

Outlook and Opportunities: Federal Funding for Biomedical and Health Research

Lewis-Burke Associates, LLC
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About Lewis-Burke

- Founded in 1992; located in Washington, DC
- In 2019, 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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SLU/Lewis-Burke Relationship

- Began working with SLU in July 2017
- Lewis-Burke works with the VPR office and the Medical School Dean's office to advise on strategic research development priorities
 - Work as a team with Ken Olliff, Vice President for Research and Jasmin Patel, Assistant Vice President for Research Development
 - Jasmin Patel serves as the liaison and primary point of contact for us on campus
- Work together with leadership to identify opportunities, support faculty, and develop strategies
- Lewis-Burke supports efforts by providing a suite of services to facilitate SLU's engagement with federal research funding agencies

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Political Landscape

Federal S&T enterprise has enjoyed significant funding increases in recent years

- Consecutive bipartisan budget agreements enabled historic funding increases for research agencies in FY 2018-19 and moderate increases in FY 2020
- Trump Administration has identified priorities in artificial intelligence (AI), quantum, opioids, and STEM education and workforce development
 - OSTP Director Kelvin Droegemeier views universities as key stakeholders in U.S. innovation ecosystem

BUT challenges and vulnerabilities remain on the horizon

- 2020 Presidential election is 15 months away—as politics heat up, universities on guard
- Congress and federal agencies taking actions to prevent foreign influence, protect intellectual property
 - Additional immigration and visa threats emerging or expected; increased reporting and disclosure rules
- Personnel shakeup continues to undermine federal agencies
 - Loss of career staff reduces capacity and responsiveness with lasting effects
 - Continued attempts to dismantle regulatory agencies
- Despite FY 2020 budget agreement and progress on appropriations, shutdown possibility still looms as end of fiscal year approaches

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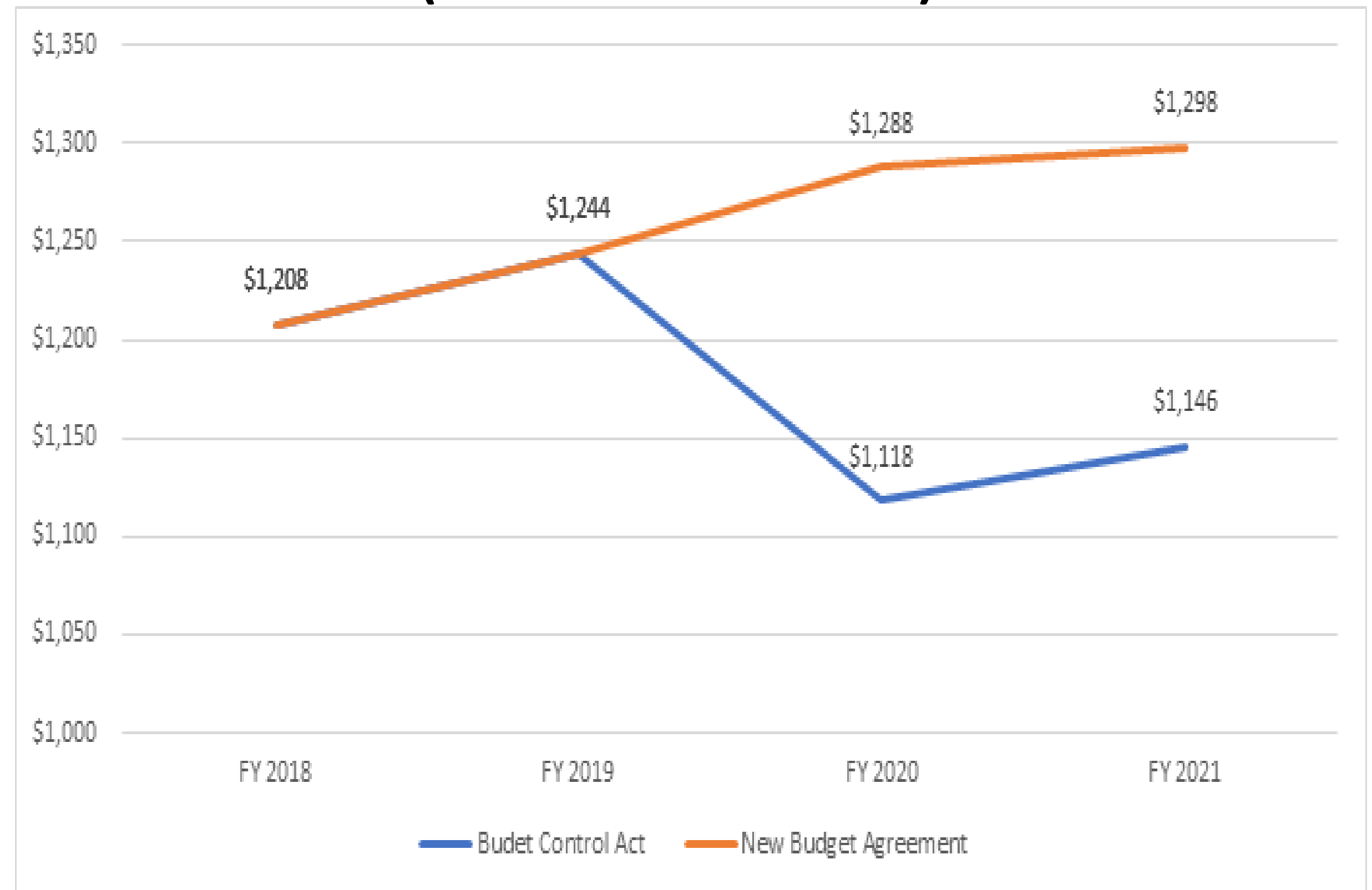
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Federal Funding Outlook

- New two-year bipartisan budget agreement raises discretionary spending by \$321 billion in FY 2020 and FY 2021
 - Avoids a \$126 billion cut in discretionary spending in FY 2020 compared to FY 2019 funding levels
 - Creates a path for Congress to complete FY 2020 spending bills
 - Likely outcome:
 - Some federal agencies will see boost in funding (NIH, DOE)
 - Others may see partial or full year Continuing Resolution at FY 2019 funding levels (NSF, NASA)

Comparison of Discretionary Spending between the Budget Control Act and the New Budget Agreement (in billions of dollars)



FY 2021 OSTP/OMB Priority Memo

Memo expands on FY 2020 priorities with an emphasis on a “Second Bold Era in S&T”; transformational leaps in science; focus on grand challenges and free from unnecessary admin burdens

Trump Administration Priorities in Science and Technology

While the FY 2020 president’s budget request proposes significant cuts to science and technology programs across the federal government, increased investments are proposed in top research and development priorities, including:

- quantum information science,
- artificial intelligence and machine learning,
 - strategic computing,
 - autonomous systems,
- genomics and engineered biology,
- next-generation microelectronics,
 - space exploration, and
 - precision agriculture.

R&D Priority Areas

– **Security of the American People**

- Military capabilities – Nuclear and Space
- **NEW** focus on critical minerals
- Critical infrastructure resilience & Semiconductors

– **Industries of the Future**

- AI, quantum science and computing
- Advanced communications and autonomy, including civil supersonic aircraft
- Advanced manufacturing

– **NEW Earth and Environmental Leadership**

- Nuclear energy R&D
- Oceans
- Earth systems predictability

– **Expanded Health and Bioeconomic Innovation**

- Biomedicine
- Veteran Health
- **NEW** Bioeconomy - Advancing biotechnology

– **Space Exploration & Commercialization**

Cross-Cutting Priorities

- Educating and Training a Workforce for the 21st Century Economy – build R&D capacity in HCU/MI
- **NEW**: Research environments that reflect American values
- **NEW**: Leveraging the power of data
- **NEW**: High Risk High Reward research
- Expand multi-sector partnerships

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Snapshot of Agency Priorities

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National Institutes of Health (NIH)

- **NIH on track for a fifth consecutive funding increase; House would provide \$41.1 billion in FY 2020**
 - Strong bipartisan support for the agency ensures increases and smooths defeat of damaging policy changes (e.g. F&A costs)
 - Future support for such increases unclear: deficits are growing; agency reaching growth limit?
- **Areas of trans-agency emphasis**
 - Opioids, addiction, pain management: \$1.1 billion total in FYs 2018 and 2019
 - Alzheimer’s Disease: \$2.4 billion in FY 2019
 - BRAIN Initiative: \$429 million in FY 2019, including \$115 million in *Cures* funding
 - Precision Medicine *All of Us*: \$376 million in FY 2019
 - Cancer Moonshot: \$400 million in FY 2019
- **Emerging trends:**
 - “AI + X”—leveraging AI & ML to address programmatic priorities
 - Favoring collaborative funding mechanisms (U awards) over program projects
 - Combating foreign influence
 - Next Generation Research Initiative (NGRI)—support for “at risk” investigators
- **Selected competitions on the horizon:**
 - Research facilities and construction (C06)
 - COEs on environmental health disparities
 - Emerging COEs in genomic sciences
 - Conte Centers for translational neuroscience and mental health
 - Administrative supplements in areas of trans-agency emphasis (e.g. opioids; aging; AI/ML; data science)

Department of Health and Human Services(HHS) Crosscutting Priorities

- Secretary Azar's priorities are carried through activities across HHS
 - Addressing the Opioid Crisis
 - Drug Pricing
 - Healthcare Reform

Agency for Healthcare Research and Quality (AHRQ)

- AHRQ's focus is health services research
 - Produce evidence to support health systems and providers to ensure high quality, safe, equitable, and high-value care through activities such as research, practice improvement, data, and analytics
- Research:
 - Current Priorities
 - “Research to improve health care patient safety
 - Harnessing data and technology to improve health care quality and patient outcomes and to provide a 360-degree view of the patient
 - Research to increase accessibility and affordability of health care by examining innovative market approaches to care delivery and financing”
 - New priorities:
 - Transforming care for people with multiple chronic conditions
 - Decision making through analytics
 - Improving diagnosis/reducing diagnostic errors

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AHRQ (Continued)

- Supports investigator-initiated research
- Relatively small funding compared to NIH (\$338 million)
- Uses “Special Emphasis Notices (SEN)” to communicate priorities
 - Current SEN:
 - Health Services Research Priorities for Achieving a High Value Healthcare System
- The Project Research Online Database (<https://prod.ahrq.gov/projectsearch/>) can provide an idea of the types of projects AHRQ funds

Health Resources and Services Administration (HRSA)

- HRSA's focus is to improve the health of underserved and vulnerable populations
 - Primary care
 - Maternal and Child Health
 - Workforce
 - Rural Health
- Focus areas: HIV/AIDS, opioids, mental and behavioral health, telehealth, and rural health
 - Focusing on HIV/AIDS as Part of the Trump Administration's efforts to End HIV but efforts are targeted and not really an opportunity for education or training
- Maternal and Child Health (MCH) at HRSA has smaller opportunities for research but funding and competitive
- Rural Health
 - Oversees telehealth
 - Supports rural opioid health activities
 - Research on population health and health care policy impacting rural area
 - Supports research centers
 - Great weekly newsletter if you are interested in rural health/research

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HRSA (Continued)

- **Health Professions**

- Title VII Health Professions support grant programs to support workforce education and training in medicine, mental and behavioral health, psychology, oral health and geriatrics
 - Focus: Interprofessional; access in rural and underserved areas; behavioral health; telehealth
 - Geriatrics Academic Career Awards were re-established this year and 26 awards were made (SLU was one of the 26 awards!)
 - Geriatric Workforce Enhancement Program was re-competed for five years and new awardees were announced in June (SLU was awarded a GWEP!)
 - Additional funding from Congress would likely result in increases to existing grantees or support additional grantees in a program
 - Title VII Programs are often competed for four or five years, so it is important to apply when available
 - Possible new Mental and Substance Use Disorder Workforce Training Demonstration grant if Congress appropriates funding this fiscal year (FY 2020)
 - Funding was included in the House Labor/HHS Appropriations bill but Senate still needs to pass a bill
 - Provides loans and scholarships
 - Scholarships for disadvantaged students
 - Faculty Loan Repayment Program
 - Title VIII Nursing Education Programs support nursing education for primary care, advanced practice nurses, nurse anesthetist training, veterans transitioning to nursing, and enhancing nursing education
 - House provided slight increases for other Title VIII programs; Senate unclear

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Substance Abuse and Mental Health Services Administration (SAMHSA)

- SAMHSA aims to reduce the impact of substance abuse and mental illness on America's communities
- Bipartisan support for mental health and substance abuse programs
- Current areas of focus:
 - Opioids
 - Serious Mental Illness (SMI)
 - Suicide Prevention
 - School Safety
 - Evidence-based practices – Policy Lab, National Technical Assistance and Resource Centers
- Reconfiguring its technical assistance approach to encompass a more national focus
 - This approach emphasizes training on evidence-based and effective practices to communities
 - **Center of Excellence for Eating Disorders:** national “hub” for developing and disseminating training and technical assistance for health care practitioners pertaining to eating disorders
 - **Center of Excellence for Protected Health Information Related to Mental and Substance Use Disorders:** national center focused on developing and disseminating, training, technical assistance, and educational resources on various privacy laws and regulations as they relate to information about mental and substance use disorders
- Leverage state government relations/connections

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Patient-Centered Outcomes Research Institute (PCORI)

- PCORI is interested in clinical comparative effectiveness research (CER)
- Focus on improving care delivery (prevention, screening, diagnosis, treatment), informing healthcare decisions, reducing disparities, and improving health communication techniques
- Bipartisan support in Congress for reauthorization (expires October 1)
 - Issues discussed during reauthorization process
 - How PCORI is funded
 - Dissemination
 - Value of PCORI
 - Currently two bills in the House; one reauthorizes for seven years, one for three years
 - New focus areas highlighted in these bills:
 - »Substance use (opioids), mental health, maternal morbidity and mortality
 - Senate bill is in draft form (expected but not introduced)
 - If PCORI releases FOA, it will have funding to support it

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Office of Minority Health (OMH)

- OMH supports activities to improve the health of racial and ethnic minority populations and eliminate health disparities
- Generally OMH has limited opportunities that come out in the spring
 - Fewer opportunities = more competitive
- Minority Health Resource Center
 - Resource for grant development; free, customizable search available for universities and faculty
 - Knowledge Center is the largest dedicated repository of health disparities information
- Division of Program Operations (DPO) – administers federal grants and co-op agreements to support community-based practices and models to address health disparities through education, prevention, awareness.
- Examples of current and past programs:
 - Empowered Communities for A Healthier Nation Initiative
 - Eliminating Lupus Health Disparities Initiative (ELHDI)
 - Minority Youth Tobacco Elimination Project (MYTEP)

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DOD Medical Research Priorities

- **General mission** – Support the Service Members, Veterans, and their families to aid and promote national security and defense
- **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
- **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
- **Human Performance Optimization** – readiness, rehabilitation, fatigue/sleep, nutrition

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DOD Health vs. NIH

NIH
\$39.1 B

Defense Health
~\$2 B

Defense Health Funding Agencies

- Defense Medical Research and Development Program (DMRDP)
- Congressionally-Directed Medical Research Program (CDMRP)
- Defense Advanced Research Projects Agency (DARPA)
- Office of Naval Research (ONR)
- Army Research Lab (ARL/ARO)
- Air Force Office of Scientific Research (AFOSR)
- Defense Threat Reduction Agency (DTRA)

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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
- 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

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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)
- 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)
- Reconstructive Transplant (\$12 m)
- **Melanoma (\$10 m)***
- **Chronic Pain Management (\$10 m)***
- Amyotrophic Lateral Sclerosis (\$10 m)
- Hearing Restoration (\$10 m)
- Orthotics and Prosthetics (\$10 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 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

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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

- 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

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.amedd.army.mil/SitePages/Home.aspx>
- **DTRA Chemical and Biological Science and Technology (CBD S&T) Conference:** DTRA hosts the biennial conference in different locations. This year's conference is November 18-21, 2019, in Cincinnati, Ohio. 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 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

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