Methodology Core for Community Translational Health Sciences

Lewis-Burke Associates LLC
May 2018
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
Agency for Healthcare Research and Quality (AHRQ)

- **Priorities**: create and disseminate effective tools and measures for health care systems to improve care and outcomes
  - Focus on opioids, health IT, investigator-initiated research
  - Agency’s reimagine efforts will highlight three proposed areas for future funding:
    - Patient Safety – hospital-acquired infections (HAIs)
    - Practice – evidence-based practices, patient-reported outcomes and quality
    - Data and Insight – interactive maps on opioids (prescribing practices; overdose events)
  - Trends of congressional funding cuts to the agency over the last few years
  - Concerns about “duplicative” efforts by AHRQ and other agencies
  - Proposals to consolidate AHRQ into NIH have been rejected by Congress in the past
  - If PCORTF is not reauthorized before September 30, 2019, AHRQ will face an approximate 25 percent budget reduction starting in FY 2020
  - Taking conservative approach to issuing new awards in FY 2018 due to budget uncertainty
Patient-Centered Outcome Research Institute (PCORI)

- **Priorities**: Comparative clinical effectiveness research (CER); patient-centered outcomes research (PCOR)
- **Anticipated solicitations**:
  - Pragmatic clinical trials (e.g. cancer; pain; rare diseases; trauma/injury, mental health, etc.)
  - Methods for conducting patient-centered outcomes research
  - Shared decision making
  - Improving healthcare systems
  - Addressing health disparities
  - Communication and dissemination research
- **Created under the Patient Protection and Affordable Care Act (ACA)**
  - Several skeptics about impact
  - Funding dissolves in 2019 (PCOR Trust Fund), unlikely to be reauthorized
  - **BUT** current opportunities will be fully funded
  - After 2019, activities likely sustained independently via PCORnet, the National Patient-Centered Clinical Research Network
Clinical Outcomes Research & Prevention

• PCORI
  – Focus on comparative clinical effectiveness research (CER) and patient-centered outcomes research
  – Pragmatic clinical trials: cancer; dental health; mental & behavioral health; neurological disorders, respiratory disease; trauma, etc.

• AHRQ
  – Optimizing care for individuals with multiple chronic conditions; shared decision making tools; improving ambulatory care; hospital-acquired infections

• NIH
  – Many ICs interested in implementation science—increasing and promoting the adoption and integration of evidence-based practices, interventions, and policies:
    • Colorectal cancer (NCI)
    • Substance Use Disorders and Treatment (NIDA; NIMH; NIAAA)
    • Dental, Oral, and Craniofacial Health (NIDCR)
    • Sickle Cell Disease (NHLBI)
    • HIV Prevention and Treatment (NIAID; NIMH; NICHD)
Translational Research

• NIH continues to feel congressional pressure to accelerate the translation of basic, discovery science into interventions that improve health

• NCATS
  – Translation on a system-wide level as a scientific and operational problem by focusing what is common across diseases and the translational process
  – Clinical and Translational Science Awards (CTSA), support network of large centers at more than 60 academic health centers that work together to improve the translational research process
  – Other activities, such as the Bridging Interventional Development Gaps (BriDGs), Therapeutics for Rare and Neglected Diseases (TRND), and Discovering New Therapeutic Uses for Existing Molecules include partnerships with pharmaceutical companies

• Other ICs have translational research offices and programs to encourage/support translation of basic discoveries into novel therapeutics (e.g. NCI Office of Translational Resources)

• SBIR/STTR grants support innovative research conducted by small business that has potential for commercialization
  – Many ICs seeking to ramp up their small business grants portfolio to meet statutory set-asides
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)
Health Disparities

**NIMHD**
- Over last two years, and under new leadership, have ramped up support for individual investigators through RPGs (moving away from all but statutory Centers programs)
- Next Centers of Excellence (COE) competition likely in 2020
- Research priorities: integrative biological and behavioral research; clinical and health services research; community health and population sciences
- Research framework for promoting minority health and reducing health disparities
  - Domains: biological; behavioral; physical/built environment; sociocultural
  - Levels: individual; interpersonal; community, societal
  - Health Outcomes: individual health; family/organizational health; community health; population health

**HHS Office of Minority Health**
- Priorities: support 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
  - Knowledge Center is the largest dedicated repository of health disparities information
- Examples of currents and past programs:
  - Eliminating Lupus Health Disparities Initiative (ELHDI)
  - Minority Youth Tobacco Elimination Project (MYTEP)