

The DOD Health Enterprise

Lewis-Burke Associates LLC
January 2019

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Today's talk

- Introduction to Lewis-Burke Associates LLC
- Overview of the DOD/Defense Health Research
- Strategies for Interacting
- 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

- Contact: Reed@lewis-burke.com or Ben@lewis-burke.com
- Develop an initial white paper introducing your research
- 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

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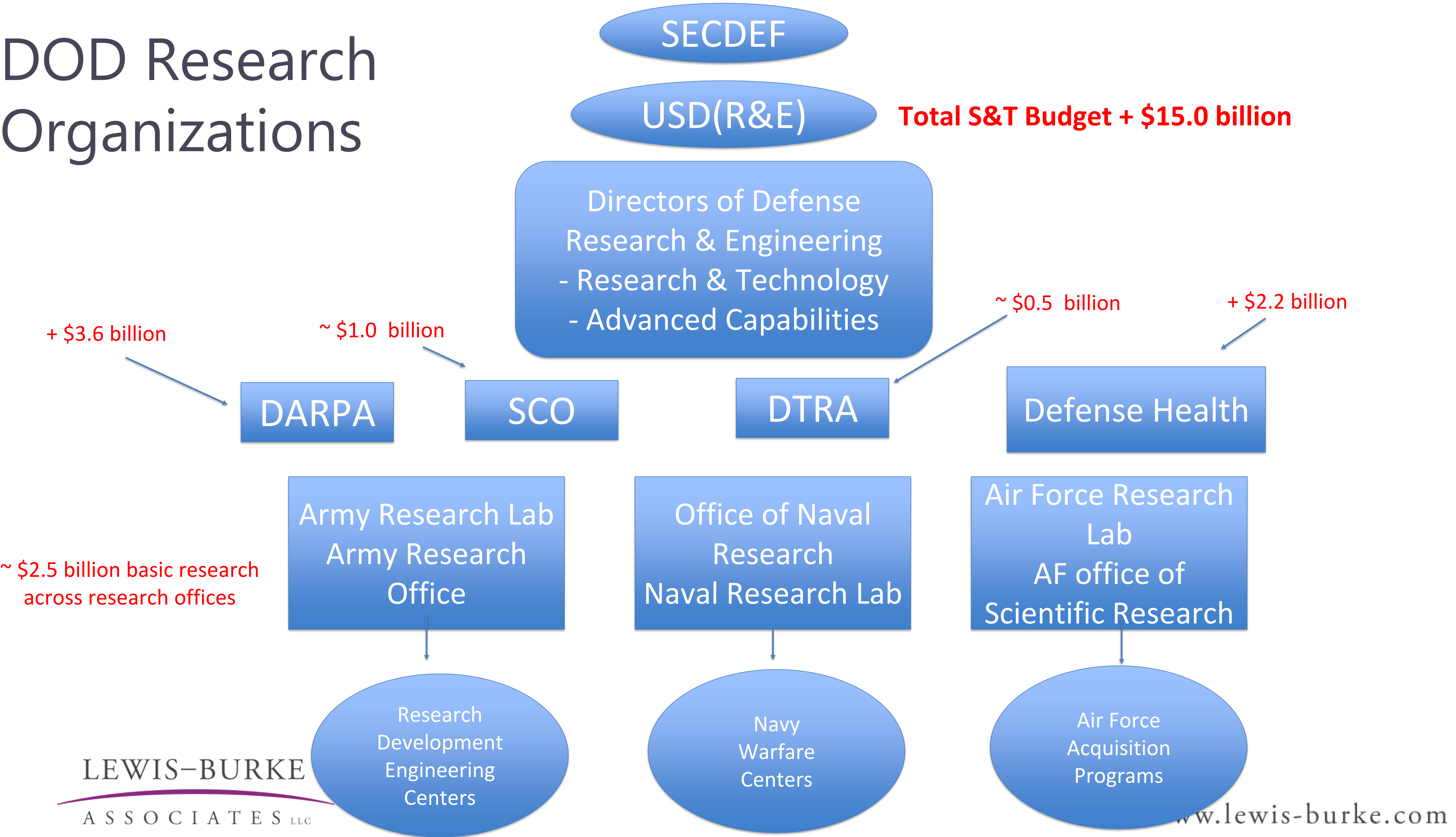
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Department of Defense (DOD)

- **FY 2019 Appropriations** - DOD received \$95.1 billion within the Research, Development, Test, and Evaluation (RDT&E) account a 7.7% increase vs. FY 2018
 - Science and Technology (S&T) accounts – Basic Research (6.1), Applied Research (6.2), and Advanced Technology Development (6.3) – received \$15.4 billion, a 7.4 % increase
 - Basic Research would receive \$2.7 billion, a 8 % increase
- 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
- **FY 2019 NDAA:** emphasizes secure microelectronics; quantum information science; artificial intelligence; cyber; manufacturing; Small Business Innovation Research (SBIR) programs and accessing non-traditional partners; and test and evaluation research for strategic weapons.
 - Authorizes a Joint Artificial Intelligence (AI) Research Activity and a senior official to oversee all DOD AI and machine learning activities
 - Establishes an independent National Security Commission on AI
 - Establishes a Defense quantum information science and technology R&D program
- **Major Areas of Interest:**
 - Hypersonics (FY19 - \$357 million)
 - DE Weapons (FY18 - \$661 million)
 - Quantum (FY18 - \$96 million)
 - Autonomy and Robotics (FY18 - \$1.9 billion)
 - AI and Machine Learning
 - Space capabilities (FY18 - \$619 million)
 - Cybersecurity/Information Assurance (FY18 - \$8.3 billion)
 - Trusted Micro-electronics (FY18 - \$42 million)
 - Materials/Manufacturing
 - Test and evaluation science
 - Expedited tech transition and acquisition
 - STEM Education

DOD Research Organizations



DOD Medical

- 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
- DoD 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**
- 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

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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 2019 Topics

Bolded items reflect increases and * reflect new programs in FY 2019

- Peer-Review Medical (**\$350 m**)
- Breast Cancer (\$130 m)
- Traumatic Brain Injury and Psychological health (\$125 m)
- Prostate Cancer (\$100 m)
- Peer-Review Cancer (**\$90 m**)
- Joint Warfighter Medical (\$50 m)
- Peer-Review Orthopedic (\$30 m)
- Spinal Cord (\$30 m)
- Gulf War Illness (**\$22 m**)
- Ovarian Cancer (\$20 m)
- Kidney Cancer (**\$20 m**)
- Vision (**\$20 m**)
- Neurofibromatosis Research (\$16 m)
- Neurotoxin Exposure Treatment Parkinson's (\$16 m)
- **Combat Readiness Medical Research (\$15 m)***
- Alzheimer's Disease (\$15 m)
- Lung Cancer Research (\$14 m)
- HIV/AIDS program increase (\$12.9 m)
- Reconstructive Transplant (\$12 m)
- **Melanoma (\$10 m)***
- **Chronic Pain Management (\$10 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)
- Tuberous 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 2019 Topics

- Acute Lung Injury
- Antimicrobial Resistance
- Arthritis
- Burn Pit Exposure
- Cardiomyopathy
- Cerebellar Ataxia
- Chronic Migraine and Post-Traumatic Headaches
- Congenital Heart Disease
- Constrictive Bronchiolitis
- Diabetes
- Dystonia
- Eating Disorders
- Emerging Infectious Diseases
- Epidermolysis Bullosa
- Focal Segmental Glomerulosclerosis
- **Frontotemporal Degeneration***
- Guillain-Barre Syndrome
- **Hemorrhage Control***
- Hepatitis B
- Hereditary Angioedema
- Hydrocephalus
- Immunomonitoring of Intestinal Transplants
- Inflammatory Bowel Diseases
- Interstitial Cystitis
- Lung Injury
- Metals Toxicology
- Mitochondrial Disease
- Musculoskeletal Disorders
- Myotonic Dystrophy
- **Nanomaterials for bone regeneration***
- Nutrition Optimization
- Pancreatitis
- Pathogen-Inactivated Blood Products
- **Polycystic Kidney Disease***
- Post-Traumatic Osteoarthritis
- Pressure Ulcers
- Pulmonary Fibrosis
- **Resilience Training***
- Respiratory Health
- Rett Syndrome
- Rheumatoid Arthritis
- Scleroderma
- Sleep Disorders
- Spinal Muscular Atrophy
- Tinnitus
- Tissue Regeneration
- Tuberculosis
- Vascular Malformations
- Women's Heart Disease

***Denotes** new topic in FY 2019

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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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Tick-Borne Disease FY2016 Programmatic Panel:

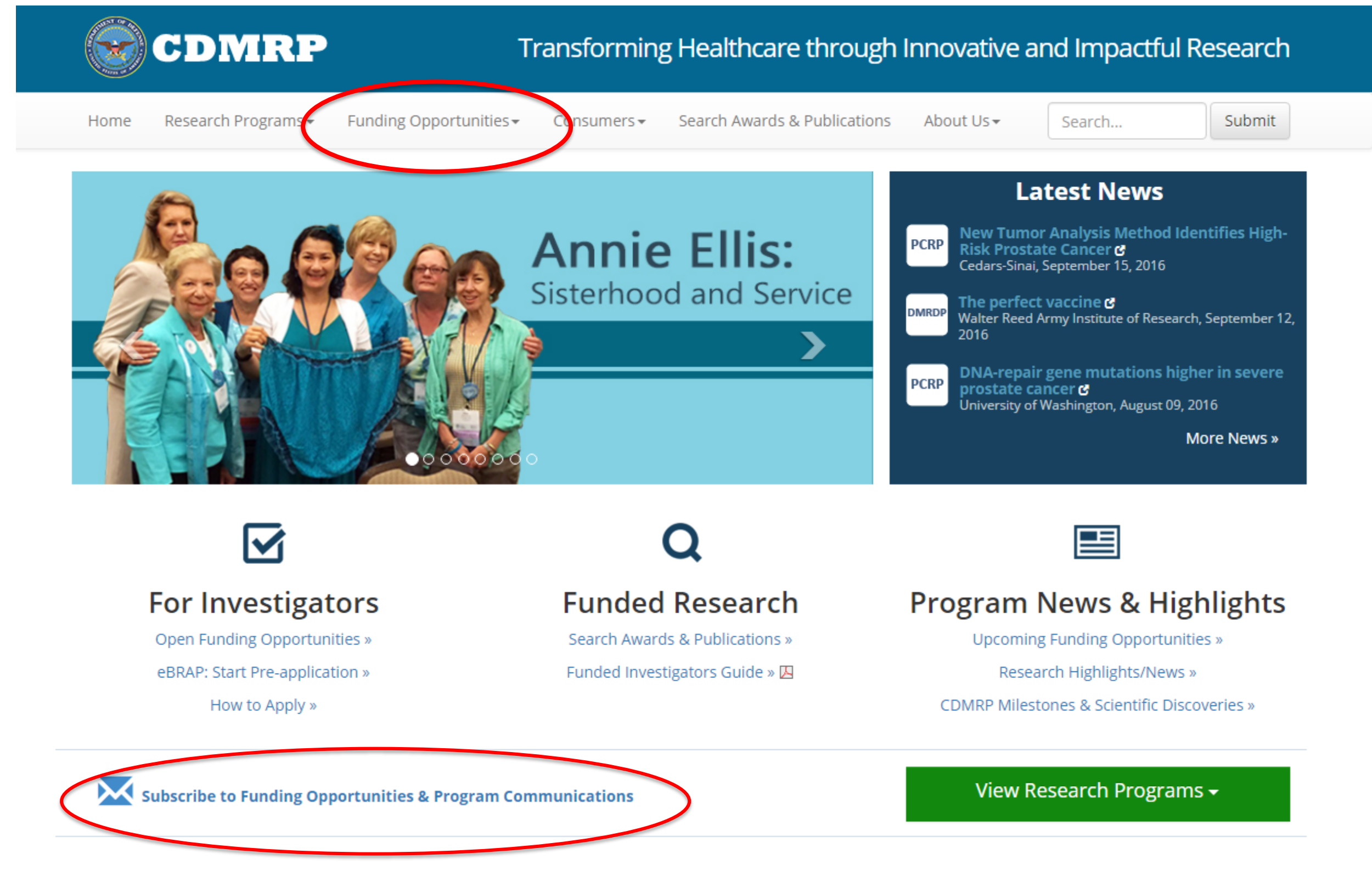
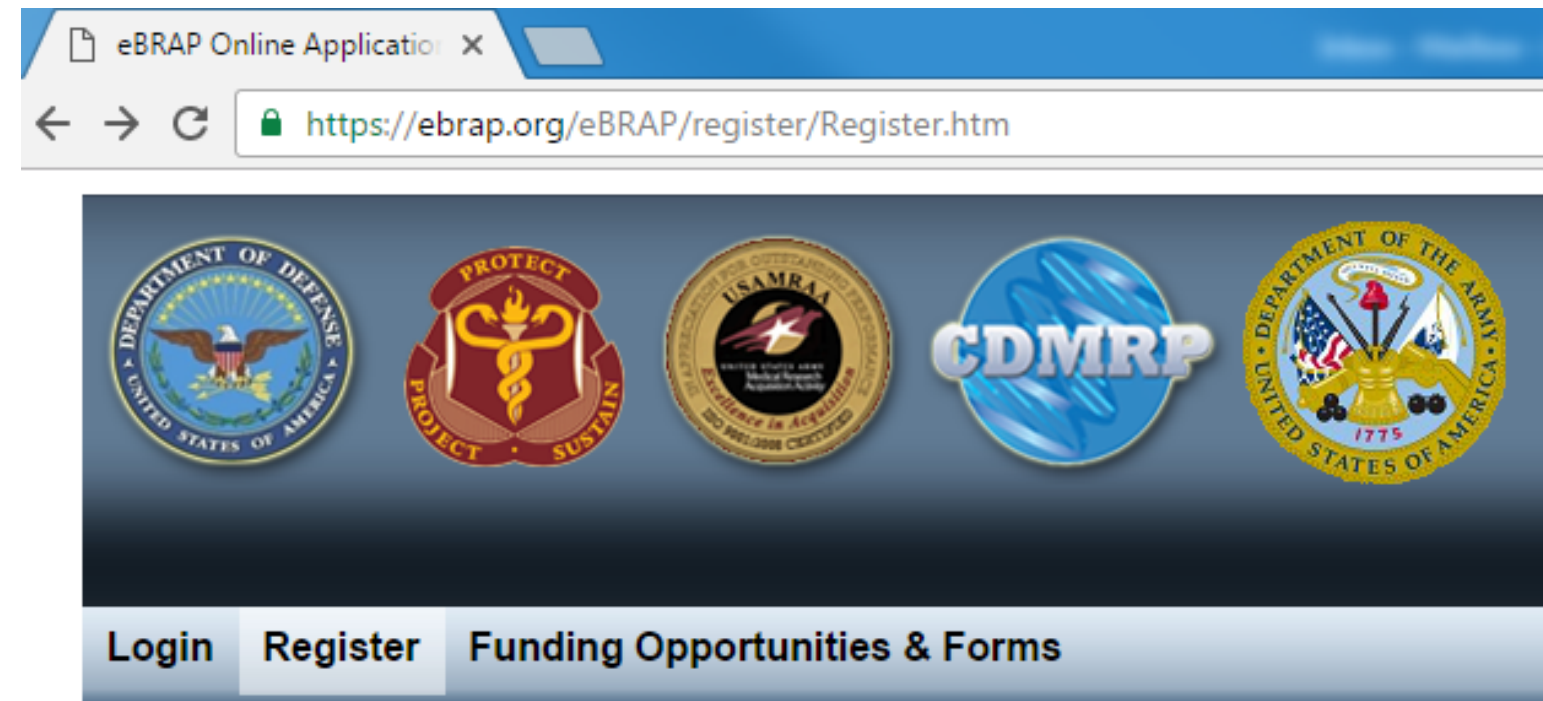
- **Stephen Barthold, D.V.M., Ph.D.**
University of California, Davis
- **C. Ben Beard, Ph.D.**
Division of Vector-Borne Diseases, CDC
- **Sam Donta, M.D.**
Physician Consultant
- **Noel Gerald, Ph.D.**
Center for Devices and Radiological Health, FDA
- **Samuel Perdue, Ph.D.**
National Institute of Allergy 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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Medical FOA Resources

Funding Opportunity Postings:

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



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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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DARPA

FY19 ~ \$3.4 B

Areas of Focus:

- *Controlling Electro Magnetic (EM) Spectrum*
- *Distributed Lethality*
 - *Sensing in difficult environments*
- *Space*
 - *Small satellite constellations*
- *Hypersonics*
 - *Missiles*
- *Artificial Intelligence*
 - *Machine Learning*
 - *Neural Networks*
 - *Human-Machine interactions*
- *Biology*
 - *Neuroscience*
 - *Infectious Diseases*
 - *Synthetic Bio*

- *Trusted microelectronics*
- *Machine learning and Artificial Intelligence – 3rd Wave/AI Next \$2 billion*
- *Cyber, information assurance*
- *Autonomous systems and counter-UAS*
- *New materials programs in FY 2019*

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DOD Applied/Advanced Technology Development Opportunities

- **Rapid Innovation Fund (RIF) Annual BAA:** Collaborative vehicle for small businesses to provide the department with innovative technologies that can be rapidly inserted into acquisition programs that meet specific defense needs
 - Awards of up to \$3 million for 24 months or less
 - Selection preference to small business-led proposals
- Proposals or projects should:
 - Satisfy an operational or national security need, accelerate or enhance military capability, in support of a major defense acquisition program
 - Stimulate innovative technologies, address technical risk
 - Reduce acquisition/lifecycle costs, improve timelines and thoroughness of test and evaluation outcomes
- **Small Business Innovation Research/Small Business Technology Transfer (SBIR/STTR):** Each Service manages its own SBIR/STTR solicitation open on an annual basis; often these funds go unclaimed
- **Combating Terrorism Technology Support Office (CTTSO) Annual BAA:** CTTSO identifies and develops capabilities to combat terrorism and irregular adversaries and to deliver these capabilities to DoD components and interagency partners through rapid research and development, advanced studies and technical innovation, and provision of support to U.S. military operations
 - BAA topics include: Advanced Analytics; CBRNE; Improvised Device Defeat/Explosives Countermeasures; Investigative and Forensic Science; Irregular Warfare and Evolving Threats; Personnel Protection; Physical Security; Tactical Operations Support; Training Technology Development; Surveillance, Collection, and Operations Support
 - Each portfolio includes specified requirements and an unspecified requirement for proposals related to that topic
 - Three-phase submission: One-page quad chart (Feb-March), then brief white paper no more than 12 pages (April-May), then full proposal (June-July)
 - Proposers must register on BIDS: <https://bids.cttso.gov/>

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DOD Prototyping/Demonstration Events

- **Army Expeditionary Technology Search (xTechSearch):** \$1.95 million prize competition to help the Army enhance engagements with the entrepreneurial funded community, small businesses, and other non-traditional defense partners, by:
 - Understanding the spectrum of technologies being developed commercially that may benefit the Army
 - Integrating the sector of nontraditional innovators into the Army's research and development ecosystem
 - Providing mentorship and expertise to accelerate, mature, and transition technologies of interest to the Army– Focused on six Army modernization priority areas
- **AFWERX, Service Rapid Acquisition Offices, Defense Innovation Unit:** Pilot contracts for innovative solutions to posted defense problems; seeks primarily commercial products suitable for DOD use; uses OTA
 - <https://www.diux.mil/work-with-us/companies>
- **MD5 National Security Technology Accelerator:** Collaborative community for national security innovation; host of “Hack-a-thons” and Hacking 4 Defense
 - Three portfolios
 - Education
 - Collaboration
 - Acceleration

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Working with Lewis-Burke After Today

- Engage us..ASK us to
 - Identify new opportunities and programs
 - Review white papers
- Support for planning for solicitations
- Shaping opportunities
 - Develop white papers
 - Meet with agency officials
 - Be responsive both to faculty interests and agency directions
 - Different kinds of funding mechanisms may require different types of collaborations (e.g. OTA; IDIQ; center-like; SBIR; public-private; end of fiscal year)

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Questions?

Please contact:

Reed Skaggs, PhD: reed@lewis-burke.com

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