HEALTH AND BIOMEDICAL RESEARCH AT THE DEPARTMENT OF DEFENSE

Lewis-Burke Associates LLC
June 29, 2021
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

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<tr>
<th>Defense Health Program</th>
<th>National Institutes of Health</th>
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<td>• $2.3 billion in FY 2021</td>
<td>• $42.9 billion in FY 2021</td>
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<td>• Other limited funding through the Services and DARPA/DTRA</td>
<td>• 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”</td>
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<td>• Mission: “Responsively and responsibly create, develop, acquire, and deliver capabilities for the warfighter”</td>
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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)
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 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
**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
• 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:

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**Research Awards**

- Initial Concepts
- Early Ideas
- Clinical/Translational
- Team Science
- Clinical Trials

**Career Development**

- Predoctoral
- Postdoctoral
- Physician Scientist
- New Investigator
- Established Investigator
CDMRP REVIEW PROCESS

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

- 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
- 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
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

Additional Funding Opportunity Postings:
- www.grants.gov
- https://sam.gov/content/home
- www.eBRAP.org
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

  - 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/
• **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](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
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?
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)
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- Scleroderma ($5 m)
- Alcohol and Substance Abuse Disorders ($4 m)
- Neurofibromatosis ($20 m)
- Military burn ($5 m)
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**FY 2021 PRMRP Topic Areas**

- Arthritis
- Burn pit exposure
- Cardiomyopathy
- Congenital heart disease
- 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 toxicity
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- 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
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.mhrsrs.net/](https://www.mhrsrs.net/)
- Contact CDMRP through the **feedback submission tool** ([https://cdmrp.army.mil/contact](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](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:

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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.

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Sources and Additional Resources

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- Subscribe for CDMRP funding updates: [https://ebrap.org/eBRAP/programSubscription/Subscribe.htm](https://ebrap.org/eBRAP/programSubscription/Subscribe.htm)