About Lewis-Burke

• Founded in 1992; located in Washington, DC
• In 2018, 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
National Institutes of Health (NIH)

- $3 billion increase in FY 2018, bringing the agency to $37.1 billion in total funding
  - Congress thoroughly rejected Administration’s attempts to cap F&A costs on NIH grants
- Current areas of trans-NIH emphasis:
  - Opioids, addiction, neurobiology of pain and pain management ($500 million in 2018)
  - Alzheimer’s Disease ($1.8 billion investment in FY 2018)
  - BRAIN Initiative ($400 million in FY 2018)
  - Precision Medicine—the All of Us Program ($290 million in FY 2018)
  - Cancer ($300 million in FY 2018)
  - Biomedical Data Science Strategic Plan
- Award trends—agency focused on “research productivity and efficiencies”
  - Pulling back on Program Project grants (P awards)
  - Collaborative funding mechanisms enhance program officers’ input on project (U awards)
  - Next Generation Researchers Initiative: enhanced support mechanisms for early and mid-career investigators
    - $100 million dedicated fund within OD proposed for FY 2019
  - Seeking to reduce PI salary support on grants
Microbiome

- **Interagency Strategic Plan for Microbiome Research FY 2018-2022** (published April 2018)
  - Develop predictive capabilities of microbiome function and the effects of disruption in 8 key environments (agriculture; aquatic; human; laboratory; built environment; terrestrial; energy; atmospheric)
  - Develop platform technologies
  - Expand the microbiome workforce (big data and computation)

- **NIH**
  - Human Microbiome Project (HMP): transitioned from Common Fund support in 2017; emphasis on computational tools and research resources, demonstration projects; multi-omics
  - Trans-NIH Microbiome Working Group: individual ICs continue to support microbiome research; limited number of center awards/cooperative agreement awards
    - Translational and Clinical Probiotic/Prebiotic and Human Microbiome Research (NCI; NICH; NIDA; NCCIH)
    - Role in nutrition, obesity, digestive, and liver diseases (NIDDK; NCCIH)
    - Oral microbiome and sensors (NIDCR)
  - *All of Us* Research Program: microbiome as precision medicine component

- **NSF**
  - Forecasting and Emergence in Living Systems (Rules of Life)
    - Understanding genomic and environmental inputs to predict complex biological systems
    - Current cycle of EAGER and RAISE awards; conference proposals

- **Office of Naval Research (prior years)**
  - Gut Microbiology for Warfighting Resilience Program: host-intestinal microbial interactions in response to specific stressors (rapid environmental shifts; fatigue; anxiety; abnormal circadian cycles)

- **USDA—NIFA (prior years)**
  - Animal and Plant Phenomics and Microbiomes: technology development to speed characterization and research
  - Food safety: microbial, chemical, and physical safety and quality of foods

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**Neuroscience**

**BRAIN Initiative**
- NIH: only agency actively continuing this Obama Administration Initiative towards 2025
  - $1.5 billion over 10 years (*21st Century Cures*)
  - FY 2018: $390 million, inclusive of Cures funding
- Approved concept clearances for FY 2018 include Development of Next-Gen Human Brain Imaging Tools; Next-Gen Devices for Recording and Modulation in Human Central Nervous System; Biology and Biophysics of Neural Stimulation
- Support for BRAIN proposals that target nociceptive and pain circuits
- NINDS/NIMH launching effort to assess BRAIN Initiative progress, a set of assessment questions and metrics being developed to assess BRAIN Initiative progress towards its stated goals.
- NSF: formal NSF plan for BRAIN ended in 2017; continue to pursue programmatic objectives in neuroscience; identified the human-technology frontier as one of “Ten Big Ideas” for priority investment in the future
- DOE: collaborations with NIH to leverage DOE high-performance computing, nano-fabrication, and modeling
- DARPA: Biological Technologies Office (BTO) continues to support through BAAs, but no new programs at this time

**Alzheimer’s Disease (AD) and aging**
- $1.8 billion in FY 2018
- Priorities: precision medicine approaches to AD; predictive drug development; biomarkers; clinical trials; expand SBIR/STTR portfolio; support for caregivers

**Neurodegeneration**
- Priorities: biomarkers; Lewy Body Dementia; vascular dementias; proteomics and protein folding/trafficking (NINDS)
Opioids and Pain

Congressional activities:
• FY 2018 Omnibus: ~$3 billion total in opioid response funding across HHS, DOJ, USDA
• Both House and Senate Prioritizing opioids and Considering new legislation:
  – Pending legislation could expand NIH authority to use “other transactional authority” for public health emergency research (not traditional peer review process)
  – Wants to move quickly on passage

NIH:
• $500 million split evenly for NIDA/NINDS in the FY 2018 omnibus
• HEAL Initiative: $1 billion trans-NIH focusing on preventing addiction, neurobiology of pain and pain management, and improving treatments for opioid use disorder
  – Understand the transition from acute to chronic pain (longitudinal studies)
  – Identify causes of opioid use disorder
  – Develop more medication-assisted treatments for opioid addiction and overdose reversal
  – Identify non-opioid treatments for pain

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Precision Medicine

• Trans-NIH priority—21st Century Cures Act
• All of Us Research Program
  – Enroll 1 million or more volunteers to enable research for range of diseases, including statistical power to detect genetic and environmental exposures - $1.4 billion over 10 years (21st Century Cures)
  – Awards thus far focused on research infrastructure and participant enrollment: data and research center (Vanderbilt), participants technologies (Scripps), healthcare providers organizations, and biobank (Mayo)
  – Big data: biospecimens; lifestyle factors; environmental factors; electronic health records
• Many ICs taking a “precision medicine” approach to their portfolios
  – Precision aging and cognitive resilience (NIA)
  – Kidney biology (NIDDK)
  – Addiction and substance use disorders (NIDA)
  – Management of chronic illnesses (NINR)