



Psychological Health and Traumatic Brain Injury (PH/TBI) Research Program Fiscal Year 2007

**Presented to:
Defense Health Board
TBI External Advisory Subcommittee**

**Presented by:
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Deputy Director, CDMRP**

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Introduction

- ◆ **CDMRP overview**
- ◆ **PTSD/TBI* Research Program overview**
- ◆ **Investment strategy**
- ◆ **PTSD/TBI Research Program Award mechanisms**
- ◆ **Outcomes of Programmatic Review**

*Former name of the Program

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CDMRP History

- ◆ **In 1993, grassroots advocacy heightened political awareness of breast cancer**
- ◆ **Federal budgetary opportunities spurred Congress to appropriate \$210M to the DOD budget for the Breast Cancer Research Program**
- ◆ **Program assigned to the USAMRMC; subsequent consultation with the Institute of Medicine (IOM) for programmatic advice**
- ◆ **Additional research programs added and managed by the CDMRP**

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Partnerships

Advocates

- ◆ Demonstrate need
- ◆ Participate at all levels
- ◆ Passion and perspective



Congress

- ◆ Add funds to budget
- ◆ Targeted guidance
- ◆ Opportunity to leverage



IMPROVE
HEALTH
(CURE)

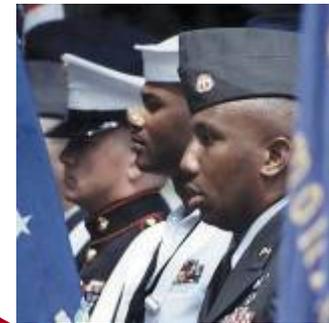
Researchers

- ◆ Innovation and gaps
- ◆ Risk/Benefit
- ◆ Product-oriented



DOD

- ◆ Program management
- ◆ Regulatory/budget requirements
- ◆ IOM model



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Program Features

- ◆ **Directed by Congress**
- ◆ **Targeted research**
- ◆ **Two-tier formal review of proposals – Institute of Medicine model**
- ◆ **Responsive management**
- ◆ **Consumer participation**
- ◆ **Two-tier review**



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Two-Tier Review Process

Peer Review

- ◆ Evaluation of scientific merit
- ◆ Criteria-based evaluation
- ◆ Proposals evaluated within related disciplines

Products:

- ◆ Proposal scoring
- ◆ Summary statements

Programmatic Review

- ◆ Evaluation of programmatic relevance
- ◆ Comparison-based evaluation
- ◆ Proposals evaluated across multiple disciplines

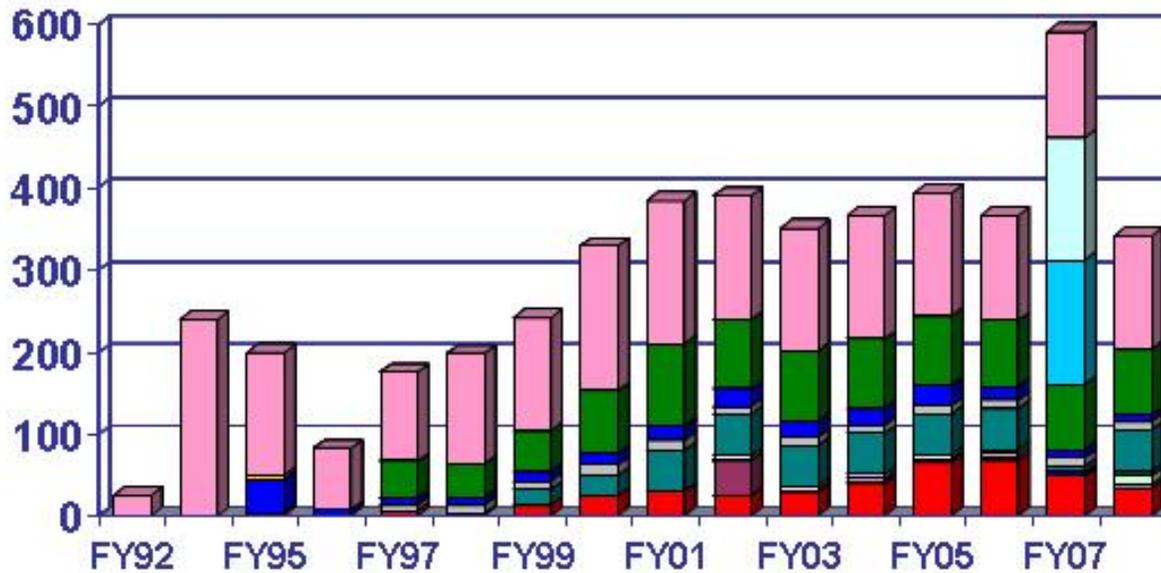
Product:

- ◆ List of funding recommendations for the USAMRMC Commander





CDMRP Funding History



- Institutionally Based
- Defense Women's Health
- Osteoporosis
- National Prion
- Cooperative DOD/VA Medical
- Myeloproliferative Disorders
- Tuberos Sclerosis
- Chronic Myelogenous Leukemia
- Gulf War Veterans' Illnesses
- Amyotrophic Lateral Sclerosis
- Autism
- Peer Reviewed Medical
- Ovarian Cancer
- Neurofibromatosis
- Prostate Cancer
- Psychological Health
- Traumatic Brain Injury
- Breast Cancer

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Congressional Language

FY07 PTSD, TBI, Burn Orthopedic and Trauma Supplemental Funding:

The “U.S. Troop Readiness, Veterans’ Care, Katrina Recovery, and Iraq Accountability Appropriations Act,” Public Law 110-28, appropriated \$331,700,00 to the Defense Health Program account for research, development, test, and evaluation to remain available until September 30, 2008. Consistent with Congressional intent, as established by related Conference Committee report, these funds are allocated for peer reviewed research as follows: \$150,000,000 for PTSD research; \$150,000,000 for TBI research; and \$31,700,000 for BOT research.





Background

◆ Stakeholders Meetings

- ❖ 11-12 June 2007
- ❖ Purpose: Discuss state of the science and research gaps
- ❖ Participants: Army, Navy, Air Force, Marine Corps, OSD(HA)*, Veterans Affairs, NIH, Private Industry, and Academia

◆ Vision Setting Meeting: 13 June 2007

- ❖ Conducted by the Joint Program Integration Panel (JPIP)
- ❖ Established program vision
- ❖ Prioritized research gaps
- ❖ Established investment strategy

*OSD(HA): Office of the Assistant Secretary of Defense for Health Affairs

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FY07 Joint Program Integration Panel

Chair

COL Karl Friedl

Alternate Chair

Mr. Michael Leggieri

DCoE* Director

COL (P) Loree Sutton

Alternate to DCoE Director

CDR Russell Shilling

ASBREM†

Secretariat Members

Army:

COL R. Keith Martin

Navy:

CAPT Doug Forcino

Air Force:

Dr. Garrett Polhamus

DDR&E:

Mr. Bart Kuhn

OSD(HA):

Dr. Sal Cirone

Interagency

VA:

Dr. Joseph Francis

NIH:

Dr. Walter Koroshetz

USUHS:

Dr. Steve Kaminsky

Medical Materiel Developer

Dr. Keith Prusaczyk

Other Representatives

COL Jonathan Jaffin (Army)

COL Tony Carter OSD(HA)

Col Robert Ireland OSD(HA)

Dr. James Wargo (JIEDDO‡)

Service Clinical Consultants

Air Force:

LtCol Debra Malone

Col Michael Jaffee

Maj William Isler

Army:

COL Mary Erickson

COL Elspeth Ritchie

LTC Kurt Grathwohl

Marine Corps:

CDR William Tanner

Mr. Bruce Barnes

Navy:

CAPT Robert Koffman

CAPT James Bloom

*Department of Defense Center of Excellence

†Armed Services Biomedical Research Evaluation Management

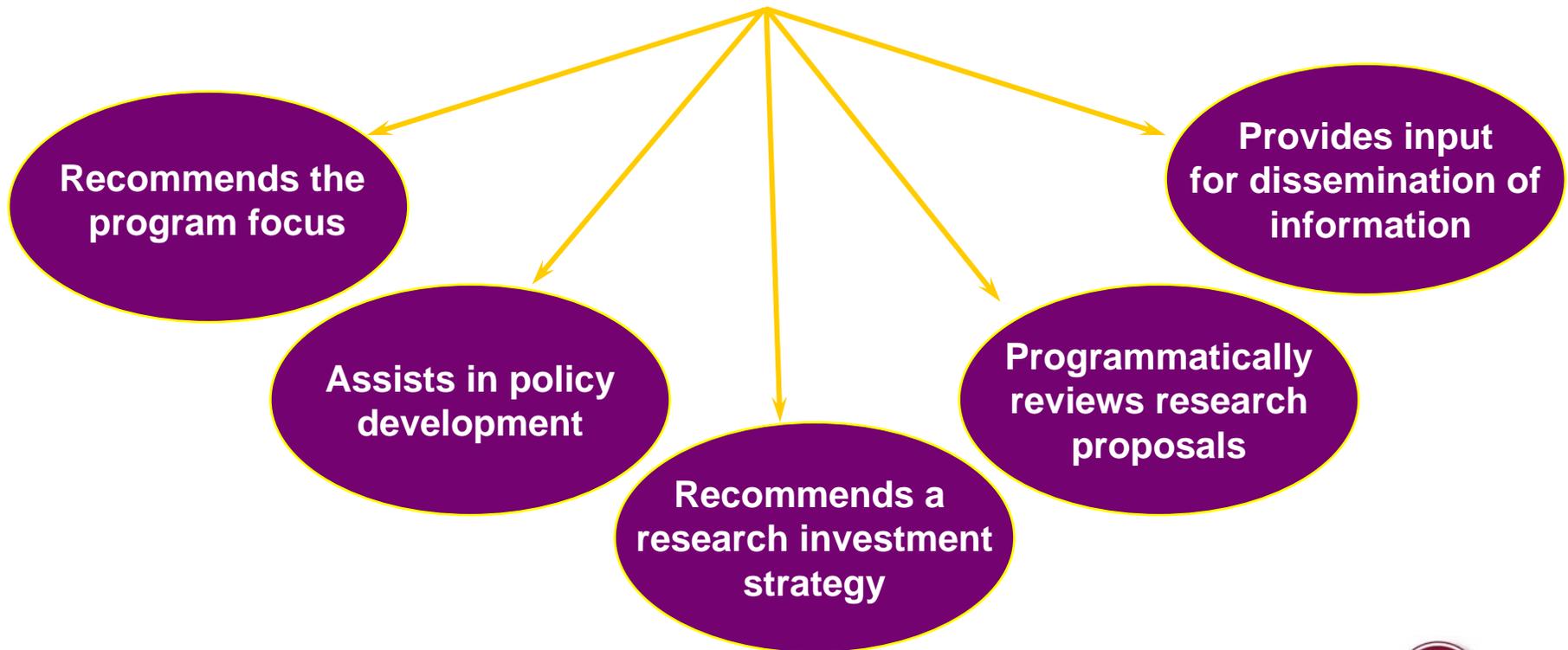
‡Joint Improvised Explosive Device Defeat Organization





Integration Panel (IP)

Recommending Body to the CDMRP



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Vision and Mission

VISION: To prevent, mitigate, and treat the effects of traumatic stress and traumatic brain injury on function, wellness, and overall quality of life for Service members as well as their caregivers and families

MISSION: Establish, fund, and integrate both individual and multi-agency research efforts that will lead to improved prevention, detection, diagnosis, and treatment of post-traumatic stress disorder and traumatic brain injury



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Prioritized TBI Research Gaps and Percent of Funds Allocated

- ◆ **Treatment and Clinical Management: 40%**
- ◆ **Neuroprotection and Repair Strategy: 22.5%**
- ◆ **Rehabilitation/Reintegration Strategies: 15%**
- ◆ **Field Epidemiology: 15%**
- ◆ **Physics of Blast as It Relates to Brain Injury: 7.5%**



Prioritized PTSD Research Gaps and Percent of Funds Allocated

- ◆ **Treatment and Intervention: 50%**
- ◆ **Prevention: 15%**
- ◆ **Measures in Screening, Detection, and Diagnosis: 10%**
- ◆ **Epidemiological Studies: 10%**
- ◆ **Families/Caregivers Projects: 10%**
- ◆ **Neurobiology/Genetics: 5%**

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FY07 Budget

◆ Congressional Appropriation	\$301.0M
◆ Less: Withholds (e.g., SBIR*/USAMRMC)	(\$14.9M)
◆ Appropriation Received	\$286.1M
◆ Less: 6% Management Costs	(\$17.2M)
◆ Amount Available for FY07 Research	\$268.9M

* Small Business Innovation Research

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Final Investment Strategy

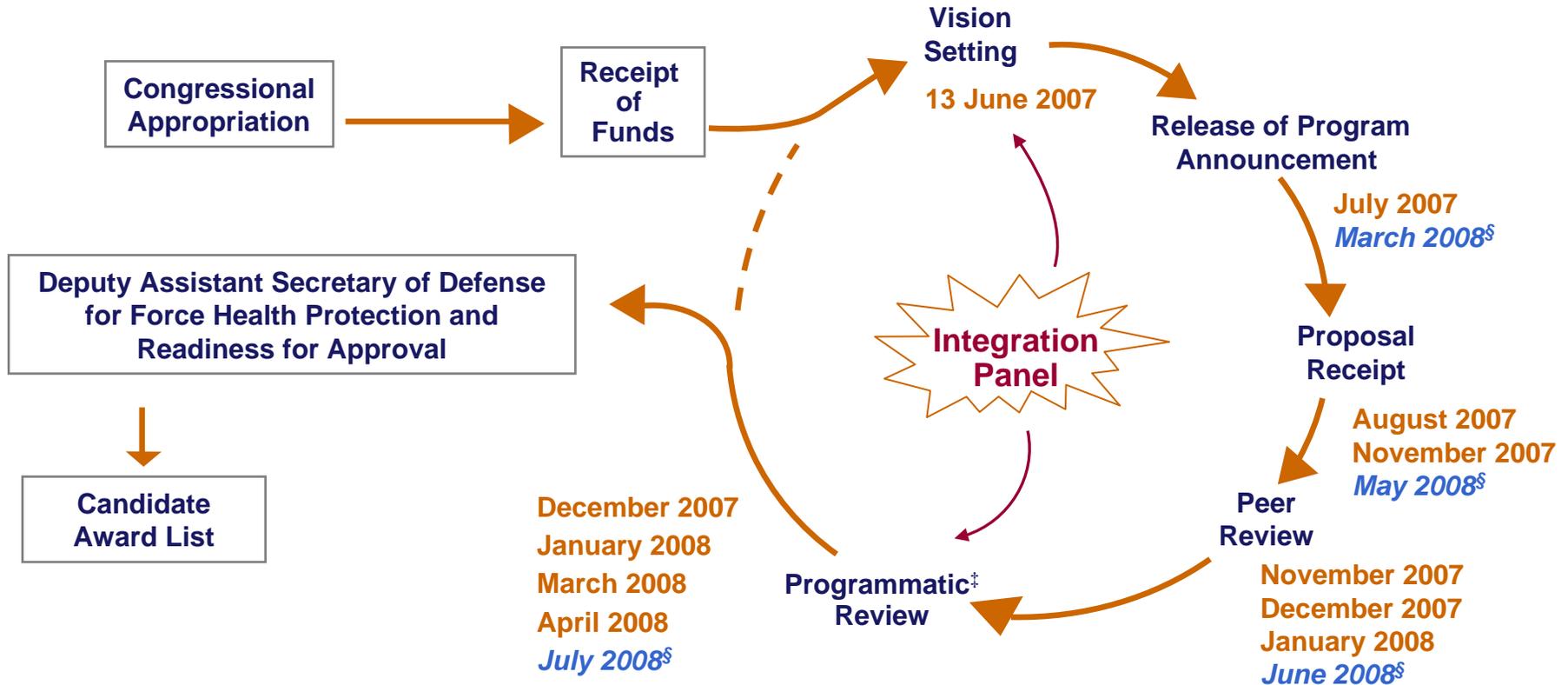
Funding Mechanisms	Allocation
◆ Fast-Track Intramural	\$ 74M
◆ Advanced Technology – Therapeutic Development	
◆ Investigator-Initiated Research	
◆ Extramural	\$150M
◆ Investigator-Initiated Research	\$10M
◆ New Investigator	\$6M
◆ Concept	\$8M
◆ PTSD*/TBI Clinical Consortium (Coordinating Center and Study Sites)	\$60M
◆ Advanced Technology – Therapeutic Development	\$16M
◆ Multidisciplinary Research Consortium	\$50M
◆ Center of Excellence	\$45M
Total	\$269M

* Post-Traumatic Stress Disorder





Program Cycle



[§]Complementary and Alternative Medicine Research Program





FY07 PTSD/TBI Award Mechanisms

Mechanism: Maximum Direct Costs	Key Initiative
Intramural Investigator-Initiated Research (IIRA): \$600K/4years	To accelerate ongoing basic and clinically oriented DOD and VA research that supports (1) substantial improvements over today's approach to the treatment and clinical management of PTSD and/or TBI, (2) the development of novel preventive measures, and (3) the implementation of processes and procedures to enhance the quality of life of persons with PTSD and/or TBI
Intramural Advanced Technology – Therapeutic Development (AT-TDA): \$4M/4 years	To accelerate the introduction of improved therapies, treatments, devices, or technologies for PTSD and/or TBI into the clinical setting
Concept Award: \$150K/18 months	To spark new ideas, innovative technologies, and ground-breaking concepts that will drive the field of PTSD and/or TBI research forward
New Investigator: \$300K/3 years	To increase the number of established PTSD and/or TBI researchers

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FY07 PTSD/TBI Award Mechanisms (Continued)

Mechanism: Maximum Direct Costs	Key Initiative
Investigator-Initiated Research: \$600K/4 years	To support basic and clinically oriented research that will (1) result in substantial improvements over today's approach to the treatment and clinical management of PTSD and/or TBI, (2) facilitate the development of novel preventive measures, and (3) enhance the quality of life of persons with PTSD issues and/or TBI
Advanced Technology – Therapeutic Development: \$4M/4years	To assess therapeutics and devices for the treatment, prevention, detection, and diagnosis for PTSD and/or TBI
Multidisciplinary Research Consortium: \$25M/5years	To optimize research and accelerate the solution of a single critical major overarching problem in PTSD and/or TBI research relevant to the prevention, detection, diagnosis, and/or treatment of PH issues and/or TBI
PTSD/TBI Clinical Consortium: \$60M/5 years (total costs)	To escalate development and marketing of novel, military-relevant PTSD and TBI treatments and interventions

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PH/TBI Research Program Investment by Research Gaps to Date

PTSD Research Gaps	Funded/Received	Budget*	% Invested	% Recommended by JPIP
Treatment and Intervention	41/225	\$99.5M	74.0	50
Prevention	7/37	\$4.2M	3.1	15
Screening, Detection, and Diagnosis	4/93	\$3.4M	2.5	10
Epidemiological Studies	8/54	\$4.2M	3.1	10
Families/Caregivers	5/29	\$2.9M	2.1	10
Neurobiology/Genetics	19/180	\$10.1M	7.5	5
TBI Research Gaps	Funded/Received	Budget	% Invested	% Recommended by JPIP
Treatment and Clinical Management	26/305	\$92.8M	69.0	40
Neuroprotection and Repair Strategies	20/432	\$20.5M	15.2	22.5
Rehabilitation/Reintegration Strategies	8/145	\$6.2M	4.6	15
Field Epidemiology	8/66	\$3.5M	2.6	15
Physics of Blast	12/73	\$7.5M	5.6	7.5

*The \$60M budget for the Clinical Consortium Center and Sites was distributed between both PH and TBI gaps

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PTSD Multidisciplinary Research Consortium - The STRONG STAR Multidisciplinary PTSD Research Consortium

The overarching goal of the Consortium is to develop and evaluate the most effective early-interventions possible for the detection prevention, and treatment of combat related PTSD in active-duty and recently discharged OIF/OEF veterans

Investigators

Alan Peterson
Brett Litz
Patricia Resick
David Riggs
Edna Foa
Robert Gatchel
Michael Escamilla
Peter Fox
John Roache
Randy Strong

Institutions

Texas, University of, Health Science Center at San Anton
Boston VA Research Institute, Inc. (BVARI)
Boston VA Research Institute, Inc. (BVARI)
Henry M. Jackson Foundation
Pennsylvania, University of
Texas, University of, at Arlington
Texas, University of, Health Science Center at San Antonio
Texas, University of, Health Science Center at San Antonio
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Texas, University of, Health Science Center at San Antonio

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TBI Multidisciplinary Research Consortium - Mission Connect Mild TBI Translational Research Consortium

The long-term goal of this Consortium is to improve the diagnosis and treatment of mTBI through collaborative basic and clinical research by experienced TBI investigators operating within the existing Mission Connect Consortium which was established in 1997

Investigators

Alex Valadka

Claudia Robertson
Harvey Levin
Michael Friedlander
Thomas Kent
Stephen LaConte
Matthew Rasband
Stelios Smirnakis
Andreas Toliás
Kimberly Toliás
Eli Mizrahi
James Tour
Ping Wu
Jose Perez-Polo
Pramod Dash
Andrew Papanicolaou
Ponnada Narayana
Paul Swank
Raymond Grill
Brent Masel

Institutions

Texas, University of, Health Science Center at Houston

Baylor College of Medicine
Rice University
Texas Medical Branch, University of, Galveston
Texas Medical Branch, University of, Galveston
Texas, University of, Health Science Center at Houston
Transitional Learning Center at Galveston

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TBI Concept Awards

- ◆ **Peter Bergold, State University Of New York, Downstate Medical Center**
 - ❖ **“Multidrug Treatment of Traumatic Brain Injury”**
 - Study will investigate whether combinations of atorvastatin, minocycline, erythropoetin, N-acetyl cysteine, cyclosporine A and progesterone can successfully treat TBI in a rat model

- ◆ **Jun Chen, University of Pittsburgh**
 - ❖ **“Scaffold/Neural Stem Cells-Based Tissue Engineering in a Traumatic Brain Injury Model”**
 - The goal of the study is to evaluate the efficacy of a biodegradable porous conductive scaffold on the long-term survival and integration of transplanted stem cells following TBI

- ◆ **John Judge, Catholic University**
 - ❖ **“Fabrication and Testing of a Blast Concussion Burst Sensor”**
 - The goal of this project is the development and laboratory testing of small, wearable, passive (non-powered) sensors to quantify levels of blast exposure to which soldiers are subjected

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TBI Concept Awards (Cont)

◆ Amy Wagner, University of Pittsburgh

❖ “Data Modeling Approaches for Biomarkers in Clinical Traumatic Brain Injury”

- This study will investigate the use of potential biomarkers in cerebral spinal fluid and serum to characterize secondary TBI

◆ Kenneth Watkin, University of Illinois Urbana Champaign

❖ “Helmet Integrated Nanosensors, Signal Processing and Wireless Real Time Data Communication for Monitoring Blast Exposure to Battlefield Personnel”

- The goal of this project is to develop and test a special battlefield helmet integrated with smart nanotechnology sensors and wireless communication to record before and after blast exposure of soldiers on the battlefield

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TBI Intramural IIRA

- ◆ Mikulas Chavko, Naval Health Research Center
 - ❖ “Sensors to Assess Pressure-Mediated Effects on Blast-Induced Traumatic Brain Injury”
 - This study will identify the potential pathways in which blast energy is transferred to brain tissue by the use of fiber optic pressure sensors and by detection of blast wave propagation through the body in a rat model of blast injury
- ◆ Anthony Chen, Northern California Institute For Research And Education
 - ❖ “Translation of Cognitive Neuroscience to Rehabilitation for Patients with TBI”
 - The overall goal of this proposal is to develop and test a computer-assisted cognitive neuroscience-based training program that improves executive control functioning for patients with TBI
- ◆ Jay Erickson, Madigan Army Medical Center
 - ❖ “A Randomized Controlled Trial of Medical Therapies for Chronic Post-Traumatic Headaches”
 - This study will determine the efficacy of propranolol, amitriptyline, and valproate as treatments for chronic Post-Traumatic Headaches
- ◆ Joseph Long, Walter Reed Army Institute Of Research
 - ❖ “Kevlar Vest Protection against Blast Overpressure Brain Injury: Systemic Contributions to Injury Etiology”
 - This project will use rats exposed to airblast generated by a compression driven shock tube to measure, compare, and correlate BOP-induced pressure changes external and internal to the experimental subject, and assess the impact of Kevlar vests on these latter changes

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TBI Intramural AT-TDA

◆ **Frank Tortella, Walter Reed Army Institute Of Research (AT-TDA)**

❖ **“Treatment of Traumatic Brain Injury Using NNZ-2566: Clinical Trials”**

- The goals of this phase II trial are to evaluate the efficacy of NNZ-2566 compared to placebo in reduction of: 1) cognitive impairment; 2) psychological sequelae; 3) impairment of global outcomes; 4) severity of post-concussive symptoms; and 5) impairment of activities of daily living





PTSD Concept Awards

- ◆ **Laurel Hourani, Research Triangle Institute**
 - ❖ **“Deployment, PTSD Symptoms, and Comorbid Mental Health Conditions in the Active Force and Reserve Components”**
 - The goal of this research is to develop models of PTSD risk from a wide array of deployment, stress, trauma, and mental health factors
- ◆ **Sandra Kaplan, North Shore University Hospital**
 - ❖ **“Development and Pilot of an Intervention for Military Personnel and Their Families”**
 - This project will assess the mental health needs of young adult Reservists and National Guard personnel and their families of origin throughout deployment cycles, and assess the relationship between perceived family criticism and PTSD
- ◆ **He Li, Uniformed Services University of The Health Sciences**
 - ❖ **“Corticosterone Administration to Promote Fear Memory Forgetting in an Animal Model of PTSD”**
 - This study will investigate the effectiveness of administration of corticosterone prior to or shortly after a period of intense, repeated stress will promote the traumatic memory forgetting process and prevent fear memory retrieval
- ◆ **Shira Maguen, Northern California Institute For Research And Education**
 - ❖ **“PTSD, Comorbid Disorders, and Service Utilization in Women Veterans”**
 - This study will use a pre-existing database of veterans returning from Iraq and Afghanistan to determine rates of PTSD and military sexual trauma in men and women returning from recent deployments

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PTSD Intramural IIRA

- ◆ **Ronald Acierno, VA Medical Center, Charleston**
 - ❖ **“Innovative Service Delivery for Secondary Prevention of PTSD in At-Risk OIF-OEF Service Men and Women”**
 - The goal of this study is to extend a study that measures behavioral activation treatment exposure in person compared to home-based telepsychology versus supportive counseling in person
- ◆ **Lori Davis, Tuscaloosa Research And Education Advancement**
 - ❖ **“The Impact of Supported Employment Versus Standard Vocational Rehabilitation in Veterans With PTSD”**
 - This study will evaluate the impact of Individual Placement and Support model of Supported Employment for unemployed veterans with PTSD compared to standard vocational rehabilitation program on occupational functioning and symptoms of PTSD
- ◆ **Gregory Gahm, Madigan Army Medical Center**
 - ❖ **“Comparing Virtual Reality Exposure Therapy to Prolonged Exposure in the Treatment of Soldiers with PTSD”**
 - This project will compare Virtual Reality Exposure Therapy (VRET) and Prolonged Exposure Therapy in the treatment of Soldiers with combat-related PTSD. These groups will be compared to demonstrate whether VRET increases arousal and if increased arousal contributes to better treatment outcomes
- ◆ **Murray Raskind, VA Puget Sound Health Care System**
 - ❖ **“A Placebo-Controlled Augmentation Trial of Prazosin for Combat Trauma PTSD”**
 - This clinical trial will evaluate the efficacy and tolerability of the alpha-1 adrenergic antagonist, prazosin, in OIF and OEF combat exposed returnees with PTSD and persistent trauma-related nightmares and disrupted sleep

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PTSD Intramural AT-TDA

◆ Roger Pitman, Massachusetts General Hospital

❖ “Developing Memory Reconsolidation Blockers as Novel PTSD Treatments”

- The goal of this project is to accelerate the translation of therapeutics and devices for prevention, detection, diagnosis, and treatment into clinical usage. This study will explore the concept of memory blockade reconsolidation as a new treatment for PTSD.

◆ Leslie Morland, VA Health Care System, Pacific Islands

❖ “Telemental Health and Cognitive Processing Therapy for Rural Combat Veterans with PTSD”

- This prospective randomized clinical trial will compare the delivery of cognitive processing therapy via video teleconferencing to that of in-person delivery. The investigations will use subjects with PTSD recruited from nine sites and randomized to either VTC CPT or CPT alone delivered twice a week over 6 weeks.

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What's New

UPDATE! - PTSD/TBI date changes to several funding opportunities. All dates can be found in Synopsis of Current Program Announcements.

Biodesign Institute Leads Innovative Project to Prevent Breast Cancer [\(external link\)](#)

Improved Breast Cancer Risk Prevention in Women With Atypia [\(external link\)](#)

FY06 BCRP Proposals Recommended for Funding

- Concept Awards
- Innovator Awards
- Multidisciplinary Postdoctoral Awards
- Synergistic Ideas Awards

FY07 Funding Opportunities:

- Intramural PTSD/TBI **NEW**
- PTSD/TBI **NEW**
- Autism Spectrum Disorder

[More News...](#)

Research Highlights

The Fight Against CML Moves to the Garden

New Clues to TSC1/2 and TORC Mediated Signaling

Delivering a One-Two Punch to Prostate Cancer

The Power of Applied Knowledge in Prostate Cancer Biomarker Development

[Previous Highlights...](#)

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