AWARD NUMBER: W81XWH-15-2-0089

TITLE: A National Coordinating Center for Trauma Research

PRINCIPAL INVESTIGATOR: Donald Jenkins, M.D.

CONTRACTING ORGANIZATION: National Trauma Institute

REPORT DATE: OCTOBER 2020

TYPE OF REPORT: Annual – Year 5

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
OCTOBER 2020	Annual- Year 5	30 Sept 2019 – 29 Sept 2020

4. TITLE AND SUBTITLE
A National Coordinating Center for Trauma Research

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-15-2-0089

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Donald H. Jenkins, MD, National Trauma Institute

E-Mail: jenkinsd4@uthscsa.edu

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

National Trauma Institute
9901 IH 10, Suite 730
San Antonio, TX 78230-2258

8. PERFORMING ORGANIZATION REPORT

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT
The purpose of this project is to focus DoD high priority research in: vascular injury, pain, and airway management. These studies are extending evidenced-based pre-hospital interventions as well as populate the National Trauma Research Repository (NTRR). During the third year, the PROOVIT study data collection was completed. The ketamine pain study was closed due to excessive delays and logistical issues. The airway management simulator development was completed and volunteer testing was performed. The National Trauma Research Repository (NTRR) was launched (www.nti-ntrr.org). The program officer and contracting officer granted a fifteen month no cost extension for project completion and additional development of the NTRR. NTI submitted a journal article on data sharing and the NTRR that was published in June 2018.

15. SUBJECT TERMS Vascular injury, airway management, pain management, Ketamine, National Trauma Research Repository

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
					USAMRMC
a. REPORT	b. ABSTRACT	c. THIS PAGE		23	19b. TELEPHONE NUMBER *(include area code)*
U	U	U	UU		

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std.

TABLE OF CONTENTS

INTRODUCTION:

Advances in trauma care in both pre-hospital and hospital settings have reduced trauma-related deaths and morbidities markedly; however, there is a substantial opportunity to further reduce deaths in the pre-hospital setting. Gaps in civilian and military pre-hospital care must be closed in order to reduce the number of potentially preventable deaths among wounded Warriors and civilian trauma patients. The purpose of this project is to focus on three specific areas of research identified high priority by the DoD: better solutions for vascular injuries, improved pain management, and better approaches for airway management. These studies will extend evidenced-based hospital interventions as well as populate the National Trauma Research Repository (NTRR) that will allow for data sharing, secondary analysis and greater power to detect statistical significance. As available research funding shrinks and federal budget pressure increases, it is essential that the return from dollars invested in research be maximized by replacing the expensive and repetitive assembly and disassembly of short-lived clinical investigator networks with a stable and enduring operational infrastructure for clinical trauma research.

KEYWORDS:

Vascular injury, airway management, pain management, Ketamine, National Trauma Research Repository, research dissemination

ACCOMPLISHMENTS:

Major Objectives of the Project:

Objective: To conduct research projects addressing military research gaps in airway management, pain management and vascular injury; and to develop tools to allow for the collection and dissemination of results and data from studies

Technical Objective 1: To conduct research projects addressing military research gaps in airway management, pain management and vascular injury**;** the contractor will perform Award management and compliance to include subcontracts, contract compliance, and all appropriate USAMRMC HRPO requirements.

Technical Objective 2: To develop tools to allow for the collection and dissemination of results and data from studies, including:

1) Develop a scalable repository of translational research data.
   a) Determination of common data element based on previously NTI funded project and other database sources.
   b) Creation of the data dictionary
   c) Development of policies for utilization guidance which includes repository requirement documents and website development.
   d) Conduct vendor solicitation and vendor selection process based upon requirements and capabilities identified.
   e) Build a scalable repository
   f) Alpha and beta testing with previous NTI funded studies and studies funded through this grant.

2) Provide a forum for dissemination of research outcomes to the trauma community.

Accomplishments under these Goals:

Major activities of this grant are organized under two study protocols and two projects.

STUDY 1:
Protocol Title: Determining the Efficacy and Safety of Ketamine as a Battlefield Analgesic
Principal Investigator: John Fauerbach, PhD
Participating Site: Johns Hopkins University School of Medicine
HRPO Assigned A-number: A-19299.2
Abstract: Background: Early, effective pain control for acute traumatic injury is important for successful outcomes. Despite the known importance of pre-hospital pain management, few studies have reported the use of analgesics and the type of analgesics used in combat. Ketamine has emerged recently as a potentially effective analgesic alternative to narcotics for use in combat-associated casualties. While early case reports attest to its effectiveness, these reports are anecdotal. Ketamine is the only single-agent anesthetic capable of producing a "dissociative" anesthesia, which has been useful for a variety of outpatient and inpatient surgical procedures. More than 50,000 service members have been injured in OIF, OEF, and OND and experience varying degrees of pain throughout their care. Of these injured service members, 31.8% are also diagnosed with PTSD.
Hypothesis: The addition of ketamine to narcotic analgesics will reduce significantly self-rated pain during dressing change/debridement on the Visual Analogue Scale for Pain (VAS-Pain):
Methods: Persons enrolled in the study through the informed consent process will be patients admitted to the Johns Hopkins Burn Center after sustaining burns less than 25% total burn surface area and not requiring initial endotracheal intubation. This would enable them to participate in structured interviews conducted by a psychologist assigned to the Burn Unit. These interviews would evaluate:

- The effectiveness of sub-anesthetic doses of ketamine as a sole analgesic vs. as a narcotic sparing drug for the treatment of acute post-traumatic pain
- The side effect profile of ketamine when administered in sub-anesthetic doses
- Whether the early administration of ketamine during the first three days following injury has a sustained effect on reducing the incidence or severity of Post-Traumatic Stress Disorder (PTSD)
- Whether the early administration of ketamine during the first three days following injury has a sustained effect on reducing the incidence or severity of clinical depression

Once IRB and HRPO approval is secured, patients will be randomized to a trial comparing a usual pain regimen, typically narcotics and benzodiazepines (UR-N) against a low dose ketamine regimen supplemented with usual pain medications (K+UR) on the effect of self-reported pain severity at the start of the procedure, every 5 minutes during the procedure and 5 minutes after the procedure ending, as well as the incidence and severity of PTSD and Depression at 24 hours, one week, and one month.

Military Significance: The DOD has identified capability gaps in combat casualty care. Several of the high priority gaps are well-suited for research in the civilian setting including en route care. A specific gap in these capabilities that the DoD has identified as high risk to the military and amenable to study in the civilian setting is: Ability to provide 100% acute and chronic pain management for wounded and injured soldiers, starting at the point of injury and continuing across the spectrum of care.

Progress Reported:

This study was closed in Year 3.

STUDY 2

Protocol Title: The PROspective Observational Vascular Injury Trial (PROOVIT)
Principal Investigator: Joseph DuBose, MD (Travis Air Force Base)
Lead Site: University of California at Davis
Participating Sites: Baylor College of Medicine/Ben Taub Hospital, Emory University, Loma Linda Medical Center, University of Southern California, Scripps Health, University of Maryland/R. Adams Cowley Shock Trauma, University of Tennessee – Memphis, University of Texas Health Science Center at Houston, University of Wisconsin School of Medicine and Public Health, Wright State University, East Carolina University
HRPO Assigned A-number: A-19299.1a-1m
Abstract: Background: Few if any decisions throughout the phases of vascular trauma management are guided by strong evidence. This fact is unfortunate, as many new diagnostic, therapeutic and surveillance strategies have the potential to improve morbidity and mortality following this vexing injury pattern. The lack of evidence-based practice is even more concerning given the devastating consequences associated with mismanaged vascular trauma. To date, no studies exist that would allow the prospective aggregation of larger amounts of data pertaining to all phases of vascular trauma management.
Hypothesis: This prospective, multicenter, observational study will provide the necessary data to develop best practices and optimize the care of this unique population of patients.
Specific Aims: 1. To determine the impact of tourniquet utilization after extremity vascular injury on limb-specific complications and limb salvage; 2. To determine the optimal utilization of endovascular versus open repair modalities after vascular injury; 3. To determine the role of early anticoagulation in mitigating complications after vascular injury repair.
Study Design: This study is a prospective multi-center observational trial on the management of vascular trauma. Data and endpoints will be observational and involve no proscribed therapeutic interventions or alterations in patient care. Waiver of informed consent has been received. Institutions and providers are conducting normal diagnosis, management and surveillance procedures without interference by this study. The location and type of endovascular therapy for vascular trauma is tracked including comparison of outcomes to those following open operative repair of similar injury patterns. Finally, data elements are gathered in a wide range of age groups with vascular trauma including the challenging scenarios of pediatric and geriatric vascular injury.
Military Benefit: Hemorrhage from vascular injury, at both Non-Compressible Vascular Injury (NCVI) and Compressible Vascular Injury (CVI) sites, remains a primary cause of mortality and morbidity on modern battlefields. This study will provide linkage to crucial elements of subsequent limb salvage and long-term outcomes – data that are presently not available on any significant scale in the military realm.

Progress Reported:

This study was completed in Year 3.

PROJECT 1
Project Title: High Anatomic Fidelity Surgical Airway Training System
Principal Investigator: Robert Buckman, MD
Lead Site: Operative Experience, Inc.
HRPO Assigned A-number: Not applicable
Abstract: Background: Airway obstruction is the third most common cause of potentially-preventable combat death. Because of this, surgical management of the threatened or obstructed airway is an essential skill for special operations medics and combat surgeons. Cricothyroidostomy and tracheostomy are infrequently performed, life-saving surgical procedures required when a casualty's airway cannot be maintained by other means. Surgical airway procedures may be required at any level along the continuum of care/evacuation. Published data from recent theaters of war indicate that these

emergency procedures are often performed incorrectly. Due to the limitations of existing methods of training, surgical airway management procedures are not currently taught to all combat medics. Improved, simulation-based methods of training will not only improve the training and enhance the capability of SOF medics and surgeons, but also will allow additional military healthcare providers and even combat lifesavers to be trained in this critical skill.
The Defense Health Board recommended optimized airway devices and training as a research priority for the Combat Casualty Care Research Program, contributing to the identification of a Combat Casualty Care Capability Gap.
Methods: Develop a prototype surgical airway simulator that provides high anatomical and surgical fidelity and challenges trainees with increasing degrees of clinical difficulty.

This project will develop an airway simulator that is capable of accurate anatomic representation of the airway from the mouth to the lungs, simulates a variety of traumatic tissue disruption with the face and neck, bleeds realistically, and supports training in tracheostomy and cricothyroidotomy. Development includes anatomic design, engineering design, medical modeling, physical modeling, engineering and system integration.

Progress Reported:

This project was completed in Year 4.

PROJECT 2

Project Title: National Trauma Research Repository
Principal Investigator: Donald Jenkins, MD
Lead Site: The National Trauma Institute
HRPO Assigned A-number: Not applicable
Abstract: There is a critical need for a national trauma research repository to synthesize study data for maximum use. Advances due to clinical trauma research have been accomplished largely through separate, organizationally distinct and disconnected efforts. Even when funding has derived from federal entities, individual projects have been somewhat dispersed and uncoordinated. This situation leads to research delays, duplications, inefficiencies and increased costs. To date there relatively little attention has focused on data exchange in the clinical research domain. While clinical researchers in different locations may have similar lines of investigation, the computer systems in use to store and retrieve data locally do not, and for the most part cannot, transmit, receive, combine, analyze and use shared data as information. Clinical research data are fragmented, sometimes within one facility, and can rarely be repurposed to answer additional research questions. Sharing data maximizes its value, promotes follow-up studies and minimizes duplicative data collection. Universal developments in information technology, like the creation of distributed data networks and virtual data access, provide ways to address clinical research needs that did not exist before. It is time to exploit and enhance these technologies to support clinical trauma research.

The consolidation and linkage of data sets in a shared data repository would greatly expand their use and provide a robust scientific platform; pooled data sets can create the additional statistical power necessary to improve statistical significance. This clinical research repository employing common data elements will be particularly beneficial in maximizing trauma study data because it is often difficult to obtain informed consent since the injury and the need for early interventions often coincide; the patient is often unable to give consent due to the level of consciousness; and family are often unavailable in the early stages of treatment after trauma. The ability to make aggregated research data widely available to clinical investigators is critical to reform trauma research and care because, while the practice of medicine should be evidence-based, within the field of trauma there is surprisingly little evidence to support clinical practice. The formation of a national trauma research repository will ensure maximum utilization of trauma data for translation into evidence-based practice.

The NTRR will be built as a scalable, customizable repository that is capable of receiving data feeds from other data systems through a conversion method. NTRDB will be structured such that any study can contribute any portion of its data, besides the core common data elements, and those

elements remain linked to the original source as well as available for secondary analysis in concert with any other data set. The initial module will be a set of generic data elements that is as globally representative across all trauma patients as possible yet is robust enough to support a data analysis plan.

Progress Reported:

This year, we continued to import legacy studies. This work includes identifying the data elements and their attributes that need to be created in the NTRR based upon the individual study data dictionaries, clinical research forms, and the data; creating/importing the data elements into the NTRR; creating forms with the NTRR (a collection of the data elements) to include grouping elements and recurring frequencies; mapping study data to the form created; and ultimately uploading the data into the NTRR for each study. The table of progress in gaining agreement for Investigators to submit data, executing Data Transfer and Use Agreements, receiving data dictionaries and other study forms/documents, and the process of creating the study and importing the data into the NTRR is attached as an Appendix. There are two sites for the NTRR – a production site and a demo site. The Production site is completely clean and was mirrored to the Demo environment. Data was imported for a traumatic brain injury study. All Form Structures for PROPPR study have been created, one FS has been updated with study data and validated in the system.

Enduring Funding: An Extension WithOut Funding (EWOF) was submitted and approved in the first quarter extending the period of performance to 12/29/2020.There have been ongoing discussions with the Combat Casualty Care Research Program regarding the possibility of enduring funding. A presentation was given by the program to the Defense Health Agency. In December 2019, Dr. Jenkins and NTI staff met with Dr. Terry Rauch to discuss enduring funding and he was supportive. He suggested we approach the Uniformed Services University of the Health Sciences (USU) for partnership. An initial conversation between Dr. Jenkins and Dr. Elster at USU was positive. In a phone call mid-June Col Davis reported that CAPT Cohn's supervisor was briefing Dr. Rauch with updated slides. DHA had agreed to provide $1.4M in RDT&E funds as a bridge while we work on securing O&M funding. Col Laird at DHA was to be involved in this action. The bridge funds are to be added to this current agreement. In August 2020 CDR Travis Polk became the Director of the Combat Casualty Research Program and CNTR staff briefed him and his staff. **During this briefing, CDR Polk stated that the previous $1.4m in RDT&E funds were used for something else and no longer available for the NTRR. He was looking at different funding sources. At the time of this report, we've not heard anything further regarding enduring funding.**

NTI and Sapient met routinely throughout the year to discuss system usage, training needs, and NTRR specific change requests. Sapient Governmental continues to host, develop and maintain the NTRR. General maintenance and security work took place throughout the year.

The NTRR Communication Plan continued to be executed to ensure that trauma researchers were aware of the repository and the research opportunities and data sharing it provides. NTI staff exhibited the NTRR at the January 2020 Eastern Association for the Surgery of Trauma annual meeting in Orlando, Florida and virtually exhibited at the 2020 American Association for the Surgery of Trauma meeting.

Study/Projects Major Tasks and Accomplishments to Date (Years 1 - 5)

Protocol 1: KETAMINE STUDY	**Timeline in Months**	**Actual completion date**	**% of completion**
Major Task 1: Prepare and adapt Research Protocol for DoD Funded Status for Study 1			
Subtask 1: Refine research protocol	1-3	06/28/2016	100%
Refine eligibility criteria, exclusion criteria, screening protocol, enrollment protocol	1-3	06/28/2016	100%
Finalize consent form and human subjects protocol	1-3	06/28/2016	100%
Coordinate IRB protocol submission	1-3	06/28/2016	100%
Submit for Military 2nd level IRB review (ORP/HRPO)	3-6	05/30/2017	100%
Submit amendments, adverse events and protocol deviations as needed	6-18	Ongoing	N/A
Milestone Achieved: Protocol for Study 1 developed	3	06/28/2016	100%
Milestone Achieved: Local IRB approval	4-5	03/20/2017	100%
Milestone Achieved: HRPO approval	8	06/21/2017	100%
Major Task 2: Data Analysis for Study 1			
Subtask 1: Monitor data collection and data quality	8-20	Closed	0%
Protocol 2: PROOVIT STUDY			
Major Task 3: Adapt PROOVIT Protocol for DoD Funded Status for Study 2			
If applicable, coordinate with sites for IRB protocol submission	1-6	01/05/2016	100%
Coordinate with sites for Military 2nd level IRB review (ORP/HRPO)	1-6	03/31/2016	100%
Submit amendments, adverse events and protocol deviations as needed	As needed	Closed	N/A
Coordinate with sites for annual IRB report for continuing review	Annual	06/28/2017	100%
Prepare and submit quarterly progress report to DoD	Qrtly	06/28/2017	100%
Milestone Achieved: Local IRB approval at all sites	3	03/29/2016	100%
Milestone Achieved: HRPO approval for all protocols	6	04/22/2016	100%
Major Task 4: Subcontract with all Study Sites for Study 2			
Verify sub-award documents: budget, budget justification, salary verification	1-3	03/22/2016	100%
Issue and execute sub-award document	1-3	04/13/2017	100%
Receive quarterly progress reports	Qtrly	03/15/2017	100%
Review quarterly progress reports	Qtrly	04/11/2017	100%
Milestone Achieved: Subawards issued for all sites	3	04/13/2017	100%

Major Task 5: Data Analysis for Study 2			
Subtask 1: Coordinate with sites and NTI for monitoring data collection rates and data quality	4-6		100%
Perform all analyses according to specifications, share output and findings with all investigators	Ongoing		100%
Project 1: SURGICAL AIRWAY SIMULATOR			
Major Task 6: Develop High Fidelity Airway Simulator			
Execute Subaward	1	05/12/2016	100%
Develop a model base	1-4	07/01/2016	100%
Engineer hydraulic, mechanical and pneumatic systems for head movement, airway lubrication, respiration and circulation	1-4	07/01/2016	100%
Develop and integrate a programmable logic controller	1-4	07/06/2016	100%
Integrate subsystems into the infrastructure built upon the base	5-9	03/31/2017	100%
Develop a layered, high-fidelity anatomical model for face, neck and upper thorax	5-9	02/24/2017	100%
Separate the components of high-fidelity anatomical model for molding	5-9	8/31/2018	100%
Create molds of the anatomical components including bones, selected individual muscles, fascia, larynx, trachea, thyroid gland, major arteries and veins	10-12	8/31/2018	100%
Create serial iterations of the models and molds to complete engineering	10-12	8/31/2018	100%
Research materials for high anatomical and surgical fidelity laryngo-tracheal complex	10-12	08/31/2018	100%
Major Task 7: Requirements Function Testing			
Confirm requirements function through volunteer use	19-24	8/31/2018	100%
Coordinate with volunteer pool to test	19-24	8/31/2018	100%
Report evaluations of volunteer testing	19-24	12/13.2018	100%
Project 2: NATIONAL TRAUMA RESEARCH REPOSITORY			
Major Task 8: Determine Data Dictionary and Vendor Requirements			
Coordinate with Steering Committee to determine Common Data Element Workgroup	1-6	03/29/2016	100%
Common Data Element Determinations	6-9	03/30/2018	100%
Develop Data Dictionary	6-9	03/30/2018	100%
Milestone Achieved: Data dictionary			

Major Task 9: Vendor solicitation and selection	1-6	08/11/2016	100%
Determine repository requirements	6-9	08/11/2016	100%
Vendor solicitation and selection process	6-9	08/11/2016	100%
Milestone Achieved: Repository requirements document	6-9	07/19/2017	100%
Milestone Achieved: Vendor Selected			
Major Task 10: Repository build and testing	9-12	06/25/2018	100%
Repository build (back and front end)	9-12	06/25/2018	100%
Go Live	9-12	06/25/2018	100%
Milestone Achieved: Repository Live	9-12	06/25/2018	100%
Major Task 11: Website development and policy	3-9	6/25/2018	100%
Develop management policies	6-15	6/25/2018	100%
Develop website and interfaces	6-15	6/25/2018	100%
Milestone Achieved: Policies available on functional website		6/25/2018	100%
Major Task 12: Repository Hosting			
Repository hosting	37-52	Ongoing	
Importing legacy studies	37-48	Ongoing	
Supporting investigators with new studies	37-52	Ongoing	

Training and Professional Development

No training activities were held in Year 5.

Dissemination of Results to Communities of Interest

Study 1: Determining the Efficacy and Safety of Ketamine as a Battlefield Analgesic

Study was closed; therefore, no dissemination of results will be reported.

Study 2: PROOVIT Study

Study was closed; therefore, no dissemination of results will be reported.

Project 1: Airway Management Simulator

Project was completed; therefore, no dissemination of results will be reported.

Project 2: National Trauma Research Repository

We distributed our marketing piece at the EAST Scientific Meeting in January 2020 and virtually exhibited at the American Association for the Surgery of Trauma Clinical Congress in September 2020.

Plans for the Next Quarterly Reporting Period

Study 1: Determining the Efficacy and Safety of Ketamine as a Battlefield Analgesic - Study closed, no further reporting.

Study 2: PROOVIT Study - PROOVIT sites are closed, no further reporting.

Project 1: Airway Management Simulator - Project is closed, no further reporting.

Project 2: National Trauma Research Repository – We will submit an EWOF to extend minimal hosting efforts through March 2021 in hopes of achieving an enduring funding solution.

IMPACT:

There are no developments in the principal discipline, other disciplines, technology transfer or to society beyond science and technology to report at this time.

CHANGES/PROBLEMS:

Should enduring funding not be achieved, the NTRR will be dismantled as of March 2021 (assuming the EWOF is approved). It may be possible to restart the servers and site after a compete shut down, but the cost for that process is unknown at that time.

PRODUCTS:

Products completed in Year 5 are included in the appendices of this report.

PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

Name	Project Role	Nearest person month worked	% Effort	Contribution to the project
Donald Jenkins	Principal Investigator	0.6	5% entire year	Oversight of entire project
Amy Flores	Controller	.6	5% entire year	Subaward financial and contract management, tracking grant expenditures
Monica Phillips	Research Operations Director	9.6	Average of 80% over the year	Responsible for creating common data elements in the repository; executing DUA's with legacy study PIs, creating study data element sets; importing study data
Pam Bixby	Communications	0.25	5% October 2019 – February 2020	Responsible for the communication and dissemination tasks of the projects.

Sharon Smith	Project Administrator	1.29	43% October-December 2019	Encouraged legacy study PI's to contribute data, assisted in obtaining DUA and study materials.
Michelle Price	Co-Investigator/ Program Manager	0.84	7% entire year	General oversight of repository work.
Lizette Villarreal	Program Manager	.45	15% October – December 2019	Responsible for regulatory oversight and coordination of regulatory reviews and reporting for the 13 research subawards.

Other Collaborating Organizations

Organization	Location	Contribution to Project
Baylor College of Medicine/Ben Taub General Hospital	1504 Taub Loop, Houston, TX 77030	PROOVIT Clinical Site (PI: Dr. Ramyar Gilani)
Emory University	201 Dowman Drive, Atlanta, GA 30322	PROOVIT Clinical Site (PI: Dr. Ravi Rajani)
Loma Linda Medical Center	11234 Anderson Street, Loma Linda, CA 92354	PROOVIT Clinical Site (PI: Dr. Richard Catalano)
University of Southern California	1983 Marengo Street, Los Angeles, CA 90033	PROOVIT Clinical Site (PI: Dr. Kenji Inaba)
Scripps Health	4077 Fifth Avenue, San Diego, CA 92103	PROOVIT Clinical Site (PI: Dr. Michael Sise)
University of California, Davis	2315 Stockton Boulevard, Sacramento, CA 95817	PROOVIT Clinical Site (PI: Dr. Joseph Galante)
University of Maryland/R. Adams Cowley Shock Trauma	22 S. Greene Street, Baltimore, MD 21201	PROOVIT Clinical Site (PI: Dr. Thomas Scalea)
University of Tennessee – Memphis	920 Court Street, Memphis, TN 38163	PROOVIT Clinical Site (PI: Dr. Timothy Fabian)
University of Texas Health Science Center at Houston	6410 Fannin Street, Houston, TX 77030	PROOVIT Clinical Site (PI: Dr. Laura Moore)
University of Wisconsin School of Medicine and Public Health	750 Highland Avenue, Madison, WI 53276	PROOVIT Clinical Site (PI: Dr. Suresh Agarwal)
Wright State University	1 Wyoming Street, Dayton, OH 45409	PROOVIT Clinical Site (PI: Dr. John Bini)
University of Texas Health Science Center at San Antonio	7703 Floyd Curl Drive, San Antonio, TX 79230	PROOVIT Statistical Analysis (PI: Dr. Joel Michalek)
Johns Hopkins University	600 North Wolfe Street, Blalock 1415, Baltimore, MD 21287	Ketamine Clinical Site (PI: Dr. John Fauerbach)
Operative Experience, Inc.	500 Principio Parkway West, Suite 300, North East, MD 21901	Airway Management Simulator Development (PI: Dr. Robert Buckman)

SPECIAL REPORTING REQUIREMENTS

The Quad chart for this project follows.

APPENDICES:

1. Quad chart
2. NTRR Study List Status
3. NTRR 6-panel display
4. NTRR CDE Sheet
5. Postcard-Data Sharing

A National Coordinating Center for Trauma Research

PI: Donald Jenkins, MD **Org:** National Trauma Institute

Study/Product Aim(s)

Hypothesis: The civilian trauma research community can be used as a surrogate for military combat casualty care research, maximizing the return from dollars invested by replacing the expensive and repetitive assembly and disassembly of short-lived clinical investigator networks with a stable and enduring operational infrastructure for clinical trauma research.

- Technical Objective 1: To manage specific research projects addressing military research gaps in airway management, pain management and vascular injury.
- Project 1: Determining the Efficacy and Safety of Ketamine as a Battlefield Analgesic;
- Project 2: High Anatomic Fidelity Surgical Airway Training system;
- Project 3: The PROspective Observational Vascular Injury Trial (PROOVIT);
- Technical Objective 2: Develop tools to allow for the collection and dissemination of results and data from studies.

NTRR Launched in June 2018 at www.nti-ntrr.org

Timeline and Cost (direct + indirect)

Activities	FY16	FY17	FY18	FY 19	FY20
Ketamine Study					
Airway Simulator Development					
PROOVIT					
NTRR Development					
Total Budget ($M)	$1.1M	$1.2M	$1.2M	$1.1M	

Goals and Milestones

CY16 Goal –
☑ HRPO approval for studies; Subcontracting complete; Studies commence
☑Common Data Elements and NTRDB functional requirements

CY17 Goals
☑Airway simulator developed
☑ NTRR developer solicited and chosen

CY 18 Goals
☑Ketamine study concludes
☑PROOVIT study concludes

CY19 & CY20 Goals
☐ NTRR development continues (ongoing)

Comments/Challenges/Issues/Concerns: Ketamine study closed due to non-performance, PROOVIT sites completed, Airway Simulator completed.

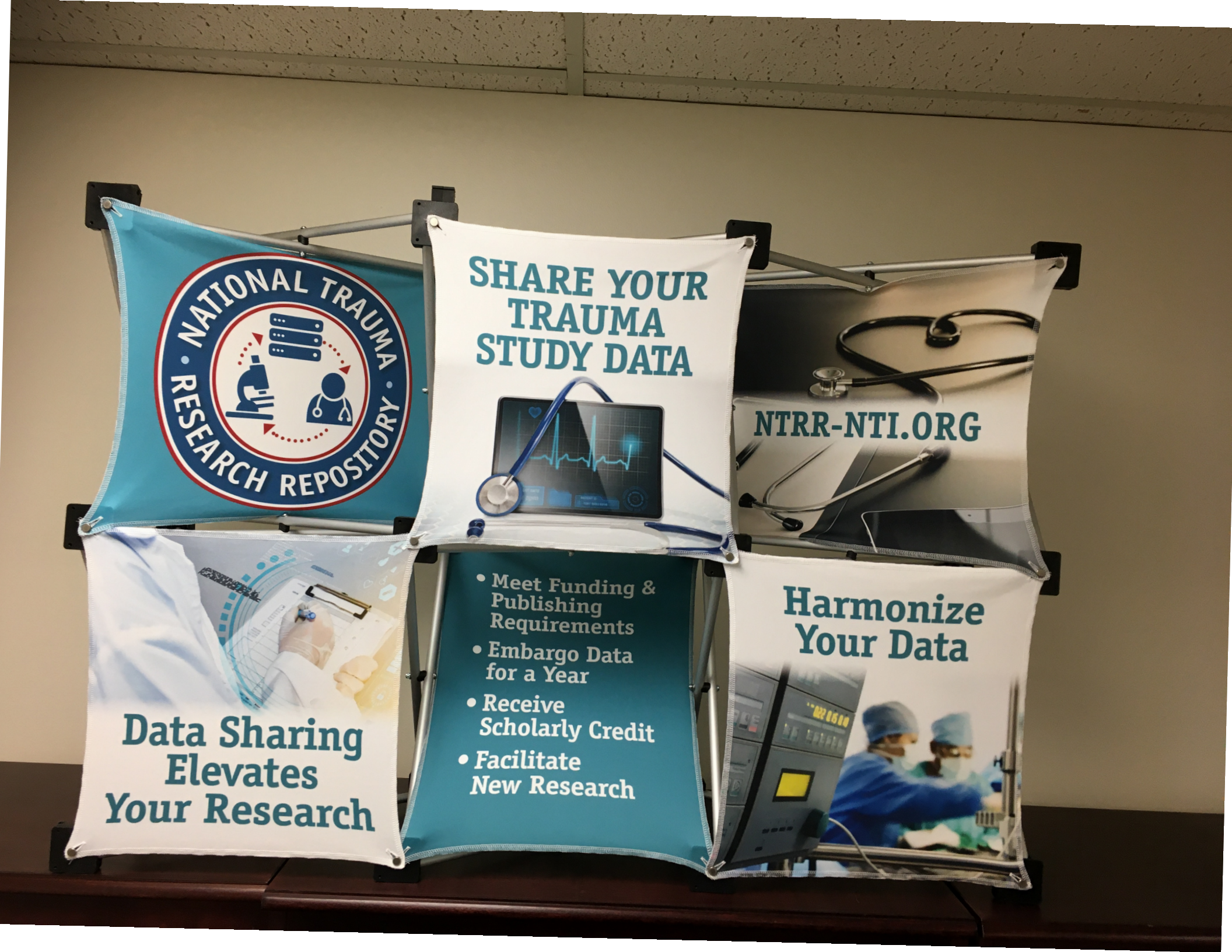
Budget: $4,642,861 Actual: $4,611,669 (as of 9/29/2020)

Patrick Regan, PhD 301-619-4197 patrick.m.regan6.ctr@mail.mil

Study	PI	Lead Institution	Funding Source	Contract Number	Enrolled subjects	Estimated # data elements	Agreed to submit Data	DTUA Executed	Data Dictionary Received	Data elements created	Data Elements Imported	Data Received	Data Imported
Pragmatic, Randomized Optimal Platelet and Plasma Ratios (PROPPR)	Charles Wade	UT Houston	NHLBI; DoD; Defense Research and Development Canada	U01HL077863; CRR-120612	680	484	x	x	x	x	x	x	In progress
Prospective Observational Multicenter Major Trauma Transfusion (PROMMTT)	Hossein Rahbar.	UT Houston	DoD/NIH through CTSA for DCC infrastructure	W81XWH-08-C-0712/UL1 RR024148	1245	400							
Multicenter Observational Prehospital Resuscitation on Helicopter Study (PROHS	Charles Wade	UT Houston	NIH/DoD	U01HL077863; CRR-120612	1058	298	x	x	x	in progress		x	
Prehospital Air Medical Plasma (PAMPer)	Jason Sperry		DoD	W81XWH-12-2-0023	501		x						
Resuscitation Outcomes Consortium (ROC) Hypertonic Saline Trial Shock Study (HS) and Traumatic Brain Injury Study (TBI)		ROC	Multi	NIH 5U01HL077863-05	2226	865	x		x	in progress			
Fit-to-Fly" Biomarkers after Severe Traumatic Brain Injury with or without Additional Severe Trauma ("Multitrauma")	Deborah Stein		Multi		84	90	x	x	n/a	x	x	x	x
Thromboelastography (TEG®) based dosing of enoxaparin for thromboprophylaxis: a prospective randomized trial	Martin Schreiber	OHSU	DoD	W81XWH-11-10841	96		x						
Transfusion using Stored Fresh Whole Blood	Henry Cryer	UCLA	DoD	W81XWH-11-10841	66		x		x				

Vasopressin Supplementation during the Resuscitation of Hemorrhagic Shock	Carrie Sims	University Pennsylvania	DoD	W81XWH-10-1-0924	25								
Timing and Mechanism of Traumatic Coagulopathy	Mitch Cohen	UCSF	DoD	W81XWH-10-1-0924	317								
Multicenter Prospective Evaluation of the Ventilator Bundle in Injured Patients	Martin Croce	UT Memphis	DoD	W81XWH-08-1-0758	630		x	x					
Detection and Management of Non-Compressible Hemorrhage by Vena Cava Ultrasonography	Jay Doucet	UCSD	DoD	W81XWH-11-10841	59		x						
Methicillin-Resistant Staphylococcus aureus in a Trauma Population: Does Decolonization Prevent Infection?	Robert Maxwell	UT Chattanooga	DoD	W81XWH-11-10841	56		x						
Transfusion of Stored Fresh Whole Blood in a Civilian Trauma Center: A Prospective Evaluation of Feasibility and Outcomes	Mark Cipolle	Christiana	DoD	W81XWH-11-10841									
Hepcidin and Anemia in Trauma	Lena Napolitano	U Michigan	DoD	W81XWH-11-10841	98								
Characterization of the effects of the early sex-hormone environment following injury.	Jason Sperry	UPMC	DoD	W81XWH-10-1-0924	293		x						
Splenic Injury Prospective Outcomes Trial	Ben Zarzaur	UT Memphis	DoD	W81XWH-11-10841	383		x		x				
A Multicenter, Randomized, Double-blind Comparison of Intravenous Iron Supplementation to both Enteral Iron Supplementation and Placebo for the Anemia of Traumatic Critical Illness	Fred Pierraci	Denver	DoD	W81XWH-08-1-0758	150		x						

Multiinstituional Multidisciplinary Injury Mortality Investigation in the Civilian Prehospital Environment (MIMIC) - data available 2021	Brian Eastridge	NTI	DoD	W81XWH-170200010	3000		x						
The Pathogenisis of Post Traumatic Pulmonary Embolism: A Prospective Multicenter Investigation by the CLOTT study group (CLOTT) - data available 2021	Peggy Knudson	UCSF	DoD	W81XWH-17-2-0673	9400		x						
Prospective ObservationalVascular Injury Treatment (PROOVIT) Registry	Joe DuBose		DoD	W81XWH-15-2-0089	6773								
Management of Non-compressible Hemorrhage using Vena Cava Ultrasound	Jay Doucet	UCSD	DoD	W81XWH-15-1-0079	102		x						
Transfusion using Stored Fresh Whole Blood	Henry Cryer	UCLA	DoD	W81XWH-15-2-0039	60		x						
National Trauma Research Action Plan	Eileen Bulger	NTI	DoD	W81XWH18C0179			x					Anticipate available 2021	
Hemorrhage Control for Major Traumatic Vascular Injuries Phase II	Laura Moore	UT Houston	DoD	W81XWH-14-1-0112			x	x					
Microbiome study	Susannah Nicholson	UTHSCSA					x						
Safety/Efficacy of Platelet Transfusion in patients receiving antiplatelet therapy that sustains intracranial hemorrhage	Mark Cipolle	Christiana	DoD	W81XWH-11-10841									
27					27,302	427.4	20	5	6		1		1


NATIONAL TRAUMA RESEARCH REPOSITORY
SHARE YOUR TRAUMA STUDY DATA
NTRR-NTI.ORG
Data Sharing Elevates Your Research
• Meet Funding & Publishing Requirements
• Embargo Data for a Year
• Receive Scholarly Credit
• Facilitate New Research
Harmonize Your Data

DATA SUBMISSION PROCESS

- Execute a Data Transfer and Use Agreement with the National Trauma Institute.
- Certify data as de-identified or as a limited data set.
- Certify that an appropriate IRB has considered the risks and that the data have been de-identified in accordance with federal regulations.
- Upload your data -- it is typically embargoed for one year following your first publication.

Contact Help@NTRR-NTI.org to begin the data sharing process.

COMMON DATA ELEMENTS

Common Data Elements (CDEs) are those data collected for every subject of every trauma study, an intentionally small set. The NTRR will also upload Unique Data Elements (UDEs), specific to a given study or number of studies. To date, the NTRR includes the following CDEs:

CORE DATA SET

- Person Sex
- Ethnicity USA Category
- Race USA Category
- Comorbidities
- Injury date/time
- ICD version and external cause codes
- Injury Severity Score
- Abbreviated Injury Scale version, body region, severity score, clinical description and PreDot

PREHOSPITAL DATA SET

- Vital Signs - Heart Rate, Respiratory Rate, Systolic Blood Pressure, and Diastolic Blood Pressure - first, last, highest, lowest with date/time
- Glasgow Coma Score with date/time
- Unit counts of blood products transfused in the prehospital setting, including packed red blood cells, fresh frozen plasma, freeze dried plasma, and whole blood

INPATIENT DATA SET

- Vital Signs in the Emergency Department - Heart Rate, Resipiratory Rate, Systolic Blood Pressure, and Diastolic Blood Pressure - first, last, highest, lowest with date/time
- Glasgow Coma Score with date/time
- Unit counts of blood products transfused in the Emergency Department, including packed red blood cells, fresh frozen plasma, freeze dried plasma, whole blood, platelets, cryoprecipitate
- Emergency Department admission and discharge date/time
- Emergency Department discharge location - list from NTDS
- Weight/Height
- Hospital admission and discharge date/time
- Hospital discharge disposition - list from NTDS
- Complications

Most federal funding sources- including the NIH, DoD and NSF-require data sharing for funded research.

Most major medical journals now require researchers reporting results of clinical trials to submit data sharing plans.

NATIONAL TRAUMA RESEARCH REPOSITORY

In 2018, the National Trauma Institute (NTI) and Sapient Government Services (the developer of the NIH's Federal Interagency Traumatic Brain Injury Research Informatics System, or FITBIR) created the National Trauma Research Repository. The NTRR is a centralized, cloud-based data repository and discovery portal. For more information, contact Help@NTRR-NTI.org.

BENEFITS & GUARANTEES

- The NTRR facilitates new research using existing data, expanding the return on investments made in clinical trials.
- Investigators receive scholarly credit for sharing their data through linkage to the original study's Digital Object Identifier (DOI) and the creation of a unique DOI for the data set.
- Data uploaded to the NTRR are typically embargoed for use by others for at least a year.
- Investigators requesting data must meet access criteria and fulfill acknowledgement requirements (original investigator/study) when publishing studies using the data.

The U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick MD 21702-5014 is the awarding and administering acquisition office. This work is supported by the Office of the Assistant Secretary of Defense for Health Affairs, through the Defense Medical Research and Development Program under Award No. W81XWH-15-2-0089.

Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the Department of Defense.

NATIONAL TRAUMA INSTITUTE

DATA SHARING ELEVATES YOUR RESEARCH

NTRR-NTI.ORG

The National Trauma Research Repository (NTRR) supports data sharing among trauma investigators, enabling them to share their study data, collaborate on secondary analyses, and combine and analyze data across studies.

DATA SHARING ELEVATES YOUR RESEARCH

The National Trauma Research Repository (NTRR) is a Department of Defense-funded, cloud-based data repository for clinical trauma research data.

NTRR-NTI.ORG