The Congressionally Directed Medical Research Programs

Veteran Engagement Initiative Cyberseminar Consumer Involvement in the CDMRP

22 June, 2016

The views expressed in this presentation are those of the author and may not reflect the official policy or position of the Department of the Army, Department of Defense, or the U.S. Government.
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Outline

- CDMRP History and Overview – Consumer Driven
- Programmatic Panel – Stakeholders/Vision Setting
- Peer Review – Consumer Integration
- CDMRP Consumer Experience
- Programmatic Panel – Programmatic Review and Research
- Summary and Close
- Questions?
Who is the CDMRP?

Department of Defense

Department of the Army

Army Medical Command

Medical Research and Materiel Command

Congressionally Directed Medical Research Programs
About CDMRP

◆ CONGRESSIONAL PROGRAMS:
  - Manage extramural research programs directed by Congress
  - Started in 1992 with Breast Cancer, now 27 programs
  - Congress specifies disease area, CDMRP determines research strategy and competitively selects the best projects
  - Unique public/private partnership encompassing the military, scientists, disease survivors, consumers, and policy makers
  - Fund 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:
  - Provide support to Program Area Directorates (PADs) / Joint Program Committees (JCPs) for managing extramural and intramural research portfolios to advance their missions

◆ DIRECTOR:
  - Col Wanda Salzer

- Alcohol and Substance Abuse Disorders
- Amyotrophic Lateral Sclerosis
- Autism
- Bone Marrow Failure
- Breast Cancer
- Duchenne Muscular Dystrophy
- Epilepsy
- Gulf War Illness
- Joint Warfighter Medical
- Lung Cancer
- Military Burn
- Multiple Sclerosis
- Neurofibromatosis
- Neurotoxin Exposure Treatment Parkinson’s
- Orthotics and Prosthetics Outcomes
- Ovarian Cancer
- Peer Reviewed Alzheimer’s
- Peer Reviewed Cancer
- Peer Reviewed Medical
- Peer Reviewed Orthopaedic
- Prostate Cancer
- Reconstrctive Transplant
- Spinal Cord Injury
- Tick Borne Disease
- Trauma Clinical
- Tuberous Sclerosis Complex
- Vision

Additional Supported DoD Programs
- Defense Medical R & D
- Defense Medical R & D Restoral
- Psychological Health and Traumatic Brain Injury

Program Announcement Release
Vision Setting
Pre-Application Receipt
Congressional Appropriations
Pre-Application Screening & Invitation
Application Receipt
Peer Review
Programmatic Review
Funding Recommendation
Approval
Authority Decision
Awards Management 1-7 Years
Negotiations

CUTTING EDGE RESEARCH

CDMRP
Department of Defense
Vision and Mission

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
History

- In the early 1990’s, grassroots efforts heightened political awareness of breast cancer
- Congress appropriated $210M to the FY93 DoD budget for a new Breast Cancer Research Program (BCRP)
- DoD was directed to manage the BCRP
- The Army sought the advice of the National Academy of Medicine (previously Institute of Medicine), which resulted in:
  - A two-tier review process
  - A new model for research – incorporating consumers into program policy, investment strategy, and research focus
- Since 1996, additional research programs and topics have been added by Congress and administratively managed by CDMRP
Funding History

**Millions ($)**

- Alcohol and Substance Abuse Disorders
- Bone Marrow Failure Disorder
- Defense Women's Health
- Duchenne Muscular Dystrophy
- Gulf War Illness
- Lung Cancer
- Myeloproliferative Disorders
- Neurotoxin Exposure Treatment Parkinson's
- Ovarian Cancer
- Peer Reviewed Medical
- Reconstructive Transplant
- Trauma Clinical Research
- Defense Medical R&D*
- Amyotrophic Lateral Sclerosis
- Breast Cancer
- Deployment Related Medical
- Epilepsy
- Institutionally Based Programs
- Military Burn
- National Prion
- Orthotics and Prosthetics Outcomes
- Peer Reviewed Alzheimer
- Peer Reviewed Orthopaedic
- Spinal Cord Injury
- Tuberous Sclerosis
- Defense Medical R&D CSI Restoral*
- Autism Research
- Chronic Myelogenous Leukemia
- DOD/VA Medical
- Genetic Studies of Food Allergies
- Joint Warfighter Medical
- Multiple Sclerosis
- Neurofibromatosis
- Osteoporosis
- Peer Reviewed Cancer
- Prostate Cancer
- Tick-Borne Disease
- Vision
- Psychological Health/Traumatic Brain Injury*

*FY15, FY16 - Managed estimate on behalf of others
Hallmarks

◆ Consumers participate throughout process
◆ Funds high-impact innovative research
◆ Each program’s vision and investment strategy are adapted annually, allowing rapid response to changing needs
◆ Avoid Duplication with other funding agencies
  ❖ Fills Unfunded/Unmet Gaps
◆ Funding flexibility
  ❖ Funds obligated up-front; limited out-year budget commitments
  ❖ Limited continuation funding
  ❖ No “pay line” – in addition to technical merit, funding recommendations based on portfolio composition, adherence to intent of mechanism, and relative impact
Consumers

The voices and experiences of consumers continue to play a pivotal role in the establishment and growth of research programs.

- Moment of Silence beginning each meeting

Over 2,100 consumers representing over 1,000 organizations have served on CDMRP Peer Review and Programmatic Review panels
Unique Partnerships

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

Congress
- Add funds to budget
- Targeted guidance

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

DoD
- Program management
- Contracting actions
- Regulatory requirements
## FY16 Funding

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*CDMRP is assisting with the management of a specified portion of a larger appropriation*
### Defense Medical Research Support

#### Medical Simulation and Information Sciences (JPC-1)
- Medical Modeling, Simulation, and Training
- Health Information Technology and Informatics

#### Military Infectious Diseases (JPC-2)
- Bacterial Diseases
- Viral Diseases
- Diagnostics Development

#### Military Operational Medicine (JPC-5)
- Musculoskeletal Injury
- Cognitive Health and Performance
- Psychiatry and Clinical Psychology Disorders
- Behavioral Health, Wellness, and Resilience
- Warfighter Physical Performance
- Nutrition and Weight Balance
- Sensory Performance, Injury, and Protection
- Millennium Cohort Study
- Environmental Toxicant Exposure
- Aircrew Health and Performance

#### Combat Casualty Care (JPC-6)
- Damage Control Resuscitation
- Neurotrauma, Neuroprotection, and Neurodiagnostics
- Patient Movement/En Route Combat Casualty Care
- Extremity Trauma
- Systems of Critical Care Delivery
- Burn Injury
- Maxillofacial Trauma and Combat Dentistry
- Pre-Hospital Tactical Combat Casualty Care
- Military Medical Photonics

#### Radiation Health Effects (JPC-7)
- Radiation Medical Countermeasures Development

#### Clinical & Rehabilitative Medicine (JPC-8)
- Neuromusculoskeletal Rehabilitation
- Pain Management
- Regenerative and Rehabilitative Medicine
- Sensory Systems (Vision, Hearing, and Balance)
VA Collaborations

♦ CDMRP Program coordination with VA

♦ Veterans and VA investigators serving on CDMRP Peer and Programmatic Panels

♦ CDMRP-funded VA investigators

♦ VA collaborations for research

CAP
CONSORTIUM TO ALLEVIATE PTSD
Applications and Awards

Number of Preapplications, Applications, and Awards

Percentage Rates of Applications Funded

Preapplications
Applications
Awards
Rate
Program Cycle

1. **Congressional Appropriation** (Restart cycle annually)
2. **Vision Setting**
3. **Program Announcement Release**
4. **Pre-Application Receipt**
5. **Pre-Application Screening and Invitation to Submit**
6. **Application Receipt**
7. **Peer Review**
8. **Programmatic Review**
9. **Approval Authority Decision**
10. **Funding Recommendations**
11. **Stakeholders Meetings**
12. **Award Negotiations**
13. **Award Management**
14. **Award Closeout**
15. **Research Outcomes**
16. **Research News and Reports**
17. **Monthly Appropriation, Review, and Award Cycle**

*As needed*
Stakeholders Meetings

What happens?
• Held when new programs are initiated
• Purpose:
  o Survey the research landscape
  o Identify gaps in both scientific and consumer interest areas
  o Capture as many aspects as possible

Who participates?
• Stakeholders are world-renowned consumers, scientists, and clinicians
• Coordination occurs with other agencies (Federal and NGOs) to determine unmet research gaps

Outcomes
• Recommendations as they pertain to the current landscape of the disease, condition, or injury
Vision Setting Meetings

What happens?
- Held annually
- Purpose
  - Maintain program relevance
  - Discuss the current landscape of the disease, condition, or injury (focus on scientific and clinical research gaps)
  - Develop a strategy to fill these gaps

Who participates?
- Consumers representing their advocacy community join other experts from the research community, the clinic, and the military
- Coordination across various agencies continues
- These individuals make up the Programmatic Panel
- Size and composition of the Programmatic Panel varies by program
Vision Setting Meetings

**Outcome**

- Annual Investment Strategy
  - It includes:
    - Program’s Vision and Mission statements
    - Focus Areas/Topic Areas/Areas of Encouragement
    - Funding Mechanisms/Program Announcements

- Example:

<table>
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<tr>
<th>Award Mechanism</th>
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<th>Est. # of Awards</th>
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<td><strong>Total</strong></td>
<td><strong>$22.50M</strong></td>
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The Program Announcement (PA) describes the components required for a full application.

Typical CDMRP application components are:

- Project Narrative
- Lay Abstract
- Impact Statement
- Military Benefit Statement
- Technical Abstract
- Statement of Work
- Biosketches
- Budget

PAs include language that guides applicant to describe project elements in a manner that will be readily understood by lay readers, as well as those without a background in science or medicine.

PAs also describe the application review criteria that will be used in both the first-tier (Peer Review) and second-tier (Programmatic Review) review.
Program Cycle

Congressional Appropriation (Restart cycle annually)

Vision Setting

Program Announcement Release

Pre-Application Receipt

Pre-Application Screening and Invitation to Submit*

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Research Outcomes

Research News and Reports

Research & Program Activities

*As needed

Month 6
Annual Appropriation, Review, and Award Cycle

Month 12
To Month 24

Month 18
Awards Management

To Month 84
Consumer Involvement in the Department of Defense Congressionally Directed Medical Research Programs – Peer Reviews

Ann Dodelin, CSRA CRA
Carolyn Branson, CSRA CRA
Jim Mayer, Veteran Consumer Reviewer
Patient Engagement – DoD CDMRP Peer Review and Consumer Involvement

DoD CDMRP Peer Review

• Overview of Peer Review
  - Who is Involved (SR and CR)

• Consumer Engagement Process
  - Outreach
  - Selection
  - Assignment
  - Support

• Post Peer Review

• Consumer Perspective (Jim Mayer)
CSRA Consumer Reviewer Engagement
DoD CDMRP Scientific Peer Review

Peer Review Participants and Purpose

- Part of CDMRP’s two-tiered process
- Who Participates
- Reviewer engagement
- Goal of Peer Review

*Equal Voice and Equal Vote

Panel composition
- 2-3 Consumer reviewers (CR)
- 8-10 Scientist reviews
- 1 Chair
- 1 Scientific Review Officer (SRO)

Consumer Engagement

Evaluate and discuss application’s merits

Gold Standard
CSRA Consumer Reviewer Engagement
DoD CDMRP Scientific Peer Review

Tasks of Peer Review

• Pre-meeting
  ➢ Reviewing Application
  ➢ Specific Review Criterion
  ➢ Writing a Critique
  ➢ Scoring Application

• Meeting:
  ➢ Panel Discussion
  ➢ Re-Scoring Application
  ➢ Summary Statement

• Peer Review Tasks
  ➢ Evaluate merit of each individual application

• Tools of review
  ➢ Award mechanism
  ➢ Program announcement
  ➢ Review criterion
    - Impact (CR)

• Critique writing
• Scoring
• End product
CSRA Consumer Reviewer Engagement for DOD
Outreach → Selection → Assignment → Support

**Outreach**

- Determine program-specific requirements
- Define the consumer reviewer
- Identify appropriate organizations
- Network extensively and often
- Tailored approach for military and veteran organizations

**Consumer reviewer administrators work closely with CDMRP program managers and CSRA scientific review managers**

- Identify program topics and focus areas
- Recruitment of advocates (civilians, service members and veterans) representing multiple organizations
- Strategic approaches to recruitment
CSRA Consumer Reviewer Engagement for DOD
Outreach ➔ Selection ➔ Assignment ➔ Support

**Selection**

- Evaluate nominee packets
- Add candidates to database
- Conduct interviews
- Assess candidate
- Score candidates

- Assess nominee for –
  - Status in their journey
  - Advocacy/ community support experience
  - Broad knowledge and understanding
  - Verbal skills and writing ability
  - Program eligibility
Assignment

• Assess availability to serve
• Match candidates to program topic areas
• Assign candidates to appropriate panel and award mechanism

• Match candidates with CDMRP specifications and panel needs

• Assign to panels based on:
  - Program-specific needs
  - Experience level (novice versus experienced)
  - Organizational and demographic representation
Support

• Train through various modalities
• Accommodations needed
• Technical and process support
• Observation and assessment throughout
• Debrief in person and by surveys

• Plan accommodations for travel and meeting participation
• Support for consumers, caregivers and team members
• Assess for future modifications as needed
• Engagement of the consumer reviewer in the DoD CDMRP research efforts
  - Identifying potential consumer reviewers
  - Representing and promoting their program
  - Communicating with the community and stakeholders
  - Opportunities to serve on research grant development and implementation
Patient Engagement –
DoD CDMRP Peer Review and Consumer Involvement

Mr. James (Jim) Mayer,
CDMRP/CSRA Consumer Reviewer (Retired US Army)
 Patient Engagement –
DoD CDMRP Peer Review and Consumer Involvement

Consumer Perspective
by Jim Mayer

- Continuing to Serve
- Comments that are Heard, Acknowledged and Valued
- Equal Panel Participants
- Research that Matters

“Pay It Back and Pay It Forward”
- Serves as Reality Check
- Giving Voice to the Veteran

“As a consumer reviewer it is powerful and important to be able to be the voice for the many wounded warriors, our families and us. We bring many different skills and experiences to the table and through this diversity complete the intellectual circle. We appreciate the opportunity and take it seriously.”
- Bob Frame, Veteran and Consumer Reviewer
“I think it is important for those of us who have been through the process of being wounded, treated, and living with the injuries to give back if we can.”

MAJ (Ret) David Underwood, Peer Reviewed Orthopaedic Research Program Peer Reviewer

“The (consumer) advocates are the people who can relate beyond the science to the importance of the treatments/research being proposed.”

Mr. Jon Sadler, Peer Reviewed Medical Research Program (PRMRP) Peer Reviewer

“I am in awe at the way the program incorporates and values the consumer opinion.”

Mrs. Tracy Dixon-Salazar, PRMRP Peer Reviewer
Program Cycle

Congressional Appropriation (Restart cycle annually)

Vision Setting

Pre-Application Receipt

Program Announcement Release

Application Receipt

Pre-Application Screening and Invitation to Submit

Peer Review

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Research Closeout

Research Outcomes

Research News and Reports

Month 6

Month 12

To Month 24

Annual Appropriation, Review, and Award Cycle

To Month 84

Awards Management

*As needed

Research & Program Activities
Goal of the Two-Tier Review Process

**Peer Review**
- Criterion-based evaluation of full proposal
- Determination of “absolute” scientific merit
- Outcome: Written critique and scores for individual criteria and overall merit

**Programmatic Review**
- Comparison among proposals of high scientific merit
- Determination of adherence to intent and program relevance
- Outcome: Funding recommendations

**Partnership**
Programmatic Review

Programmatic Panel assesses products from Peer Review

Inputs:
- **Summary Statement** - a supportive description of the evaluation
- **Overall Score** - scientific review panel’s assessment of application merit after consideration of all criteria

Assessment of:
- Scientific Merit
- Impact
- Program Needs
- Portfolio Balance

List of award applications that are recommended for funding
Program Cycle

Congressional Appropriation (Restart cycle annually)

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Annual Appropriation, Review, and Award Cycle

Month 6

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Peer Review

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Research Outcomes

Research News and Reports

As needed

Research & Program Activities
Research & Program Activities

- Program Publications and Websites
- Direct Consumer Involvement in the Research
• Some CDMRP PAs require applications to include consumers in active roles

• Example: **Breakthrough Award, Breast Cancer Research Program (BCRP)**
  
  o The research team must include two or more breast cancer consumer advocates
  
  o Consumer Advocates must play an integral role throughout the planning and implementation of the proposed research project.
  
  o Consumer interactions with other team members should be well integrated and ongoing
  
  o Consumer role should be focused on providing objective input on the research and its potential impact for individuals with, or at risk for, breast cancer.
Value of Consumer Participation

“The most important aspect of being part of the BCRP, for me, has been the interaction with consumer advocates. They have certainly affected the way that I think about breast cancer, but they have also impacted the way that I do science more generally. They are a constant reminder that our goal should be to impact people’s lives.”

Greg Hannon, Ph.D., Chair
FY10 BCRP Programmatic Panel
Value of Consumer Involvement

- Contributes unique professional and personal experiences
- Adds perspective, passion, and a sense of urgency
- Ensures that human dimensions of disease are incorporated into scientific considerations, program policy, investment strategy, and research focus
- Asks why by questioning the impact of proposed research
Frequent Flyer David Masson
A Vietnam Veteran's Story

Consumer Involvement

“it is intellectually challenging and a big commitment. But that is part of what I like so much about serving as a Peer Reviewer: it’s hard work but you come away from it feeling as if you have made a significant contribution, it is incredibly rewarding.”

- Linnea Duff LCRP