

## **Defense Health Program**

# Peer Reviewed Orthopaedic Research Program

Provide all Warriors affected by orthopaedic injuries sustained in the defense of our Constitution the opportunity for optimal recovery and restoration of function.













U.S. Army Medical Research and Materiel Command

## CDMRP VISION

Transform healthcare for Service members and the American public through innovative and impactful research

### MISSION

Responsibly manage collaborative research that discovers, develops, and delivers health care solutions for Service members, Veterans, and the American public

#### "Direct participation in the PRORP as a peer reviewer was a true honor as our primary focus was on the recovery and restoration of our injured Service members. The organization of the review - as well as featuring expert, civilian, and military panel members - was phenomenal, and the time spent critiquing and reviewing the proposals some of the most rewarding time spent during my career. The innovations that will result from successful completion of the high-impact funded proposals will benefit musculoskeletal injury care for generations."

—Franklin Shuler, PRORP Peer Reviewer

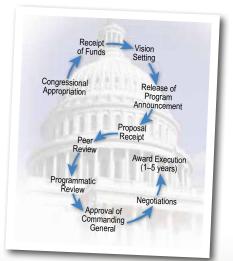
## Congressionally Directed Medical Research Programs

#### **History of the CDMRP**

The Congressionally Directed Medical Research Programs (CDMRP) was organized in fiscal year 1992 (FY92) from a powerful grassroots effort to secure a congressional appropriation of funds for breast cancer research. This initiated a unique partnership among the public, Congress, and the military. The CDMRP has grown to encompass multiple targeted research programs and has received more than \$9.7 billion in appropriations since its inception through FY15. Funds for the CDMRP are added by Congress to the Department of Defense (DoD) budget annually, with support for individual research programs allocated via specific guidance from Congress. The CDMRP executes programs such as the Peer Reviewed Orthopaedic Research Program (PRORP) on behalf of the DoD Defense Health Agency, Research, Development, and Acquisition Directorate, which provides health support across the full range of military operations.

#### **Application Review Process**

The CDMRP uses a two-tier review process for application evaluation, with both tiers employing dynamic interaction among scientists and disease survivors. The first tier of evaluation is a scientific peer review of applications measured against established criteria determining scientific merit. The second tier is a programmatic review conducted by a Programmatic Panel composed of leading scientists, clinicians, and consumer advocates, that compares applications to each other and makes recommendations for funding based on scientific merit, adherence to the intent of the award mechanism, portfolio composition, and relevance to overall program goals.





## **Consumer Story: Edwin Salau**

Edwin "Ed" Salau served the U.S. Marine Corps until 2000, when he joined the Army National Guard in the infantry battalion. On November 15, 2004, Salau was caught in an ambush north of Baghdad and sustained severe injuries that led to the loss of his left leg. Prior to learning how to walk again with assistance from staff at the Walter Reed Army Medical Center, Salau learned to ski with a fellow injured comrade. The experience reinvigorated his spirit, and he recalls, "When we



got off the chairlift at the top of the run, we checked our bindings and our gloves. Just before we tipped our skis over the edge, we were both struck by the same feeling - the one you have before you ask a lady for a date, or just before a job interview - we each felt that rush again." These days, Salau aims to impact the research that will guide civilians and Service members to the most effective treatments and rehabilitation. Reminded daily of the need for advocacy, Salau works hard to assist this community by paying attention to the real-world problems of the injured, connecting the dots to close relevant research gaps, all in an effort to find solutions for optimal recovery. Salau reflects on his consumer advocacy experience in CDMRP's peer review process stating, "There is appreciation for having a consumer reviewer at the table. What might be great science might not be a worthwhile pursuit from my perspective, and vice versa. The scientists and clinicians on the panel hear my point of view and they believe it. I am able to advocate for individuals with orthopaedic injuries at the user level." He recognizes the commitment and passion of each person who participates in the peer review process regardless of background or education. In serving the PRORP, Salau has been fortunate to interact with consumer advocates for other disease-focused programs, such as breast and prostate cancer. He remarks, "Those folks have lived through very grim prognoses and have beaten serious odds. With research for orthopaedic injuries, we are more likely to pursue improved quality of life rather than extension of life. No matter the cause, there is respect among all of the consumer reviewers. We are all in, and the same passion goes into it."

#### - Edwin Salau, PRORP Consumer Peer Reviewer

"It is my duty to share the practical knowledge of what I have learned and what others have taught me along the way. I know that I would not be where I am today, physically or mentally, without others sharing their knowledge with me. I am always learning and will continue to share the knowledge I gain through my participation as a consumer reviewer with PRORP."



—Daniel Metzdorf, PRORP Consumer Peer Reviewer

### CONSUMER ADVOCACY

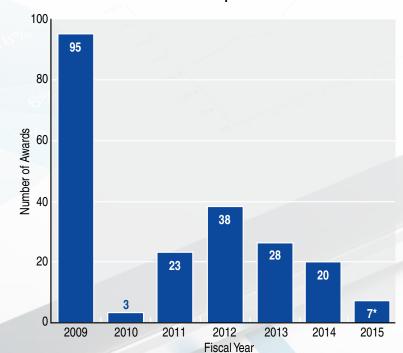
A unique aspect of the CDMRP is the active participation of consumers through the program's annual cycle. Consumers work collaboratively with leading scientists and clinicians in setting the PRORP's program priorities, reviewing applications, and making funding recommendations. From the unique perspective gained through personal experience—a Service member who suffered a traumatic orthopaedic injury obtained on the battlefield—a consumer brings a sense of urgency and focus to all levels of decision making. Consumers evaluate applications based on the potential impact and benefit to the patient population, encouraging funding recommendations that reflect the concerns and needs of the orthopaedic injury population, their families and caregivers, and the clinicians who treat them.

## Peer Reviewed Orthopaedic Research Program

#### **History of the PRORP**

Since its inception in FY09, the PRORP has dedicated its congressional appropriations, totaling \$278.5M, to supporting military-relevant orthopaedic research with the expectation that any research findings would also provide benefit to the general population. FY09–FY14 appropriations for the PRORP support a total of 207 awards in different research areas (see figure below). Orthopaedic injuries represent more than half of all injuries seen in combat and are the largest source of long-term disability in returning Service members. The impact of these injuries points to an urgent need for orthopaedic research that will provide superior medical care and treatment options for injured Service members.

Orthopaedic injuries sustained during combat-related activities tend to be both heterogeneous and complex in nature. Blast and other combat-related injuries frequently involve multiple limb traumas to an extent not seen in the civilian setting and are sustained in an environment where access to optimal acute care is limited. Frequent outcomes and complications include amputation, infection, compartment syndrome, heterotopic ossification, and functional muscle loss, among others. The PRORP crafts investment strategies to address these challenges, with the goal of helping injured Service members achieve optimal recovery.



#### PRORP Awards per Fiscal Year

The number of PRORP awards funded per fiscal year is shown above. The PRORP appropriation was \$112M in FY09, \$22.5M in FY10, \$24M in FY11, and \$30M every year from FY12 to FY15.

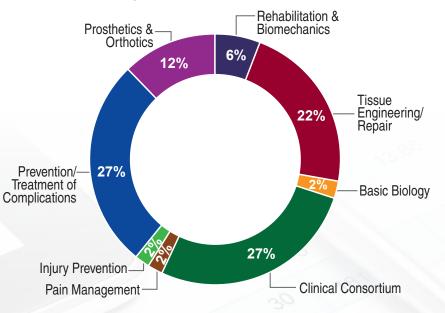
\* Depending on the quality of applications received, the FY15 PRORP appropriation will fund approximately seven awards.

## VISION

Provide all Warriors affected by orthopaedic injuries sustained in the defense of our Constitution the opportunity for optimal recovery and restoration of function.

### MISSION

Address the most significant gaps in care for the leading burden of injury and loss of fitness for military duty by funding innovative, highimpact, clinically relevant research to advance optimal treatment and rehabilitation from musculoskeletal injuries sustained during combat or combat-related activities



#### PRORP Awards by Dollar Amount per Research Area, FY09–FY14

"Participating as a scientific reviewer for the PRORP has been a career highlight. I cannot think of a more important and rewarding experience for an active duty orthopaedic surgeon than to help decide how to invest current and future research funds to help our Wounded Warriors."

> —Josef Eichinger, PRORP Peer Reviewer

"All members of the PRORP Programmatic Panel are honored to be able to assist wounded Service members through research dedicated to their care."

—Romney Andersen, PRORP Programmatic Panel Chair, FY15 and FY16





# **PRORP's Continuum of Care**

#### Leon Nesti and David Kopperdahl

have been developing a "virtual stress test" model that will allow surgeons to quantitatively measure the strength and stability of healing bones and to optimize fracture monitoring and care following severe tibial injuries.



**Francis Lee** has successfully fabricated a "ready to use" and biocompatible tissue scaffold to facilitate bone and cartilage reconstruction in an in-vivo model of high-energy blast-induced joint and segmental bone injuries.

#### Warren Haggard and Jared Cooper

have demonstrated that mechanically stimulating the extracellular matrix in a prototype scaffold activates tissue-specific genes in stem cells; they are using this finding to develop a co-cultured biomaterial scaffold to improve and expedite healing of the tendon-to-bone interface for soft tissue repair.

### **Acute Care**

## Definitive/ Reconstructive Care

#### Joseph Boggs has

generated promising preliminary evidence to support the efficacy of NerveSpace therapy for the relief of post-amputation residual limb and phantom limb pain.

#### Mark Smeltzer is

investigating sarA-based therapeutics in combination with bone-targeting and antibiotic therapy in an effort to enhance the treatment of infections post-injury.

**Jeffrey Gimble** is utilizing state-of-theart mass spectrometry to identify novel serum biomarkers that contribute to osteogenesis in patients that develop heterotypic ossification following traumatic injury.

**Cari Whyne** and **Jeffrey Fialkov** have fabricated an implantable "bone tape" with the flexibility and strength required to stabilize traumatic craniomaxillofacial fractures and assist in three-dimensional (3D) surgical reconstruction and healing of skeletal injuries. **Rocky Tuan** determined that mesenchymal progenitor cells can be used to grow 3D bioactive nerve conduits and will optimize this technology in small animal models of nerve repair in upcoming studies.

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## Rehabilitation

## Nance Ericson and Ethan Farguhar have developed a

mobile gait analysis system to improve prosthetic fit, alignment, training, and eventual re-introduction into pre-injury activities.

#### **Sherri Weiser-Horwitz**

is investigating the efficacy of a psychologically based physical therapy intervention aimed to mitigate psychological risk factors associated with musculoskeletal injuries.

**James Irrgang** is conducting a multi-center clinical trial to determine how the timing of surgery and rehabilitation impact the clinical outcomes and return-to-duty or activity in Service members and civilians with musculoskeletal injuries. **Aaron Dollar** has developed a body-powered anthropomorphic prosthetic hand with eleven degrees of freedom, which allows for soft touch and passive adaptation to the shape of an object within its grasp.

#### • Kristen LeRoy and Todd Farrell are developing a prosthetic

socket liner with moisture wicking control and an active cooling system to improve residual limb skin care and health.

## Prosthetics and Orthotics

Joan Sanders has developed a bioimpedance analysis system to measure residual limb volume changes, and a socket volume maintenance system using an elastomeric liner with liquid-filled bladders that allow socket pressures to be released.

# **Making an Impact**



Dr. Harold Sears (pictured 6th from the left) and his team.

#### A New Powered Wrist and Modular Prosthesis System

#### Harold Sears, Motion Control, Inc., Salt Lake City, UT

Existing prosthetic terminal devices, such as hands and wrists, have limited capability for manual work activities due to complex construction, restricted range of motion and force, and coverings which can tear and stain. A prosthesis that incorporates reliability in heavy duty work environments with sophisticated control and aesthetic appeal has been difficult to achieve. However, such characteristics will help upper-limb amputees, especially Soldiers, to return to their former work lifestyles.

With funding from an FY09 PRORP Technology Development Award, Motion Control, Inc. (Principal Investigator, Dr. Harold Sears) is working to advance the design and capabilities of the Electric Terminal Device (ETD), an existing "hook-type" prosthetic device provided by Motion Control since 2005. For many patients in U.S. military hospitals, the ETD is the first choice hand replacement for function and versatility. The ETD is the only upper-extremity prosthetic device that achieves true resistance against water, dirt, dust, and grease, and therefore allows amputees the flexibility to wear it in diverse work and recreation environments. Motion Control upgraded the existing ETD by coupling a shorter and lighter forearm section with a series of modular wrist joints that vary in complexity and offer both electronic and manual control of wrist position. The

modular wrists will be interchangeable and compatible with existing arm prosthetics, featuring a new quick disconnect system as part of the device design. The innovations envisioned and achieved by Dr. Sears and his team preserve the rugged dependability of the existing ETD, while improving range of motion, gripping security, and aesthetic appeal for its wearers. Prototypes of the second-generation ETD have entered field trials, and are used daily by a number of individuals with upper-limb loss. Recent follow-on funding awarded to Motion Control from DoD's Joint Warfighter Medical Research Program will support the development of a similar ultra-rugged elbow system, further leveraging the devices generated in this highly successful project.





#### In Vivo Modeling of Vibration Injury to the Spine

#### Beth Winkelstein, University of Pennsylvania, Philadelphia, PA

Body vibration is a source of painful spinal injury commonly associated with ground and aircraft conditions faced by Soldiers in present-day theater. In order to prevent and treat vibration-induced injuries, it is essential to develop an understanding of the biomechanical effects of vibration on the body, how vibration produces tissue injury and pain, and the conditions that pose the greatest risk for spinal injury. With funding from an FY09 Technology Development Award, Dr. Beth Winkelstein leveraged data corresponding to human vibration injuries sustained in theater with simulated biomechanical models to mimic whole-body and jolt vibration injuries in animal paradigms. Her results show that just a single exposure to low-level vibration is sufficient to produce a long-

lasting pain phenotype. Variations in the vibration application or oscillation frequency also yield sustained and transient pain profiles that are associated with different physiological effects and biomarker patterns in the central and peripheral nervous systems. Dr. Winkelstein's studies show that whole-body vibration applied at a frequency that resonates the spine can enhance spinal deformation, pain severity, and activation of neuroimmune responses in the body when compared to a non-resonant frequency. Her latest research suggests that neurotrophins, including brain-derived neurotrophic factor and nerve growth factor, may play a role in the development of spinal pain following exposure to body vibration. The animal models established in Dr. Winkelstein's laboratory provide a platform from which injury risk can be evaluated and data can be generated to inform vibration guidelines that protect Warfighters from combat-related injuries.

#### Insole Sensor to Determine Optimal Limb Loading in Fracture Rehabilitation

*Erik Kubiak (pictured left), Robert Hitchcock (pictured right), University of Utah, Salt Lake City, UT; Justin Orr (not pic-tured), William Beaumont Army Medical Center, El Paso, TX* 

Combat-related tibia fractures are among the most common lowerextremity injuries sustained by military personnel. Open tibia fractures are associated with high rates of complications that include infection and delayed fracture union, which can lead to prolonged healing.



Current rehabilitation protocols for tibia fractures involve a progressive increase in the amount of weight placed on the injured leg, allowing the fracture to heal properly. However, data to guide this procedure is very limited and has been restricted by a lack of durable and accurate technology for continuous monitoring of limb loading. With funding from an FY09 Translational Research Partnership Award, Drs. Erik Kubiak, Robert Hitchcock, and Justin Orr have collaborated to develop an inexpensive, convenient, and continuously recording load sensor to be utilized during fracture rehabilitation in ambulatory patients. The load-sensing technology ATLAS (Ambulatory Tibial Load Analysis System) have been successfully integrated into the insole of the CAM Walker brace commonly worn by patients undergoing tibia fracture therapy. When worn by patients over a ten-week period, the ATLAS system collected data demonstrating that patients gradually recruit the use of their impaired limb and apply increasingly greater loads on the injured limb over time. In addition to sensing weight loaded on the heel and forefoot, the ATLAS system is capable of detecting gait characteristics through measurements of pace and number of steps. This device has advanced the field of orthopaedic rehabilitation by providing physicians objective feedback that is used in the development of optimized treatment protocols.

#### **Enhancing Post-Traumatic Pain Relief with Alternative Perineural Drugs**

Brian Williams, Michael Gold, and Gerald Gebhart, University of Pittsburgh, Pittsburgh, PA; Chester Buckenmaier, Walter Reed National Military Medical Center, Bethesda, MD

Acute pain following traumatic injury is extremely common among wounded Soldiers. The use of peripheral "nerve blocks" for pain management on the battlefield is advantageous over opioid analgesics due to more effective pain relief and relative absence of side-effects. However, the duration of nerve blockade with a single injection



of a local anesthetic is too short (less than 12 hours) for rapid evacuation plans, and continuous infusions of local anesthetic are restricted by the technical difficulties of catheter placement on the battlefield. With funding from an FY09 Translational Research Partnership Award, Drs. Brian Williams, Michael Gold, Gerald Gebhart, and Chester Buckenmaier collaborated to identify a single-injection drug combination utilizing U.S. Food and Drug Administration-approved drugs that could block post-traumatic pain for a longer period of time without side-effects. Of the drugs tested, midazolam (MDZ) produced a painfiber selective blockade, suggesting it could prevent pain while preserving motor control with minimal side effects. However, because higher concentrations of MDZ (in past studies) were neurotoxic due to the release of calcium from intracellular stores, pursuing this compound clinically is considered with caution. More promising was that bupivacaine, a local anesthetic, combined with clonidine, buprenorphine, and dexamethasone may provide relief of moderate-to-severe pain. Each drug combination provided more than 24 hours of pain relief. For FY16, Dr. Williams and his partners received funding from the Defense Medical Research and Development Program to translate this promising new therapy into a clinical trial to compare their drug combinations against the current gold standard – nerve block with plain local anesthetics – in Veterans undergoing knee and hip joint arthroplasty. If successful, their research could lead to improved management of acute pain following battlefield injuries.

# **Making Breakthroughs**



#### **Engineering Advanced Materials for Bone Regeneration**

#### Luis Alvarez, National Cancer Institute, Frederick, MD

The repair of segmental bone defects is a big challenge facing Wounded Warriors. In fact, orthopaedic injuries account for the vast majority of combat injuries. Synthetic bone grafts offer a promising approach to promote bone regeneration in large bone voids but lack the osteoconductive cues needed for resident stem cells to engage in regenerative processes. In addition, resident stem cells found locally in bone are often depleted upon injuries that leave segmental bone voids. With funding from an FY10 Career Development Award, and mentorship by Dr. George Muschler at the Cleveland Clinic and Dr. Linda Griffith at the Massachusetts Institute of Technology, Dr. Luis Alvarez

has been conducting research to impart enhanced efficacy to existing osteoconductive materials utilized in bone grafts, specifically beta tricalcium phosphate (βTCP). The surface of βTCP is difficult to modify. Nevertheless, Dr. Alvarez identified a peptide sequence that binds tightly to βTCP (βTCP-BP) and, conceptually, would allow any protein to be tethered to its surface. Building on the success of the CDMRP Career Development Award, LTC Alvarez assembled a team to develop this technology for three orthopaedic clinical indications. In 2015, he was awarded a Joint Warfighter Medical Research Program contract to conduct pre-clinical evaluation of this technology with a significantly more challenging bone-inducing protein. LTC Alvarez, now at the United States Military Academy, has partnered with Dr. Michael Yaszemski at the Mayo Clinic, Dr. George Muschler at the Cleveland Clinic, and Dr. Joshua Wenke at the U.S. Army Institute of Surgical Research to conduct these studies, which will be under way through 2019. Commercialization of this technology may ultimately lead to a much safer, lower-cost, and more efficacious alternative to the current state-of-the-art in bone repair.



#### A Clinically Realistic Large Animal Model of Intra-Articular Fracture

#### Jessica Goetz and Yuki Tochigi (not pictured), University of Iowa, Iowa City, IA

A leading cause of post-traumatic osteoarthritis (PTOA) is intra-articular fractures resulting from exposure to high-energy injury events sustained by Soldiers on the battlefield. Unfortunately, even the best surgical reconstructions of injured joints have not been successful in returning young, active patients to the levels of mobility they enjoyed before their injury. Thus, preventing or delaying the development of advanced osteoarthritis would greatly benefit Wounded Warriors. With funding from an FY09 Technology Development Award, Drs. Jessica Goetz and Yuki Tochigi collaborated with other researchers to develop a new, clinically realistic animal model of distal tibial intra-articular

fracture. The newly developed porcine model replicates the major pathophysiological attributes of a human intra-articular fracture, from the initial bone and cartilage injury, to the long-term abnormal cartilage loading that eventually leads to cartilage breakdown after the fracture itself has healed. Dr. Goetz hopes that the use of this model will facilitate translational research of new orthopaedic treatments to reduce the risk of PTOA following intra-articular fractures. Dr. Goetz received an FY14 PRORP Expansion Award to determine whether mechanically unloading joints during early injury treatment can prevent the development of PTOA in the porcine model. This effort will provide a basis for future clinical trials in human patients aimed to transform clinical care of joint injury in the military.

"As a consumer reviewer, I have experienced so much joy and satisfaction because I still feel that I can be of service to someone again. And when I am called upon to lend my unique perspective related to my personal injury, it makes me feel as though my injury was not in vain. I realize that critiquing proposals and making critical assessments of someone's hard work can be challenging, but the reward on the other side is that someone, even me, may truly have their lives enriched by the outcome of the proposals. And that is why I continue to review for the PRORP. Thank you for the opportunity to once again serve my fellow man."

—Zaneta Adams, PRORP Consumer Peer Reviewer

# **Expanding Outcomes**

In FY14, the PRORP granted six Expansion Awards to support the continued investigation and development of highly impactful research projects previously funded by the program. Dr. Stefania Fatone was the sole recipient of an Expansion Award with a clinical trial option, with which she will advance a novel prosthetic socket technology into testing with lower limb amputees.

#### **Vacuum-Assisted Prosthetic Socket for Transfemoral Amputees**

#### Stefania Fatone, Northwestern University, Evanston, IL

Existing prosthetic sockets for above-the-knee (transfemoral) amputations that encase the pelvis and hip joint restrict both range of motion and comfort for the user. These limitations pose a significant challenge to highly active persons with amputations, including injured Service members wishing to return to active duty. Dr. Stefania Fatone leads a highly successful research project geared toward optimizing the comfort and boosting performance of transfemoral amputees.

In FY09, Dr. Fatone received a Technology Development Award with which she and her co-investigators developed a vacuum fit prosthetic socket for enhanced range of motion and comfort for transfemoral amputees. Known as the NU-FlexSIV (Northwestern University



Flexible Sub-Ischial Vacuum) Socket, the device is shorter, with lower edges than those in currently available sockets, thus preventing impingement of the socket on the pelvis when the hip is moved and improving overall mobility. The socket is also more flexible, allowing the muscles of the residual limb to move comfortably within the socket during active movement and offering added comfort in a sitting position. The socket is held securely to the leg via suction from a vacuum pump, which provides a firmer connection between the residual limb and the prosthesis. Dr. Fatone (pictured left) and prosthetist, Ryan Caldwell (pictured right), generated instructional materials for training certified prosthetists to cast, fit, and fabricate the custom socket, and received funds from DoD's Joint Warfighter Medical Research Program in FY12 to prototype and test hybrid vacuum pumps for prosthetic suspension in highly active transfemoral amputees (US patent #9,066,822).

The clinical trial Dr. Fatone proposed under her FY14 Expansion Award will assess the functional performance and comfort of the NU-FlexSIV Socket, as well as patient outcomes, in a population of individuals with unilateral (single-sided) transfemoral amputation. Information gathered from this clinical trial will aid providers in prescribing this new socket technology for above-the-knee amputees. The NU-FlexSIV socket is expected to enhance prosthetic care and functional performance for transfemoral amputees and will promote improved quality of life and active lifestyles in Service members who have sustained combat-related injuries.



"I have had the distinct pleasure serving as a scientific reviewer for the Peer Reviewed Orthopaedic Research Program. As a retired Army orthopaedic surgeon, I fully understand the significance of injuries and subsequent rehabilitation obstacles faced by my brothers and sisters in arms. I remain committed to them on both personal and professional levels and am thankful for programs, such as the PRORP, that restore hope and function to such a deserving population."

-Kenneth Taylor, PRORP Peer Reviewer

# **PRORP Clinical Consortia:** Facilitating

The PRORP supports high-impact research through multiple mechanisms including, notably, two complementary clinical consortia, each designed to provide new solutions along the continuum of care for Wounded Warriors with orthopaedic injuries. The partnerships within each consortium are intended to bring military patients, leading researchers,



#### Major Extremity Trauma Research Consortium (METRC)

In FY09, the PRORP awarded a Clinical Consortium Award totaling \$34.6M to METRC, led by **Dr. Ellen MacKenzie of Johns Hopkins University**, and **Dr. Michael Bosse at Carolinas Medical Center**. METRC's mission is to provide the evidence needed to establish better treatment guidelines for optimal care of the Wounded Warrior, and to improve the clinical, functional, and quality-of-life outcomes of Service members and civilians who sustain high-energy trauma to the extremities. The Coordinating Center, located at the Johns Hopkins

Bloomberg School of Public Health, collaborates with four MTFs, 22 civilian study sites, and over 40 satellite centers to conduct five core studies, in addition to several others supported by an FY08 Orthopaedic Extremity Trauma Research Program Award. METRC studies\* supported by the PRORP include:

- **OUTLET:** Comparing patient outcomes post limb salvage and amputation among patients with severe foot and ankle injuries
- **TAOS:** Comparing outcomes in patients undergoing transtibial amputation with or without tibia-fibula synostosis
- **PACS:** Developing a novel tool to aid clinicians in timely and accurate diagnoses of acute compartment syndrome
- **PAIN:** Evaluating multimodal approaches for peri-operative pain management in treatment of lower limb fractures
- **TCCS:** Implementing a collaborative care intervention to address patients' psychosocial needs and improve health-related quality of life



\* Studies described here were funded under the PRORP FY09 Clinical Consortium Award. METRC investigators conduct other studies funded by a previous Orthopaedic Extremity Trauma Research Program Award and by individual PRORP Clinical Trial and Outcomes Research Awards.

## **Collaborative Partnerships**

and military treatment facility (MTF) clinicians together with the infrastructure, patients, and expertise of highly qualified civilian organizations in concerted studies to impact military orthopaedic and rehabilitative medicine.

#### Bridging Advanced Developments for Exceptional Rehabilitation (BADER)

In FY10, the PRORP granted a \$19.7M Orthopaedic Rehabilitation Clinical Consortium Award to the BADER Consortium at the University of Delaware

(UD) to establish a strong clinical infrastructure for advancing evidence-based, orthopaedic rehabilitation care for Soldiers with musculoskeletal injuries to help them return to optimal function in their daily lives. BADER is a partnership of four MTFs, the U.S. Department of Veterans Affairs (VA), academia, and industry, engaging more than 100 research affiliates throughout the U.S. that have unified to identify and address critical issues challenging the recovery of combat and civilian trauma patients. Directed by **UD Professor Dr. Steven J. Stanhope**, BADER provides essential research capacity building and supporting infrastructures to advance ongoing research at DoD and VA sites which collaboratively conduct eight BADER-funded clinical research studies. Collectively, these studies are projected to enroll more than 1,500 wounded Service members by completion. These studies and their goals include:

- **STEP2STEP:** Improving step-to-step control of walking in lower-limb amputees using a virtual reality training intervention
- **RETRAIN:** Helping subjects return to a high level of performance through walk-torun training with real-time kinetic feedback
- Trauma Outcomes: Studying qualitative outcomes to benchmark current care levels in orthopaedic rehabilitation
- *K2 Power:* Identifying differences across multiple measures in persons using passive versus powered BiOM ankle prosthesis
- **ProLegRx:** Prescribing running-specific leg prosthesis in transtibial amputees via a science-based method
- MORE: Assessing rehabilitation outcomes in the clinical environment to support
  evidence-based practice in MTFs
- Outcomes Toolbox: Defining outcome measures to serve as common data elements across different research studies and clinical evaluations
- Ruck Foot: Evaluating and prescribing prosthetic ankle–foot components for amputees to conduct physically demanding tasks





# **PRORP's FY15 Vision**

The PRORP received \$30M in FY15 to support innovative, high-impact, clinically relevant applications for research that will foster new directions and address neglected issues in the field of combat-related orthopaedic injury. The program will fund strong grant proposals aimed at advancing optimal treatment and rehabilitation from injuries sustained during combat or combat-related activities.

Each award mechanism required applications to address specific research Focus Areas identified by the FY15 PRORP Programmatic Panel:

- Segmental Peripheral Nerve
  Defects
- Prevention of Heterotopic
  Ossification
- Volumetric Muscle Loss
- Lower Extremity Fractures
- Economic Impact
- Biomarkers and Clinical Parameters
- Pelvic Ring Injuries

- Post-Operative Pain Management
- Prosthetic and/or Orthotic Devices
- Secondary Physical Health Effects
- Physical and Occupational Therapy
- · Rehabilitation Outcomes



Focus	Award Mechanism
Applied Research	Applied Research Award: Supports applied research focused on advancing optimal treatment and restoration of function for military personnel with musculoskeletal injuries sustained during combat or combat-related activities. Research must also be applicable to the general population.
Clinical	<i>Clinical Trial Award:</i> Supports the rapid implementation of clinical trials with the potential to have a significant impact on military combat-relevant orthopaedic injuries. Trials may evaluate promising new products, pharmacologic agents (drugs of biologics), devices, clinical guidance, and/or emerging approaches and technologies.
Research	<b>Orthopaedic Care and Rehabilitation Consortium</b> <b>Award:</b> Supports clinical studies that are focused on improving both (1) acute care treatment outcomes and function, and (2) long-term rehabilitation outcomes of severe musculoskeletal injuries commonly associated with military combat or combat-related activities.

"The PRORP is a very generous and important research equity that allows the military and its medical research programs to innovate knowledge and materiel solutions that advance the management of high-priority orthopaedic conditions. Co-directed by the Combat Casualty Care (JPC-6) and Clinical & Rehabilitative Medicine (JPC-8) Research Programs, the PRORP is able to synergize with the Defense Health Program and Army Medical Research investment to maximize impact for U.S. Service personnel. Together, this integrated military medical research program has advanced the management of complex orthopaedic conditions such as war-related mangled extremities (e.g., efforts to maximize quality limb salvage) and functional recovery after extremity amputation (i.e., innovative prosthetic technologies and rehabilitation strategies). Importantly, many of the advances in complex orthopaedic care spurred by the PRORP translate almost immediately to civilian medicine to improve care of those injured from accidents, acts of violence, or natural disasters in the U.S."

– Col Todd Rasmussen, Director, U.S. Army Medical Research and Materiel Command, Combat Casualty Care Research Program, FY15 Programmatic Panel





Address the most significant gaps in care for the leading burden of injury and loss of fitness for military duty by funding innovative, high-impact, clinically relevant research to advance optimal treatment and rehabilitation from musculoskeletal injuries sustained during combat or combat-related activities



For more information, visit *http://cdmrp.army.mil* or contact us at: *usarmy.detrick.medcom-cdmrp.mbx.cdmrp-public-affairs@mail.mil* (301) 619-7071

