

Navigating the DOD Health and Biomedical Research Landscape

Lewis-Burke Associates LLC
June 2018

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Today's talk

- Introduction to Lewis-Burke Associates LLC
- General advice on interacting with federal agencies
- Overview of the Department of Defense (DOD) priorities
 - Research, Development, Test, and Evaluation (RDT&E)
 - Defense Health Program Research Priorities
- Engaging DOD program officers
- Questions

About Lewis-Burke

- Twenty-eight 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

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How to Utilize Lewis-Burke

- Develop an initial white paper introducing your research to DOD
- Help transform NSF/NIH style proposals into DOD-appropriate proposals
- Get one-on-one help to identify relevant DOD programs and program officers
- Develop a plan to engage with relevant DOD officials
- Get advice on DOD young investigator proposals
- Contact: Reed@lewis-burke.com or Laura@lewis-burke.com

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General Advice for Interacting with Federal Agencies

- Build relationship – be courteous
- Make initial contact via email and be specific
- Ensure follow up
- Prepare concise one-page summaries (or other appropriate formats) of your research
- Attend relevant workshops / conferences
- Offer to serve as reviewer where appropriate
- Get feedback on your proposal from more experienced colleagues
- Do your homework:
 - Read solicitation / FOA / program home page
 - Research other awards supported through program
 - Read relevant community / workshop reports

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Department of Defense (DOD)

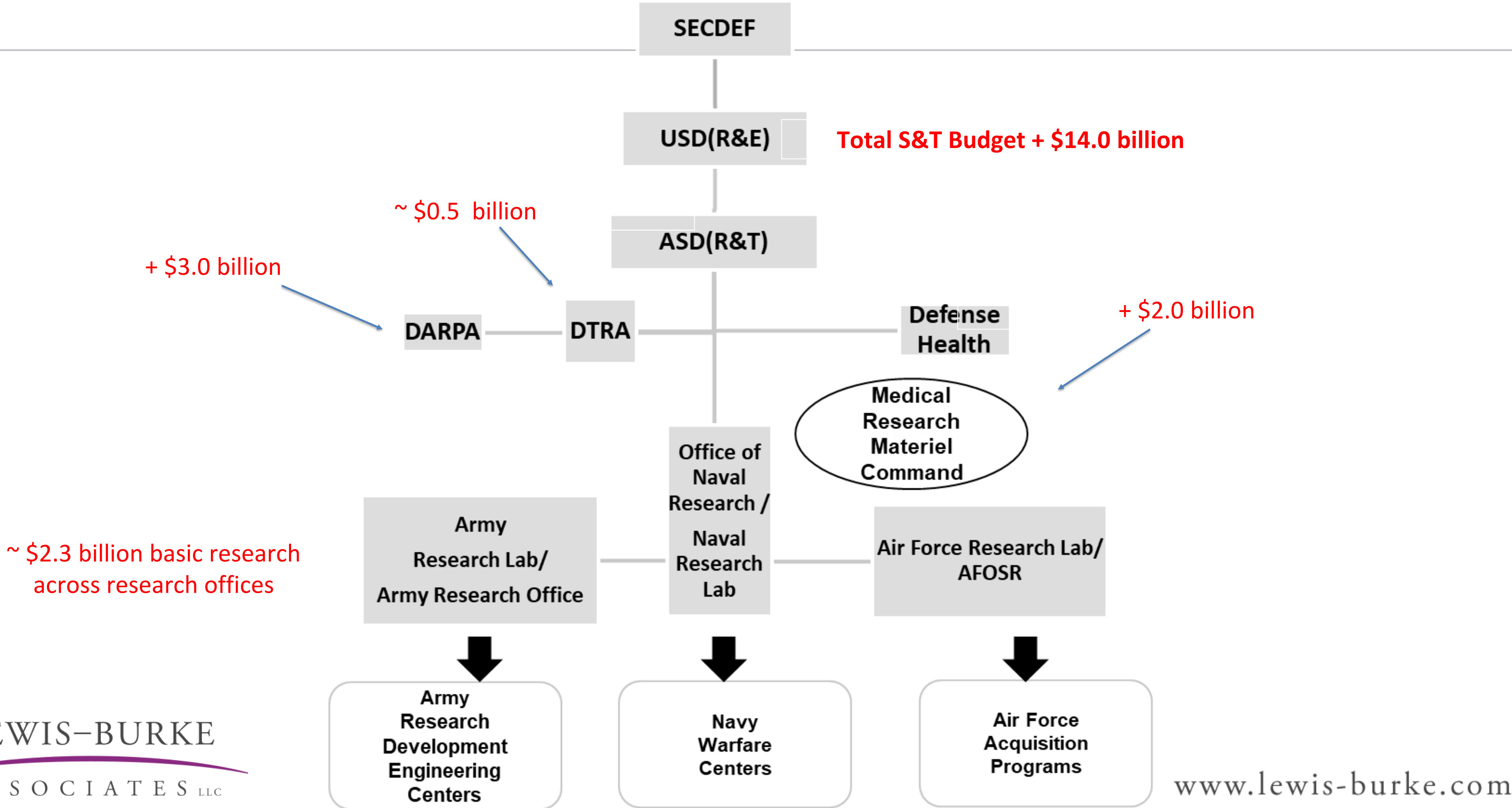
- DOD received a 14.2 % increase in FY 2018, with the Research, Development, Test, and Evaluation (RDT&E) account receiving **\$88.3 billion**, a 22.1 % increase
 - The Science and Technology (S&T) accounts – Basic Research (6.1), Applied Research (6.2), and Advanced Technology Development (6.3) – received **\$14.8 billion**, a 6.1 percent increase
 - Basic Research received a 2.9 % increase
- Advanced Technology Development and Systems Engineering continue to be major priorities as DOD is focused on READINESS and MODERNIZATION
 - Emphasis on use of Prototyping and Experimentation to reduce risk early in the development cycle and rapidly field new capabilities
- DOD continues to consider new methods of engaging with the extramural research community, like ARL's Open Campus Initiative and the Air Force's on-going S&T study to consider new methods of conducting research
- DOD starting to develop its 2020 budget – time to pitch ideas!

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DOD Research Organizations



Defense Health Program – Research Priorities

- DOD Health Research Priorities: approximately \$2 billion invested
 - **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
 - **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
 - **Infectious Disease** – prevention, diagnostics, therapeutics; surveillance; warfighter v. civilian health
 - **Combat casualty care** – surgical systems and procedures, surgical en-route care, neurotrauma, minimizing blast-related injury
 - **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
- Work executed through U.S. Army Medical Research and Materiel Command (MRMC) & Congressionally Directed Medical Research Programs (CDMRP), as well as DOD basic research offices with some medically-oriented programs - ONR, AFOSR, DARPA, DTRA
- Also involved with multi-agency priorities, including:
 - Global Health Security Agenda (biosurveillance, antimicrobial resistance, and Ebola/infectious disease research and response)
 - Precision Medicine
 - Big Data: data sharing standards, software tools, enhanced training, centers of excellence
 - BRAIN: targeted investment to accelerate development of neurotechnologies
 - Alzheimer's and aging: new investments in research and care to address growing number of patients and increased costs

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Army Medical Research & Materiel Command (USAMRMC)

- Priority Disciplines
 - Military Infectious Diseases** (~\$36m)
 - Walter Reed Army Institute of Research
 - U.S. Army Medical Research Institute of Infectious Diseases
 - Combat Casualty Care** (~\$27 m)
 - U.S. Army Institute of Surgical Research
 - Walter Reed Army Institute of Research
 - Military Operational Medicine** (~\$57m)
 - U.S. Army Research Institute of Environmental Medicine
 - U.S. Army Aeromedical Research Laboratory
 - Walter Reed Army Institute of Research
 - Clinical and Rehabilitative Medicine Research Program** (~\$18m)
- Releases annual BAA that outlines wide-ranging research interests for the fiscal year
 - White papers accepted on a rolling basis
- Program managers vary in their willingness to discuss ideas
 - Conferences and symposia can be best places to connect despite travel restrictions
- Critical to link your research to a military population/mission/outcome

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Congressionally-Directed Medical Research Program (CDMRP)

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 20 topic areas
- Created as way for Congress to assert influence over biomedical research agenda
- Congress helps dictate topics, but open competitions/peer review employed in funding decisions
- CDMRP funds added annually by appropriators – Not part of President’s Budget Request

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CDMRP – FY 2018 Topics

Bolded items reflect increases in FY 2018; Red items have been released

- ✓ Peer-Review Medical (**\$330 m**)
- ✓ Breast Cancer (**\$130 m**)
- Traumatic Brain Injury and Psychological health (\$125 m)
- Prostate Cancer (**\$100 m**)
- ✓ Peer-Review Cancer (**\$80 m**)
- Joint Warfighter Medical (\$50 m)
- Peer-Review Orthopedic (\$30 m)
- ✓ Spinal Cord (\$30 m)
- ✓ Gulf War Illness (**\$21 m**)
- ✓ Ovarian Cancer (\$20 m)
- Neurotoxin Exposure Treatment Parkinson's (\$16 m)
- ✓ Alzheimer's Disease (\$15 m)
- ✓ Kidney Cancer (**\$15 m**)
- ✓ Neurofibromatosis Research (\$15 m)
- Vision (\$15 m)
- ✓ Lung Cancer Research (**\$14 m**)
- HIV/AIDS program increase (\$12.9 m)
- Reconstructive Transplant (\$12 m)
- Trauma Clinical (\$10 m)
- ✓ Amyotrophic Lateral Sclerosis (**\$10 m**)
- ✓ Hearing Restoration (\$10 m)
- Orthotics and Prosthetics (\$10 m)
- Global HIV/AIDS Prevention (\$8 m)
- Military Burn (\$8 m)
- ✓ Epilepsy (\$7.5 m)
- ✓ Autism Research (\$7.5 m)
- ✓ Tuberos Sclerosis (\$6 m)
- ✓ Multiple Sclerosis (\$6 m)
- ✓ Tick-Borne Disease Research (\$5 m)
- ✓ Lupus (\$5 m)
- Alcohol and Substance Abuse (\$4 m)
- ✓ Duchenne Muscular Dystrophy (\$3.2 m)
- ✓ Bone Marrow Failure (\$3 m)

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Peer Reviewed Medical Research Program (PRMRP): FY 2018 Topics

- Acute Lung Injury
- Antimicrobial Resistance
- Arthritis
- Burn Pit Exposure
- **Cardiomyopathy***
- **Cerebellar Ataxia***
- Chronic Migraine and Post-Traumatic Headaches
- **Chronic Pain Management***
- Congenital Heart Disease
- Constrictive Bronchiolitis
- Diabetes
- Dystonia
- Eating Disorders
- Emerging Infectious Diseases
- **Endometriosis***
- Epidermolysis Bullosa
- Focal Segmental Glomerulosclerosis
- Fragile X Syndrome
- Guillain-Barre Syndrome
- Hepatitis B and C
- Hereditary Angioedema
- Hydrocephalus
- Immunomonitoring of Intestinal Transplants
- Inflammatory Bowel Diseases
- Interstitial Cystitis
- **Lung Injury***
- Malaria
- Metals Toxicology
- Mitochondrial Disease
- Musculoskeletal Disorders
- Myotonic Dystrophy
- Nonopioid Pain Management
- **Nutrition Optimization***
- Pancreatitis
- Pathogen-Inactivated Blood Products
- Post-Traumatic Osteoarthritis
- **Pressure Ulcers***
- Pulmonary Fibrosis
- Respiratory Health
- Rett Syndrome
- Rheumatoid Arthritis
- Scleroderma
- Sleep Disorders
- Spinal Muscular Atrophy
- Sustained-release Drug Delivery
- Tinnitus
- Tissue Regeneration
- Tuberculosis
- Vaccine Development for Infectious Diseases
- Vascular Malformations
- Women's Heart Disease

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*Denotes new topic in FY 2018

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CDMRP - continued

- 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:

Research Awards



Career Development



CDMRP – Review Process

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

Peer Review

- Evaluate scientific merit
- Provide written critique and scores for criteria and overall merit
- Panels comprised of scientific and consumer reviewers
- No standing peer review panels
- No contact between reviewers and applicants



Programmatic Review

- Proposals with high scientific merit compared for programmatic review
- Evaluate relevance to mission and DOD
- Evaluate adherence to award mechanism's intent (ex. new idea v. clinical trial)
- Consider portfolio composition
- Provide recommendations for funding
- No pay line
- Funds obligated up front
- No continuation funding

Examples of Programmatic Panels:

Parkinson's FY2016 Programmatic Panel:

- **Jeffery Bronstein, M.D., Ph.D.**
University of California - Los Angeles
- **Mark R. Cookson, Ph.D.**
National Institute of Aging, NIH
- **David Eidelberg, M.D.**
Feinstein Institute for Medical Research
- **Karl E. Friedl, Ph.D.** (Chair)
University of California San Francisco
- **Gretchen L. Snyder, Ph.D.**
Intra-Cellular Therapies, Inc.
- **Jeffery M. Vance, M.D., Ph.D.**
University of Miami Miller School of Medicine
- **Israel Robledo** (Consumer)
Parkinson's Action Network
- **Michael Greenbaum** (Consumer)
Parkinson's Action Network
- **Peter Schmidt, Ph.D.** (Consumer)
National Parkinson Foundation

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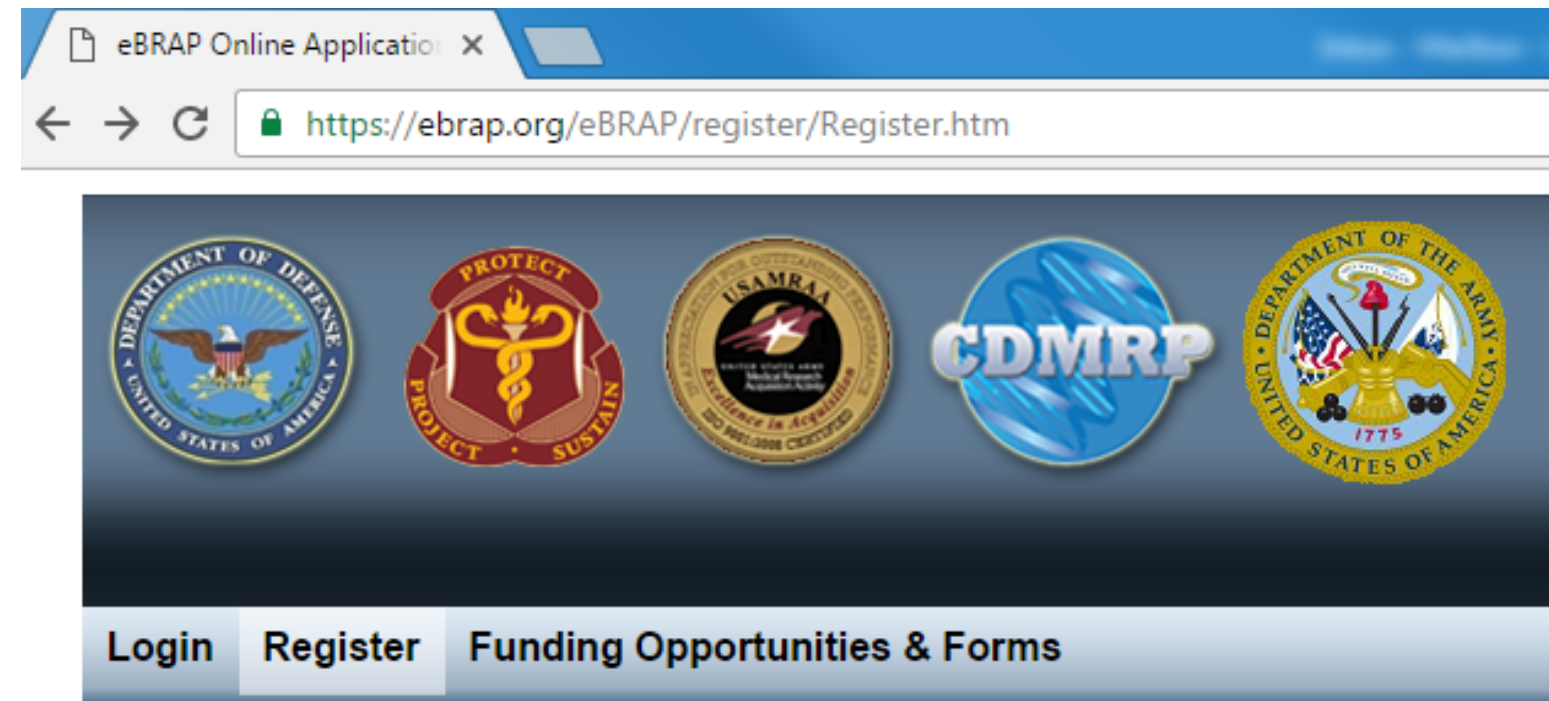
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Tick-Borne Disease FY2016 Programmatic Panel:

- **Stephen Barthold, D.V.M., Ph.D.**
University of California, Davis
- **C. Ben Beard, Ph.D.**
Division of Vector-Borne Diseases, CDC
- **Sam Donta, M.D.**
Physician Consultant
- **Noel Gerald, Ph.D.**
Center for Devices and Radiological Health, FDA
- **Samuel Perdue, Ph.D.**
National Institute of Allergy and Infectious Diseases, NIH
- **Allen Richards, M.D.**
Viral and Rickettsial Diseases Department, Naval Medical Research Center
- **Jason Richardson, LTC, Ph.D.** (vision setting ad hoc)
Viral and Rickettsial Diseases Department, Naval Medical Research Center
- **Paul Ross**
Global Lyme Alliance
- **Patricia Smith**
Lyme Disease Association
- **Ellen Stromdahl, BCE**
US Army Public Health Command
- **David Walker, M.D.**
University of Texas Medical Branch

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FOA Resources



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

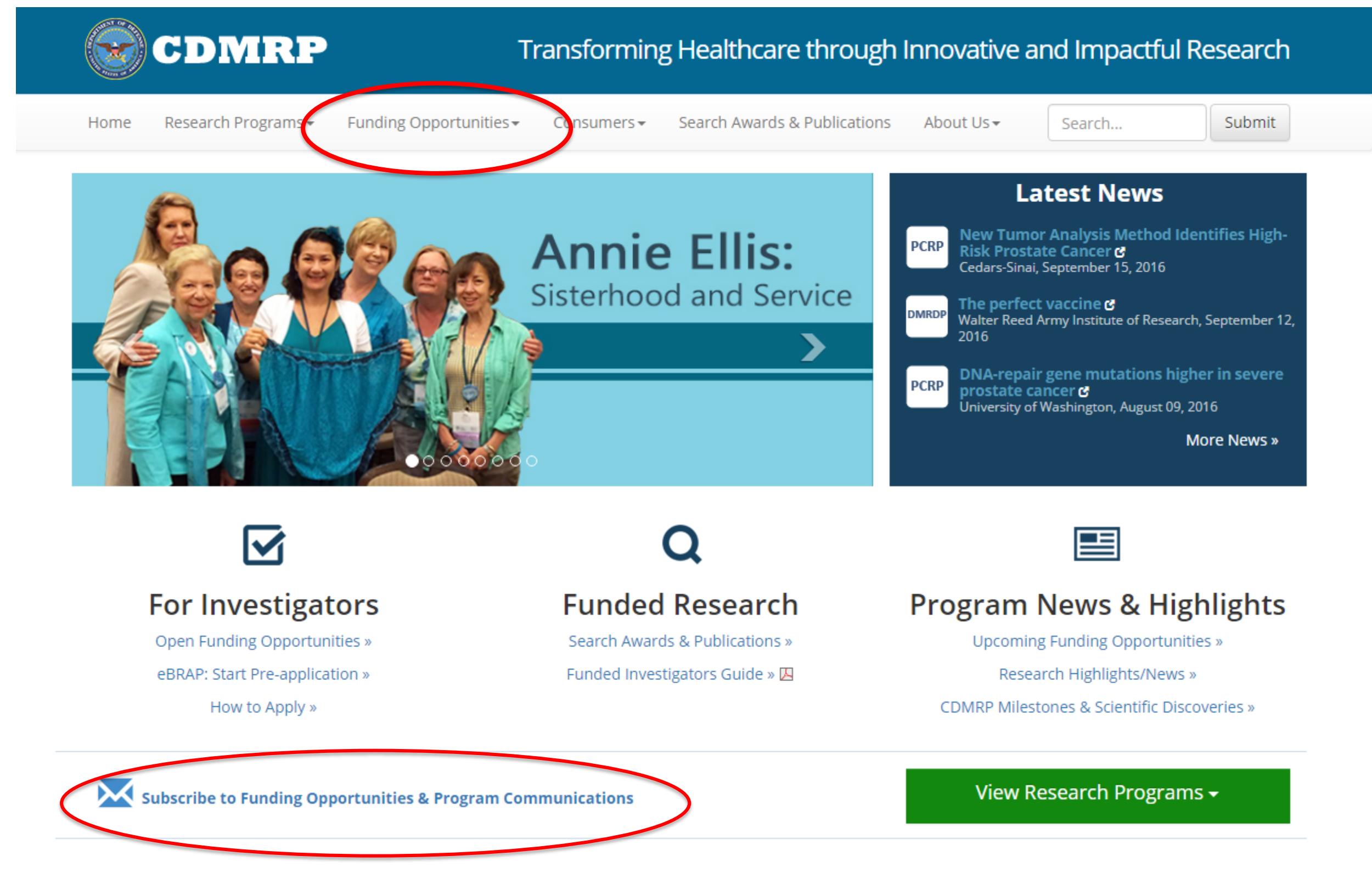
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- To remove your email from program subscription list, please [click here](#)

Help

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

Funding Opportunity Postings:

- www.grants.gov
- FedBizOps – www.fbo.gov
- www.eBRAP.org



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Ways to Propose: Questions to Consider

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?

Engaging DOD for Health and Biomedical Research

- **CDMRP Feedback Submission:** CDMRP recently launched a new 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>
- **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.amedd.army.mil/SitePages/Home.aspx>
- **Chemical and Biological Defense Science and Technology Conference (CBD S&T):** The Defense Threat Reduction Agency (DTRA) hosts the CBD S&T annually. Through the Conference, DTRA seeks to review and project cutting-edge basic and applied research in chemical and biological defense: <https://www.cbdstconference.com/home2017/>

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What Happens After Today

- Lewis-Burke can work with individuals and groups on follow up
 - It's an iterative relationship
- CDMRP Director Rebecca Fischer is coming to Rochester for regional seminar
 - What questions do you have that she can address?
 - Developing quad charts/one-pagers for DOD audiences
- Lewis-Burke can help identify targets, develop roadmaps, expand/clarify ideas, host check in calls, etc.

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Questions?

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