National Institutes of Health Update

Council of Councils

January 27, 2017

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Principal Deputy Director, NIH

Topics for Today

- 21st Century Cures Act Implementation

- Update on Associate Director for Data Science (ADDS) Office and Big Data to Knowledge (BD2K) Program

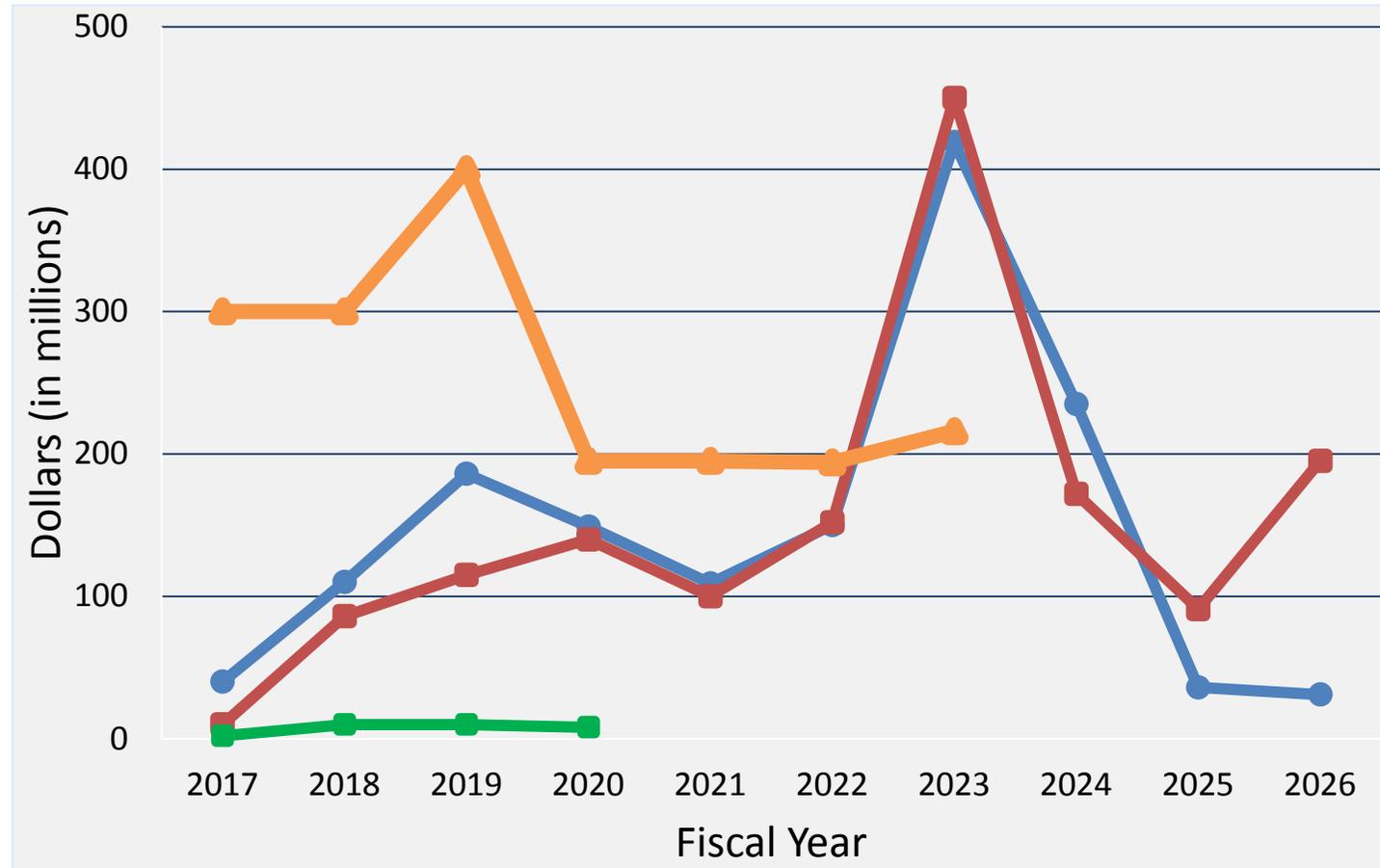- Transitioning to a New Administration

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NIH in the 21st Century Cures Act
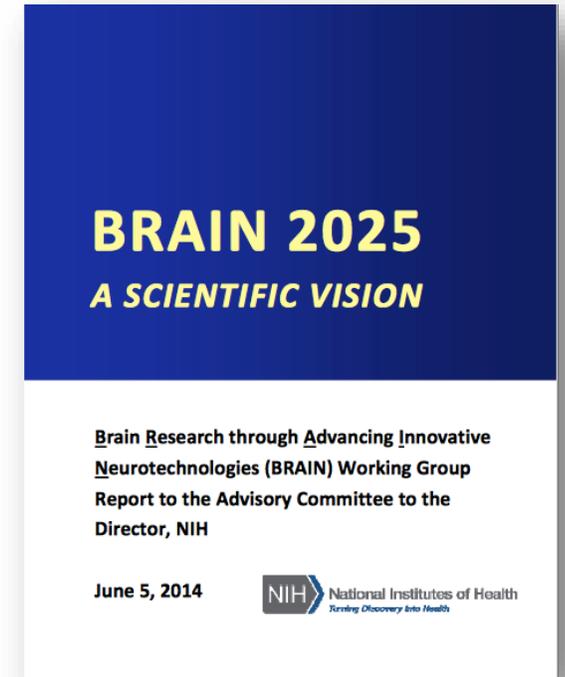
- **Establishes the NIH Innovation Account**
  - Funding: $4.8B for 10 years that must be appropriated each year
  - Does not count against the budget caps
  - Reauthorizes NIH:
    - FY18: $34,851,000,000
    - FY19: $35,585,871,000
    - FY20: $36,472,442,775

PMI = $1.45 B   **BRAIN** = $1.5 B   **Moonshot** = $1.8 B
Regenerative Med = $30 M

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BRAIN* Initiative

- **Goal:** To understand how individual cells and the neural circuits they form interact in both time and space to store and process information and enable the spectrum of human behavior

- **Long Term Goal**: The ability to monitor and regulate brain circuits will transform our ability to diagnose and treat neurological/mental health disorders
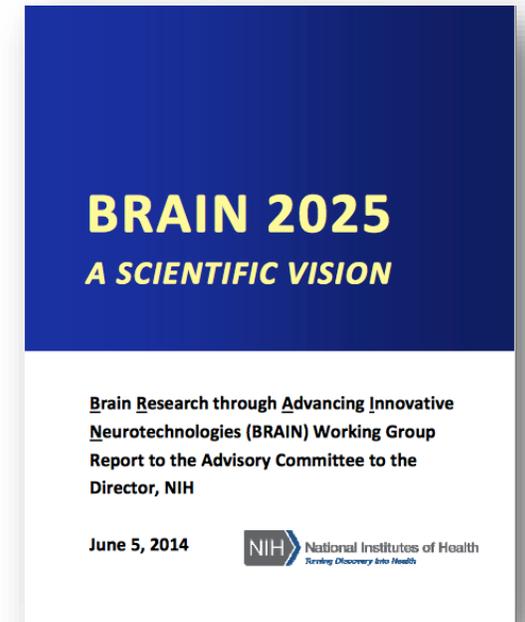

*Brain Research through Advancing Innovative Neurotechnologies

http://acd.od.nih.gov/presentations/BRAIN_working_Group_Report_06052014.pdf

BRAIN* Initiative

- **To Date**: a collaboration among five federal agencies including 10 NIH Institutes and Centers, non-federal foundations and institutes, industry, and Universities
  - BRAIN has released almost 2 dozen funding opportunities with the potential to fund ~ $100 M in new awards in FY17
- **Early 2017**:
  - Applications for 3 new FOAs due in March 2017

BRAIN 2025
A SCIENTIFIC VISION

Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Working Group Report to the Advisory Committee to the Director, NIH

June 5, 2014   NIH National Institutes of Health
Turning Discovery Into Health

*Brain Research through Advancing Innovative Neurotechnologies

http://acd.od.nih.gov/presentations/BRAIN_working_Group_Report_06052014.pdf

Precision Medicine Initiative (PMI)/
All of Us^{SM} Research Program

- **Long Term Goal:** Deliver a national resource of clinical, environmental, lifestyle, and genetic data from one million or more participants who are consented and engaged to provide data on an ongoing, longitudinal basis that will accelerate scientific discovery and breakthroughs in precision medicine

https://www.nih.gov/allofus-research-program

PMI/*All of Us*^{SM} Research Program

- **To Date**:
  - Built awardee network (50+); collaborating well
  - Version 1 protocol nearing completion
  - Completed workshops to define community outreach plan and target partners
  - Development almost complete of enrollment website, 1-800#, smartphone apps, data center
  - Testing IT interfaces for data/sample transfer and testing/documenting security systems for ATO
  - Started build out of biobank capacity (>35M samples)

https://www.nih.gov/allofus-research-program

PMI/*All of Us*^{SM} Research Program

- **Early 2017**:
  - One FOA to be released
  - Once IRB approval obtained, platform fully tested and privacy/security reviews complete, begin launch activities (~Q1/Q2)
  - Implement NIH's revised policies on Paperwork Reduction Act, data sharing, certificates of confidentiality following Cures
  - Building public confidence that the project has support/sustainability - including the on-going funding needed to compete on the global stage
  - Workshops to identify research questions that will inform near-, mid-, and long-term Program goals

Cancer Moonshot

BLUE RIBBON PANEL 2016
CANCER MOONSHOT

- **Goals:**
  - Manipulating tumor pathways and immune responses to improve treatments
  - Understanding specific tumor genes and how they contribute to pediatric cancer
  - Expanding and creating tissue-engineered systems that mimic tumors
  - Encouraging greater cooperation and collaboration within and between academia, government, and private sector
  - Enhancing data sharing

- **Long Term Goals**:
  - Accelerating progress in cancer, including prevention and screening, from cutting edge basic research to wider uptake of standard of care

https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/blue-ribbon-panel

Cancer Moonshot

BLUE RIBBON PANEL 2016
CANCER MOONSHOT

- **To Date:**
  - Blue Ribbon Panel report released

- **Early 2017:**
  - Completing release of 14 FOAs
  - Preparing for rigorous peer review of applications

https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/blue-ribbon-panel

Regenerative Medicine

- **Goal**: in coordination with FDA, support clinical research using adult stem cells (including autologous stem cells), to further the field of regenerative medicine; applicants required to provide matching funds

- **Early 2017:**
  - Develop potential options for the funds:
    - Design new FOA(s) to be supported with Cures funds
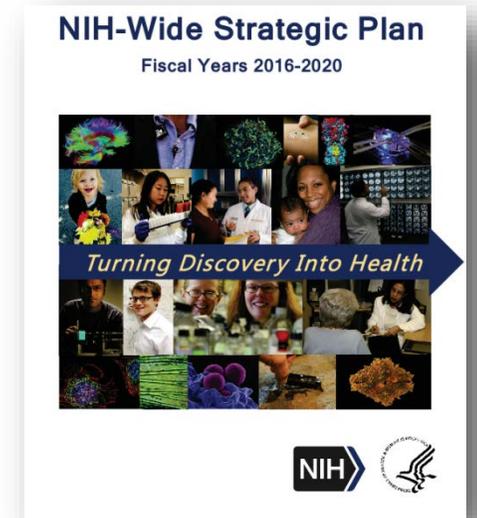
Next Generation Researchers Initiative

- The NIH Director will coordinate all policies and programs within the agency aimed at promoting and providing opportunities for new researchers and earlier researcher independence

- Consolidates NIH's current loan repayment programs (LRPs) into extramural and intramural LRPs
  - the current LRPs listed as subcategories under each section
  - raises the cap to $50,000

- Requires a GAO report within 18 months after enactment on NIH efforts to attract, retain, and develop emerging scientists

Eureka Prize Competitions

- The NIH Director will support prize competitions for one or both of the following goals
  - Identifying funding areas of biomedical science that could realize significant advancements through a prize competition
  - Improving health outcomes, particularly with respect to human diseases and conditions that:
    - Have relatively small research investment compared to prevention and treatment investments
    - Represents a significant US disease burden; or
    - For which there is the potential for significant return on investment
- NIH Director will collection information on the effect of innovations funded though the prize mechanism and the effect of mechanisms on Federal expenditures

NIH in the 21st Century Cures Act – Requirements

- Establishes Reporting Requirements for:
  - The NIH-Wide Strategic Plan
    - Update NIH-Wide Strategic Plan every 6 years
    - Will serve as foundation for common template used for IC Strategic Plan updates
  - Inclusion of women and minorities in NIH-funded research

- Establish ACD Working Group to provide recommendations to enhance rigor and reproducibility
  - NIH Director will consider recommendations within 18 months and develop/update policies as appropriate
  - NIH Director will issue a report within 2 years regarding recommendations and potential policy changes

NIH-Wide Strategic Plan: Ensuring Rigor and Reproducibility

- Raise Community Awareness
  - Commentaries, workshops, and Principles and Guidelines for Reporting Preclinical Research

- Enhance Formal Training
  - Training modules, workshops, and supplements

- Adopt a More Systematic Review Processes
  - Clarified and revised application instructions and review criteria

- Share Information/Data
  - PubMed Commons, symposium

- Increase Stability for Investigators
  - Pilots to award longer grants, providing more stable support

https://www.nih.gov/research-training/rigor-reproducibility

NIH in the 21st Century Cures Act – Additional Provisions

- Exempts scientific meetings from the travel & conference approval requirements but requires reporting

- Exempts NIH research from the Paperwork Reduction Act requirements

- Requires NIH Director to implement measures to reduce administrative burden on sub-recipient monitoring

- Allows central IRBs for review of investigational device exemptions and human device exemptions

- Authorizes NIH Director to require awardees to share data that is generated from NIH-funded research

- Creates a FOIA exemption for individual biomedical information that is, or has the potential to be, identifiable

- Requires the NIH Director to improve research related to sexual and gender minority populations

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- Transitioning to a New Administration

Big Data to Knowledge (BD2K) Program

- Initiated in 2012 as a trans-NIH initiative
  - To enable biomedical research as a digital research enterprise

- Support committed from NIH Common Fund and all ICs through FY2021

- Associate Director for Data Science (ADDS)
  - Sets the vision for trans-NIH data science and oversaw BD2K programs
  - Dr. Phil Bourne stepped down in early January 2017

- Going forward
  - Dr. Patti Brennan (Director, NLM) is serving as Interim ADDS
  - BD2K will be managed as a Common Fund program through DPCPSI/OSC

https://datascience.nih.gov/bd2k

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A New Administration

- Mr. Norris Cochran is currently acting Secretary, HHS
- Dr. Tom Price is the Administration's nominee for Secretary, HHS
- Dr. Francis Collins has been held over into the new Administration

NIH...

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Turning Discovery Into Health