentence "If I had to obtain consent, the research could not be conducted because...":**
   If consent were obtained this would not be a feasible project to undertake as there are 4000 total patient participants that would require contact. Many of these patients likely have outdated information in the records further making contacting all of these patients impossible. Investigators would not be able to answer the intended questions.
5. **Explain why the research and privacy risk of the research are no more than *minimal:***
   Will only review minimal information from each patient charge and none will be sensitive in nature.
6. **Describe the measures you will take to ensure the waiver or alteration will not adversely affect the rights and welfare of the *subjects:***
   Patient information was collected at time of treatment, as this is a retrospective review no care will be altered.
7. **Explain how you will, if applicable and appropriate, provide the subjects with additional pertinent information *after* they have participated in the study, or indicate *"Not applicable":***
   Individuals are not directly or indirectly impacted by the results of the study, we will therefore not contact each individual.