

HEALTH AND BIOMEDICAL RESEARCH AT THE DEPARTMENT OF DEFENSE

Lewis-Burke Associates LLC

June 29, 2021



LEWIS-BURKE
ASSOCIATES LLC

TODAY'S TALK

- Introduction to Lewis-Burke
- Overview of Defense Health Research Funding and Agencies
- Best Practices and Opportunities for Engaging with DOD
- Discussion

ABOUT LEWIS-BURKE

- Twenty-seven policy experts with range of expertise/backgrounds allow multi-layered issue teams with deep expertise in agencies and scientific/higher education areas
- Support federal relations activities to develop and implement federal strategies to pursue, shape, and create new sources of funding to increase and diversify research portfolio
- Able to engage on multiple levels:
 - Individual faculty (including early career faculty)
 - Teams of faculty
 - Associate deans for research
 - Deans and center directors
 - University leadership and campus-wide priorities/activities
- Lewis-Burke began working with TTUS in fall 2015
- Primary points of contact: Dr. Min Kang, Dr. Cynthia Jumper, Smiley Garcia, Jennifer Brown, and Kristina Butts

OVERVIEW OF DEFENSE HEALTH RESEARCH FUNDING AND AGENCIES

DOD VS. NIH

Defense Health Program

- \$2.3 billion in FY 2021
- Other limited funding through the Services and DARPA/DTRA
- Mission: “Responsively and responsibly create, develop, acquire, and deliver capabilities for the warfighter”

National Institutes of Health

- \$42.9 billion in FY 2021
- Mission: “To seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability”

DEFENSE HEALTH RESEARCH PRIORITIES

- **Infectious Disease** – COVID-19, prevention, diagnostics, therapeutics, surveillance, warfighter v. civilian health
 - **Hemorrhage** – blood products (storage, transportation, in theater transfusions); extend blood platelet shelf life; improved pre-hospital treatments for critical patients; alternatives to using anti-biotics for post wound care
 - **Combat casualty care** – surgical systems and procedures, surgical en-route care, neurotrauma, minimizing blast-related injury
 - **Traumatic Brain Injury (TBI)** – classification of TBIs that can inform future technology and treatment strategies; biomarkers to replace CAT scans (affordability); development of chronic traumatic encephalopathy (CTE)
 - **Mental Health** – PTSD, suicide prevention; substance abuse, rural healthcare/telemedicine
 - **Pain Management** – Burn care, opioid use/misuse
 - **Health IT** – electronic health records, mobile health technology, telemedicine (in theater and at home)
 - **Chemical, Biological, Radiological, and Nuclear (CBRN) Threats** – surveillance, prevention, detection, and treatment
 - **Human Performance Optimization** – readiness, rehabilitation, fatigue/sleep, nutrition
-

DEFENSE HEALTH FUNDING AGENCIES

Defense Health Program

- Defense Medical Research and Development Program (DMRDP) / Army Medical Research and Development Command
- Congressionally Directed Medical Research Program (CDMRP)

Defense-Wide and the Services

- Defense Advanced Research and Development Authority (DARPA)
- Defense Threat Reduction Agency (DTRA)
- Office of Naval Research (ONR)
- Air Force Office of Scientific Research (AFOSR)

DEFENSE MEDICAL RESEARCH AND DEVELOPMENT PROGRAM

DOD Core Programs/Projects Program Area Directorates/Joint Program Committees:

- Combat Casualty Care
- Radiation Health Effects
- Military Infectious Diseases
- Medical Simulation and Information Sciences
- Military Operational Medicine
- Clinical and Rehabilitative Medicine

Funding Mechanisms:

- USAMRDC FY 2018-2022 broad agency announcement (BAA): <https://www.usamraa.army.mil/Pages/BAA.aspx>
- USAMRDC new products and ideas submission tool: <https://mrdc-npi.amedd.army.mil/>
- As-needed FOAs released through CDMRP website: <https://cdmrp.army.mil/dmrdp/default>

CONGRESSIONALLY-DIRECTED MEDICAL RESEARCH PROGRAM

Mission: *“Responsibly manage collaborative research that discovers, develops and delivers health care solutions for Service Members, veterans, and the American public.”*

- Started in 1992 to support breast cancer research – has since supported research in more than 50 topic areas
- Created as way for Congress to assert influence over biomedical research agenda
- CDMRP funds added annually by appropriators – not part of President’s Budget Request or NDAA
- Congress dictates topics, but open competitions/peer review employed in funding decisions

CDMRP FY 2021 TOPICS

- Peer-Review Medical (**\$370 m**)
- Traumatic Brain Injury and Psychological Health (**\$175 m**)
- Breast Cancer (\$150 m)
- Peer-Review Cancer (**\$115 m**)
- Prostate Cancer (\$110 m)
- Joint Warfighter Medical (\$40 m)
- Spinal Cord (\$40 m)
- Kidney Cancer (**\$50 m**)
- Ovarian Cancer (\$35 m)
- Peer-Review Orthopedic (\$30 m)
- Gulf War Illness (\$22 m)
- Amyotrophic Lateral Sclerosis (**\$40 m**)
- Vision (\$20 m)
- Melanoma (**\$30 m**)
- Multiple Sclerosis (**\$20 m**)
- Neurotoxin Exposure Treatment Parkinson's (\$16 m)
- Neurofibromatosis Research (**\$20 m**)
- Chronic Pain Management (\$15 m)
- Combat Readiness Medical Research (\$10 m)
- Alzheimer's Disease (\$15 m)
- Autism Research (\$15 m)
- Orthotics and Prosthetics Outcomes (\$15 m)
- Epilepsy (\$12 m)
- Lupus (\$10 m)
- Duchenne Muscular Dystrophy (\$10 m)
- Lung Cancer Research (\$20 m)
- Reconstructive Transplant (\$12 m)
- Military Burn (\$10 m)
- Hearing Restoration (\$10 m)
- Rare Cancers Research (**\$17.5 m**)
- Tuberous Sclerosis (**\$8 m**)
- Pancreatic Cancer (**\$15 m**)
- Scleroderma (\$5 m)
- Bone Marrow Failure (**\$7.5 m**)
- Alcohol and Substance Use Disorders (\$4 m)

Bolded items reflect increases in FY 2021

PEER REVIEWED MEDICAL RESEARCH PROGRAM FY 2021 TOPICS

- Arthritis
- Burn Pit Exposure
- **Cardiomyopathy***
- Congenital Heart Disease
- Constrictive Bronchiolitis
- Diabetes
- Dystonia
- Eating Disorders
- Emerging Viral Diseases
- Endometriosis
- Epidermolysis Bullosa
- Familial Hypercholesterolemia
- Fibrous Dysplasia
- Focal Segmental Glomerulosclerosis
- Food Allergies
- Fragile X
- Frontotemporal Degeneration
- Hemorrhage Control
- Hepatitis B
- Hydrocephalus
- **Hypertension***
- Inflammatory Bowel Diseases
- **Malaria***
- Metals Toxicology
- Mitochondrial Disease
- Myalgic Encephalomyelitis/Chronic Fatigue Syndrome
- Myotonic Dystrophy
- **Non-opioid therapy for pain management***
- Nutrition Optimization
- Pathogen-Inactivated Blood Products
- **Peripheral Neuropathy***
- Plant-Based Vaccines
- **Platelet Like Cell Production***
- Polycystic Kidney Disease
- Pressure Ulcers
- Pulmonary Fibrosis
- Respiratory Health
- Rheumatoid Arthritis
- Sleep Disorders and Restriction
- **Suicide Prevention***
- Sustained Release Drug Delivery
- Vascular Malformations
- Women's Heart Disease

***Denotes** new or revised topic in FY 2021

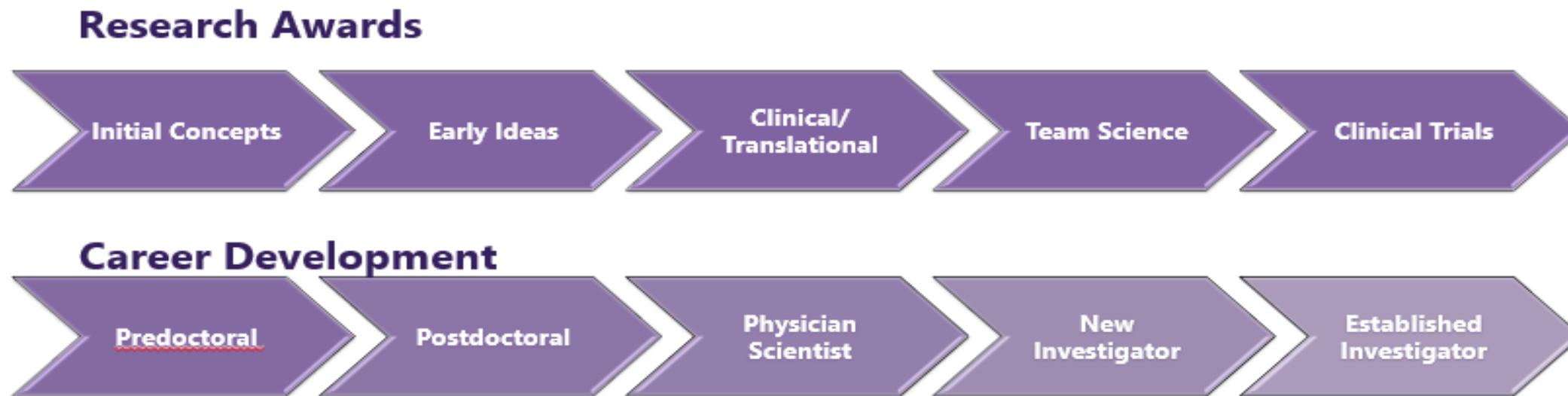
PEER REVIEWED CANCER RESEARCH PROGRAM

- **Cancers associated with the use of beryllium***
- Bladder cancer
- Blood cancers
- Brain cancer
- Colorectal cancer
- **Endometrial cancer***
- Esophageal cancer
- **Germ cell cancer***
- Head and neck cancer
- Liver cancer
- **Lymphoma***
- Mesothelioma
- Metastatic cancers
- Neuroblastoma
- Pediatric brain tumors
- Pediatric, adolescent, and young adult cancers
- **Sarcoma***
- Stomach cancer
- **Thyroid cancer***
- **Link between scleroderma and cancer***

*Denotes new or revised topic in FY 2021

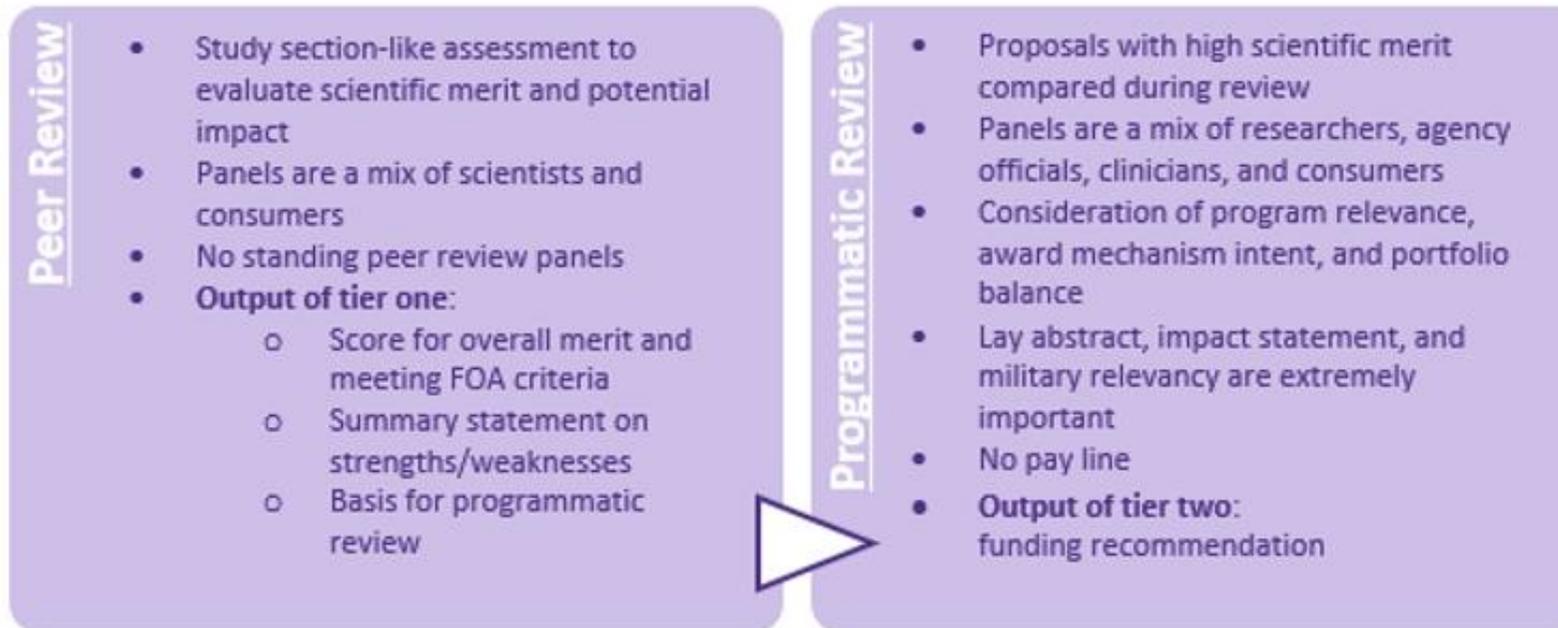
CDMRP PROPOSAL PROCESS

- Proposal windows vary throughout the year
- Pre-application required
- Highly competitive: Success rates average around 15% (range of 10-30 percent)
- Various research awards at all career stages:

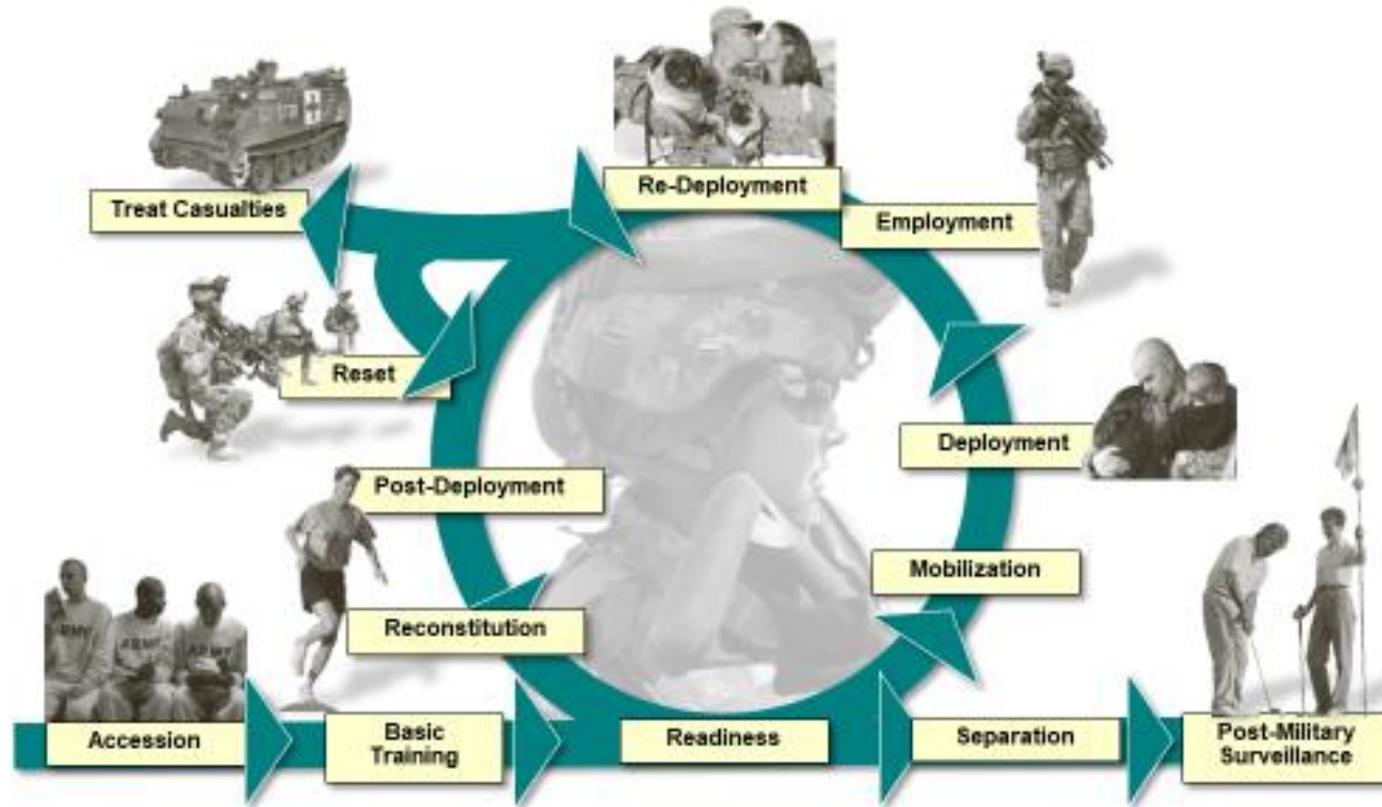


CDMRP REVIEW PROCESS

Two-tier review process: peer review for scientific merit and programmatic review to ensure the DOD mission and needs are met

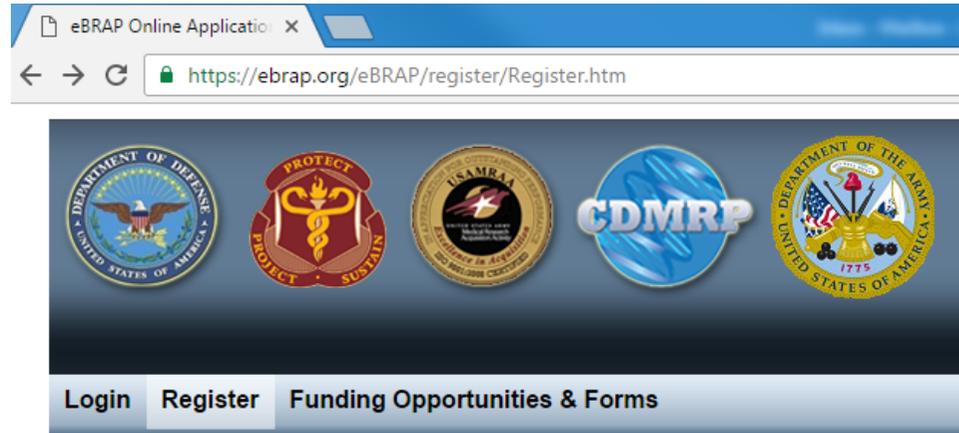


Military Medical Research Impacts the Service Member, Their Family, and Their Community



DEVELOPING AND MAINTAINING A FIT AND READY FORCE

RESOURCES FOR DMRDP AND CDMRP



Welcome to eBRAP

Register

I am a new:

*Select from drop down

Program News and Updates

- Welcome to eBRAP. To access the user guide, please [click here](#).

Email Subscriptions

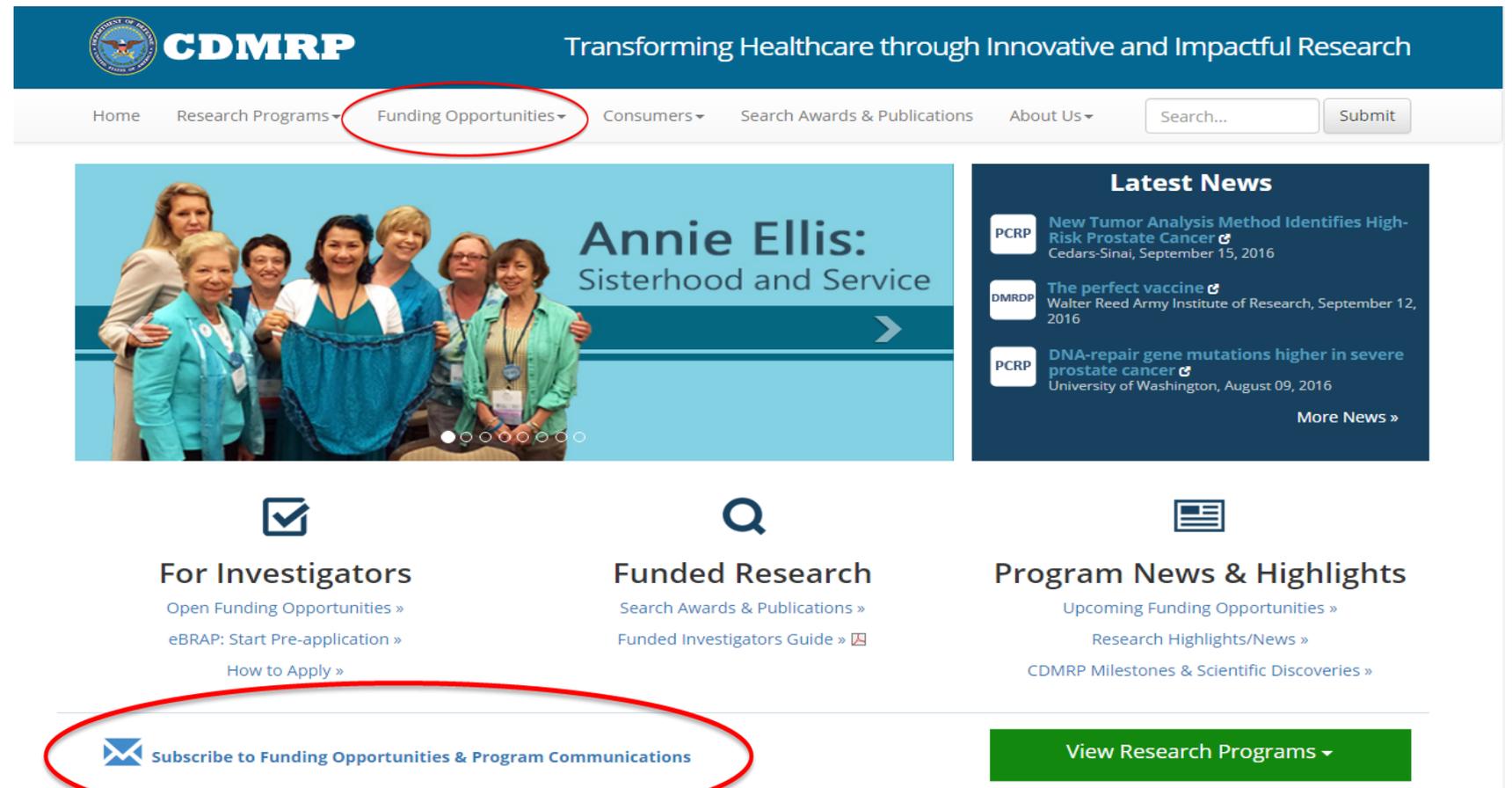
- To subscribe to program specific news and updates, please [click here](#)
- To remove your email from program subscription list, please [click here](#)

Help

- [Frequently Asked Questions](#)
- [Commonly Made Mistakes](#)
- [Contact the helpdesk/webmaster](#)

Additional Funding Opportunity Postings:

- www.grants.gov
- <https://sam.gov/content/home>
- www.eBRAP.org



For Investigators

- [Open Funding Opportunities »](#)
- [eBRAP: Start Pre-application »](#)
- [How to Apply »](#)

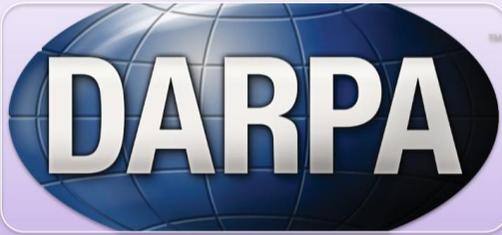
Funded Research

- [Search Awards & Publications »](#)
- [Funded Investigators Guide »](#)

Program News & Highlights

- [Upcoming Funding Opportunities »](#)
- [Research Highlights/News »](#)
- [CDMRP Milestones & Scientific Discoveries »](#)

DEFENSE-WIDE AND THE SERVICES



- High-risk, high-reward basic and applied biomedical research
- Biological Technologies (BTO) and Defense Science (DSO) Offices fund relevant research
- Current priorities: human-machine teaming, vaccine delivery, infectious diseases, synthetic biology, and neuroscience



- Warfighter Performance (Code 34) funds biomedical and health-related research
- Current priorities: stress response, undersea medicine and performance, neuroscience, gut microbiology, physiological monitoring, synthetic biology, and biomaterials



AFOSR funds biomedical-related research through Chemistry and Biological Sciences, focusing on:

- Biophysics: bio-molecular imaging while preserving structure and functionality, electromagnetic bioeffects, quantum biology
- Human Performance and Biosystems: “better understanding of the biophysical, biochemical, and physiological mechanisms responsible for the behavioral, genetic, cellular, tissue and systems changes;” sensory systems (acoustic information analysis); and others



- Funds basic and applied research to reduce chemical, biological, radiological, and nuclear threats
- Current Biological Defense priorities: diagnostic technology, vaccines, therapeutics
- May 2019 DTRA transitioned to University Research Alliance model (a few large-scale, multi-year, multi-performer cooperative agreements); away from smaller grants

BEST PRACTICES AND OPPORTUNITIES TO ENGAGE WITH DOD

ENGAGING DOD FOR HEALTH AND BIOMEDICAL RESEARCH

- **Watch CDMRP Webinar series:** https://cdmrp.army.mil/pubs/Webinars/webinar_series
 - Funding Opportunities and Strategies for Success
 - High Risk/High Gain Funding Opportunities
 - Team Science Funding Opportunities
 - Clinical Research and Clinical Trial Funding Opportunities
 - Funding Opportunities for the Development of Technology and/or Resources
 - Funding Opportunities for Early Career Investigators
 - Consortium-Type Funding Opportunities
 - **Military Health System Research Symposium (MHSRS):** DOD hosts the annual MHSRS in August, in Orlando, Florida. MHSRS is the Department's scientific meeting, focusing on military medicine and research: <https://mhsrs.net/>
 - **DTRA Chemical and Biological Science and Technology (CBD S&T) Conference:** DTRA hosts the biennial conference in different locations. This is an opportunity to give talks and meet with DTRA and other federal program managers: <https://www.cbdstconference.com/>
-

ENGAGING DOD (CONTINUED)

- **CDMRP Feedback Submission:** CDMRP has a feedback submission feature to its website. Investigators can use the tool to submit an abstract for feedback or ask questions. Stakeholders now have the option to provide input on programs and process recommendations, as well as submit reviewer nominations and other feedback: <http://cdmrp.army.mil/contact>
- **Connect with program managers:** For AFOSR, ONR, and DARPA, send white papers to program managers and request feedback or a meeting/phone call. This is an opportunity to build relationships and solicit feedback prior to having prepare a full proposal
- **DARPA Proposers Days:** DARPA hosts proposers days for most new programs. This is an opportunity to meet the program manager and potentially partner with other performers on joint projects

PREPARING FOR DISCUSSIONS

White Paper Framed by *Heilmeier Questions*

- What are you trying to do? Articulate your objectives using absolutely no jargon. What is the problem? Why is it hard?
- How is it done today, and what are the limits of current practice?
- What's new in your approach and why do you think it will be successful?
- Who cares?
- If you're successful, what difference will it make? What impact will success have? How will it be measured?
- What are the risks and the payoffs?
- How much will it cost?
- How long will it take?
- What are the midterm and final "exams" to check for success? How will progress be measured?

Quad Chart – Format

BAA Number: *(Number of the BAA Announcement)*
 Mission Area: *(Title of Mission Area from BAA Package)*
 Requirement Number: *(Only 1 Per Chart)(Document Identifier) (See para 3.1.5.1)*
 Proposal Title: *(Brief/short Title to describe offeror's proposed effort)*

Offeror Name
Date

Photograph or artist's concept of the project end-item.
 Ideally, this will convey the main idea of the final capability/use of the prototype.
 It should further give an idea of the size and weight of the end item.

Operational Capability:
 Describe how the system would provide new or enhanced operational capability to user agencies.
 Describe system specifications to be met.
 If known, list specific agencies that have expressed interest in this approach.

Proposed Technical Approach:
 Specifically, how will the problem be approached.
 Describe tasks to be performed.
 Describe any actions done to date.
 Describe any related on-going effort by the offeror.
 Describe the technology involved and how it will be used to solve the problem.

Rough Order of Magnitude Cost and Schedule:
 Provide any milestone decision points that will be required. Describe period of performance and total costs. If there are phases, provide funding per phase.
Deliverables:
 Include all hardware and the following data deliverables: monthly status report, final report, test plans, test reports, specifications, computer program end items, user's manual, drawings, transition plan, etc.
Corporate Information:
 You must include Offeror Name, POC full name, address, phone numbers and email.



QUESTIONS?

Contact

Eve Granatosky – eve@lewis-burke.com

Grace Hancik – grace@lewis-burke.com

Department of Defense Congressionally Directed Medical Research Program

What is the DOD Congressionally Directed Medical Research Program (CDMRP)?

CDMRP Mission: *“Responsibly manage collaborative research that discovers, develops, and delivers health care solutions for Service Members, veterans, and the American public.”*

- CDMRP was created in 1992 to support innovation in biomedical research through DOD
- CDMRP now supports over 30 research programs and addresses nearly 50 additional topic areas through the Peer Reviewed Medical Research Program (PRMRP)
- CDMRP funds high-risk, high-impact research projects
- Congress sets the CDMRP/PRMRP topics through annual appropriations and is not included in the President’s budget request. Topics may change each fiscal year (FY)

What research topics do CDMRP and PRMRP cover?

FY 2021 CDMRP Research Programs and Funding

- | | | |
|---|---|---|
| • Peer-Reviewed Medical (\$370 m) | • Amyotrophic Lateral Sclerosis (\$40 m) | • Hearing Restoration (\$10 m) |
| • Traumatic Brain Injury and Psychological Health (\$175 m) | • Multiple Sclerosis (\$20 m) | • Lupus (\$10 m) |
| • Breast Cancer (\$150 m) | • Vision (\$20 m) | • Combat Readiness Medical (\$10 m) |
| • Peer-Review Cancer (\$115 m) | • Rare Cancers Research (\$17.5 m) | • Tuberos Sclerosis Complex (\$8 m) |
| • Prostate Cancer (\$110 m) | • Alzheimer’s Disease (\$15 m) | • Bone Marrow Failure (\$7.5 m) |
| • Kidney Cancer (\$50 m) | • Autism Research (\$15 m) | • Tickborne Disease (\$7 m) |
| • Joint Warfighter Medical (\$40 m) | • Pancreatic Cancer (\$15 m) | • Scleroderma (\$5 m) |
| • Spinal Cord (\$40 m) | • Orthotics and Prosthetics Outcomes (\$15 m) | • Alcohol and Substance Abuse Disorders (\$4 m) |
| • Ovarian Cancer (\$35 m) | • Chronic Pain Management (\$15 m) | • Neurofibromatosis (\$20 m) |
| • Melanoma (\$30 m) | • Epilepsy (\$12 m) | • Military burn (\$5 m) |
| • Peer-Reviewed Orthopedic (\$30 m) | • Reconstructive Transplant (\$12 m) | • Gulf War Illness (\$22 m) |
| • Lung Cancer (\$20 m) | • Duchenne Muscular Dystrophy (\$10 m) | |
| | • Neurotoxin Exposure Treatment (\$16 m) | |

FY 2021 PRMRP Topic Areas

- | | | |
|--------------------------------------|--|-----------------------------------|
| • Arthritis | • Hemorrhage control | • Peripheral neuropathy |
| • Burn pit exposure | • Hepatitis B | • Plant-based vaccines |
| • Cardiomyopathy | • Hydrocephalus | • Platelet like cell production |
| • Congenital heart disease | • Hypertension | • Polycystic kidney disease |
| • Diabetes | • Inflammatory bowel diseases | • Pressure ulcers |
| • Dystonia | • Malaria | • Pulmonary fibrosis |
| • Eating disorders | • Metals toxicology | • Respiratory health |
| • Emerging viral diseases | • Mitochondrial disease | • Rheumatoid arthritis |
| • Endometriosis | • Myalgic encephalomyelitis/chronic fatigue syndrome | • Sleep disorders and restriction |
| • Epidermolysis bullosa | • Myotonic dystrophy | • Suicide prevention |
| • Familial hypercholesterolemia | • Non-opioid therapy for pain management | • Sustained release drug delivery |
| • Fibrous dysplasia | • Nutrition optimization | • Vascular malformations |
| • Focal segmental glomerulosclerosis | • Pathogen-inactivated blood products | • Women's heart disease |
| • Food allergies | | |
| • Fragile X | | |
| • Frontotemporal degeneration | | |

How do investigators engage with CDMRP program managers?

- Attend the annual **Military Health System Research Symposium** to build relationships with program managers and other researchers across the Defense Health Program enterprise: <https://www.mhsrs.net/>
- Contact CDMRP through the **feedback submission tool** (<https://cdmrp.army.mil/contact>) to:
 - Ask administrative questions about submissions and process, not to discuss proposals
 - Volunteer to serve on peer and programmatic review panels
- This **webinar series** has best practices for applying: https://cdmrp.army.mil/pubs/webinars/webinar_series#ctfo

How and when do investigators submit proposals?

- Proposal windows vary throughout the year and are dependent on the federal appropriations process
- Pre-applications or letters of intent are required and vary by solicitation
- These programs are highly competitive. Success rates average around 15% (range of 10-30 percent)
- There are various research mechanisms and opportunities at all career stages:

Research Awards	Researcher Development
<ul style="list-style-type: none">- Initial Concepts- Early Ideas- Clinical/Translational- Team Science- Clinical Trials	<ul style="list-style-type: none">- Predoctoral- Postdoctoral- Physician Scientist- New Investigator- Established Investigator

How are proposals reviewed?

CDMRP uses a **two-tier** review process: **peer review** for scientific merit and **programmatic review** to ensure the DOD mission and research portfolio needs are met. Ultimately, funding decisions are approved by the Commanding General of the Defense Health Agency J9, Research and Development Directorate.

Peer Review

- Study section-like assessment to evaluate scientific merit and potential impact
- Panels are a mix of scientists and consumers
- No standing peer review panels
- **Output of tier one:**
 - Score for overall merit and meeting FOA criteria
 - Summary statement on strengths/weaknesses
 - Basis for programmatic review

Programmatic Review

- Proposals with high scientific merit compared during review
- Panels are a mix of researchers, agency officials, clinicians, and consumers
- Consideration of program relevance, award mechanism intent, and portfolio balance
- Lay abstract, impact statement, and military relevancy are extremely important
- No pay line
- **Output of tier two:** funding recommendation

Sources and Additional Resources

- CDMRP website: <https://cdmrp.army.mil/default>
- Subscribe for CDMRP funding updates: <https://ebrap.org/eBRAP/programSubscription/Subscribe.htm>
- CDMRP 2019 Annual Report: <https://cdmrp.army.mil/pubs/annreports/2019annrep/2019annreport.pdf>