Congressionally Directed Medical Research Programs

Peer Reviewed Orthopaedic Research Program (PRORP)
2021 Stakeholders Meeting Briefing

CUTTING EDGE RESEARCH

Akua Roach, Ph.D. Program Manager















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Moment of Silence

Moment of Silence – Dr. Lee Childers





Outline

- Meeting Objectives
- Overview of the CDMRP
- PRORP History, Funding, and Portfolio
- Other Funders with PRORP-related Portfolios
- Review Stakeholders Book and Survey Data
- Breakout Groups
- **♦** Report Outs
- Next Steps



Meeting Objectives



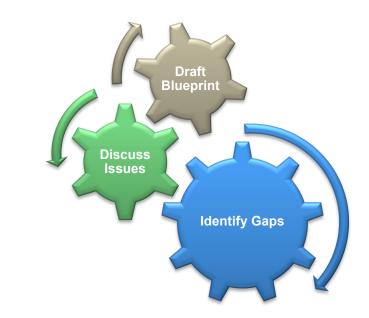
Stakeholders Meeting

♦ Purpose and Intent

A stakeholder is a person or group who has an interest – vested or otherwise – in an enterprise and whose support is required in order for an enterprise to be successful

http://searchcio.techtarget.com/definition/stakeholder

- Experts from different subject areas are brought together to pinpoint the knowledge gaps, discuss the landscape of orthopaedic research, identify the outcomes and needs for orthopaedic military and civilian care, and recommend a way forward
- Account for various voices and opinions to refine a research program focused on improving care and options for patients who sustain traumatic orthopaedic injuries









Objectives

- **♦** State of the Science/Patient Care
- Understand the needs of the military and general orthopaedic communities
- Discuss current funding landscape
- ◆ Identify of knowledge gaps
 - Key challenges and themes
 - Military and civilian considerations
 - Current research capabilities
 - Needs of the patient and clinical care teams
- **◆** Account for stage of science
 - Gaps along the research continuum

♦ Outcome

- ◆ Inform future PRORP research funding investment discussions
- ◆ Incorporated into PRORP Strategic Plan







Stakeholder Meeting Agenda

| 10:10 a.m. | Welcome and Introductions | Dr. Akua Roach and Ms. Elizabeth Guman |
|--------------------------|--|---|
| 10:20 a.m. | Moment of Silence | Dr. Lee Childers |
| 10:25 a.m. | Meeting Overview and Objectives, Ground Rules for Discussion | Ms. Guman |
| 10:30 a.m. | Leidos Administrative Remarks | Ms. Nancy Ayad |
| 10:35 a.m. | Overview of the CDMRP and PRORP | Dr. Roach |
| 10:55 a.m. | Military Operational Medicine Research Program/Joint Program Committee 5 (JPC-5) | Dr. Richard Shoge |
| 11:05 a.m. | Combat Casualty Care Research Program (JPC-6) | Dr. Therese West |
| 11:15 a.m. | Department of Veterans Affairs | Dr. Brian Schulz |
| 11:25 a.m. | National Institutes of Health/National Institute for Arthritis Musculoskeletal and Skin Disorders | Dr. Chuck Washabaugh |
| 11:35 p.m. | Survey Monkey Data Review | Dr. Roach and Ms. Guman |
| 11:40 p.m. | Breakout Session Rules and Responsibilities | Ms. Guman |
| 11:45 p.m. – 12:30 p.m. | Lunch | All Participants |
| 12:30 p.m. | Concurrent Breakout Sessions | All Participants |
| $3:00 \ p.m 3:15 \ p.m.$ | Break | All Participants |
| 3:15 p.m. | Report-outs from Session Chairs | Session Chairs |
| 4:45 p.m. | Final Discussion and Next Steps | Dr. Roach and Ms. Guman |
| 5:00 p.m. | Adjourn | All Participants |



Overview of the CDMRP





WHO is the CDMRP?



Department of Defense





Department of the Army





Army Futures Command





U.S. Army Medical Research and Development Command (USAMRDC)





Congressionally Directed Medical Research Programs





About CDMRP



◆ CONGRESSIONAL PROGRAMS

- Manages extramural research programs directed by Congress
- Started in 1992 with a focus on breast cancer research; currently includes over 30 research programs
- Congress specifies the focus area; the CDMRP determines research strategy and competitively selects the best projects
- Unique public/private partnership encompasses the military, scientists, disease survivors, consumers, and policy makers
- Funds high-impact, innovative medical research to find cures, reduce the incidence of disease and injury, improve survival, and enhance the quality of life for those affected

◆ DoD PROGRAMS

Provides support to Program Area Directorates (PADs)/Joint Program Committees (JPCs) for managing extramural and intramural research portfolios to advance their missions

♦ DIRECTOR

COL Sarah Goldman





CDMRP Vision and Mission

Vision

Transform healthcare for FUNDING GROUNDBREAKING, HIGH-IMPACT RESEARCH

Mission

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





CDMRP FY21 Appropriations

| Research Program | FY21 \$M | Research Program | |
|---------------------------------------|-------------|--|----------|
| Alcohol and Substance Abuse Disorders | \$4.0 | Neurofibromatosis | \$20.0 |
| Amyotrophic Lateral Sclerosis | \$40.0 | Neurotoxin Exposure Treatment Parkinson's | \$16.0 |
| Autism | \$15.0 | Orthotics and Prosthetics Outcomes | \$15.0 |
| Bone Marrow Failure | \$7.5 | Ovarian Cancer | \$35.0 |
| Breast Cancer | \$150.0 | Pancreatic Cancer | \$15.0 |
| Chronic Pain Management | \$15.0 | Peer Reviewed Alzheimer's | \$15.0 |
| Combat Readiness Medical | \$10.0 | Peer Reviewed Cancer (20 Topics) | \$115.0 |
| Duchenne Muscular Dystrophy | \$10.0 | Peer Reviewed Medical (42 Topics) | \$370.0 |
| Epilepsy | \$12.0 | Peer Reviewed Orthopaedic | \$30.0 |
| Gulf War Illness | \$22.0 | Prostate Cancer | \$110.0 |
| Hearing Restoration | \$10.0 | Rare Cancers | \$17.5 |
| Joint Warfighter Medical | \$40.0 | Reconstructive Transplant | \$12.0 |
| Kidney Cancer | \$50.0 | Scleroderma | \$5.0 |
| Lung Cancer | \$20.0 | Spinal Cord Injury | \$40.0 |
| Lupus | \$10.0 | Tick-Borne Disease | \$7.0 |
| Melanoma | \$30.0 | Traumatic Brain Injury and Psychological Health Research | \$175.0 |
| Military Burn | \$10.0 | Tuberous Sclerosis Complex | \$8.0 |
| Multiple Sclerosis | \$20.0 | Vision | \$20.0 |
| | | TOTAL = | = \$1.5B |

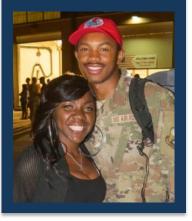




Hallmarks



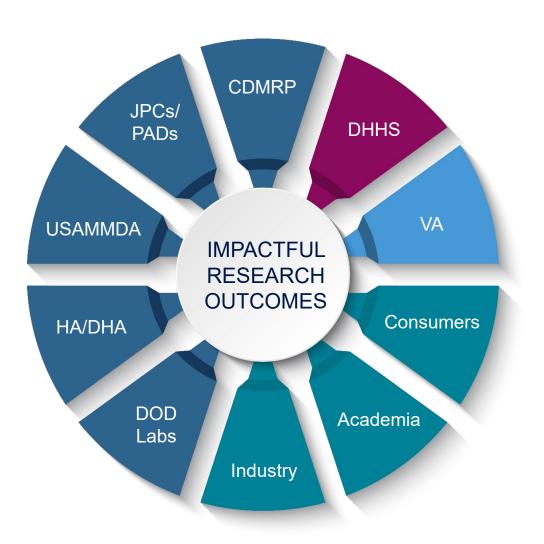




- Congress adds targeted research funds to the DoD budget
- Funds high-impact innovative research
- Avoids duplication with other funding agencies and targets unfunded/unmet gaps
- Follows the National Academy of Medicine-recommended model for application review
- Consumers participate throughout the process and are the "True North" and foundation of the programs
- Annually adapts each program's vision and investment strategy allowing rapid response to changing needs
- Funding flexibility
 - Funds obligated up-front; limited out-year budget commitments
 - No continuation funding
 - No "pay line" funding recommendations are based on portfolio composition, adherence to mechanism intent, relative impact, and technical merit
- Transparency and accountability to stakeholders
- Low management costs maximize research dollars



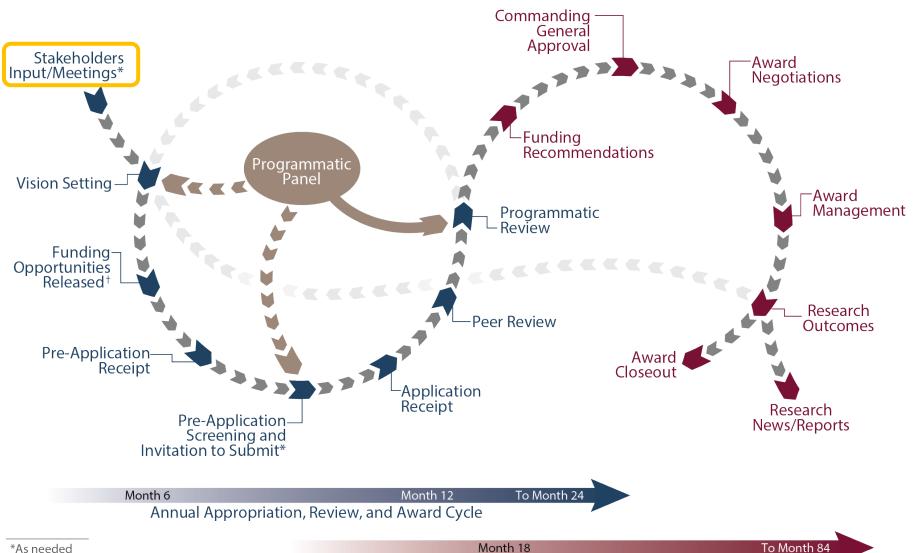
Major Partners and Collaborations



- Strategic input and planning
 - ❖ 58 from DHHS (NIH, CDC, FDA, BARDA, etc.) and 29 from VA on programmatic and other panels across CDMRP
 - Coordinated funding
- Research performers
 - Both extramural and intramural.
 - Consumer inclusion
- Research and technology transitions
 - Next phase of research or development – commercial or federal
- Implementation and dissemination



CDMRP Program Cycle



Month 18

[†]Pending Congressional appropriation



PRORP History, Funding, and Portfolio



Orthopaedic Injuries Impacting Military

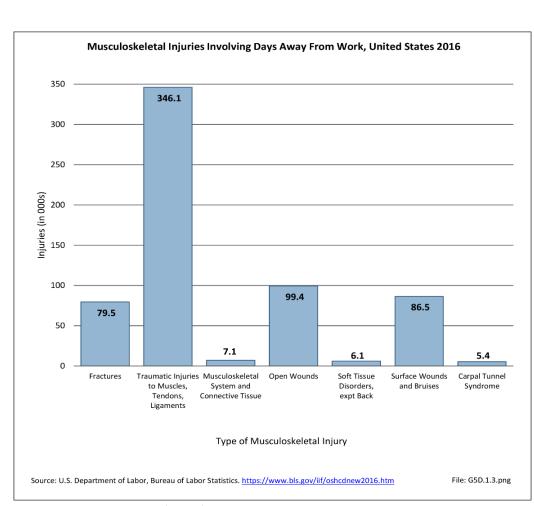
- The most common reason for medical discharge from the Armed Services is the inability to return to full duty due to musculoskeletal injury or preexisting musculoskeletal condition.
- Disability discharge due to a musculoskeletal injury or condition: ~78% of male Army personnel and 85% of female Army personnel (Piccirillo AL, Packnett ER, Cowan DN, Boivin MR. Risk factors for disability discharge in enlisted Active Duty Army soldiers. Disabil Heath J. 2016 Apr;9(2):324-331.)

| Rank | Injury | Estimated DLD | Person-years of limited luty | % total DLD | Injury frequency |
|------|--|------------------|---------------------------------|----------------|---------------------|
| 1 | Lower extremities overuse (pain, inflammation, and stress fractures) | 3,803,512 | 10,420 | 15.3 | 240,796 |
| 2 | Lower extremities fractures | 2,869,320 | 7,861 | 11.5 | 23,911 |
| 3 | Upper extremities fractures | 2,354,490 | 6,450 | 9.4 | 26,161 |
| 4 | Torso overuse (pain, inflammation, and stress fractures) | 2,165,562 | 5,933 | 8.7 | 154,683 |
| 5 | Lower extremities sprains and strains | 1,877,918 | 5,144 | 7.5 | 134,137 |
| 6 | Lower extremities dislocations (cartilage tears) | 1,520,600 | 4,166 | 6.1 | 15,206 |
| 7 | Upper extremities overuse (pain, inflammation, and stress fractures) | 1,314,330 | 3,600 | 5.3 | 93,750 |
| 8 | Spine and back sprains and strains | 1,202,190 | 3,293 | 4.8 | 40,073 |
| 9 | Unspecified overuse (pain, inflammation, and stress fractures) | 999,035 | 2,737 | 4.0 | 44,707 |
| 10 | Lower extremities sprains, strains, and ruptures | 692,132 | 1,896 | 2.8 | 49,438 |



Orthopaedic Injuries Impacting Civilians

- 70% of MSKI patients report lost work days (216.5 Million days), 2012
- 77% of all injury health care visits (65.8 Million) are for MSKIs, 2011
- Annual cost for treating MSKIs: \$176.1 Billion, 2011



United States Bone and Joint Initiative: The Burden of Musculoskeletal Diseases in the United States (BMUS), Fourth Edition, 2020. Rosemont, IL. Available at http://www.boneandjointburden.org. Accessed on 1 Feb 2021.



Challenges with Conducting Orthopaedic Research

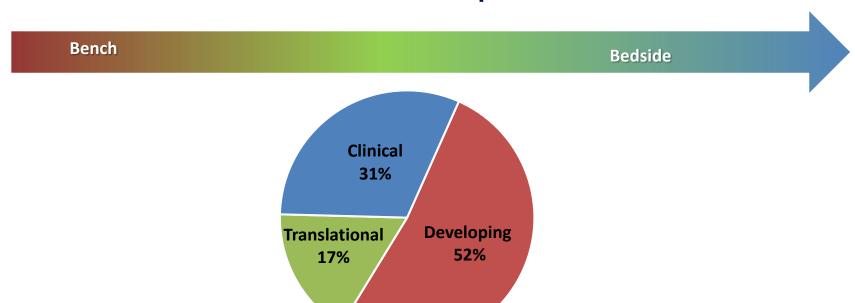
- **◆** Difficult to enroll trauma patients
- **♦** Injury variability, polytrauma
- ◆ Number of patients (civilian and military) to reach statistical significance is sometimes unattainable
- Multiple sites needed to enroll, requiring additional coordination/oversight
- **♦** Cost of care and insurance reimbursement concerns
- ◆ Long-term effects data difficult to collect; loss to follow-up
- Patient vicinity to care (esp. for rehabilitation studies)
- ◆ Rehabilitation studies difficult to control and conduct (practice varies across centers, dependent on injury, patient drop out, length and duration of rehab)





The Role of the PRORP

- **◆** Find solutions that improve outcomes
- High risk/high gain projects
- Develop the field for collaborative orthopaedic trauma research
- Fund translational research to move the field forward
- Fund clinical trials to move interventions into the clinic
- Provide the clinical evidence to impact clinical care







PRORP Vision and Mission

Vision

Provide all Military Service members with orthopaedic injuries the opportunity for optimal recovery and restoration of function.

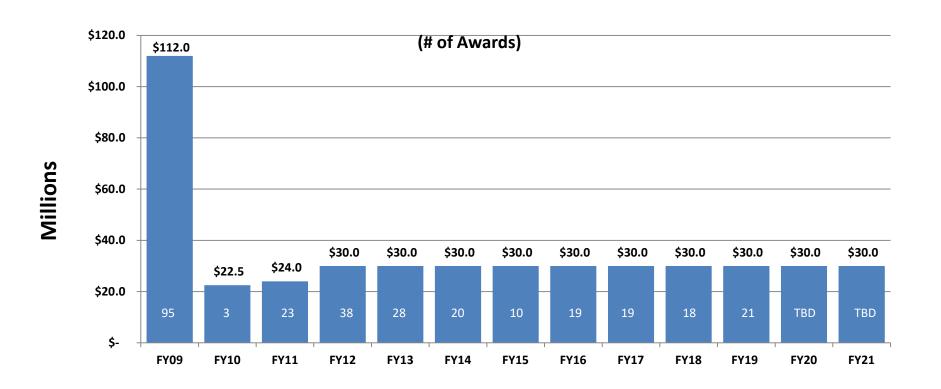
Mission

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





Funding History



■ Total Congressional appropriations: \$458.50M

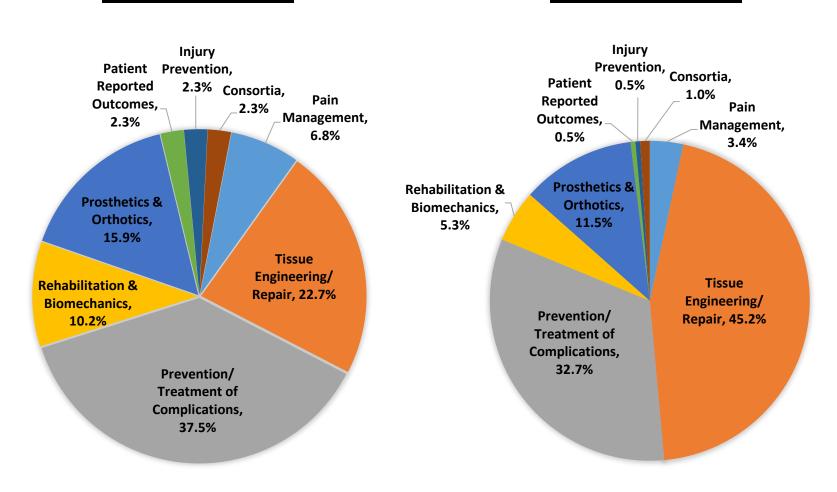
■Total Awards made (through FY19): 294



PRORP Portfolio, by Portfolio Buckets



FY15-FY19





Other Funders with PRORP-related Portfolios





Today's Presenters

- ◆ Military Operational Medicine Research Program/Joint Program Committee 5 (MOMRP/JPC-5) — Dr. Richard Shoge
- ◆ Combat Casualty Care Research Program (CCCRP/JPC-6) Dr. Therese West
- ◆ **Department of Veterans Affairs (VA)** Dr. Brian Schulz
- National Institutes of Health/National Institute for Arthritis Musculoskeletal and Skin Disorders (NIH/NIAMS) – Dr. Chuck Washabaugh



Review Stakeholders Book and Survey Data



Breakout Groups - Rules



Guidelines for Discussion

- Everyone participate; no one dominate
- Listen to understand; all ideas are valid
- Share your unique perspective
- Disagree without being disagreeable; Use "I" statements
- Critique ideas, not people
- Respect each other's thinking and value their contributions
- Treat everything you hear as an opportunity to learn and grow
- ◆ State your "headline" first, then the supporting information as necessary
- ◆ Be brief and meaningful when voicing your opinion
- Seek common ground and understanding (not problems and conflict)
- Stay on schedule; honor time limits
- Stay out of the weeds

Tips for Teleconferences/Virtual Meetings

- Participate 100%
- Introduce yourself prior to speaking
- Use mute when not speaking
- Utilize chat for technical support when available





Breakout Sessions by Topic Area

| Session Number | Topic Area |
|--------------------|--|
| Breakout Session 1 | Care for return to duty (within 1 year of injury) for military Service Members |
| Breakout Session 2 | Diagnosis and acute care of prehospital musculoskeletal trauma injuries in military and civilian populations |
| Breakout Session 3 | Emerging areas in preclinical orthopaedic research |
| Breakout Session 4 | Emerging areas in clinical orthopaedic research |
| Breakout Session 5 | Knowledge gaps in surgical care for musculoskeletal combat casualties |
| Breakout Session 6 | Knowledge gaps in surgical care for musculoskeletal non-combat casualties |





Breakout Session Leaders

Breakout Session 1

- Jessica Goetz, Ph.D., University of lowa
- James Irrgang, P.T., Ph.D., FAPTA, University of Pittsburgh

Breakout Session 2

- Constance Chu, M.D., Stanford University
- Aksone Nouvong, D.P.M., University of California, Los Angeles; U.S. Department of Veterans Affairs Greater Los Angeles Healthcare System

Breakout Session 3

- Luis Alvarez, Ph.D., Theradaptive
- Leon Nesti, COL, M.D., Ph.D., Uniformed Services University of the Health Sciences

Breakout Session 4

- Stephen Goldman, Ph.D., Extremity Trauma and Amputation Center of Excellence
- Mike Hahn, Ph.D., University of Oregon

Breakout Session 5

- Jessica Rivera, M.D., Ph.D., Louisiana State University Health Science Center
- Robert O'Toole, M.D., University of Maryland School of Medicine

Breakout Session 6

- Jon Dickens, LTC, M.D., Walter Reed National Military Medical Center
- I. Leah Gitajn, M.D., M.S., Dartmouth-Hitchcock Medical Center



Report Outs



Next Steps

- Prioritized Top 5 Gaps from each breakout group will directly inform the FY22 PRORP vision setting and investment strategy discussions
- ♦ Secondary/Tertiary Gaps will be incorporated into PRORP strategic planning discussions
- All gaps will be referenced for inclusion in future PRORP vision setting discussions (if appropriated)
- All gaps will be provided to our funding partners for crossagency data sharing
- ◆ Files and outcomes of the Stakeholder meeting will be made public on the CDMRP website





For your Service and Participation







PRORP Information

Website http://cdmrp.army.mil/prorp

- **♦** Program Book, Portfolio Summary
- ♦ Strategic Plan, Research News & Highlights
- Press Releases

Twitter

@CDMRP

(twitter.com/CDMRP)

YouTube youtube.com/user/CDMRP

