The Congressionally Directed Medical Research Programs

Peer Reviewed Medical Research Program (PRMRP)

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Hydrocephalus Research Workshop

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Transforming Healthcare through Innovative and Impactful Research



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Vision and Mission





Vision

Transforming healthcare through innovative and impactful research



Mission

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



STEWARDSHIP



- Manages targeted research funds added by Congress to the DOD budget
- Obligates funds up-front; limited out-year budget commitments
- Maximizes funding available for research through low management costs and efficient processes
- Maintains transparency and accountability

COLLABORATION



- Integrates consumers as full participants throughout program processes and as the "True North" of CDMRP
- Collaborates with other funding organizations complimentary, not duplicative

Hallmarks



STRATEGY



- Annually adapts each program's vision and investment strategy, allowing rapid response to changing needs, opportunities, and congressional intent
- Publicly announces and competes funding opportunities
- Ensures scientific excellence and programmatic relevance through the National Academy of Medicine-recommended two-tiered review process

IMPACT



- Targets research that fills gaps and addresses high-priority needs
- Funds impactful, innovative research for specific programs added by Congress to the Defense Appropriations Bill
- Focused on improving health, well-being, and health care quality for those affected

CDMRP FY24 Appropriations



Research Program	FY24 \$M	Research Program	FY24 \$M
Alcohol and Substance Use Disorders	\$4.0	Neurofibromatosis	\$25.0
Amyotrophic Lateral Sclerosis	\$40.0	Ovarian Cancer	\$45.0
Arthritis (New for FY24)	\$10.0	Pancreatic Cancer	\$15.0
Autism	\$15.0	Parkinson's	\$16.0
Bone Marrow Failure	\$7.5	Peer Reviewed Alzheimer's	\$15.0
Breast Cancer	\$150.0	Peer Reviewed Cancer (18 Topics)	\$130.0
Combat Readiness Medical	\$5.0	Peer Reviewed Medical (42 Topics)	<mark>\$370.0</mark>
Duchenne Muscular Dystrophy	\$10.0	Peer Reviewed Orthopaedic	\$30.0
Epilepsy	\$12.0	Prostate Cancer	\$110.0
Hearing Restoration	\$5.0	Rare Cancers	\$17.5
Glioblastoma (New for FY24)	\$10.0	Reconstructive Transplant	\$12.0
Joint Warfighter Medical	\$20.0	Spinal Cord Injury	\$40.0
Kidney Cancer	\$50.0	Tick-Borne Disease	\$7.0
Lung Cancer	\$25.0	Toxic Exposures	\$30.0
Lupus	\$10.0	Traumatic Brain Injury and Psychological Health	\$175.0
Melanoma	\$40.0	Tuberous Sclerosis Complex	\$8.0
Military Burn	\$10.0	Vision	\$20.0
Multiple Sclerosis	\$20.0		
		TOTAL = \$1.51B	

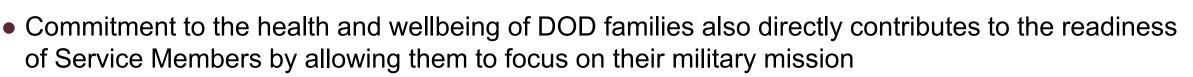
CDMRP Relevance and Impact



 Every program aligns with CDMRP's overarching vision of transforming healthcare for Service Members (SMs), Veterans and the American public

Select examples of incidence in the military:

- Post-traumatic epilepsy affects >2,000 Iraq/Afghanistan War Veterans, with 5x higher mortality rate
- Female active duty SMs have a higher incidence rate of breast cancer
- SMs are at a 50% greater risk for ALS
- Substance abuse responsible for ~30% of Army's suicide deaths
- Deployment associated with 1.8-fold increased risk of Parkinson's
- Risk of dementia is 2-4x higher in SMs; increases by 70% following a TBI



- Over 15,000 military dependents have a diagnosis of autism spectrum disorder

 CDMRP-funded research generates products that provide better preventions, novel diagnostics and prognostics, improved treatments and therapies, and more effective rehabilitation and restorative strategies – <u>to improve lives</u>



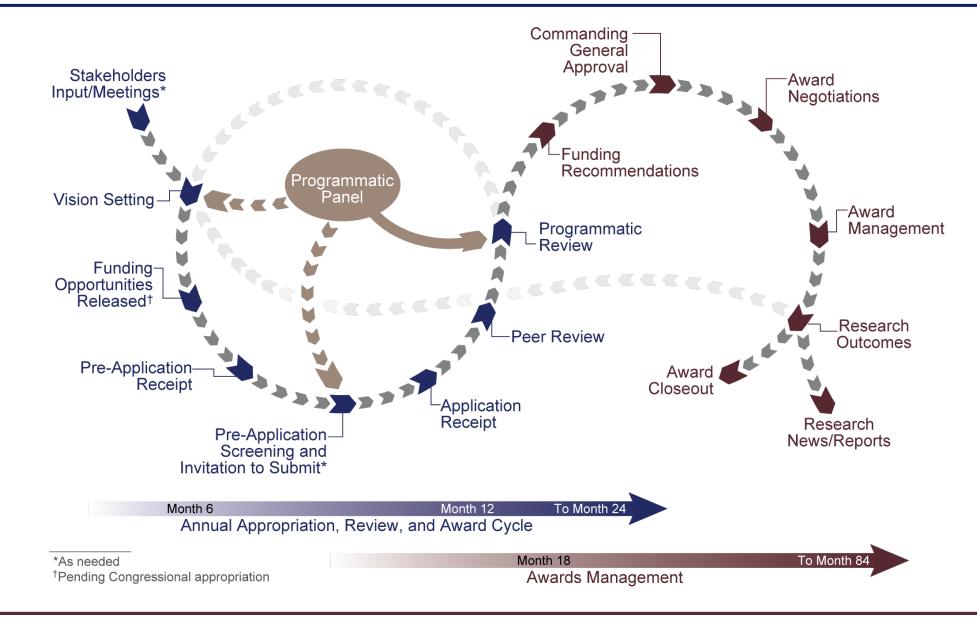
CDMRP Program Cycle and Review Process

Transforming Healthcare through Innovative and Impactful Research



Program Cycle





CDMRP Award Mechanisms



- Funding Opportunities are Program Announcements (PAs) or program-specific broad agency announcements (BAAs)
 - Grants/Cooperative Agreements (few contracts/other transactions)
- Numerous types of award mechanisms
 - Tailored to the goals of each program
 - Programs, topics, and focus areas may vary from year to year
 - Fund the full continuum of research





To develop funding recommendations that balance *the most meritorious science* across many disciplines and offer the highest promise to *fulfill the programmatic goals* set forth in the funding opportunity



No continuation funding



Video and additional information available at: https://cdmrp.health.mil/about/2tierRevProcess

Consumers are the "True North" and Foundation of the CDMRP



CDMRP includes consumers - patients, survivors, family members, and/or caregivers in every aspect of the program lifecycle.

Consumers serve as full voting members on peer review and programmatic panels. Through their lived experiences with the target disease, disorder, or injury, consumers represent their respective communities and add valuable perspectives and a sense of urgency to the program mission, investment strategy, and research focus.





FY22 Consumer Involvement

80 consumers* were assigned to Programmatic Panels as members and ad hoc reviewers representing 65 consumer advocacy organizations, active-duty Service Members, or

855 consumer reviewers** were assigned to Peer Review Panels

(nominating) organizations

Consumer advocates also participate on research teams

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Peer Reviewed Medical Research Program (PRMRP)

Transforming Healthcare through Innovative and Impactful Research





Vision: Improve the health, care, and well-being of all military Service Members, Veterans, and their Families

Mission: Encourage, identify, select and manage medical research projects of clear scientific merit that lead to impactful advances in health care of Service Members, Veterans, and their Families

- Initiated in 1999 to address diseases and conditions with relevance to military health
- Direction from congress to support research of "clear scientific merit" and "direct relevance to military health" in specified <u>topic areas</u>

Peer Reviewed Medical Research Program





https://cdmrp.health.mil/prmrp/default

FY24 Topic Areas (42 total) for Peer Reviewed Medical Research Program

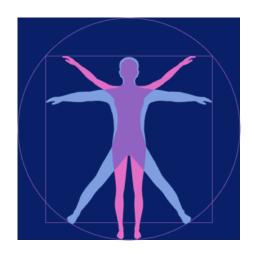


- Accelerated Aging Processes Associated with the Military*
- Celiac Disease
- Computational Biology for Precision Health*
- Congenital Cytomegalovirus*
- Congenital Heart Disease
- Dystonia
- Eating Disorders
- Ehlers-Danlos Syndrome
- Epidermolysis Bullosa
- Far-UVC Germicidal Light*
- Fibrous Dysplasia/McCune Albright Syndrome
- Focal Segmental Glomerulosclerosis
- Food Allergies
- Fragile X
- Frontotemporal Degeneration
- Guillain-Barre Syndrome

- Hepatitis B
- Hereditary Ataxia
- Hydrocephalus
- Inflammatory Bowel Disease
- Interstitial Cystitis
- Lymphedema
- Malaria
- Maternal Mental Health
- Mitochondrial Disease
- Musculoskeletal Disorders Related to Acute and Chronic Bone Conditions and Injuries
- Myalgic Encephalomyelitis/ Chronic Fatigue Syndrome
- Myotonic Dystrophy
- Nephrotic Syndrome
- Neuroactive Steroids
- Pancreatitis
- Peripheral Neuropathy

- Polycystic Kidney Disease
- Proteomics
- Pulmonary Fibrosis
- Respiratory Health
- Rett Syndrome
- Scleroderma
- Sickle-Cell Disease
- Suicide Prevention
- Vascular Malformations
- Von Hippel-Lindau Syndrome

Applicants must address at least one of the Topic Areas, which are directed by Congress



*Assigned for the first time in FY24

PRMRP's Portfolio-Driven Approach



Autoimmune Disorders and Immunology	Cardiovascular Health		Infectious Diseases		Internal Medicine	
 Celiac Disease Computational Biology for Precision Health Food Allergies Guillain-Barre Syndrome Inflammatory Bowel Disease Proteomics Scleroderma 	 Computational Biology for Precision Health Congenital Heart Disease Proteomics Vascular Malformations 	on	 Computational Biol Precision Health Congenital Cytome Far-UVC Germicida Hepatitis B Malaria Proteomics 	egalovirus	with Milit • Computa • Focal Se • Interstitia • Lympheo • Nephroti • Pancrea	dema c Syndrome titis ic Kidney Disease
• Accelerat Processe Associate Military S • Computa Biology for Health	es Disorders Related to ed with Acute and Chronic ervice Bone Conditions and		Respiratory Health	 Computational E Precision Health Proteomics 	1	Pulmonary FibrosisRespiratory Health
 Computation for Precision Eating Dison Maternal Methealth Myalgic Encephalom Chronic Fation Syndrome 	ders • Proteomics Intal • Suicide Prevention		Rare Diseases and Conditions	 Computational Bio Precision Health Dystonia Ehlers-Danlos Sy Epidermolysis Bu Fibrous Dysplasia McCune-Albright Fragile X Frontotemporal D Hereditary Ataxia 	ndrome llosa a/ Syndrome egeneration	 Hydrocephalus Mitochondrial Disease Myotonic Dystrophy Proteomics Rett Syndrome Sickle-Cell Disease Von Hippel-Lindau Syndrome

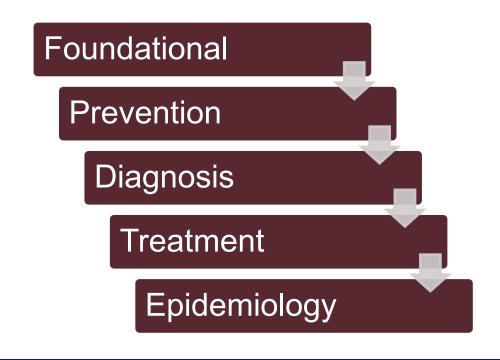
Program Priorities Set at the Portfolio Level





Portfolio-Specific **Strategic Goals**:

- Devised in coordination with key stakeholders
- Aligned to the Continuum of Care



Applications must address ONE Topic Area and ONE Strategic Goal



Example: Rare Diseases and Conditions Portfolio Strategic Goals

Foundational Studies

- Identify biological mechanisms underlying disease onset, disease progression, or phenotype/symptomatic heterogeneity, including studies to address sex, gender, ethnic and/or racial differences.
- Elucidate how biomarkers (including genotype) are linked to disease phenotype or subtype.
- Develop novel preclinical models that recapitulate the phenotype of human disease.

<u>Diagnosis</u>

- Identify and validate objective biomarkers to predict onset, response to therapy, disease complications and/or disease progression.
- Develop and validate improved diagnostic criteria and screening tools for early detection or to track disease progression.
- Determine the physiological impact related to diagnosis and/or timing of a diagnosis.

Topic Areas

- <u>Computational Biology</u>
 for Precision Health
- Dystonia
- Ehlers-Danlos Syndrome
- Epidermolysis Bullosa
- Fibrous
 - Dysplasia/McCune-Albright Syndrome
- Fragile X
- Frontotemporal
 Degeneration
- Hereditary Ataxia
- Hydrocephalus
- Mitochondrial Disease
- Myotonic Dystrophy
- Proteomics
- Rett Syndrome
- Sickle-Cell Disease
- Von Hippel-Lindau
 Syndrome

Applications must address one Strategic Goal and one Topic Area



Example: Rare Diseases and Conditions Portfolio Strategic Goals

<u>Treatment</u>

- Develop and test pharmacological or nonpharmacological treatments, or improve upon existing treatments, especially those that will minimize side effects.
- Develop and test curative strategies to include tissue engineering, genetic approaches, or protein replacement.
- Develop and test interventions to improve neuropsychological outcomes and cognitive symptoms and other comorbidities as defined by those with lived experience.
- Develop and test strategies to support ongoing treatments during life transitions (i.e., pediatric to adult care).

Epidemiology

- Conduct population-based studies to identify risk (i.e., carrier status), lifestyle determinates of health or protective factors that influence onset, progression and/or outcomes.
- Conduct natural history/longitudinal studies to understand incidence, prevalence, and progression of the disease/condition and carrier and modifier gene status.
- Develop and validate research tools to collect, mine, and integrate real-world data (patientreported data, longitudinal data, etc.) with electronic medical records to guide precision medicine approaches.
- Develop clinically relevant endpoints for clinical trials.

Applications must address one Strategic Goal and one Topic Area

Topic Areas

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FY24 PRMRP Funding Opportunities Available



Basic Research		Translationa	al Research	Clinical Trials/Clinical Research		
	Discovery Award	Investigator- Initiated Research Award	Impact Award	Technology/ Therapeutic Development Award	Lifestyle Behavioral Health Intervention Research Award	Clinical Trial Award
	<u>Direct Cost Max:</u> \$275K	Direct Cost Max: \$1M	Direct Cost Max: \$2M/\$2.6M	<u>Direct Cost Max:</u> \$4M	Direct Cost Max: \$3M	Direct Cost Max: No direct cost limit
	LOI/Invite: Letter of Intent	LOI/Invite: Letter of Intent	LOI/Invite: Letter of Intent	LOI/Invite: Letter of Intent	LOI/Invite: Letter of Intent	<u>LOI/Invite:</u> Preproposal
	Novel/ breakthrough exploratory research, high risk/high reward	Preclinical expansion, replications and/or comparative studies to validate preliminary or published data	Mature research studies with potential near term clinical impact for patients	Final steps of clinical translation (IND-/IDE- enabling or studies required to transition a product of prototype utility)	Clinical trials/research focused on non- pharmacological therapies, non- invasive devices, patient outcomes or quality of life	Early-phase or large scale interventional clinical trials to measure safety, effectiveness and/or efficacy outcomes



Award Mechanism	LOI	Pre-Proposal	Dates	Invitation to submit	Full Application Deadline
Discovery Award (DA)	\checkmark	*	06 May 2024	*	23 May 2024
Investigator-Initiated Research Award (IIRA)		*	06 May 2024	*	23 May 2024
Impact Award (IPA)	\checkmark	*	13 May 2024	*	06 June 2024
Technology/Therapeutic Development (TTDA)	\checkmark	×	13 May 2024	*	06 June 2024
Lifestyle and Behavioral Health Interventions (LBIRA)	\checkmark	*	13 May 2024	*	06 June 2024
Clinical Trial (CTA)	*		13 May 2024	17 June 2024	19 August 2024

Questions? For more information, please visit: cdmrp.health.mil



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