

The DOD Health Enterprise

Lewis-Burke Associates LLC
June 2019

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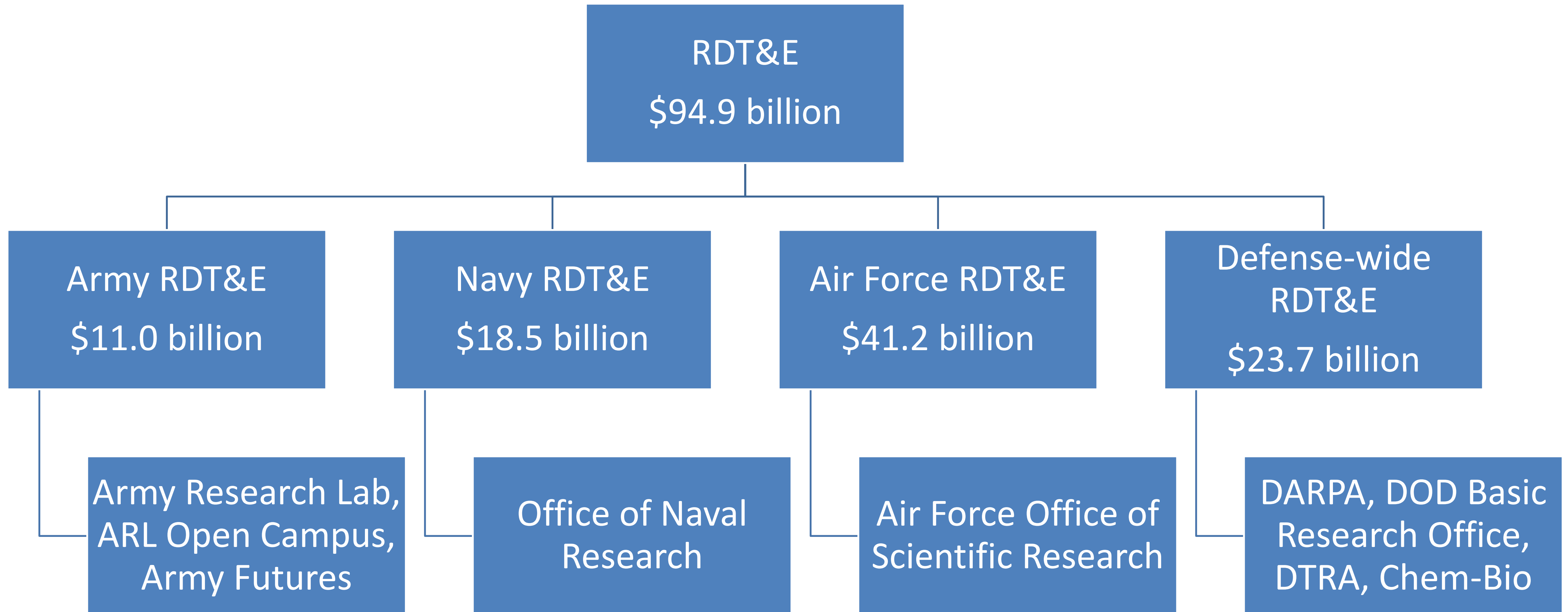
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Today's talk

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

DOD Research Organization



DOD Health vs. NIH

NIH
\$39.1 B

Defense Health
~\$2 B

DOD Medical

- **DOD Health Research Priorities:**

- **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
- **Infectious Disease** – prevention, diagnostics, therapeutics; surveillance; warfighter v. civilian health
- **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

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
 - CDMRP funds added annually by appropriators – Not part of President’s Budget Request
- Congress dictates topics, but open competitions/peer review employed in funding decisions

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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Peer Reviewed Cancer Research Program

FY 2019 Topics

- Bladder cancer
- Blood cancers
- Brain cancer
- Cancer in children, adolescents, and young adults
- Colorectal cancer
- Immunotherapy
- Listeria vaccine for cancer
- Liver cancer
- Lymphoma
- Mesothelioma
- Pancreatic cancer
- Pediatric brain tumors
- Rare cancers
- Stomach cancer

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:

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

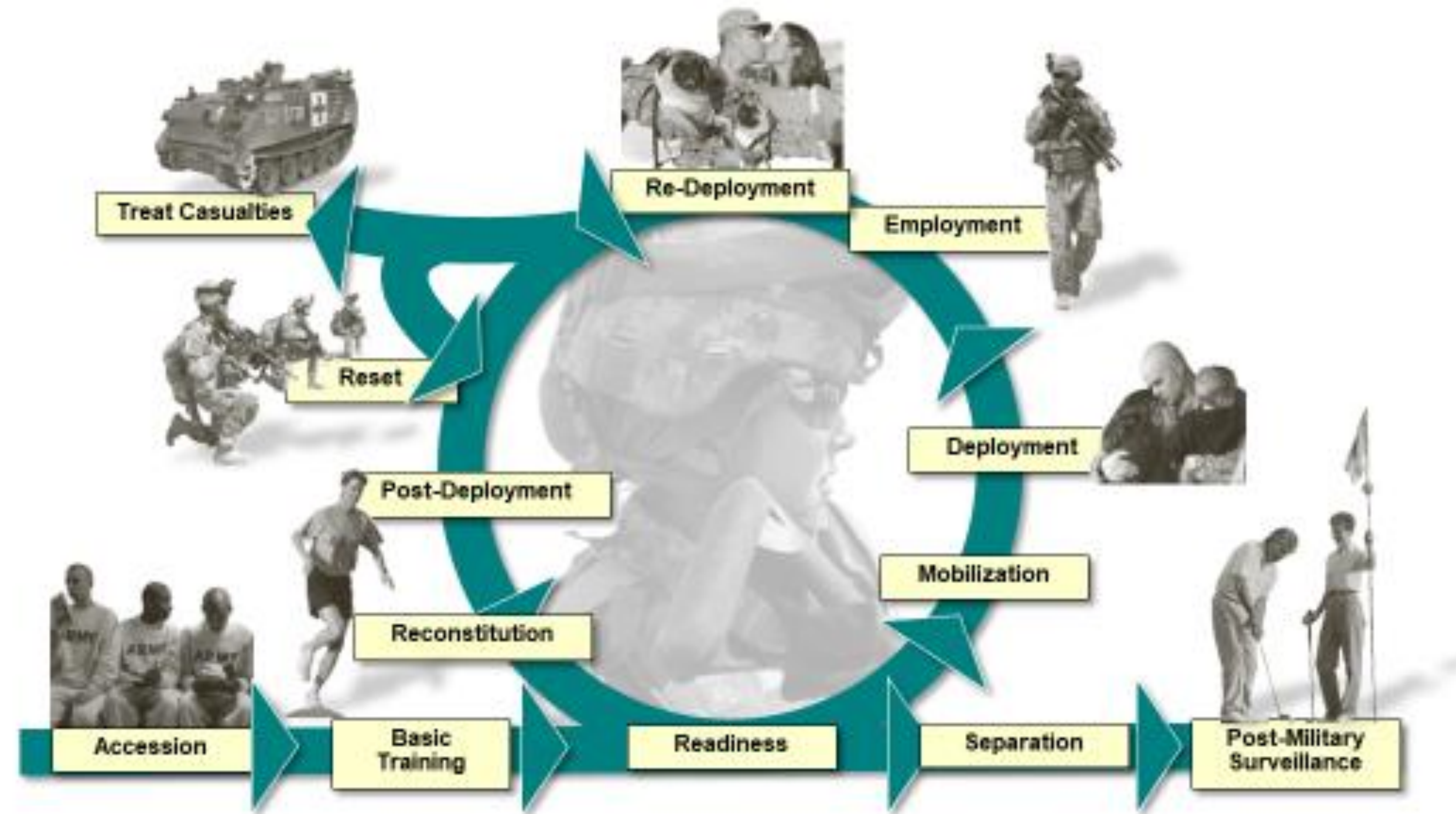
Parkinson's FY2016 Programmatic Panel:

- **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

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

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

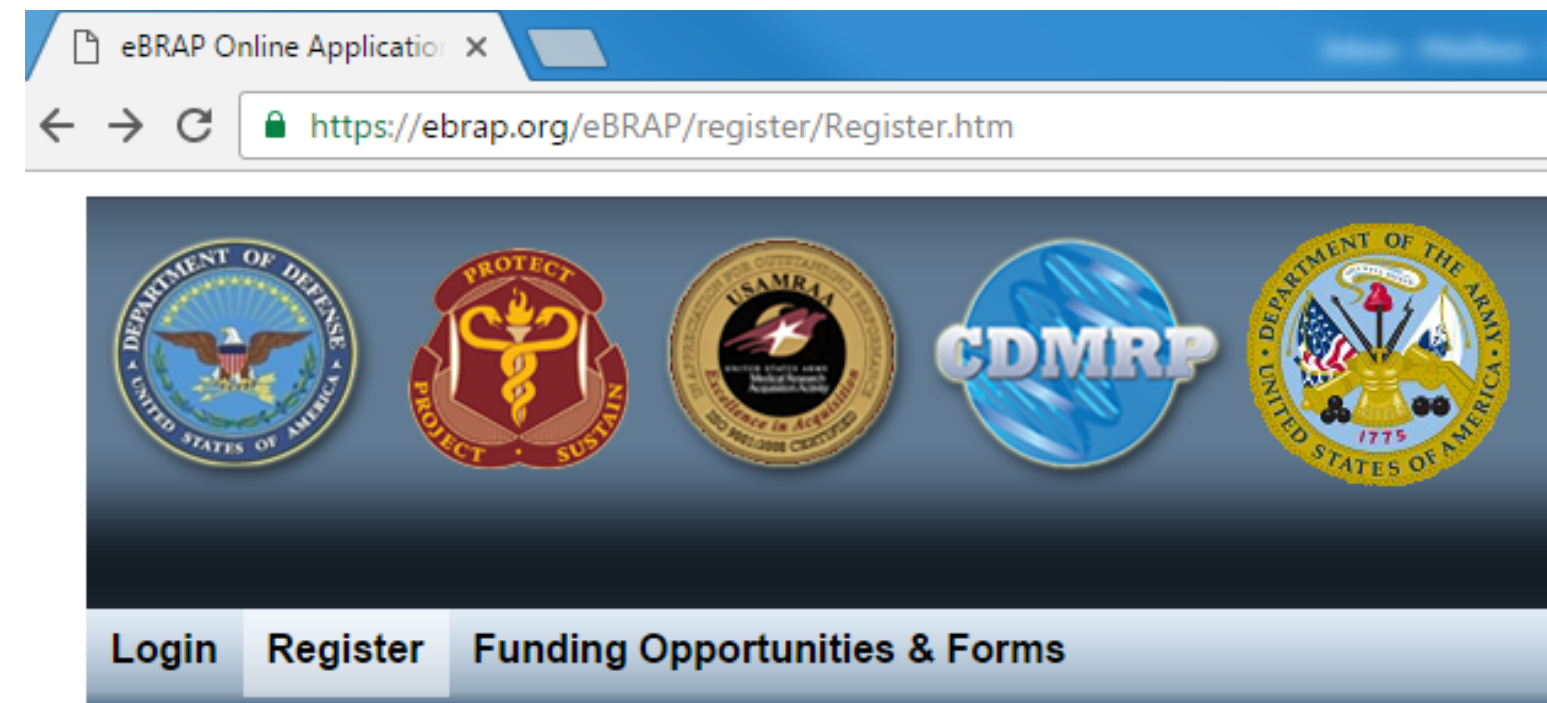


DEVELOPING AND MAINTAINING A FIT AND READY FORCE

Medical FOA Resources

Funding Opportunity Postings:

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



Welcome to eBRAP

Register

I am a new:

*Select from drop down

[Start Registration](#)

Program News and Updates

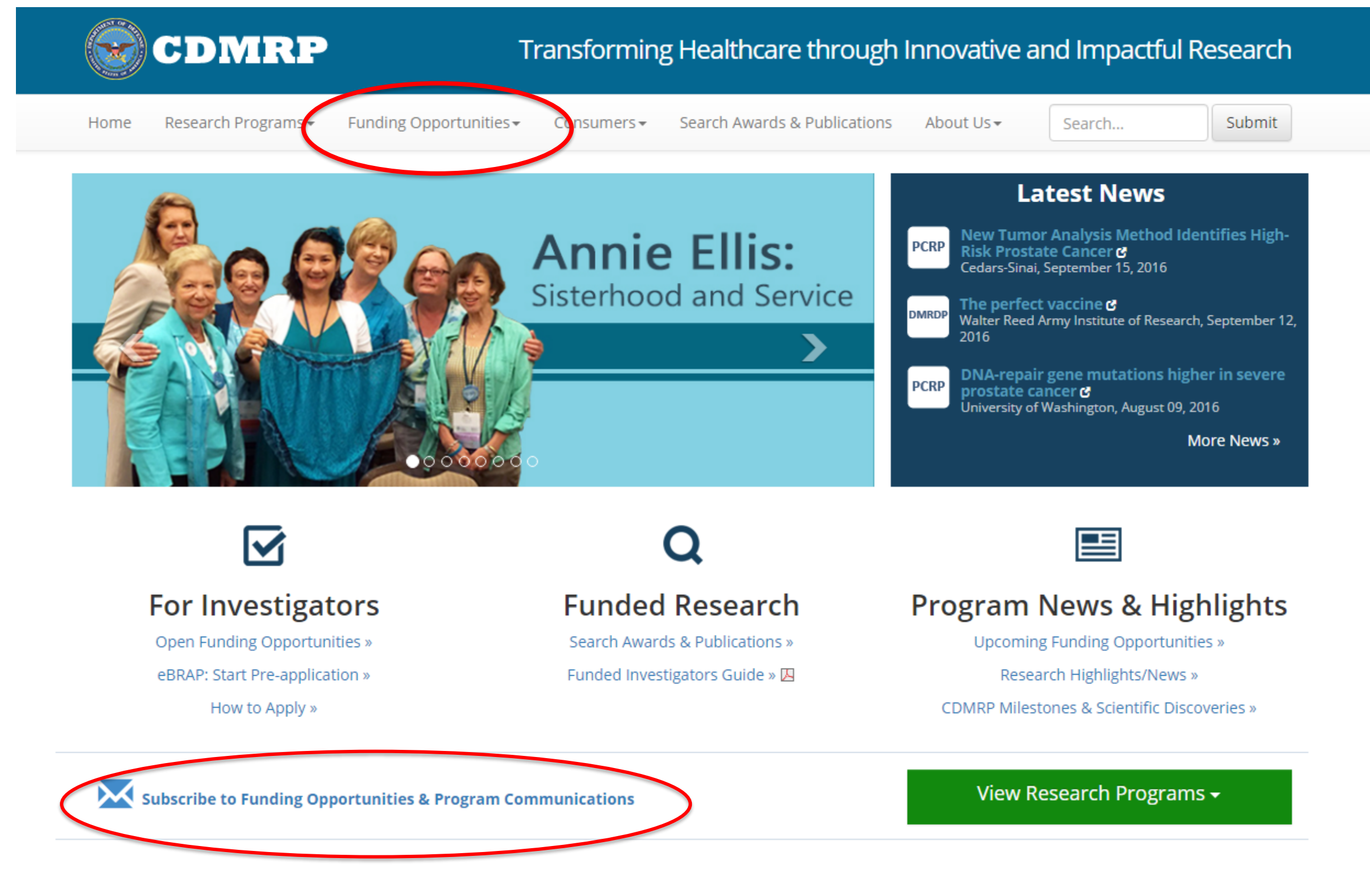
- Welcome to eBRAP. To access the user guide, please [click here](#).

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](#)



Defense Advanced Research Projects Agency (DARPA)

- DARPA funds high-risk, high-reward basic and applied biomedical research; game-changing R&D around future threats
- Six technical offices: **Biological Technologies (BTO)**, **Defense Science (DSO)**, Information Innovation (I2O), Microsystems Technology (MTO), Strategic Technology (STO), and Tactical Technology (TTO)
- BTO, DSO support most of DARPA's biomedical and health technologies research
- Current priorities of interest to the biomedical community include:
 - Human-machine teaming
 - Vaccine delivery
 - Infectious diseases
 - Synthetic bio
 - Neuroscience

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Office of Naval Research (ONR)

- ONR is the Navy's basic research organization and has five research areas:
 - Information, Cyber and Spectrum Superiority (Code 31)
 - Ocean Battlespace and Expeditionary Access (Code 32)
 - Mission Capable, Persistent and Survivable Naval Platforms (Code 33)
 - Warfighter Performance (Code 34)**
 - Aviation, Force Projection and Integrated Defense (Code 35)
- Health and biomedical priorities include:
 - Stress response
 - Undersea medicine and performance
 - Auditory neuroscience
 - Gut microbiology for resilience
 - Physiological monitoring

Defense Threat Reduction Agency (DTRA)

- Basic and applied research on bio/chemical/nuclear/information sciences geared towards countering weapons of mass destruction
- **Chemical-Biological Research (~60 million)**
 - Non-medical: Nano, cognition, information science, bioscience
 - Medical Biological Defense Transformational Medical Technologies Initiative: Diagnostic Technology, Vaccine, Therapeutic – viral, toxin, bacterial
 - Medical Chemical Defense – Smallest Area: Respiratory, Cutaneous and Ocular, Neurological, Toxicology
- **Working with DTRA**
 - Broad Agency Announcement (BAA): Science and Technology New Initiatives
 - New way for researchers to engage DTRA program managers by submitting a quad chart and white paper narrative to gauge interest in an idea and receive informal feedback.
 - Annual BASIC RESEARCH TOPICS call for pre-application white papers
 - Multi-year BAA, specific topics change annually based on program manager interest - little feedback

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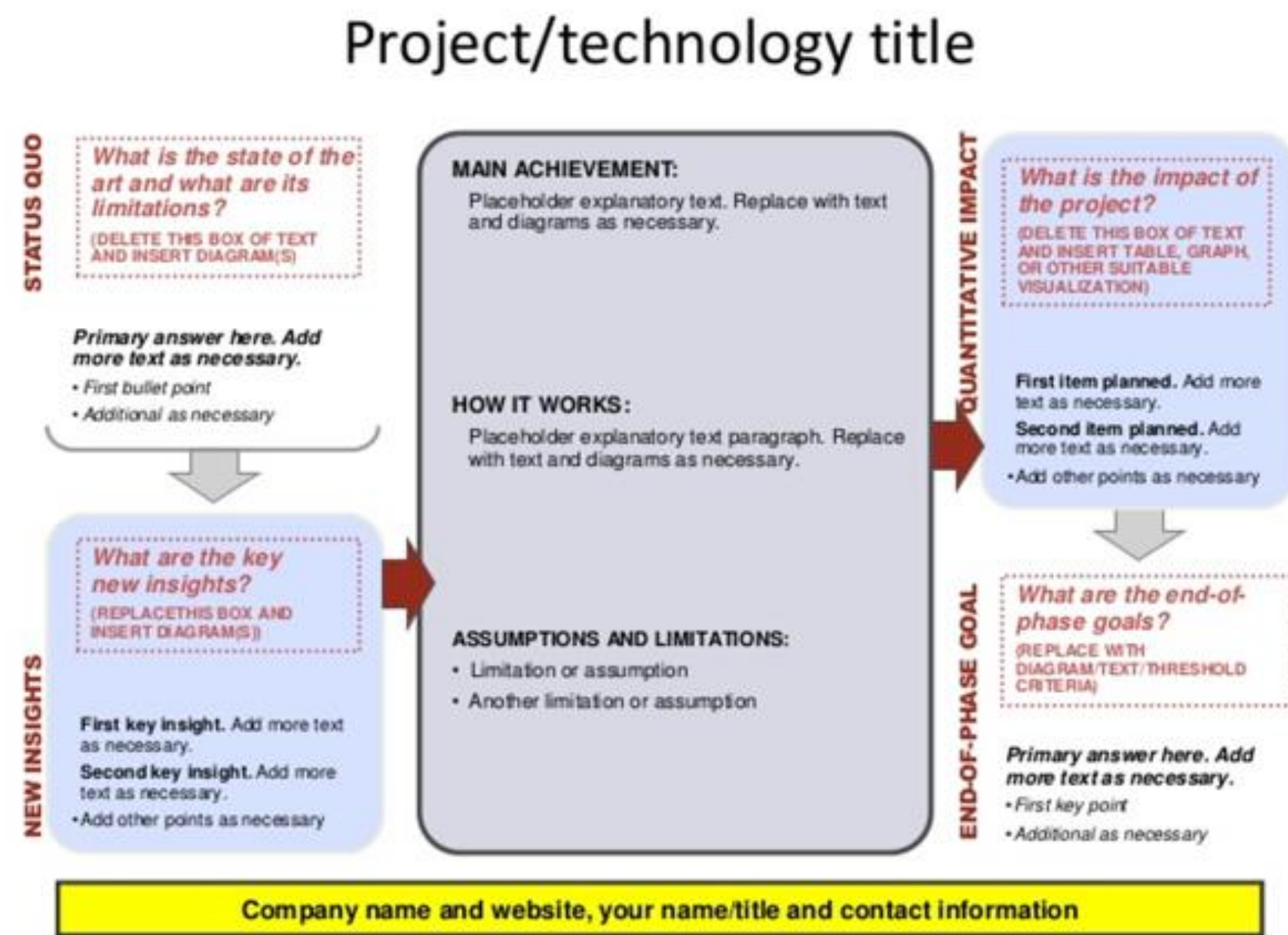
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Materials to Draft

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
	<p>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.</p> <p>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.</p>	
	<p>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.</p> <p>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.</p>	



Engaging DOD for Health and Biomedical Research

- **Attend 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.amedd.army.mil/SitePages/Home.aspx>
- **DTRA Chemical and Biological Science and Technology (CBD S&T) Conference:** DTRA hosts the annual conference in different locations and this is an opportunity to give talks and meet with DTRA and other federal program managers: <https://www.cbdstconference.com/>

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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>
- **Connect with program managers:** For ONR and DARPA, you have the ability to 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.

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Working with Lewis-Burke After Today

- Engage us...ASK us to
 - Identify new opportunities and programs or relevant program managers
 - 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
 - Advise on different kinds of funding mechanisms that may require different types of collaborations



Questions?

Please contact:

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