

# The Congressionally Directed Medical Research Programs

CUTTING EDGE RESEARCH

Veteran Engagement Initiative Cyberseminar  
Consumer Involvement in the CDMRP

22 June, 2016



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**CDMRP**  
Department of Defense



# Presenters

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**CDMRP/CSRA Consumer Reviewer (Retired US Army)**

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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
  - Reconstructive Transplant
  - Spinal Cord Injury
  - Tick Borne Disease
  - Trauma Clinical
  - Tuberos Sclerosis Complex
  - Vision
- Additional Supported DoD Programs
- Defense Medical R & D
  - Defense Medical R & D Restoral
  - Psychological Health and Traumatic Brain Injury



# Vision and Mission

## Vision

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

## Mission

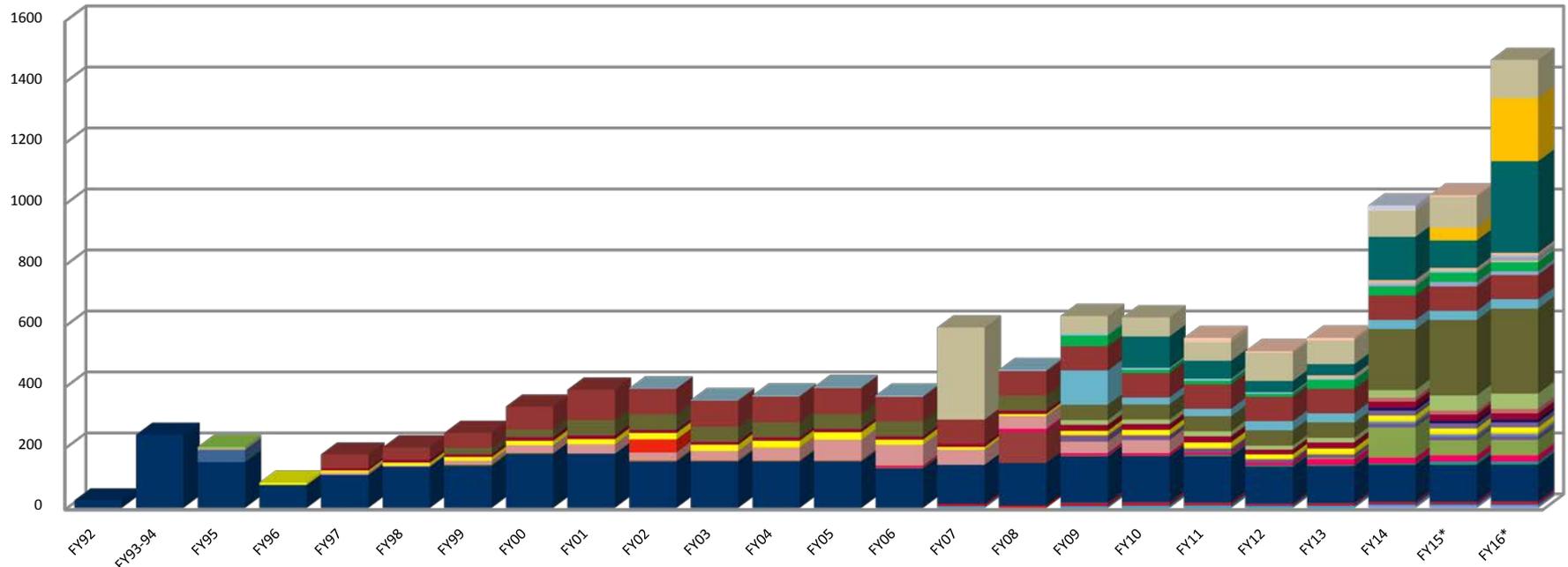
**Responsibly manage collaborative research that discovers, develops, and delivers health care solutions for Service Members, Veterans and the American public**

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

Program	\$M	Program	\$M
Alcohol and Substance Abuse Disorders	\$4.0	Peer Reviewed Alzheimer's	\$15.0
Amyotrophic Lateral Sclerosis	\$7.5	Peer Reviewed Cancer (13 Topics)	\$50.0
Autism	\$7.5	Peer Reviewed Medical (39 Topics)	\$278.7
Bone Marrow Failure	\$3.0	Peer Reviewed Orthopaedic	\$30.0
Breast Cancer	\$120.0	Prostate Cancer	\$80.0
Duchenne Muscular Dystrophy	\$3.2	Reconstructive Transplant	\$12.0
Epilepsy	\$7.5	Spinal Cord Injury	\$30.0
Gulf War Illness	\$20.0	Tick-Borne Disease	\$5.0
Joint Warfighter Medical*	\$50.0	Trauma Clinical Research	\$10.0
Lung Cancer	\$12.0	Tuberous Sclerosis Complex	\$6.0
Military Burn	\$8.0	Vision	\$10.0
Multiple Sclerosis	\$6.0		
Neurofibromatosis	\$15.0	<b>Programs Managed on behalf of Others:</b>	
Neurotoxin Exposure Treatment Parkinson's	\$16.0	Defense Medical R&D*	\$299.6
Orthotics and Prosthetics Outcomes	\$10.0	Defense Medical R&D Restoral*	207.5
Ovarian Cancer	\$20.0	Psychological Health and Traumatic Brain Injury*	\$125.0

\* 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)**

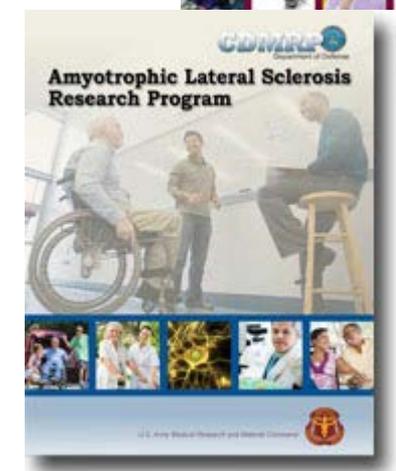
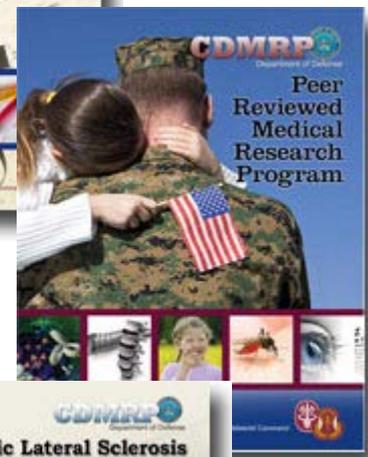
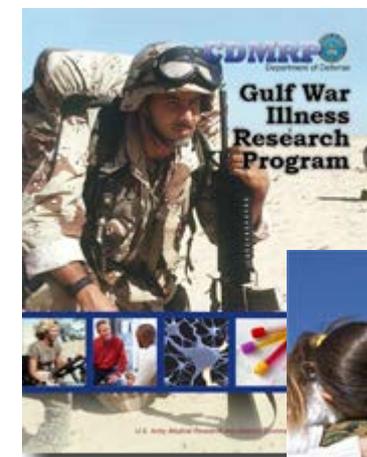
- ❖ Radiation Medical Countermeasures Development

## ◆ **Clinical & Rehabilitative Medicine (JPC-8)**

- ❖ Neuromusculoskeletal Rehabilitation
- ❖ Pain Management
- ❖ Regenerative and Rehabilitative Medicine
- ❖ Sensory Systems (Vision, Hearing, and Balance)

# VA Collaborations

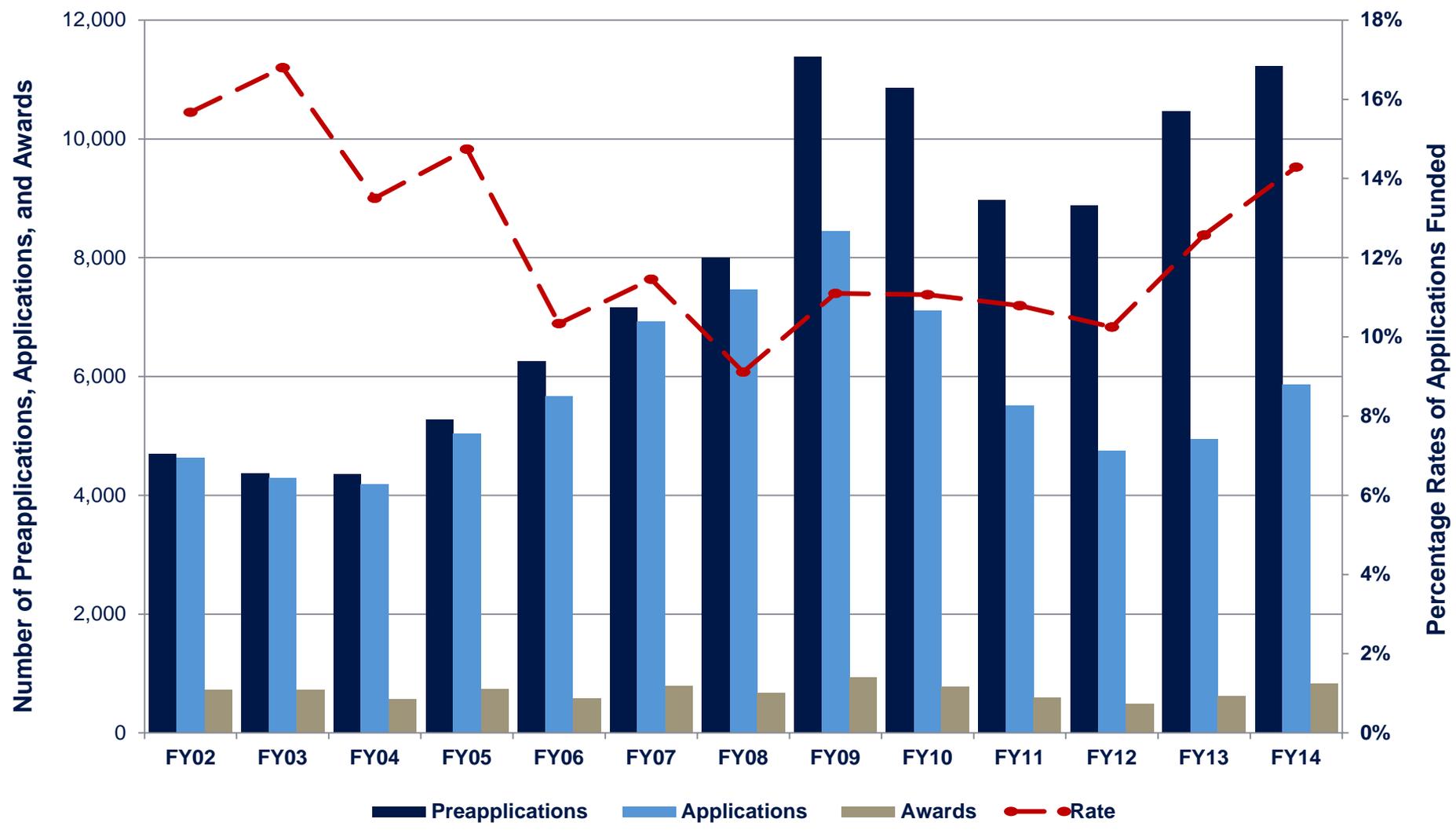
- ◆ CDMRP Program coordination with VA
- ◆ Veterans and VA investigators serving on CDMRP Peer and Programmatic Panels
- ◆ CDMRP-funded VA investigators
- ◆ VA collaborations for research



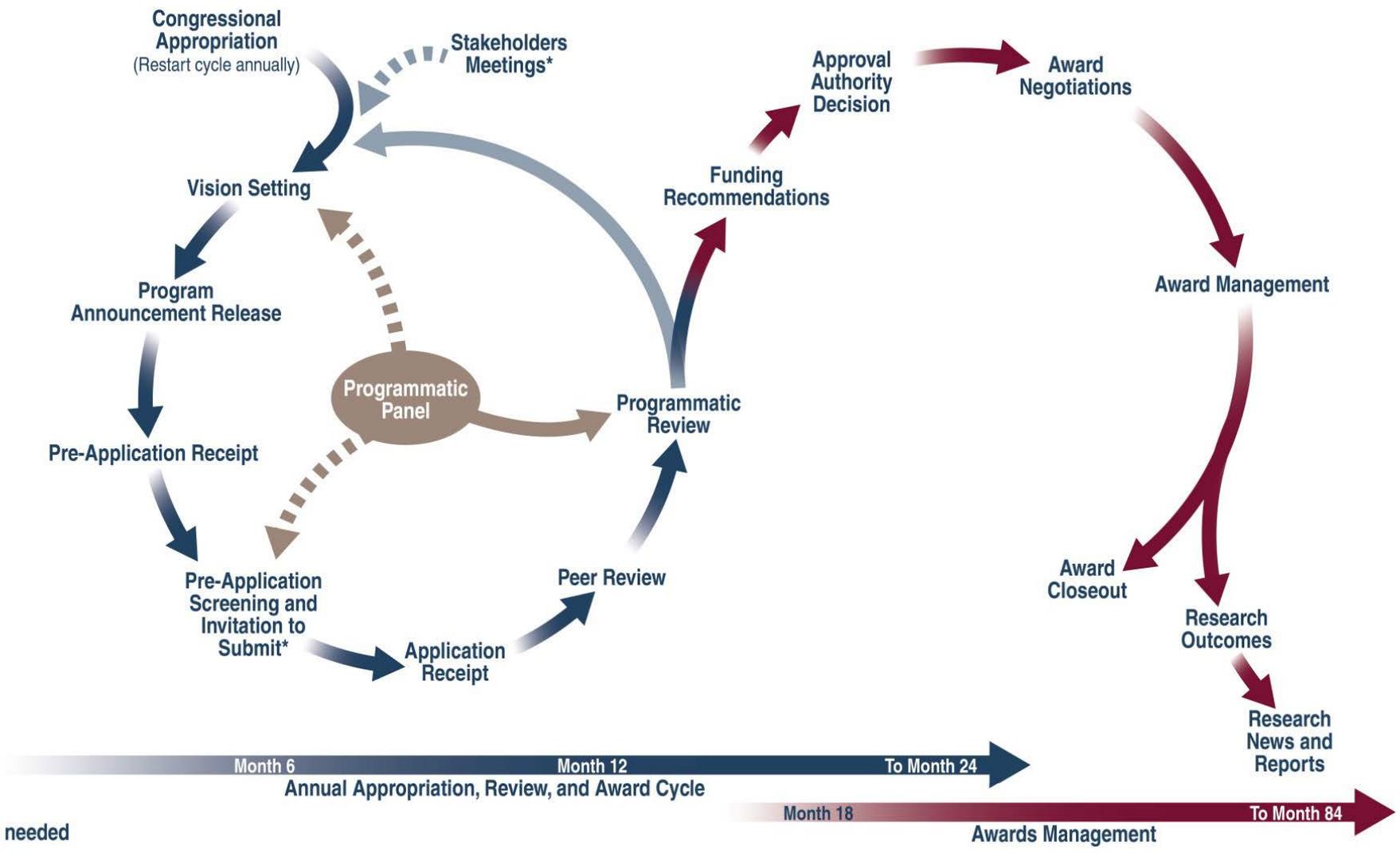
**CAP**  
*CONSORTIUM TO ALLEVIATE PTSD*

 **CENC**  
Chronic Effects of Neurotrauma Consortium

# Applications and Awards

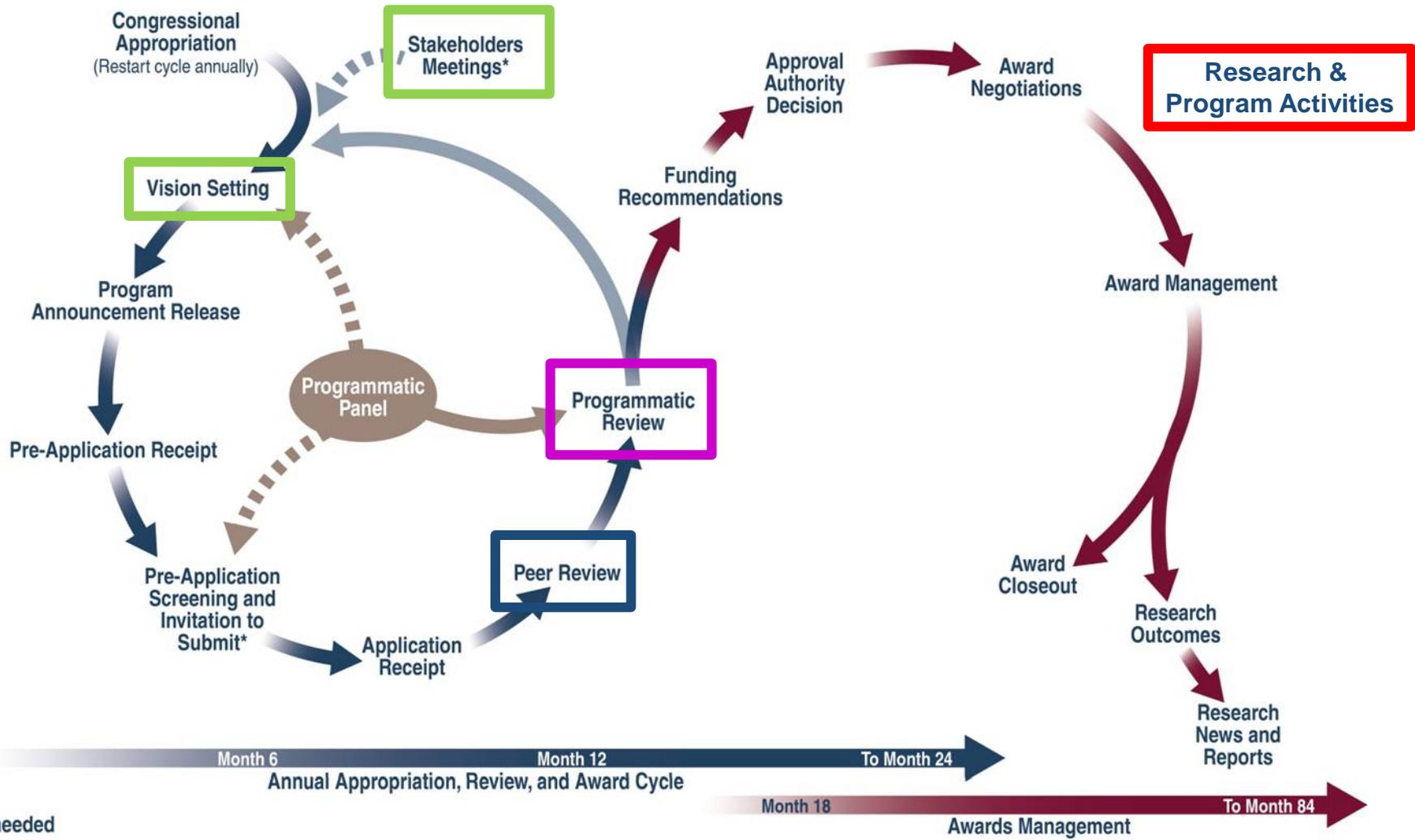


# Program Cycle



\*As needed

# Program Cycle



\*As needed

# Stakeholders Meetings

## Stakeholders

- What happens?
- Who participates?
- Outcome

## What happens?

- Held when new programs are initiated
- Purpose:
  - Survey the research landscape
  - Identify gaps in both scientific and consumer interest areas
  - 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

## Vision Setting

- What happens?
- Who participates?
- Outcome

## 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

## Vision Setting

- What happens?
- Who participates?
- Outcome

## Outcome

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

Award Mechanism	Total Costs	Est. # of Awards	Estimated Investment
Clinical Trial Award	\$3.0 M	3	\$9.0M
Innovator Award	\$5.0 M	2	\$10.0M
Concept Award	\$500K	7	\$3.5M
<b>Total</b>			<b>\$22.50M</b>

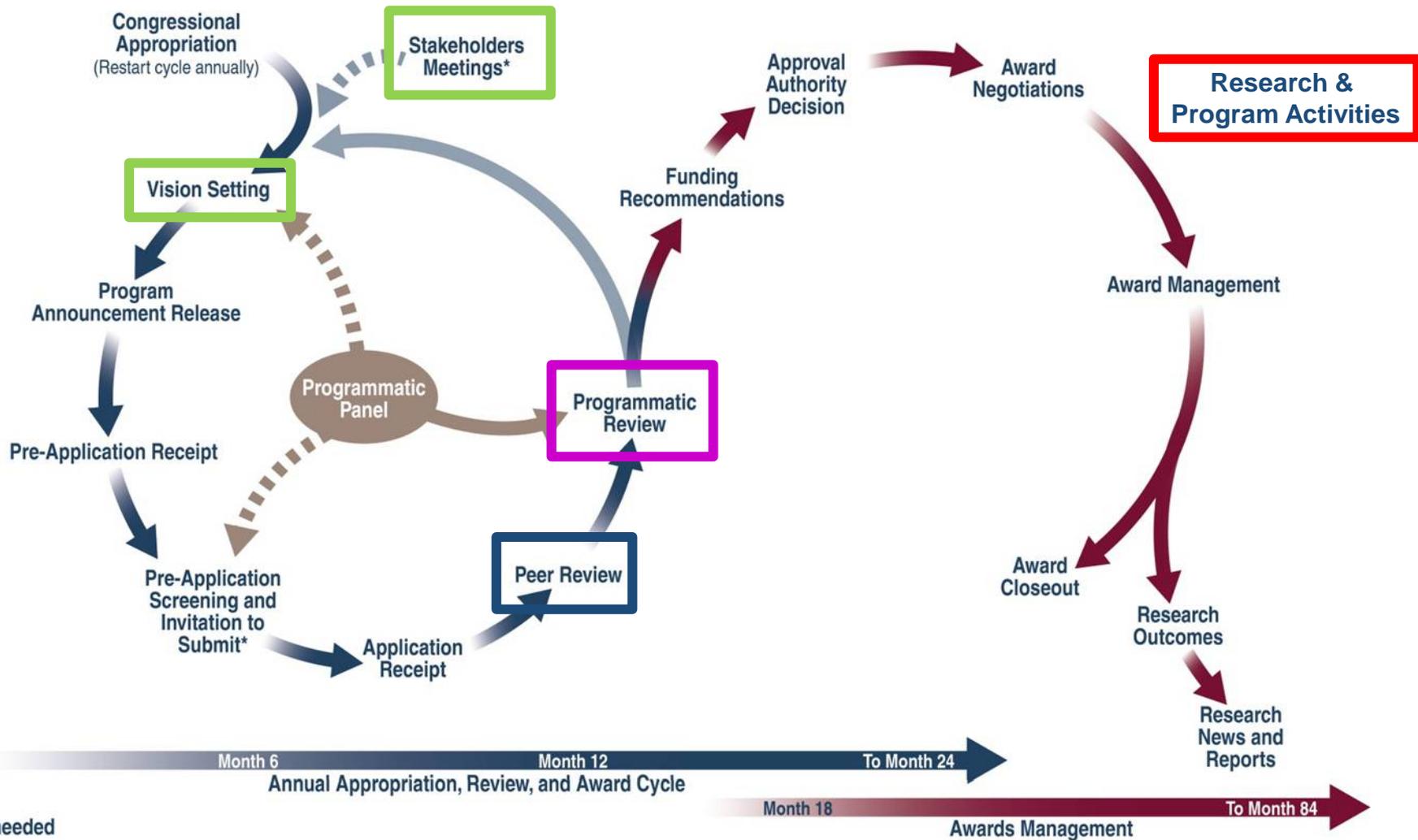
# Vision Setting Outcome: Program Announcements (PAs)

## Vision Setting

- What happens?
- Who participates?
- Outcome

- 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



\*As needed



# **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

# CSRA Consumer Reviewer Engagement for DOD Outreach ➔ Selection ➔ **Assignment** ➔ Support

## 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

# CSRA Consumer Reviewer Engagement for DOD Outreach ➡ Selection ➡ Assignment ➡ Support

## Support

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

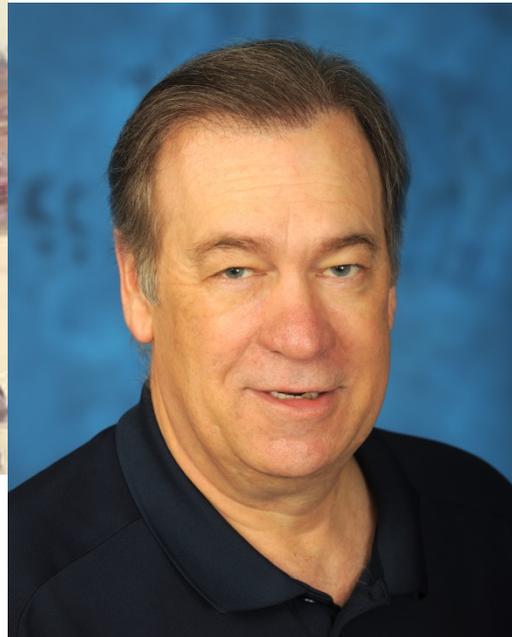
- Plan accommodations for travel and meeting participation
- Support for consumers, caregivers and team members
- Assess for future modifications as needed

# CSRA Consumer Reviewer Engagement for DOD

## Post Peer Review

- 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*

# Consumer Reviewers are Full Partners



MAJ (Ret) David Underwood

***“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**

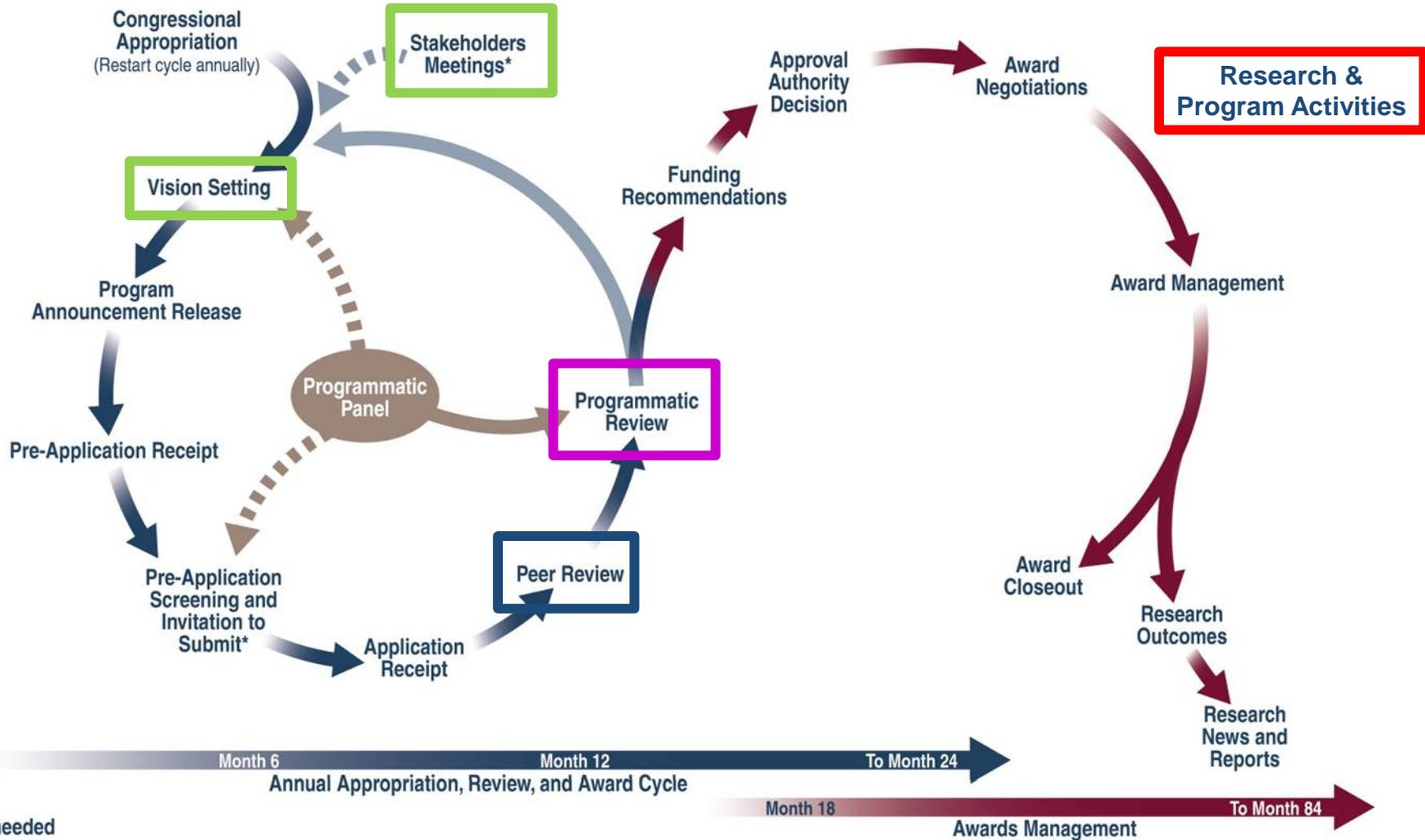
***“The (consumer) advocates are the people who can relate beyond the science to the importance of the treatments/research being proposed.”***

**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



\*As needed

# 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

## Partnership

## Programmatic Review

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

# Programmatic Review

## Programmatic Review



- Who participates?
- Inputs
- Recommended for funding list

## 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

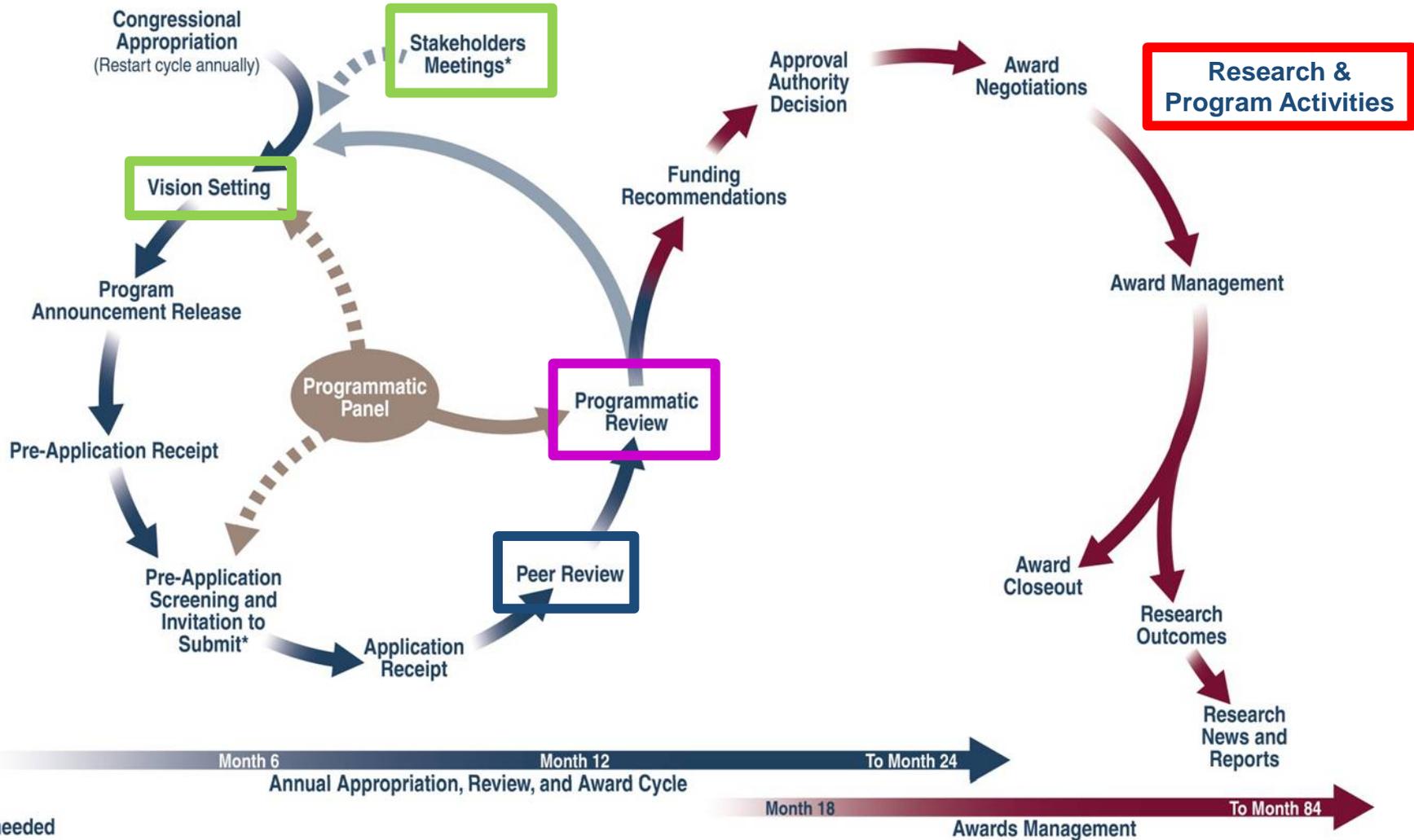


### Assessment of:

- Scientific Merit
- Impact
- Program Needs
- Portfolio Balance

List of award applications that are recommended for funding

# Program Cycle



\*As needed

# Research & Program Activities

## Research & Program Activities

- Program Publications and Websites
- Direct Consumer Involvement in the Research

**Congressionally Directed Medical Research Programs**  
ANNUAL REPORT  
SEPTEMBER 30, 2015

“There is no better way to give back to those who saved my life.”

**Vital Partnerships**

DEPARTMENT OF DEFENSE - CONGRESSIONALLY DIRECTED MEDICAL RESEARCH PROGRAMS

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A Vietnam Veteran's Story

**Latest News**

- CDMRP Vice President Biden and Dr. Jill Biden Address the Cancer Research Community at the AACR Annual Meeting 2016
- PRORP LTC Luis N. Alvarez, PHD
- PCRPP Potential Cholesterol-Lowering Drug Molecule Has Prostate Cancer Fighting Capabilities

More News >

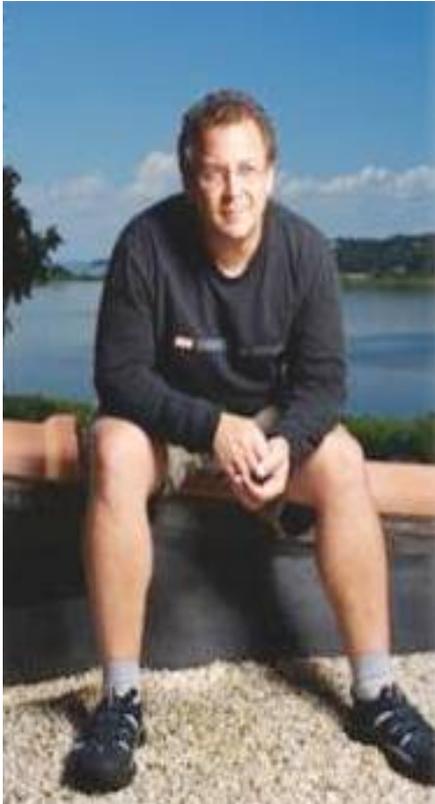
# Research and Program Activities

## 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)**
  - The research team must include two or more breast cancer consumer advocates
  - Consumer Advocates must play an integral role throughout the planning and implementation of the proposed research project.
  - Consumer interactions with other team members should be well integrated and ongoing
  - 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**





CDMRP

Transforming Healthcare through Innovative and Impactful Research

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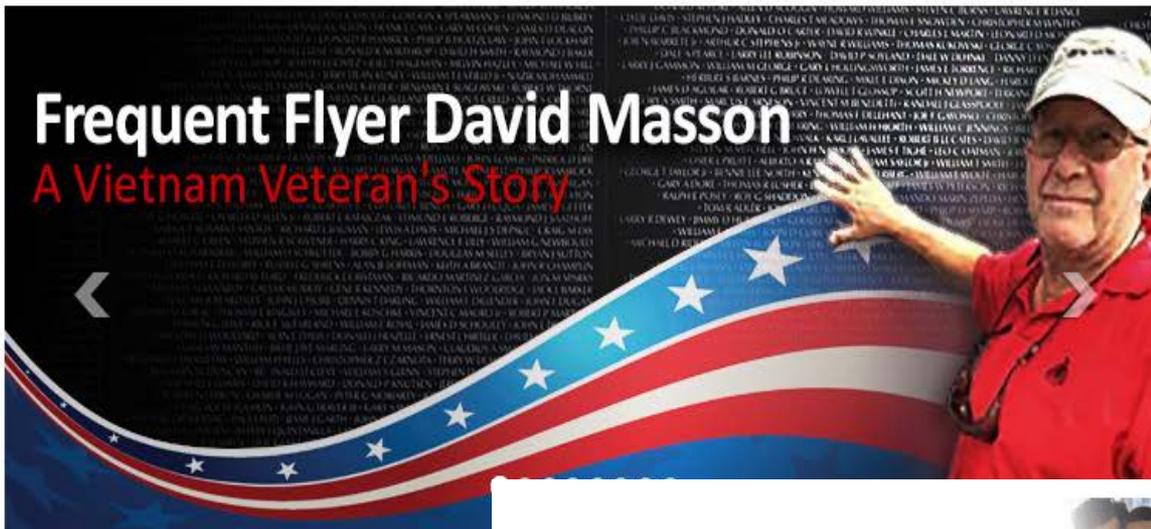
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# Frequent Flyer David Masson

## A Vietnam Veteran's Story



### Latest News



Vice President Biden and Dr. Jill Biden Address the Cancer Research Community at the AACR Annual Meeting 2016  
American Association for Cancer Research, April 26, 2016



LTC Luis N. Alvarez, PhD  
The Geneva Foundation, April 19, 2016



Potential Cholesterol-Lowering Drug Molecule Has Prostate Cancer Fighting Capabilities  
University of Missouri, April 19, 2016

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## 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



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