



NATIONAL TRAUMA INSTITUTE

RESEARCH GRANT GUIDELINES

The National Trauma Institute (NTI) is requesting pre-proposals for one year multi-center translational or clinical research on aspects of trauma. NTI's grant program is designed to provide financial support for researchers studying aspects of trauma outlined in the body of this document.

Special areas of interest are translational and clinical studies in the following areas:

- Hemorrhage/Shock/Coagulopathy
- Hospital-acquired Infection
- Technology Development
- Airway and Ventilation
- Disaster Preparedness
- Burn

SCHEDULE

Posted Date:	September 29, 2009
Pre-proposal Submission Deadline:	October 30, 2009
Call for Full Proposals:	December 18, 2009
Full Proposal Submission Deadline:	February 1, 2010
Announcement of Awards:	March, 2010

Please direct all questions and correspondence to:

NTI-research@nationaltraumainstitute.org

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RESEARCH GRANT GUIDELINES

I. SUBMISSION, REVIEW AND AWARDING PROCEDURES

A. INTRODUCTION

The National Trauma Institute (NTI) awards funds to support a broad range of trauma research. The urgent need for trauma research and enhanced technologies is important as more than 35,000 soldiers have been injured and over 5,000 have died on the battlefield in the current wars. Moreover, injury kills more than 179,000 Americans and accounts for more than \$400 billion in health care costs every year. Some of today's most urgent challenges in trauma include hemorrhage control, resuscitation, control of shock, coagulopathy, burn care and treatment, elimination of hospital acquired infection in the ICU, airway and ventilation management, development of technology, and disaster preparedness.

B. RESEARCH SCOPE OF SOLICITED PROPOSALS

The National Trauma Institute is currently accepting proposals for clinical or translational research. Multicenter, prospective or observational clinical or translational research studies relating to one or more of the following research areas will be given priority. Proposals must incorporate ICU treatment or outcomes.

1. Hemorrhage

- Local or systemic methods to manage or minimize non-compressible hemorrhage
- Early detection or minimization of shock
- Development of blood products such as freeze-dried blood or blood substitutes that could be used in austere environments
- Prediction of resuscitation requirements
- Development and selection of resuscitation fluids
- Control and monitoring of the immune response to resuscitation and trauma
- Identification of optimal resuscitation blood pressure.
- Develop or test novel transfusion products that increase fluid/blood volume and closely resemble whole blood with component clotting factors
- Develop methods to detect early signs of coagulopathy to limit exacerbation of coagulopathic symptoms.

2. Hospital acquired infection and antibiotic utilization
 - Rapid methods for detection of infection
 - Rapid methods for antibiotic or fungal identification
 - Development of computer-assisted decision support systems for antibiotic prescription
 - Monitoring and analysis of computer-assisted decision support systems in decreasing over-prescription or prevalence of hospital-acquired infection.
 - Methods for minimization of transmission of hospital-acquired infection
3. Ventilator-induced lung injury
 - Clarification, standardization, optimization and individual customization of protocols to diminish VILI
4. Technology development
 - Use or development of wireless vital signs monitors
 - Use or development of computerized clinical decision support systems
 - Use or development of biosensors
 - Use or development of topical negative pressure wound therapies
 - Development of imaging systems for improved trauma care
 - Use or development of organ simulation for medical education
5. Burn
 - Development or use of replacement skin
 - Development or use of off-the-shelf skin
 - Methods for protecting skin grafts from immune recognition
 - Methods for delivering viable skin products to austere environments
6. Disaster preparedness
 - Procedures or treatment in mass casualty situations
 - Transportation of the critically ill

C. FUNDING CONSIDERATIONS

This federal funding opportunity is administered through the Department of Defense (DOD), therefore a statement regarding military relevance of the proposed work is required. Following award and IRB approval, protocols are subject to secondary review by the DOD before work can commence.

D. BUDGET

Budgets for up to, but not exceeding, \$300,000 for one year are acceptable. Follow-on funding may be available in future funding rounds.

E. QUALIFICATIONS OF THE PRINCIPAL INVESTIGATOR (PI)

The principal investigator must hold an MD, DO, PhD, ScD, DDS, DVM or equivalent

degree. The PI must reside in the United States and must have a faculty appointment at an accredited U.S. institution, or hold a senior position at an established company. The PI must have proven ability to pursue independent research as evidenced by original research publications in peer-reviewed journals.

F. DETAILS OF PROPOSAL

1. PRE-PROPOSAL

The pre-proposal must not exceed three (3) pages. Please present the following elements in order:

- a. Title of project
- b. Name and affiliation of lead PI
- c. Names of participating institutions and site Principal Investigators
- d. Hypothesis and specific aims
- e. Goals and objectives of the proposed work
- f. Brief statement describing use of ICU treatment or outcomes in the proposed research
- g. Military relevance
- h. Significance of the proposed work with regard to NTI's stated research objectives

The pre-proposal must be single-spaced, with 1 inch margins using at least an 11-pt font. **DO NOT USE THE ATTACHED FORMS FOR THE PRE-PROPOSAL. These will be used if an invitation for a full proposal is made.** Please submit completed pre-proposal in a single pdf file via e-mail to research@nationaltraumainstitute.org by October 30, 2009. See also, Section F, Review Process for further information.

2. FULL PROPOSAL

DO NOT SUBMIT A FULL PROPOSAL UNTIL INVITED TO DO SO

The full proposal is to be submitted using the enclosed forms. Number the pages consecutively at the bottom throughout the proposal. Type the proposal single-spaced, with 1 inch margins using at least an 11-pt font. Please submit completed proposal and appendices, including figures and images in a single pdf file via e-mail to:

NTI-research@nationaltraumainstitute.org. Appendices should not be used to subvert the page limitation on the grant. Please present them in the following order according to the following instructions:

1. Title Page (Please use the form provided - 1 page)

Use the same title used for the pre-proposal.

2. Table of Contents (Use the form provided - 1 page)

3. Project Abstract and Non-proprietary Lay Person Summary (1 page each)

On a single separate page, describe precisely and clearly the nature, objective, methods of procedure and significance of the proposed research project, and how it relates to the research goal(s) outlined in Section B. (limit 300 words).

Rewrite the abstract in abbreviated *non-proprietary* form in terms suitable for presentation to lay persons (limit 300 words). This abstract should not contain any confidential information.

4. Research Plan (10 pages maximum):

- a) Title of project
- b) Goals and objectives
- c) Hypothesis and specific aims
- d) Methodology (including description of ICU treatment or outcomes)
- e) Analysis of results
- f) Military relevance

5. Budget

Complete the full budget **using the form provided**. Overhead or indirect costs should be limited to 10% of direct costs. Additionally, include:

- a. Statement that the institution will accept the allowed indirect cost rate
- b. Budget justification describing the duties of the employees funded by the grant and the itemized calculation of other budget items.

6. Other Support (2 pages)

List other support received by Principal and Co-Investigators for any projects (include yearly and total budget and duration of any grants):

- a. Current
- b. Pending
- c. Description (in a paragraph, describe each current or pending grant and whether it has scientific or budgetary overlap with the present proposal).

7. Biographical Sketches (3 pages each)

Using the supplied form, please provide biographical sketches for key personnel including participating site principal investigators.

8. Facilities Description (1 page)

Describe the research facilities (laboratory space, clinical population, etc)

available for the project.

9. Appendix

- a. Literature cited
- b. Human subjects experimental approval (IRB) or submitted protocol
- c. Letters of support from participating institutions
- d. A letter stating the confidential nature of the research if the proposal contains proprietary information

G. REVIEW PROCESS

A committee of experts in clinical or translational research will review the pre-proposal. Each pre-proposal will receive a priority score based on the evaluation of the committee. Pre-proposals will be selected and principal investigators will be invited to submit full proposals in December 2009.

Full proposals must be received by 3pm Central Time, February 1, 2010.

Full proposals will be assessed on the basis of:

1. Relevance to stated NTI research objectives
2. Scientific excellence
3. Clinical relevance and clinical impact
4. Multicenter collaboration
5. Military relevance
6. Innovation
7. Potential for follow-on studies
8. Feasibility of completing stated objectives in one-year funding period

These criteria should be considered when submitting the pre-proposal (see Section F1) for further details regarding pre-proposal submission), but **do not submit a full proposal until invited to do so.**

Funding recommendations will be forwarded to the National Trauma Institute Board, where award decisions will be made based upon scientific merit ranking of the proposals, and on priorities of the National Trauma Institute. We discourage proposals that add funding to current projects. All proposals will be held in the strictest confidence. All award decisions announced by the National Trauma Institute are final.

H. TERMS OF THE GRANT

1. **Duration.** One-year funding period.
2. **Changes of Status of Principal Investigator.** Approval should be requested if the named PI changes, or changes affiliations.

3. **Site of Project.** Grants are for studies at US national public or private universities, colleges, hospitals or biomedical research institutions.

4. **Budget.** Budgets for up to, but not exceeding \$300,000 for one-year are acceptable. Each participating institution will contract directly with NTI.

Costs allowed:

- salaries for PIs, research personnel or post-doctoral fellows engaged in the project
- research related patient costs
- up to 10% of institutional overhead
- purchase of equipment only for direct performance of the research project
- travel for direct performance of the research project and for attendance of the NTI Annual Symposium

Costs not allowed:

- construction or renovation costs
- office equipment or furniture
- tuition fees
- journal subscriptions, dues or memberships
- equipment service contracts
- indirect costs on major equipment
- salaries for office or administrative staff

Funds will be distributed on a quarterly basis following acceptance of submitted progress reports.

5. **Indemnification of NTI:** Principal Investigator, co-investigators and his/her Affiliated Institutions (AI) will be obligated to indemnify NTI from any and all liability that may arise from the PI's or co-investigator's conduct and NTI's affiliation therewith due to the grant relationship.

6. **Institutional Support.** The proposed research must comply with the regulations of the PI's Institutional Review Board (IRB) related to research on humans. A copy of the IRB approval document must be forwarded to NTI before disbursement of funds. The PI assumes responsibility for conducting research projects and supervising the work of co-investigators. The PI must demonstrate that access to a suitable caseload or patient population will be available for study during the funding period for clinical studies.

7. **Use of Humans in Biomedical Research.** All PIs must certify that the research facilities, its researchers and employees adhere to National Institutes of Health Regulations and Standards. An Institutional Review Board (IRB) or its equivalent must approve research involving human subjects and a copy of the approval, or protocol pending approval, must be sent with the full proposal. NTI will coordinate approval of human research protocols with the appropriate federal agencies.

Human studies must not be started before notification of approval by NTI. Costs of any work conducted before NTI notification of approval will not be reimbursed. Copies of annual renewal of IRB must be forwarded to NTI. IRB approval must be documented prior to dispensation of NTI funds. The proposal must include letters of support if the proposed project uses facilities not routinely available to or directly under the supervision of the sponsoring program.

8. **Publications.** All discoveries resulting from work supported in part by NTI should be made available to the public and scientific community through approved scientific channels such as national meetings, including the National Trauma Institute Annual Symposium, and peer reviewed publications. Publications will acknowledge the support of NTI and DOD. Two reprints of each publication must be forwarded to NTI immediately upon availability. If the PI would like to announce the grant award, NTI's involvement shall be acknowledged and any print or internet related notifications (i.e. marketing or promotional materials or press releases) shall be approved by NTI before distribution.
9. **Publicity.** NTI shall be permitted to use the Principal Investigator's name, image and likeness, as well as the name of the Affiliated Institution, in connection with all statements, printed materials or electronic media related to the grant or related to NTI's research program. At NTI's request, the Principal Investigator will provide NTI with appropriate photographs and biographical information to be used in connection with this grant.
10. **Reports.** Grantees will be required to submit quarterly reports and a final report within 30 days after the end of the granting period. A questionnaire will be forwarded to the grant recipient 12 months after the completion of the grant to describe any publications and subsequent funding received based on research performed using NTI's funds. Consideration for future funding will be dependent upon completion of these progress reports.



NATIONAL TRAUMA INSTITUTE

II. FULL PROPOSAL FORMS

NTI-ICU-08



**National Trauma Institute Full Proposal
NTI-ICU-08**

FACE PAGE

Principal Investigator, Degree:	
Position:	
Division:	
Address:	
Phone #:	
Fax #:	
Email:	
Institution Name:	
Institution Address:	
Title of Proposed Project:	
Amount of Funding Requested:	
Dates of Proposed Project Period:	
Site of Project:	
PI Signature and Date:	
Name and Address of Department Receiving Funds:	
Contract Office POC Name:	
Phone #; Fax#:	
Email:	
Contract Office POC Signature & Date:	

**National Trauma Institute Full Proposal
NTI-ICU-08**

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Page Numbers

_____	<i>Title Page</i>
_____	<i>Table of Contents</i>
_____	<i>Project Abstract</i>
_____	<i>Lay Person (Non-Confidential) Summary</i>
_____	<i>Research Plan</i>
_____	<i>Budget</i>
_____	<i>Budget Justification</i>
_____	<i>Biographical Sketches</i>
_____	<i>Facilities Description</i>
_____	<i>Literature Cited</i>
_____	<i>Human Subject Approvals (if available)</i>
_____	<i>Letters of Support</i>
_____	<i>Letter stating the confidential nature of the research (if applicable)</i>

**National Trauma Institute Full Proposal
 NTI-ICU-08**

BUDGET

PRINCIPAL INVESTIGATOR (last, first, middle):							
PERSONNEL		TYPE APPT. (MONTHS)	ANNUAL BASE SALARY	EFFORT ON PROJECT	DOLLAR AMOUNT REQUESTED		
NAME	ROLE ON PROJECT				SALARY REQUESTED	FRINGE BENEFITS	TOTALS
SUBTOTALS							
MATERIALS, SUPPLIES AND CONSUMABLES (ITEMIZE BY CATEGORY)							
EQUIPMENT							
RESEARCH-RELATED PATIENT COSTS							
OTHER DIRECT COSTS (ITEMIZE BY CATEGORY)							
TRAVEL COSTS							
TOTAL DIRECT COSTS							
INDIRECT COSTS (UP TO 10% OF DIRECT COSTS)							
TOTAL COSTS							

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel listed on the budget page.

NAME

POSITION TITLE

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include post-doctoral training).

INSTITUTION AND LOCATION

**DEGREE
(IF APPLICABLE)**

YEAR(S)

FIELD OF STUDY

RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list in chronological order, previous employment, experience and honors. Include present membership on any Federal Government public advisory committee. List in chronological order, the titles, all authors and complete references to all publications during the past 3 years and to representative earlier publication pertinent to this application. If the list of publications in the last 3 years exceeds 2 pages, select the most pertinent publications. **PAGE LIMITATIONS APPLY. DO NOT EXCEED 3 PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INVESTIGATOR.**

RESEARCH AND PROFESSIONAL EXPERIENCE (CONTINUED). *PAGE LIMITATIONS APPLY. DO NOT EXCEED 3 PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INVESTIGATOR.*

RESEARCH AND PROFESSIONAL EXPERIENCE (CONTINUED). *PAGE LIMITATIONS APPLY. DO NOT EXCEED 3 PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INVESTIGATOR.*