



NATIONAL TRAUMA INSTITUTE

REQUEST FOR PROPOSALS: NTI-NCH-TRA-10

The National Trauma Institute (NTI) is requesting pre-proposals for one year translational or clinical research on trauma.

SCHEDULE

Posted Date:	June 11, 2010
Pre-proposal Submission Deadline:	July 23, 2010
Call for Full Proposals:	September, 2010
Full Proposal Submission Deadline:	November 8th, 2010
Announcement of Awards:	January, 2011

Please direct all questions and correspondence to:

NTI-research@nationaltraumainstitute.org

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SUBMISSION, REVIEW AND AWARDED 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 could not be a more important health care research agenda. More than 35,000 soldiers have been injured and over 5,000 have died on the battlefield in the current wars. At home, 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 better methods of hemorrhage control with particular emphasis on non-compressible hemorrhage, identifying the most effective resuscitation strategies, new treatments for shock and a better understanding of the coagulopathy of trauma. Other priority items include the elimination of hospital acquired infections, particularly in the vulnerable ICU population, airway and ventilation management strategies for the injured, and a variety of topics related to battlefield and pre-hospital care and communication.

B. RESEARCH SCOPE OF SOLICITED PROPOSALS

The National Trauma Institute is currently accepting proposals for clinical or translational research in trauma. Single and multi-center proposals will be considered with an emphasis on prospective studies. The following research areas will be given priority:

1. HEMORRHAGE (NON-COMPRESSIBLE AND COMPRESSIBLE):

- Evaluating devices to identify patients with non-compressible hemorrhage (particularly those that can be used in the field)
- Identifying methods to control non-compressible hemorrhage on the battlefield, in the prehospital setting or in the emergency department/resuscitation bay
- Refining endpoints used to guide resuscitation in patients with hemorrhagic shock
- Defining priorities in the management of major hemorrhage from pelvic fractures
- Comparing protocols for the management of intra-cranial bleeding in the presence of coagulopathy
- Evaluating novel resuscitation fluids in the treatment of hemorrhagic shock

- Defining the effectiveness of hemostatic devices in controlling bleeding in the field, emergency department/resuscitation bay, or operating room
- Developing creative techniques for the control of bleeding in difficult areas of the body, such as the thoracic outlet, groin, retrohepatic area and pulmonary hilum

2. INTENSIVE CARE

- Defining the role for and the timing of tracheostomy in patients requiring prolonged mechanical ventilation
- Preventing thromboembolic occurrences and complications
- Decreasing infectious complications in the ICU
- Developing strategies and techniques that increase ventilator-free days and lower costs and complications
- Investigating the role of metabolic adjuvant therapy, including anti-oxidants, in the ICU
- Investigating the capabilities of computer-driven protocols and monitoring devices in ICU resuscitation

3. TRAUMA SYSTEMS AND PREHOSPITAL CARE

- Evaluating methods of airway control in the pre-hospital setting
- Exploring and defining the ideal trauma system design, including defining features of “inclusive” and “exclusive” trauma systems, critical number of trauma centers, and cost effective systems of delivering trauma care
- Developing safe and cost-effective transport protocols for critically injured patients

Animal studies will not be funded.

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

The funding available will depend upon the scope of the project and the number of centers involved. Generally, for a single center study, \$100,000 to \$300,000 will be allocated. Additional funds are available for multi-center clinical studies. Pilot and proof-of-concept projects with smaller budgetary needs will also be considered. 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 (LETTER OF INTENT)

All pre-proposals/LOI must be submitted on-line. Follow the links to the on-line application page from the funding opportunities page of the NTI website (http://www.nationaltraumainstitute.org/research/funding_opportunities.html). Elements of the pre-proposals/LOI will be:

- a. Title of Project
- b. Name and Affiliation of Lead Principal Investigator
- c. Names of Participating Institutions and Site Principal Investigators
- d. Hypothesis and Specific Aims
- e. Background and Significance
- f. Goals and Objectives of the Proposed Work
- g. Military Relevance
- h. Funds Requested
- i. Literature Cited

After review of the pre-proposal/LOI, selected proposers will be invited to submit a full proposal. Invitations for full proposal submissions will be made in September 2010.

2. FULL PROPOSAL

The full proposal is to be submitted on-line, using the instructions given. Log in using the "Proposal Submission Log-In" button on the left rail of the NTI website Research Page (http://www.nationaltraumainstitute.org/research/nti_research.html#). Invited applicants will be provided with complete instructions to gain access for Full Proposal submission.

Components of the full proposal will include:

1. Project Abstract

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).

2. Non-proprietary Lay Person Summary

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

3. Research Plan (10 pages maximum):

- a) Title of Project
- b) Hypothesis and Specific Aims
- c) Background and Significance
- d) Methodology
- e) Analysis of Results

4. Military relevance

This 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.

5. Budget

Complete the full budget **using the form provided** on the left rail of the NTI website funding opportunities page at:

http://www.nationaltraumainstitute.org/research/funding_opportunities.html.

Overhead or indirect costs should be limited to 10% of direct costs and are included in the funding level limit. 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. A budget justification template is included with the budget form.

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 form supplied on the NTI website funding opportunities page at http://www.nationaltraumainstitute.org/research/funding_opportunities.html, 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, and outline measures taken at your institution/department to adequately ensure patient availability for multiple studies using the same patient population.

9. Literature cited

10. Human subjects experimental approval (IRB) or submitted protocol

11. Budgets, Budget Justifications and Letters of Support from participating institutions

All participating institutions must provide a budget and justification ***using the form provided on the NTI website***

(http://www.nationaltraumainstitute.org/research/funding_opportunities.html) on the left rail. If participating sites are not receiving funds from the award, no budget form is required, but these institutions must still provide a letter of support or they must not be included in the study.

12. A letter stating the confidential nature of the research if the proposal contains proprietary information.

13. Additional Components and Disclosures, as required in the on-line application form.

G. REVIEW PROCESS

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

Full proposals must be received by Midnight (Central Time), November 8th, 2010.

Full proposals will be assessed on the basis of:

1. Relevance to Stated NTI Research Objectives
2. Scientific Merit
3. Clinical Relevance and Clinical Impact
4. Military Relevance
5. Innovation
6. Potential for Follow-On Studies
7. Feasibility of Completing Stated Objectives in One-Year Funding Period

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 must be commensurate with the type of proposal submitted (multicenter, single center or pilot/proof of concept).

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 (over \$5,000)
- salaries for office or administrative staff

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

5. **Institutional Support.** The proposed research must comply with the regulations of the PI's Institutional Review Board (IRB) **AND** the US Army Medical Research and Materiel Command (USAMRMC) Human Research Protection Office (HRPO) related to research on humans. A copy of the IRB approval document must be forwarded to NTI before contracting will be completed. USAMRMC HRPO must be obtained before disbursement of funds. NTI will assist investigators and liaise with USAMRMC HRPO to obtain the relevant approvals. 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.

6. **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.
7. **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 using language provided by NTI. 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. All published materials must be made available to the public within 12 months of publication.
8. **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.
9. **Reports.** Grantees will be required to submit quarterly reports and a final report within 30 days after the end of the granting period (templates will be provided). 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.