



Date: Tue Feb 07 2012 13:43:28 GMT-0800 (Pacific Standard Time)

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iStar ID: HS-10-00327

Application Version Date:9/20/2011
Version:2.0

1. Project Identification Information

1.1. * Type of Submission:

- Research Protocol or Study**
- Grant/Contract Only
- Facilitated Review (NCI CIRB)
- USC/CHLA Collaborative Review

1.2. * Full Title of Research Protocol

THORACOLUMBAR SPINE EVALUATION AND SCREENING AFTER TRAUMA

1.3. * Short Title

THE T.E.S.T. STUDY

1.4. * Please indicate which IRB you are requesting review from:

USC-Health Sciences (HSC)

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2. Study Personnel

2.1. Study Personnel and their roles:

Last Name	First Name	Organization	Study Role	Certifications	Obtain Consent
View Inaba	Kenji	TRAUMA AND CRITICAL CARE	Principal Investigator	HS GCP HIPAA	no
View Barmparas	Galinos	TRAUMA AND CRITICAL CARE	Study Contact Person	HS GCP	no
View Varga	Stephen	TRAUMA AND CRITICAL CARE	Co-Investigator	HS GCP HIPAA	no
View Branco	Bernardino	TRAUMA AND CRITICAL CARE	Data Collector/Manager	HS GCP HIPAA	no
View Konstantinidis	Agathoklis	SURGERY	Data Collector/Manager	HS GCP HIPAA	

2.2. Is the Principal Investigator a student, resident, fellow, other trainee, or visiting scholar?

Yes No

2.3. If there are any individual collaborators from other institutions, check here:

2.4. Does this study require Cancer Center Committee (CIC) approval?

Yes No

2.4.1 Are Cancer Patients Involved? Yes No

2.5. Specify the group/organization who has reviewed this study for scientific merit:

Department of Surgery - Division of Trauma Surgery and Surgical Critical Care

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3. Required Department Approvals (for a study already submitted to the IRB)

This screen indicates the division/department approvals received once the proposal has been submitted. This screen is not required during presubmission and should be left blank.

3.1. Pending Division/Department Approvals:

Name Division/Department Parent Campus

There are no items to display

3.2. Received Division/Department Approvals:

Name	Division/Department	Parent Campus
TRAUMA AND CRITICAL CARE	Division	USC-Health Sciences (HSC)
SURGERY	Department	USC-Health Sciences (HSC)

3a.3. (HSC Only) Other Health Science campus committees that will need to review and approve this protocol:

Committee Name Committee Chair Approval Memo

There are no items to display

3a.4. (HSC Only) Will the research be conducted through the CTU?

Yes No

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4. Type of Study Review

4.1. Please indicate the type of review that you are requesting for this study:[Expedited Review](#)**4.2. Attach the protocol or sponsor's template informed consent. For simple investigator initiated studies, a separate protocol may not be necessary. However, larger, complex, or multi-site studies require a fully developed protocol. If you have questions contact the IRB office to discuss.**

name	Version	Modified
TEST Protocol History	0.01	6/17/2010 9:29 PM

4.3. If there is a sponsor protocol number associated with this file, specify it here:

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4a. Type of Study Review - Expedited Review

*This screen is required if you are requesting an expedited review for this study (Question 4.1.)***4.1. Please indicate the type of review that you are requesting for this study:**[Expedited Review](#)**4a. If you checked expedited review, please choose the applicable category from the list and attach your data collection forms below (click on the abbreviated category to receive the full description):**

Short Description (click for full description)

 (1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met... (2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture... (3) Prospective collection of biological specimens for research purposes by noninvasive means... (4) Collection of data through noninvasive procedures routinely employed in clinical practice, excluding procedures involving x-rays or microwaves... (5) **Research involving materials that have been collected, or will be collected solely for nonresearch purposes...** (6) Collection of data from voice, video, digital, or image recordings made for research purposes. (7) Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies...**4a.1. Since you checked expedited review category 5, please attach a copy of the data collection forms, if applicable:**

name	Version	Modified
Form A: Screening History	0.01	4/30/2010 10:01 PM
Form B: TL Injury Report History	0.01	4/30/2010 10:01 PM

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5. Study Location(s)

5.1. Indicate the locations where this study will be conducted by the USC/CHLA investigator(s) (check all that apply):

Location

 HSC - Health Sciences Associated Locations
 UPC - University Park Associated Locations

 CHLA

 Other Sites/Institutions (In the US)
 Other Sites/Institutions (Outside the US)

5.2. (HSC or CHLA only) Is this a multi-site study?

 Yes No

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6a. HSC Location(s)

This screen is required if you indicated HSC - Health Sciences Associated Locations (Question 5.1.)

6a.1. HSC Locations (check all that apply):

Location

 LAC+USC Medical Center
 LAC+USC Outpatient Clinics

 LAC+USC 5P21 Building

 USC Ambulatory Health Center

 Keck Hospital of USC

 USC Norris Comprehensive Cancer Center

 USC Medical School

 Doheny Eye Institute and Hospital

 USC Healthcare Consultation Center I or II

 El Monte Comprehensive Health Center *

 H. Claude Hudson Comprehensive Center *

 Roybal Comprehensive Health Center *

 Other location (e.g., subjects home, community)

6a.2. If Other Location, please specify:

6a.3. If you are conducting this research in a LAC location, please specify the room numbers:

Trauma Observation Unit, wards, surgical ICU

6a.4. If you are conducting this research at a location marked with an asterisk "*", please attach a letter of approval from the medical director.

name Version Modified

There are no items to display

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6c. Other Sites/Institutions

This screen is required if you indicated Other Sites/Institutions inside or outside the US (Question 5.1.)

6c.1. Other Sites/Institutions (In the United States): List all of the non-USC/CHLA sites at which the Principal Investigator will conduct the study.

Site Name Address

There are no items to display

6c.2. Other Sites/Institutions (Outside the United States): List the institution(s) and country(ies) at which the Principal Investigator will conduct the study.

Site Name Address Country

There are no items to display

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7. Information For Multi-Site Study

This screen is required if you indicated this is a multi-site study (Question 5.2.)

7.1. Is the coordinating center at HSC, UPC, or CHLA?

Yes No

7.1.1. If yes, describe how the information relevant to protecting participants, including obtaining local IRB approval at the study sites, reporting of unexpected problems, protocol modifications, and interim results are managed.

All participating sites will obtain local IRB approval. Unexpected problems will be reported to the local IRB and to the PI. The PI will also report the unexpected problems to the IRB. Data from participating centers will be logged anonymously utilizing the American Association for the Surgery of Trauma – Multi-Institutional Trials (AAST MIT) online data entry system. Patients' data will be deidentified, minimizing the risk of confidentiality loss.

The decision for protocol modifications will be taken by the PI. Any protocol modifications will take place only after IRB approval at participating institutions.

IRB approval letters from participating sites will be submitted as soon as they are available.

7.2. If no, what is the location of the coordinating site? (If there is no coordinating site, indicate N/A).

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8. Funding Information

8.1. Are you or the institution receiving any financial support for the conduct of this study?

Yes No

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9. Methods and Procedures - Selected Descriptors

Note: Each list of items below IS NOT an all-inclusive list of methods and procedures available to investigators. The list only includes items that will trigger additional questions specific to areas of research or are necessary for the review process.

9.1. * Social-Behavioral Procedures (check any or all that apply):

Specific Descriptor

Behavioral Observations and/or Behavioral Experimentation

Behavioral Interventions

Deception

Interview/Focus Groups

Population-based Field Study

Psychophysiological Testing

Surveys/Questionnaires/Psychometric Testing

Other Social-Behavioral Procedures

None of the above Social-Behavioral Procedures apply to this study.

9.2. * Medical Procedures/Considerations (check any or all that apply):

Specific Descriptor

Biohazardous Substances

Controlled Substances

Emergency Treatment

Gene Transfer Study

Stem Cell Research

Magnetic Resonance Imaging (MRI)

- Investigational/Approved Drugs and Biologics
- Investigational/Approved Devices
- Radiation exposure other than clinically indicated tests and/or therapy
- Radionuclides
- Substance Abuse Treatment (with medication)
- Surgery
- Venipuncture
- Other Medical Procedures/Considerations
- None of the above Medical Procedures/Considerations apply to this study.**

9.3. * Data Collection Types (check any or all that apply):

Specific Descriptor

- Banking of Specimens/Data (Creation of a repository)
- Prospective Collection of Specimens/Data**
- Genetic Specimens
- Audio/Video Recordings or Photographs
- None of the above Data Collection Types apply to this study.

9.4. * Does this study involve the use of existing/retrospective data/specimens?

Yes No

9.5. * Is this project a trial of a drug, biologic, or device that is initiated by the investigator?

Yes No

9.6. Will data from this study be submitted to the NIH Genome-Wide Association Studies (GWAS) data repository?

Yes No

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10. Characteristics of the Study Subject Population

10.1. What is the maximum number of subjects you plan to recruit for this site? (Integer values only)

2500

10.1.1. If this is a multi-site study, indicate the projected total subject accrual. (Integer values only)

4571

10.1.2. Please provide further explanation of accrual goals, if necessary.

Based on estimations and for feasibility reasons, the total sample size of evaluable patients required for the study is 4,571. This sample size will provide

- 1) An estimate of a 48% sensitivity with a 95% CI and width of $\pm 5\%$ (prevalence rate of 8.4%) and
- 2) An estimate of a 78% sensitivity with a 95% CI and width of $\pm 10\%$ (prevalence rate of 2.0%)

Please see "Sample size calculation" in the attached protocol.

10.2. Indicate the inclusion criteria for enrollment. (HSC: refer to specific sections of the protocol/grant, if applicable)

- 1) Age ≥ 14
- 2) Patient is evaluable on clinical examination. This includes:
 - Glasgow Coma Scale 15
 - Cooperative
 - Not intoxicated
 - With no distracting injuries

The treating physician will determine whether the patient is evaluable or not. A positive toxicology screen will not preclude the patient from being enrolled if the treating physician deems the patient as able to reliably report pain.

- 3) Blunt mechanism of injury

If needed, please upload any tables at item 40.1 and reference in the question above.

10.3. Indicate the exclusion criteria for enrollment. (HSC: refer to specific sections of the protocol/grant, if applicable)

- 1) Age < 14
- 2) Glasgow Coma Scale < 15
- 3) Uncooperative
- 4) Intoxication
- 5) Mechanism of injury:
 - Penetrating
 - Burns
 - Isolated extremity injuries (e.g. crush injury not involving the torso)
- 6) Pre-existing paraplegia/tetraplegia
- 7) Readmission for a reason related to previous injury but not related to spinal pain/injury
- 8) Injury > 48 hours prior to admission

If needed, please upload any tables at item 40.1 and reference in the question above.

10.3.1. If there are any age, ethnic, language, or gender-based exclusion criteria, please provide justification.

Patients younger than 14 years of old will not be enrolled in this study. Cooperation of pediatric patients for the conduction of physical examination varies widely and therefore, standardized data collection may not be feasible.

11. Study Summary

- 11.1. Abstract: The abstract should provide a simple explanation of the study and should have 1 or 2 sentences written to address each of the following points: background and rationale; objectives or purpose; study population or sample characteristics; study methodology; description of study arms (if appropriate); study endpoints or outcomes; intervention and follow-up; statistics and plans for analysis.**

The criteria to obtain imaging of the thoracolumbar (TL) spine in blunt trauma patients has not been well studied and remains controversial. The purpose of this study is to determine which injury mechanism characteristics and clinical findings warrant screening imaging of the TL spine with a high sensitivity but adequate specificity so that unnecessary radiation exposure is minimized.

All evaluable trauma patients sustaining blunt trauma and admitted to one of the participating centers will be captured. This is a prospective observational study, relying on data that is collected for all patients during the physical examination of the spine. No intervention will result from the conduction of this study. The study endpoints will be TL spine injury.

Conventional statistical methods will be used to determine the sensitivity and specificity of clinical examination and to determine factors that should trigger further evaluation of the TL spine with imaging studies.

11.2. Research objectives and background

- 11.2.1. Describe the specific objectives or aims of the study and hypotheses or research questions. (HSC: refer to specific sections of the protocol/grant, if applicable)**

There is a lack of evidence based data to support a diagnostic algorithm that can determine which patients will require imaging of the TL spine. The purpose of this prospective observational study is to determine which injury mechanism characteristics and clinical findings warrant screening imaging of the TL spine with a high sensitivity but adequate specificity so that unnecessary radiation exposure is minimized. This will allow for the development of evidence based guidelines for the evaluation of the TL spine. Our objective is to identify clinical findings and mechanism characteristics that will ensure a high sensitivity and specificity for the detection of TL spine injuries.

- 11.2.2. Provide a summary of the background of the study, and explain how this research will contribute to existing knowledge. Describe previous work that provides a basis to show that the proposed research can be carried out without undue risk to human subjects. Include relevant citations. (HSC: refer to specific sections of the protocol/grant, if applicable)**

Traumatic fracture of the thoracolumbar spine is a common sequelae of severe blunt force trauma.¹ These injuries are highly clinically significant, associated with both poor short- and long-term outcomes² and have been shown to directly impact health-related quality of life.³ The early detection of those at highest risk for fractures of the thoracolumbar (TL) spine is important not only for stabilization and the prevention of neurologic deterioration, but also for optimizing resource utilization by appropriately selecting out patients who require CT scanning, as modern treatment algorithms require the utilization of advanced imaging data for the development of optimal treatment plans.⁴⁻⁶

The development of effective clinical screening criteria however, for reliably identifying those at greatest risk for TL spine fractures and therefore require imaging, remains a challenge. Although practice guidelines for clearance of the cervical spine following blunt trauma utilizing the NEXUS⁷ or Canadian C-spine Rules⁸ have been well validated, the development of similar approaches for injuries of the thoracolumbar region has proven disappointing.⁹⁻¹¹ To date, no single

screening test or constellation of findings on history or clinical examination has demonstrated adequate sensitivity for the detection of these injuries. Recently, our research group completed a prospective observation trial aiming to determine the sensitivity and specificity of a protocolized, structured clinical examination for the evaluation of the thoracolumbar spine in trauma patients injured after blunt trauma. The results of this study demonstrated that clinical examination as a stand-alone screening tool for evaluation of the thoracolumbar spine was inadequate, with a sensitivity of only 48.2% for all fractures and 78.4% for clinically significant fractures, requiring operative intervention or thoracolumbar spine orthosis (TLSO). In this series however, all of the clinically significant missed fractures were diagnosed on CT obtained for evaluation of the visceral torso. A combination of both clinical examination and CT screening based on mechanism will likely be required to ensure adequate sensitivity with an acceptable specificity for the diagnosis of clinically significant injuries of the thoracolumbar spine. Further research is warranted, targeting the at risk patient with a negative clinical examination, to determine what injury mechanisms warrant evaluation with a screening CT.

References:

1. HU R, MUSTARD CA, BURNS C. EPIDEMIOLOGY OF INCIDENT SPINAL FRACTURE IN A COMPLETE POPULATION. SPINE (PHILA PA 1976). 1996;21(4):492-499.
2. HEBERT JS, BURNHAM RS. THE EFFECT OF POLYTRAUMA IN PERSONS WITH TRAUMATIC SPINE INJURY. A PROSPECTIVE DATABASE OF SPINE FRACTURES. SPINE (PHILA PA 1976). 2000;25(1):55-60.
3. BRIEM D, BEHECHTNEJAD A, OUCHMAEV A, ET AL. PAIN REGULATION AND HEALTH-RELATED QUALITY OF LIFE AFTER THORACOLUMBAR FRACTURES OF THE SPINE. EUR SPINE J. 2007;16(11):1925-1933. 10.1007/S00586-007-0395-X.
4. HARROP JS, VACCARO AR, HURLBERT RJ, ET AL. INTRARATER AND INTERRATER RELIABILITY AND VALIDITY IN THE ASSESSMENT OF THE MECHANISM OF INJURY AND INTEGRITY OF THE POSTERIOR LIGAMENOUS COMPLEX: A NOVEL INJURY SEVERITY SCORING SYSTEM FOR THORACOLUMBAR INJURIES. INVITED SUBMISSION FROM THE JOINT SECTION MEETING ON DISORDERS OF THE SPINE AND PERIPHERAL NERVES, MARCH 2005. J NEUROSURG SPINE. 2006;4(2):118-122. 10.3171/SPI.2006.4.2.118.
5. VACCARO A. THORACOLUMBAR INJURY CLASSIFICATION AND SCORING SYSTEM. J NEUROSURG SPINE. 2008;9(6):574-5; DISCUSSION 575. 10.3171/SPI.2008.8.08560.
6. LEE JY, VACCARO AR, LIM MR, ET AL. THORACOLUMBAR INJURY CLASSIFICATION AND SEVERITY SCORE: A NEW PARADIGM FOR THE TREATMENT OF THORACOLUMBAR SPINE TRAUMA. J ORTHOP SCI. 2005;10(6):671-675. 10.1007/S00776-005-0956-Y.
7. HOFFMAN JR, MOWER WR, WOLFSON AB, TODD KH, ZUCKER MI. VALIDITY OF A SET OF CLINICAL CRITERIA TO RULE OUT INJURY TO THE CERVICAL SPINE IN PATIENTS WITH BLUNT TRAUMA. NATIONAL EMERGENCY X-RADIOGRAPHY UTILIZATION STUDY GROUP. N ENGL J MED. 2000;343(2):94-99.
8. CANADIAN CT HEAD AND C-SPINE (CCC) STUDY GROUP. CANADIAN C-SPINE RULE STUDY FOR ALERT AND STABLE TRAUMA PATIENTS: II. STUDY OBJECTIVES AND METHODOLOGY. CJEM. 2002;4(3):185-193.
9. HOLMES JF, PANACEK EA, MILLER PQ, LAPIDIS AD, MOWER WR. PROSPECTIVE EVALUATION OF CRITERIA FOR OBTAINING THORACOLUMBAR RADIOGRAPHS IN TRAUMA PATIENTS. J EMERG MED. 2003;24(1):1-7.
10. HSU JM, JOSEPH T, ELLIS AM. THORACOLUMBAR FRACTURE IN BLUNT TRAUMA PATIENTS: GUIDELINES FOR DIAGNOSIS AND IMAGING. INJURY. 2003;34(6):426-433.
11. JUNKINS EP, JR, STOTTS A, SANTIAGO R, GUENTHER E. THE CLINICAL

PRESENTATION OF PEDIATRIC THORACOLUMBAR FRACTURES: A PROSPECTIVE STUDY. J TRAUMA. 2008;65(5):1066-1071. 10.1097/TA.0B013E31818837F1.

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12. Methods and Procedures - Prospective Studies

- 12.1. Describe in detail the design and methodology of the study. If applicable, include information on stratification or randomization plans. Identify and distinguish between those procedures that are standard of care and those that are experimental. Include the frequency and duration of each activity and the total length of subject participation. (HSC: refer to specific sections of the protocol/grant, if applicable)**

This is a multicenter, prospective study that is observational and non-randomized. All patients admitted to the participating trauma centers meeting inclusion criteria will be eligible for enrollment in this study. Data capture will begin immediately after admission and will include a standardized clinical examination, directed imaging and follow-up throughout the entire hospital stay.

It is expected that both male and female subjects age 14 and older that have been injured due to a blunt mechanism will be enrolled. A non-enrolled patient log will be kept to evaluate for any selection bias that may occur. Up to 3,500 patients will be enrolled from up to 8 centers. In Phase I, 700 patients will be enrolled for a utility assessment. In Phase II, subjects will be enrolled to meet the total number of subjects required, based on the power analysis.

If needed, please upload any tables at item 40.1 and reference in the question above.

- 12.2. Provide a detailed description of the planned data collection, specific outcomes, and criteria for evaluation and endpoint definition. (HSC: refer to specific sections of the protocol/grant, if applicable)**

All data will be logged utilizing the American Association for the Surgery of Trauma – Multi-Institutional Trials (AAST MIT) online data entry system.

Data collection will be biphasic. A screening form (Form A) with a recorded study number will be completed for all admitted patients to all participating centers. Completion of the first portion of this form will determine whether the subject meets inclusion criteria or not. If not, then the remaining data points in the form will not be completed. These subjects however, will be assigned a study number that will be recorded on the form. This procedure will determine the number of excluded subjects and the reason for exclusion.

If the patient fulfills inclusion criteria, then the second portion of the form will be completed. This portion includes basic demographic data, details of the injury mechanism and the results of the structured clinical examination of the TL spine. At discharge, Form B will be completed, recording data on any acute TL spine injuries detected during the hospital stay, as well as the treatments provided.

If needed, please upload any tables at item 40.1 and reference in the question above.

- 12.3. **Describe the statistical considerations for the study, how the sample size was determined, and how the results will be analyzed, if applicable. (HSC: refer to specific sections of the protocol/grant, if applicable)**

A previous study from this institution has demonstrated that the incidence of thoracolumbar spine injuries in evaluable patients admitted following blunt traumatic injury is 8.4%. Based on this, for the study to be powered for an odds ratio of 3, with an alpha of 0.05, and a Power of 80% (B = 0.20), a sample size of approximately 3,500 subjects will be required.

Data will be analyzed by conventional statistical methods to determine the sensitivity and specificity of clinical examination and injury mechanisms in identifying those at risk for a TL spine injury.

If needed, please upload an^ tables at item 40.1 and reference in the question above.

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22. Special Subject Populations

- 22.1. Special Subject Populations (Check all that appl^).
Population

- Normal Volunteers
- Employees
- Students
- Adults not Competent to Consent
- Non-English Speaking Populations
- Minors (subjects under 18 years of age)
- Pregnant Women, Human Fetuses, or Neonates
- Prisoners/Detainees
- Wards
- None of the above

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23. Subject Identification and Stud^ Resources

- 23.1. Describe the method(s) b^ which subjects will be identified, eligibilit^ will be determined, and b^ whom.

Adult blunt trauma patients that undergo the initial ED evaluation by the on call trauma team will be identified by the appropriate research personel. ED examination and imaging findings will be documented on the data collection sheets. No patient intervention or contact is expected as a result of this study being done.

- 23.2. Describe the time the investigators have available to conduct and complete the research and justif^ that it is sufficient.

The study coordinator and the co-investigators are full time dedicated research fellows with sufficient time to complete the study.

23.3. Describe the staff and justify they are adequate in number and qualifications. If this study involves interviews, focus groups and/or assessments, please also identify the specific members of the study team responsible for conducting the interviews/focus groups and/or administering the assessments in your response.

The study coordinator and co-investigators are full time dedicated researchers, with up to date research certifications, therefore being adequate in number and qualifications.

23.4. Describe the study facilities and justify they are adequate.

This prospective observational study will be conducted in the trauma observation unit, being adequate and sufficient for this study.

23.5. Describe how staff and others will receive necessary information and training to assist in the conduct of this study.

Data collection will be performed by the study coordinator and co-investigator. All participants have examined meticulously the study research protocol and are fully aware of their duties.

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24. Subject Recruitment

24.1. Recruitment Tools (Check all that apply):

Tool
<input type="checkbox"/> E-mail/Electronic Mailing List
<input type="checkbox"/> Flyers
<input type="checkbox"/> Letters
<input type="checkbox"/> Newspaper/Magazine Advertisements
<input type="checkbox"/> Radio/Television Announcements
<input type="checkbox"/> Subject or Participant Pool
<input type="checkbox"/> Telephone Scripts
<input type="checkbox"/> Verbal (Personal Solicitation)
<input type="checkbox"/> Website
<input type="checkbox"/> Other
<input checked="" type="checkbox"/> None of the above

24.1.1. If Other Recruitment Tool, please specify:

24.2. Attach copies of all recruitment tools indicated above.

name Version Modified

There are no items to display

24.3. Describe in detail all recruitment strategies for each participant group (including controls) involved in this study. Explain who will approach the participants, how and when the participants will be approached, and what will be said.

Patients will be identified by the research fellows and information regarding clinical examination and imaging results will be recorded. No interventions are expected as a result of this study being done. Decision making will be made solely by the treating physician. No consent will be sought.

24.4. What measures will be taken during the recruitment and consent process to safeguard against potential coercion or the appearance of coercion?

This is a prospective observational study. No intervention will be performed and no decision making will be made by the research fellows concerning the care of the patient. No consent will be obtained, therefore no coercion is expected.

24.5. (HSC Only) Describe any competing protocols of which you are aware and how issues of subject selection and recruitment will be addressed.

No such protocols exist.

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25. Financial Obligation and Compensation

25.1. Financial Obligation: Describe any financial obligations that the subject may incur as a result of participating in the study. Indicate which costs will be covered by the study.

Participants will not be subjects to any financial obligations related to participating in this study.

25.2. Payment for Participation: Describe how much, if any, financial or other form of compensation will be provided to the subject/family. Describe the requisite conditions that must be fulfilled to receive full or partial compensation. Describe the proposed method of timing and disbursement. If children are involved, please specifically address how the compensation will be distributed to children.

The subject or the family will not be financially compensated by the participation in this study.

25.3. Emergency Care, Injury and Compensation for Injury: For studies of greater than minimal risk, if participants require care, medical services, or psychological services as a consequence of the research, Who will provide this care? If applicable, describe who will pay for research-related injuries.

The study design does not include any treatment modality other than the standard of care, therefore no research related injuries or interventions are expected. Should an injury occur during the study period due to one of the currently accepted standards of care appropriate treatment will be provided to the patient by the treating physician.

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26. Participant Privacy and Data Confidentiality

- 26.1. Describe the provisions to protect the privacy of the individual during screening, consenting, and conduct of the research.** (e.g. *consenting/screening subjects in a private office or area versus a busy hospital waiting room*). **NOTE:** See guidance link for definition of *privacy and examples*.

All data will be collected through the data collection form. Patient information will be coded and a log of enrolled patients will be kept in a safe closet protected with multiple physical locks at the PI office. The patients names will be kept anonymous to the greatest extent possible through the use of case numbers at all times possible. As soon as the patient is discharged, all data will be logged anonymously utilizing the American Association for the Surgery of Trauma – Multi-Institutional Trials (AAST MIT) online data entry system and identifiers that are kept for the purpose of in-hospital follow up will be immediately destroyed.

- 26.2. How will the data be recorded to protect personal confidentiality (select one)?**

Coded (Data will be linked to subjects with a code)

26.2.1. If Other is selected, please specify.

- 26.3. How will the data be recorded and stored? Please specify the physical location and describe how data will be secured to protect confidentiality.**

All the information will be coded and locked in the principal investigators office (IPT, room C5L100) in a secure cabinet. A separate file containing a code table that links the patient identifiers to the study numbers will be locked in a separate cabinet . Only the investigators will be allowed access to this information. Patient confidentiality will be maintained to the extent provided by the law. As soon as the patient is discharged, all data will be logged anonymously utilizing the American Association for the Surgery of Trauma – Multi-Institutional Trials (AAST MIT) online data entry system and identifiers that are kept for the purpose of in-hospital follow up will be immediately destroyed.

- 26.4. Who, other than the specified study team, will have access to the study records or data? Specify their name, role and affiliation. Do not list study personnel already listed on screen 2.**

Name	Role	Affiliation
There are no items to display		

There are no items to display

- 26.5. If coded or identified data will be released, specify the persons, agencies to whom the information will be released. Please also indicate the provisions that will be taken to assure that the transmission of the data will maintain confidentiality.**

The protected health information will not be released to any agencies or persons. The coded data will only be available to investigators.

- 26.6. Describe what will happen to the data or data set, when the study is completed. Please indicate your plans for destruction of identifiers at the earliest opportunity consistent with the conduct of the research and/or clinical needs, if applicable.**

As soon as the patient is discharged, all data will be logged anonymously utilizing the American Association for the Surgery of Trauma – Multi-Institutional Trials (AAST MIT) online data entry system and identifiers that are kept for the purpose of in-hospital follow up will be immediately destroyed.

26.7. Will a Certificate of Confidentiality be obtained for this study?

Yes No

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27. Risk/Benefit Assessment - Risks

27.1. Risk classification for this study (select one).

Minimal Risk

27.2. Risks, Discomforts and Potential Harms: Describe the risks associated with each intervention. Include consideration of physical, psychological, social, and other factors. If data are available, estimate the probability that a given harm may occur and the potential reversibility. (HSC: refer to specific sections of the protocol/grant, if applicable)

This prospective observational study poses no more than minimal risk to the patient because no intervention or clinical decision will be done by the researchers. All management decisions and patient care will be at the discretion of the attending surgeon and will not be affected by the research. Possible risks include loss of confidentiality.

If needed, please upload any tables at item 40.1 and reference in the question above.

27.3. Describe the precautions that will be taken to minimize risks/harms. (HSC: refer to specific sections of the protocol/grant, if applicable)

All the information will be coded and locked in the principal investigator's office (IPT, room C5L100 at LAC+ USC GH) in a secure cabinet. Only the investigators will be allowed access to this information. Patient confidentiality will be maintained to the extent provided by the law.

If needed, please upload any tables at item 40.1 and reference in the question above.

27.4. Data Safety Monitoring Plan: Describe who will monitor the studies for the safety of the participants (investigators, sponsor, independent monitor, DSMB, etc). Provide a plan (Monitoring provisions) which may include information on: the type of data or events to be captured, who is responsible for monitoring data related to unanticipated problems and adverse events, time frames for reporting adverse events and unanticipated problems to the monitoring entity, the frequency of assessments of data / events captured by monitoring, specific triggers or stopping rules that dictate when an action is required, and procedures for communicating to the IRB, sponsor, investigator, and other appropriate officials the outcome of the reviews by the monitoring entity.

In the event of unanticipated problems you will notify the IRB. Data safety monitoring will be the responsibility of the Principal investigator

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28. Risk/Benefit Analysis - Potential Benefits and Alternatives

- 28.1. Describe any potential for direct benefits to participants in the study. There may be no direct benefits.**

The participants in this study will not directly benefit from their participation

- 28.2. Describe potential benefits to society, if any.**

The results of this study may lead to decrease in the number of imaging studies ordered for patients with TL spine injury and make the evaluation of such injuries using only clinical signs and injury mechanism data very reliable and safe.

- 28.3. What are the alternatives to participation? (This could include not participating in the study)**

The patients will get the appropriate treatment for their injury even if they do not participate in the study.

Patients will be managed by the trauma Staff according to the current standards of care. No clinical decision or intervention will be performed by the researchers or as a result of this study being conducted.

- 28.4. Risk/Benefit Analysis: This analysis should indicate if the risks to subjects are reasonable in relation to the benefits (if any) to the subjects and the benefit or importance of the knowledge expected to result.**

Benefit outweighs risk.

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29. Informed Consent and Waivers

- 29.1. * Indicate the types of consent that will be involved in this study (check all that apply):**

Consent Type

- Written/signed consent by the subject
- Written/signed consent by a legally authorized representative (for an adult)
- Written/signed permission for a minor by a parent or legal guardian
- Written/signed assent by a minor
- Verbal consent or written information sheet
- Consent will not be obtained for this study**

- 29.1.1. Attach copies of all of the informed consent/assent, information sheet, verbal script, and statements of new information/findings documents that will be used for this study.**

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There are no items to display		

IRB Informed Consent Templates and Forms

29.2. * **Waivers: If you are applying for any waivers of consent (check all that apply).**

Waiver Type

-
- Waiver of consent**
-
- Waiver of assent
-
- Waiver of parental permission
-
- Waiver of written or signed consent (i.e., information sheets, telephone consent, verbal script)
-
- I am not applying for a waiver

Note: Waivers of consent are not applicable if the research is subject to FDA regulations, except the following.

FDA Exception from general requirements:

1. **Waivers of Informed Consent in FDA-regulated studies are permissible in case of life-threatening situations, inability to communicate, not sufficient time and no alternative method, even if research presents more than minimal risk [21CFR50.23];**
2. **If the study satisfies the requirements under 21CFR50.24 “Exception from Informed Consent Requirements for Emergency Research.”**

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31. Waiver of Consent

This screen is required if you indicated you are requesting a Waiver of Consent (Question 29.2.)

If you are applying for a waiver of informed consent, per 45 CFR 46.116 (d), answer ALL the following questions:

31.1. Explain why the research involves no more than minimal risk to the subjects.

This is an observational study with all patient care decisions being made by the clinical team. Inclusion in the study will not directly impact any of the patient care. Patient data will be coded. The key to the code linking the patient identifiers to the study numbers will be kept in a separate file and will be locked in cabinet to ensure confidentiality. This study poses no risk to patients. The waiver of consent is warranted based on the following:

1. A subject's participation does not involve additional medial risk since no medical care is being offered for study participation.
2. There is minimal risk of a breach in confidentiality associated with the collection of data variables for the purpose of this study and specific standardized measures will be taken to mitigate this risk.
3. The data obtained from this study will contribute to the evidence-driven practice that, by its nature, is beneficial for future patients sustaining TL spine injuries.

31.2. Explain why the waiver or alteration will not adversely affect the rights and welfare of the subjects.

The rights and welfare of the subjects will not be affected by this prospective observational study. No interventions will be performed on the participants, all decisions will be taken by

attending surgeon.

No intervention or decision will be done by the researchers therefore posing no more than minimal risk to the patient.

31.3. Explain why the research could not practicably be carried out without the waiver or alteration.

The study design is based on physiologic data collected on regular basis for this type of injuries. No intervention will be performed and no change in patient management will occur as a result of this study being conducted. Consent for this study may delay appropriate intervention by the trauma team members. In addition, obtaining an informed consent from over 3,500 patients may not be feasible and may make this study impossible to complete. Lastly, sensitivity and specificity of criteria that are expected to be applied universally to all evaluable blunt trauma patients, should be based on evaluation of all patients, without exclusion of those who may not consent.

31.4. Explain how whenever appropriate, the subjects will be provided with additional pertinent information after participation. (e.g., an information sheet).

Subjects will not be provided with additional information after participation.

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35. Is the HIPAA Privacy Rule Applicable?

35.1. Do you intend to access, use or disclose protected health information (PHI) in order to abstract medical record data (even if you are de-identifying the data abstracted), identify potential participants or to conduct your research?

Yes No

35.2. If Yes, do you intend to use data that contains any of the 18 elements defined by HIPAA as identifiers (listed below), in your research?

Yes No

The HIPAA Privacy Rule regulations [45 CFR 164.514(b)] lists 18 specific elements that are considered to be personal identifiers. The list includes:

- Name/Initials
- Street address, city*, county*, precinct*, zip code*, or equivalent geocodes*
- All elements of dates (except year) directly related to an individual (date of birth, admission date, discharge date, date of death)*
- Elements of date, including year, for persons 90 or older
- Telephone number
- Fax number
- Electronic mail address
- Social Security Number
- Medical record number
- Health plan identification number
- Account number
- Certificate/license number
- Vehicle identifiers and serial numbers, including license plate number
- Device identifiers and serial number
- Web addresses (URLs); Internet IP addresses
- Biometric identifiers, including finger and voice print
- Full face photographic images and any comparable images

- Any other unique identifying number, characteristic or code

35.3. Are you only going to obtain data marked with an asterisk (*)? If so, you may be able to obtain or use such health information from a healthcare provider for research purposes without an authorization under the HIPAA privacy rules regarding "limited data sets". If applicable, attach a copy of the signed Data Use Agreement below.

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36. HIPAA Analysis

This screen is only required if you indicated HIPAA is applicable by answering "yes" to Question 35.1.

36.1. If you are using or accessing protected health information in order to identify potential participants, indicate whether these activities fall under the rules for Activities Preparatory to Research or whether you will be applying for a Partial Waiver of HIPAA Authorization for the purposes of screening and recruiting.

-
- (CHLA Only) Activities Preparatory to Research
-
- Partial Waiver of HIPAA Authorization for screening, recruiting, and identifying subjects
-
- None of the Above**

36.2. For study research, please indicate whether you will be obtaining authorization from the subject or requesting a Full Waiver of HIPAA Authorization.

-
- Obtaining HIPAA authorization from subject
-
- Full Waiver of HIPAA Authorization**

36.2.1. If you are obtaining authorization from the subject, attach the HIPAA authorization forms here (USC Only).

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There are no items to display

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38. Waiver of HIPAA Authorization

This screen is required only if HIPAA is applicable and you indicated you are requesting a Full or Partial Waiver of HIPAA Authorization (Question 36.1. or Question 36.2.)

If you are applying for a full waiver of authorization or a partial waiver of authorization for the purposes of screening, recruitment, and subject identification, provide justification per 45 CFR 164.

38.1. Explain how the use of and disclosure of the information presents no more than minimal risk to the privacy of the individual.

This is an observational prospective study. Data will be collected from the PHI on a datasheet. Patient's identifiers will be used to cross-check reliability of our data. After cross checking, patient's identifiers will be replaced by a code, therefore posing less than minimal risk to patients because of possible violation of privacy and loss of confidentiality.

38.2. Describe the plan to protect PHI identifiers from improper use and disclosure.

We will protect the identifiers from improper use and disclosure by replacing the patients' identifiers with a code. The data will be stored in the principal's investigator office in a secure cabinet. Only the investigators will be allowed to access the data. Patients confidentiality will be maintained at all times to the extend provided by law.

38.3. Describe the plan to destroy identifiers at the earliest opportunity consistent with conduct of the research. If there is a health or research justification for retaining the identifiers, or if such retention is required by law, please provide this as well.

Patients' identifiers will be used to cross-check reliability of our data collection. The patients identifying information will be linked to a code, and once all the information has been reviewed for accuracy, we will destroy ALL patient identifying information immediately.

38.4. By checking the "I Agree" box you are providing assurance that the PHI will not be reused or disclosed to any other person or entity except (a) as required by law, (b) for authorized oversight of the research study, or (c) for other research for which the use or disclosure of the PHI is permitted by the Privacy Rule.

I Agree

38.5. Explain why the research could not be practicably conducted without the requested waiver or alteration. Note, this is the same as question 3 on screen 31 (Waiver of Consent) and your answer will be copied from there.

The study design is based on physiologic data collected on regular basis for this type of injuries. No intervention will be performed and no change in patient management will occur as a result of this study being conducted. Consent for this study may delay appropriate intervention by the trauma team members. In addition, obtaining an informed consent from over 3,500 patients may not be feasible and may make this study impossible to complete. Lastly, sensitivity and specificity of criteria that are expected to be applied universally to all evaluable blunt trauma patients, should be based on evaluation of all patients, without exclusion of those who may not consent.

38.6. Explain why the research could not be practicably conducted without access to and use of the PHI.

Patient identifiers will be used to cross-check reliability of our data collection. The patient's identifying information will be destroyed after all the information has been reviewed for accuracy.

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39. Conflict Of Interest Information

39.1. Does the Investigator, Research Personnel or Close Relation have an *ownership interest* (such as stock, stock options or warrants, but not mutual funds or a publicly traded

equity interest of less than \$10,000) in:

- The sponsor of the research; or
- An entity that has a license or is negotiating a license to the intellectual property (e.g., patents) developed from this research; or
- An entity that has an economic interest in the research.

Yes No

39.2. Does the **Investigator, Research Personnel** or **Close Relation** have a **management role** (such as director, officer, scientific, or technical appointment), or any other role with significant decision-making authority, in:

- The sponsor of the research; or
- An entity that has a license or is negotiating a license to the intellectual property (e.g., patents) developed from this research; or
- An entity that has an economic interest in the research.

Yes No

39.3. Did the **Investigator, Research Personnel** or **Close Relation** receive in the last twelve months or does the Investigator, Research Personnel or Close Relation expect to receive in the next twelve months any payments for **consulting** (such as speakers fees or payments for participation on an advisory board or assistance with protocol design) from

- The sponsor of the research; or
- An entity that has a license or is negotiating a license to the intellectual property (e.g., patents) developed from this research; or
- An entity that has an economic interest in the research.

This does not include salary for services as an investigator/staff on the research study.

Yes No

39.4. Attach a Statement of Outside Interests Related to Research Form for each person who has a potential conflict to be managed. Please note that uploading forms here does not satisfy the need to submit it to the Office of Compliance. (upload the form here)

name Version Modified

There are no items to display

39.5. To the investigator's knowledge, does the Institution have financial and or intellectual property interests in the sponsor or the products used in this project? *An institutional conflict may occur when a financial interest of the University has the potential for biasing the outcome of research conducted by its employees or students or create an unacceptable risk to human subjects.*

Yes No

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40. Additional Supporting Documents

40.1. Attach any other documents that have not been specifically requested in previous questions, but are needed for IRB Review.

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40.2. If there is any additional information that you wish to communicate about the study please include it below. Please note, this section should not be used instead of the standard application items.

This a prospective observational trial, intended to be multicenter. The Association for the Surgery for Trauma (AAST) will be notified about the conduction of this study and the study protocol, along with the collecting datasheet, will be uploaded online (<http://www.aast.org/Research/MultiInstitutionalStudies.aspx>) and will be available for any investigators wishing to participate and contribute data. Data from other centers will be logged anonymously utilizing the American Association for the Surgery of Trauma – Multi-Institutional Trials (AAST MIT) online data entry system, eliminating the possibility of loss of confidentiality with data transfer. Our experience with other multicenter studies in the past have shown that 4 to 8 centers usually contribute data to this type of studies.

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99. Instructions for Study Submission

You have reached the end of the application for a new protocol. When you are sure of the content, the following steps may be taken to submit your study for review.

1. Click the **"Finish"** button on the top or bottom application navigator bar to return to the study workspace.
2. Use the SmartForm Progress Calculator to determine that all sections of the application are filled out correctly.
3. Use the **"Send Study Ready Notification"** activity to send an email to the Principal Investigator and Co-Investigators with instructions for reviewing and submitting the application.
4. **All listed Co-Investigators (indicated in item 2.1.) must use the "Agree to Participate" activity and answer yes.**
5. Once all the Co-Investigators have agreed to participate, the **Principal Investigator** (indicated in item 2.1.) can submit the study by using the **"Submit Application to _____"**, where _____ indicates the IRB you are submitting to.
6. The PI will have to check the PI endorsement box. The PI will also have to check the student endorsement box if it is applicable.
7. The study is submitted. The state indicator in the top left of the study workspace will no longer display Pre Submission.
8. The PI and Study Contact Person will receive an email confirming the application has been submitted.