

**APPROPRIATIONS REQUEST FORM
OREGON HOUSE DELEGATION
FISCAL YEAR 2010**

DEADLINE FOR SUBMISSION: FEBRUARY 13, 2009

PLEASE NOTE: As required by the House Appropriations Committee, all requests will be made public on the requesting Member's website.

1. Project Title:

Treatment of Battlefield Spinal Cord and Burn Injuries

2. Organization Name and address:

Oregon Biomedical Engineering Institute, Inc.
9755 SW Barnes Road, Suite 505
Portland, OR 97225

3. Primary Contact name, phone number, mobile phone number, fax number and email:

Kenton W. Gregory, M.D.
503-297-3339 (office)
503-297-3449 (fax)
kentongregory@msn.com (email)

4. Project Location Address (if different from Organization): N/A

5. Please describe the requesting organization's main activities, and whether it is a public, private non-profit, or private for-profit entity:

Oregon Biomedical Engineering Institute, Inc. (OBEI) is a private for-profit research institute that performs and manages biomedical research and commercial transfer of this research. OBEI distributes and contracts funding and collaborates extensively with non-profit research entities including the Oregon Medical Laser Center (Providence Health & Services), Oregon Health & Science University and Oregon State University.

6. Briefly describe the activity or project for which funding is requested (please keep to 500 words or less.)

Treatment of Paralyzing Spinal Cord Injuries

Acute spinal cord injury from battlefield explosions and other trauma usually results in total paralysis. Recent Congressionally sponsored research related to battlefield extremity injury suggests that acute spinal cord injury, if treated as an acute neurosurgical emergency with a commonly performed surgery, can heal normally without paralysis.

Trauma to the spine usually is caused by hyperflexion of the spine causing a contusion or bruise to the spinal cord. Complete transection occurs rarely. The contusion and swelling of the cord within the bony spinal canal causes pressure that stops blood flow. This is the principal cause of spinal cord death and paralysis. In standard NIH models of spinal cord injury in animals, a laminectomy where the spinal cord is exposed within a three-hour window -- allowing the tissue to freely expand without compression and thus restore blood flow -- universally results in prevention of permanent paralysis. Tragically, current accepted treatment only manages spinal immobilization and delivers steroids that do nothing to restore the blood supply to the spinal cord.

Clinical trials are required to provide injured soldiers a decompressive laminectomy within 3 hours of injury. Medical officials at Walter Reed, and other Army medical centers as well as military and civilian surgical thought leaders, have all expressed enthusiasm for testing this concept.

Barriers to implementing this important new strategy in combat zones are primarily tactical, i.e. there are no MRI scanners available. Trials to demonstrate efficacy and safety must be undertaken in multi-center military and civilian settings. Animal studies to evaluate secondary adjunctive therapies such as local cooling or administration of anti-inflammatory drugs should be supported.

Skin Healing After Battlefield Burns

Severe burns are common causes of injury and disability in current military conflicts. Skin healing after burns produces inflexible collagen scars which result in disability particularly in burns of extremities where skin flexibility is required. Although the burned wound is covered, the soldier is left with severely limited mobility and the prospect of a lifetime of repeated surgeries to treat scar contracture.

Normal human skin is constructed of multiple matrix proteins. Elastin proteins, which are required for skin flexibility, are not produced by humans after the age of two and are not present in burn scars. Research by our Battlefield Surgical Research group, through prior congressional support, led to the discovery of the human elastin precursor protein that can be purified and polymerized into flexible elastic tissues. Using these elastin proteins, the potential exists for burned skin to heal itself into a flexible and functional skin replacement.

Creation of normal flexible skin using natural human elastin proteins may dramatically improve the quality of life, reduce disability and increase the rate of return to active duty for the soldier after battlefield burns.

7. Has this project received federal appropriations funding in past fiscal years?

This is a new project request. However, OBEI and associated institutions have a long history of work with the Armed Forces to treat battlefield injuries and federal appropriations funding has been a key element in bringing advances such as the chitosan hemorrhage control dressing to the battlefield.

7a. If yes, please provide fiscal year, Department, Account, and funding amount of any previous funding.

While this is a new project request, OBEI and predecessor organizations have received federal funding in past years for medical research as follows:

FY2009	Army	RDT&E	\$3 million
FY2008	Army	RDT&E	\$4 million
FY2006	Army	RDT&E	\$1 million
FY2005	Army	RDT&E	\$4 million
FY2004	Army	RDT&E	\$3 million
FY2003	Army	RDT&E	\$2.5 million
FY2002	Army	RDT&E	\$3.4 million
FY2001	Army	RDT&E	\$4 million
FY2000	Army	RDT&E	\$3 million

8. Federal agency and account from which funds are requested (Please be specific –e.g. Department of Housing and Urban Development, Economic Development Initiatives account):

Department of Defense, Army RDT&E, line 30 (PE0603002A) “Medical Advanced Technology”

9. What is the purpose of the project? Why is it a valuable use of taxpayer funds? How will the project support efforts to improve the economy and create jobs in Oregon?

Funding is requested to launch clinical trials to test the efficacy and safety of spinal laminectomy within a three-hour period after injury as a treatment for acute spinal injury and to explore adjunctive therapies including cooling, use of anti-inflammatory drugs and autologous cell therapies. Funding will also be dedicated to enhance production of human tropoelastin and for development of elastin deposition devices for clinical trials, animal and Phase 1 human clinical trials to treat severe burn injuries. These new paradigms for the treatment of spinal cord and burn injuries are desperately needed to improve outcomes for injured military personnel and civilians.

Burns and spinal cord injuries continue to plague our service men and women in combat in Iraq and Afghanistan. American citizens have no higher duty than to care for our wounded warriors and to do all we can to return them to normal lives. Success of these revolutionary approaches could reduce the long term cost of caring for wounded soldiers and similarly injured civilians.

As outlined in the response to question 5, it is anticipated that any funding received will be shared with other Oregon institutions with unique expertise to further this medical research. This supports numerous medical research positions throughout the state and helps maintain Oregon's prominence for medical research in the nation.

10. Have you requested funding for this project from other Members of Congress? If so, who?

Yes. Support for this project has been requested from Oregon Representatives Wu, Walden, Blumenauer, DeFazio and Schrader; Oregon Senators Wyden and Merkley; Washington Representatives Baird, Smith and Dicks; and Washington Senators Cantwell and Murray.

11. Funding Details:

a. Total project cost (all funding sources and all years):

It is estimated that total project cost to bring these two efforts to conclusion will cost in the range of \$25 million to \$40 million. While the spinal cord project is anticipated to be relatively short term, the burn project could take considerably longer. Much of this funding will be raised privately.

b. Amount being requested for this project in Fiscal Year 2010:

\$4.5 million

c. What other funding sources (local, regional, state) are contributing to this project or activity? (Please provide specific dollar amount or percentage.)

There is no local, regional or state funding available for this research. It is anticipated that considerable funding can be raised through private sources.

d. Do you expect to request federal funding in future years for this project?

Yes. We anticipate requesting additional funding for human clinical trials for burn injuries.

e. Breakdown/budget of the amount you are requesting for this project in FY 2010. (e.g. salary \$40,000; computer \$3,000):

Personnel (Salary and Fringe)	\$1,045,000
Research Studies	\$1,765,000
Assorted Supporting Equipment	\$285,000
Subtotal Direct Costs	\$3,095,000
Indirect Costs	\$1,405,000
Total	\$4,500,000

f. Please list public or private organizations that have supported/endorsed this project:

Oregon Medical Laser Center (Providence Health & Services),
Oregon State University Engineering School.
The Oregon Burn Center,
US Army Institute for Surgical Research,
Defense Advanced Research Projects Agency (DARPA),
Walter Reed Army Medical Center,
Special Forces Medical Command, Fort Bragg

g. Is this project scalable? (i.e. if partial funding is awarded, will the organization be able to use the funds in FY 2010?):

Yes.

Please return this form *no later* than February 13, 2009 (via email) to:

appropriations.blumenauer@mail.house.gov