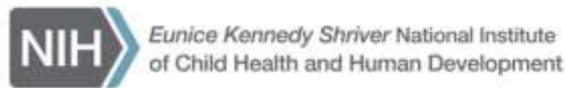


# NICHD Director's Report

Catherine Y. Spong, M.D.  
Acting Director, NICHD



# Presentation Overview

- News from NIH
- News from NICHD
- Legislative and Budget Updates
- Questions



# News from NIH



# Director of the Precision Medicine Initiative Cohort Program (PMI-CP)

- Eric Dishman
- Member of PMI working group
- Previous role: Vice President and Intel Fellow of Intel Corporation's Health & Life Sciences Group
- Will start the last week of June





# Seeking PMI-CP Chief Technology Officer

- Will assist the PMI-CP Director in the various technical and data challenges of the Precision Medicine Initiative Cohort Program
- Applications due June 24, 2016
- For more information visit:  
<https://jobs.nih.gov/vacancies/executive.htm>



# NIH Funds Biobank to Support PMI

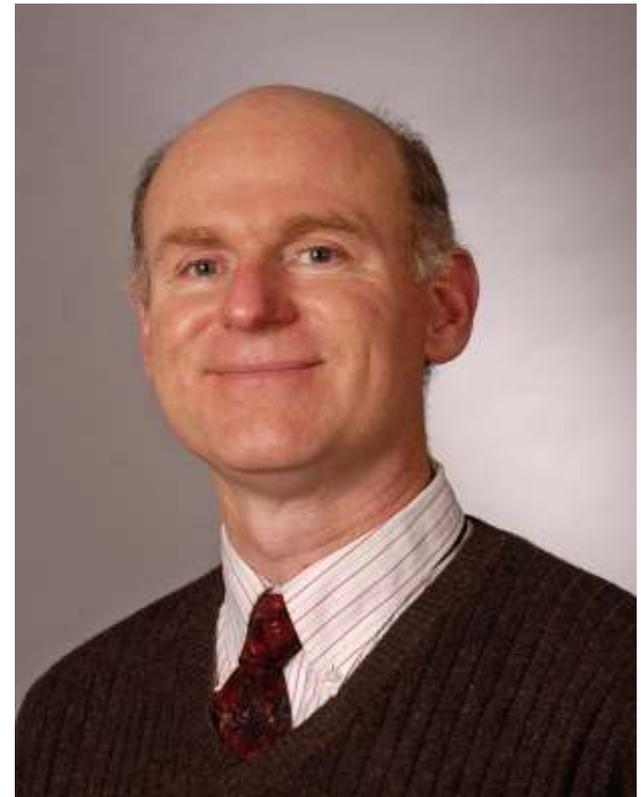
- Mayo Clinic
- \$142 million over five years to establish the world's largest research-cohort biobank for the PMI Cohort Program
- Provide infrastructure to store, analyze, and make available to researchers more than 35 million biospecimens and data





## Environmental Influences on Child Health Outcomes (ECHO) Program Director

- Matthew W. Gillman, M.D.
- Previous role: Professor of Population Medicine and Nutrition at Harvard
- Lead Project Viva
- Involved in the early stages of the National Children Study
- Will begin role in July 2016





# ECHO Seeks Senior Program Official

- Responsible for working with the ECHO Program Director to direct the planning, coordination, and integration of ECHO program activities with the NIH Institutes and Centers, and provide input into scientific decision-making of the ECHO program
- Applications due June 20, 2016
- For more information:  
<https://jobs.nih.gov/vacancies/executive.htm>



# ECHO/IDeA Program

- Applications were due April 15
- Robust response
- Grants to be awarded at the end of this fiscal year
- Matt Gillman will oversee the ECHO program, which includes oversight of the IDeA States Pediatric Clinical Trials Network
- NICHD/Dr. Robert Tamburro, a medical officer in the Pediatric Trauma and Critical Illness Branch, will manage the IDeA States Network for NIH



# New Director of National Library of Medicine Named

- Patricia Flatley Brennan, R.N., Ph.D.
- Currently: Lillian L. Moehlman Bascom Professor, School of Nursing and College of Engineering, at the University of Wisconsin-Madison
- Developed ComputerLink, an electronic network to reduce isolation and improve self-care among home care patients
- Dr. Brennan is expected to begin her new role in August 2016





# NIH Associate Director for AIDS Research and Director of the NIH Office of AIDS Research

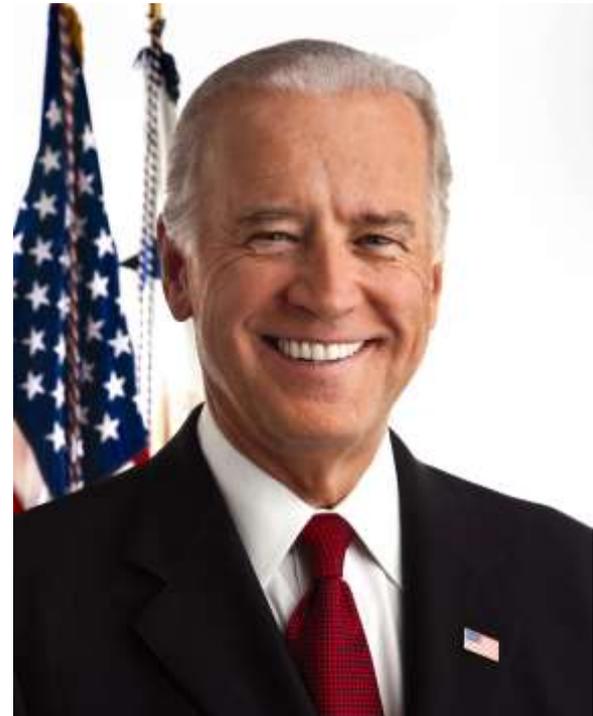
- Maureen M. Goodenow, Ph.D.
- Currently: University of Florida, Gainesville, professor of pathology, immunology, and laboratory medicine
- Join NIH in July 2016
- Will work closely with the NIH institutes and centers, to pursue new tools for preventing HIV infection including a vaccine, improved treatments, and ultimately, a cure





# Cancer Moonshot Blue Ribbon Panel

- To help guide Vice President Biden's National Cancer Moonshot Initiative
- Serves as a working group of the presidentially appointed National Cancer Advisory Board and will provide scientific guidance from thought-leaders in the cancer community
- The panel will consider how to advance the themes that have been proposed for the initiative





## Online Platform Opens to Submit Ideas about Research for Cancer Moonshot

- Enables research community and public to submit ideas on the National Cancer Moonshot efforts
- Submissions will be considered by the Blue Ribbon Panel as they develop the scientific direction for the initiative
- Submit your ideas at [CancerResearchIdeas.cancer.gov](http://CancerResearchIdeas.cancer.gov) by July 1, 2016



# NIH Clinical Center

- ACD Working Group on the Clinical Center (“The Red Team”) made recommendations on reducing risk and promoting patient safety at the NIH Clinical Center





# Clinical Center: Red Team Report Themes

- Fortify a culture and practice of safety and quality
- Strengthen leadership for clinical care quality, oversight, and compliance
- Re-align authority with responsibility to ensure optimal leadership of CC
- Address sterile processing of all injectable products and the specifics of the sentinel event



## Clinical Center Changes

- NIH has taken the following steps:
  - Establishing a Hospital Board
  - Establishing an NIH Office of Research Support and Compliance
  - Retaining two companies specializing in quality assurance for manufacturing and compounding



# Clinical Center Appointments

- The Hospital Board will be led by Chairperson Laura Forese, M.D., executive vice president and chief operating officer at New York-Presbyterian
- NIH Office of Research Support and Compliance will be directed on an interim basis by Kathryn Zoon, Ph.D., formerly Scientific Director at NIAID and Director of the FDA's Center for Biologics Evaluation and Research





# Red Team Recommendations

- Centralizing authority for intramural clinical care and research
- Leadership team with expertise and experience primarily in hospital management and patient care to complement our existing expertise in research focused on management
- NIH will conduct a nationwide search for a physician CEO with proven experience in management of a complex inpatient and outpatient facility to oversee facilities and report to the new Hospital Board

# NIH Supports Basic Research

Science, Vol. 351,  
Issue 6280 pg.  
1405



## LETTERS

Edited by Jennifer Silis

### Basic science: Bedrock of progress

ALMOST 4 YEARS ago, one of us (F.S.C.) wrote an Editorial (1) affirming the continued importance of basic research to the National Institutes of Health (NIH) mission. The Editorial emphasized that basic scientific discovery is the engine that powers the biomedical enterprise, and NIH continues to spend more than half its budget supporting basic research projects. This is critical, because the private sector generally funds projects that yield a more rapid return on investment.

Despite these assurances, some members



of the community believe that NIH's interest in basic science is flagging. For example, investigators have told us that the requirement for a "Public Health Relevance" statement in every NIH research grant application suggests that every project must relate directly to a public health concern—that NIH places less value on projects that cannot be expected to yield an immediate public health benefit. This is simply not true. As we wrote in our Strategic Plan (2), we recognize that many of the most important medical advances trace back to basic research that had no explicit disease link. To address this concern, we have revised our application instructions (3) so that the Public Health Relevance statement reflects the NIH mission and our commitment to supporting a robust, diverse research portfolio, including the pursuit of basic biological knowledge.

We are particularly concerned that misperceptions about NIH's priorities and interests may be causing investigators to submit fewer basic research applications. For example, the National Institute of

Neurological Disorders and Stroke (NINDS) noticed a gradual and significant decline in the number of basic grants awarded between 1997 and 2012 (4). This decrease in awards was not a consequence of peer review given that basic grant applications actually did substantially better in review than applied research proposals. Instead, the major driver of this decline was a decrease in the number of fundamental basic research applications submitted.

The taxpayer investment in NIH has yielded spectacular returns from basic science over the long term. These range from the discoveries of the low-density lipoprotein receptor (5) and the development of CRISPR-associated protein-9 nuclease (6, 7) to recent substantial advances in structural biology through cryo-electron microscopy (8). For this track record of success to continue, we must continue our vigorous support of the pursuit of fundamental knowledge. All of NIH's senior leaders believe strongly that progress toward these goals occurs most rapidly when investigators pursue their passions, whether they lie in basic research or in applied, disease-focused studies. By supporting a broad portfolio of basic, translational, population, and clinical research, NIH will continue to lead the way toward a healthier future.

Francis S. Collins,<sup>1\*</sup> James M. Anderson,<sup>2</sup> Christopher P. Austin,<sup>3</sup> James F. Battey,<sup>4</sup> Linda S. Birnbaum,<sup>5</sup> Josephine P. Briggs,<sup>6</sup> Janine A. Clayton,<sup>7</sup> Bruce Cuthbert,<sup>8</sup> Robert W. Eisinger,<sup>9</sup> Anthony S. Fauci,<sup>10</sup> John L. Gallin,<sup>11</sup> Gary H. Gibbons,<sup>12</sup> Roger L. Glass,<sup>13</sup> Michael M. Gottesman,<sup>14</sup> Patricia A. Gray,<sup>15</sup> Eric D. Green,<sup>16</sup> Pransiska B. Greider,<sup>17</sup> Richard Hodes,<sup>18</sup> Kathy L. Hudson,<sup>19</sup> Betsy Humphreys,<sup>20</sup> Stephen I. Katz,<sup>21</sup> George F. Koob,<sup>22</sup> Walter J. Koroshetz,<sup>23</sup> Michael S. Lauer,<sup>24</sup> Jon R. Lorsch,<sup>25</sup> Douglas R. Lowy,<sup>26</sup> John J. McGowan,<sup>27</sup> David M. Murray,<sup>28</sup> Richard Nakamura,<sup>29</sup> Andrea Norris,<sup>30</sup> Eliseo J. Perez-Stable,<sup>31</sup> Roderic I. Pettigrew,<sup>32</sup> William T. Riley,<sup>33</sup> Griffin P. Rodgers,<sup>34</sup> Paul A. Sieving,<sup>35</sup> Martha J. Somerman,<sup>36</sup> Catherine Y. Spong,<sup>37</sup> Lawrence A. Tabak,<sup>38</sup> Nora D. Volkow,<sup>39</sup> Elizabeth L. Wilder<sup>40</sup>

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3. NIH, Grant Application Instructions (<http://grants.nih.gov/grants/how-to-apply-application-guide/forms-df-general/ig220-r&r-other-project-information-form.htm#8>).
4. S. Landis, Back to Basics: A call for fundamental neuroscience research (<http://blog.ninds.nih.gov/2014/03/27/back-to-basics/>).
5. M. S. Brown, J. L. Goldstein, *Science* **232**, 34 (1986).
6. M. Jinek et al., *Science* **337**, 816 (2012).
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8. A. Bartesaghi et al., *Proc. Natl. Acad. Sci. U.S.A.* **111**, 11709 (2014).

### A research symbiont

M. MCNUTT ("I AM A RESEARCH PARASITE," Editorial, 4 March, p. 1005) can be proud to be a "research parasite." The creators of this term, Longo and Drazen (1), miss the very point of scientific research when they write that researchers may "even use the [open] data to try to disprove what the original investigators had posited." It is at the core of the scientific paradigm that researchers take nothing as final truth. In fact, using research data to try to disprove a result is



# Gabriella Miller Kids First: FY 2016 Initiative

- PAR-16-150 Discovery of the Genetic Basis of Childhood Cancers and of Structural Birth Defects: Gabriella Miller Kids First Pediatric Research Program (X01) **Applications due June 17, 2016**
- PAR-16-150 is a re-issue of PAR-15-259 with some changes

To identify samples for whole genome sequencing that will help to elucidate the genetic contribution to childhood cancers and the genetic etiology of structural birth defects. The clinical and genetic sequence data will become part of the forthcoming Kids First data resource



## NIH-BMGF Meeting

- 3rd annual consultative workshop
- Bill Gates attended
- NICHD staff discussed maternal child health topics and Zika Virus



Photo: Bill Branson



## News from NICHD

# Zika Virus

NICHD Activities





# Joining Forces with Brazil

- High level delegation visited Brazil February 18-19
- Met with Brazilian health officials
- In March, briefed Liliana Ayalde, the United States Ambassador to Brazil, about NICHD's planned cohort study and rapid funding opportunity





# NICHD Participation in Zika Activities

- Zika in the Americas Countermeasures Workshop
- Zika Action Plan (ZAP) Summit
- Zika Plenary at the Consortium of Universities for Global Health 2016 Annual Conference
- Office of Research on Women's Health Advisory Board Meeting
- Numerous HHS calls and working groups



# Zika Related Legislative Activities



Dr. Nahida Chakhtoura was part of a briefing held by Senator Ben Cardin and Johns Hopkins Medicine to discuss the topic of Zika Virus readiness with Maryland health officials



# NICHD Zika Virus Research Activities

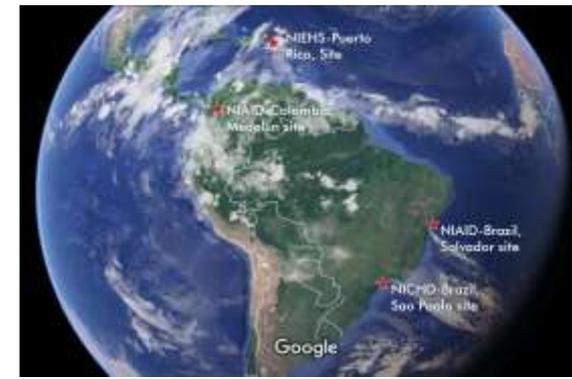


- Dr. Chakhtoura will give an update shortly
- PAR-16-106 - Rapid Assessment of Zika Virus Complications (R21)
  - Applications accepted on a rolling basis, began on April 20, 2016; first round coming to this Council for second round of review
  - Thanks to Sherry Dupere for arranging the rapid review so grants could come to June Council



# Zika in Infants and Pregnancy (ZIP) Cohort Study

- Multi-site, multi-country prospective observational cohort study
- To determine the risks of Zika infection during pregnancy on maternal and fetal outcomes while controlling for potential confounders
- 10,000 women planned
- Standardized protocol, data collection
- Supported by NICHD, NIAID, NIEHS  
Fundacao Oswaldo Cruz-Fiocruz





# Zika Workshop Focused on Children

- September 2016 in Bethesda, Maryland
- Define the evidence to understand how prenatal Zika virus infection affects child development and to identify strategies for evaluation, management, and treatment



*Photo attribution: Agência Brasil*



# U.S. Zika Virus Cases

- United States
  - 618 travel associated
  - 195 in pregnant women
  - 11 sexually transmitted
  - 1 Guillain-Barré syndrome
- US Territories
  - 4 travel associated
  - 1,110 locally acquired
  - 146 pregnant women
  - 8 Guillain-Barré syndrome



Data from 6/1/16



# RELEASE: Zika Virus Puts 2 Million Pregnant Women in the United States Potentially at Risk This Summer and Fall

May 26, 2016

Washington, D.C. — The Center for American Progress estimates that [more than 2 million pregnant women](#) in the United States from the Centers for Disease Control and Prevention, or CDC, CAP estimates the number of pregnant women potentially at risk that carry the Zika virus. CAP estimates that more the 491,000 pregnant women in Texas and more than 271,000 pregnant women number of pregnant women potentially at risk will exceed 100,000 in Georgia, New Jersey, New York City, North Carolina, and N

TABLE 1

## Population of pregnant women potentially at risk from Zika, by state or city

State or city	Estimated months of moderate to high mosquito abundance	Estimated number of pregnancies during moderate-to high-risk months
Alabama	June–October	63,457
Arkansas	June–October	41,199
Delaware	July–September	10,065
District of Columbia	July–September	8,506
Florida	May–November	271,231
Georgia	June–October	139,769
Kentucky	July–September	51,275
Louisiana	May–November	79,792

Opioid Use in  
Pregnancy  
Neonatal  
Abstinence  
Syndrome  
(NAS), and  
Childhood  
Outcomes  
Workshop

April 4–5, 2016

- President Obama has made clear that addressing opioid abuse is a priority for his Administration
- Extremely important topic for NICHD, opioid use in pregnancy and neonatal abstinence syndrome constitute major public health issues in the United States and affect the health and wellbeing of children and families.



# Opioid Use in Pregnancy and NAS Workshop Goals

- To address the gaps and understand:
  - considerations when screening for opioid use in pregnancy
  - complications of pregnancy associated with opioid use
  - the most appropriate treatment of pregnant women with opioid use disorders given all the risks and benefits
  - how to screen, treat and manage infants with neonatal abstinence syndrome; and
  - long-term effects of prenatal opioid exposure on children and the role of preventive interventions to improve childhood outcomes for this high risk population.

HPP

# Human Placenta Project



**Overarching goal:**  
Understand human placental development, structure, and function in real time



# 3rd Human Placenta Project Meeting

- April 14-15, 2016 in Bethesda, Maryland
- Focused on imaging, bioinformatics, and technology
- <https://videocast.nih.gov/summary.asp?Live=18774&bhcp=1>



# NCMRRR

National Center for  
Medical  
Rehabilitation  
Research





# Presidential Early Career Award for Scientists and Engineers

To recognize and honor outstanding scientists and engineers at the outset of their independent research careers

- Elizabeth Skidmore, Ph.D., OTR/L, FAOTA
  - Closing Gap in Stroke Rehabilitation: Early Intervention for Cognitive Disability
- Ervin Sjedic, Ph.D.
  - The Aspirometer: A noninvasive tool to detect swallowing safety and efficiency



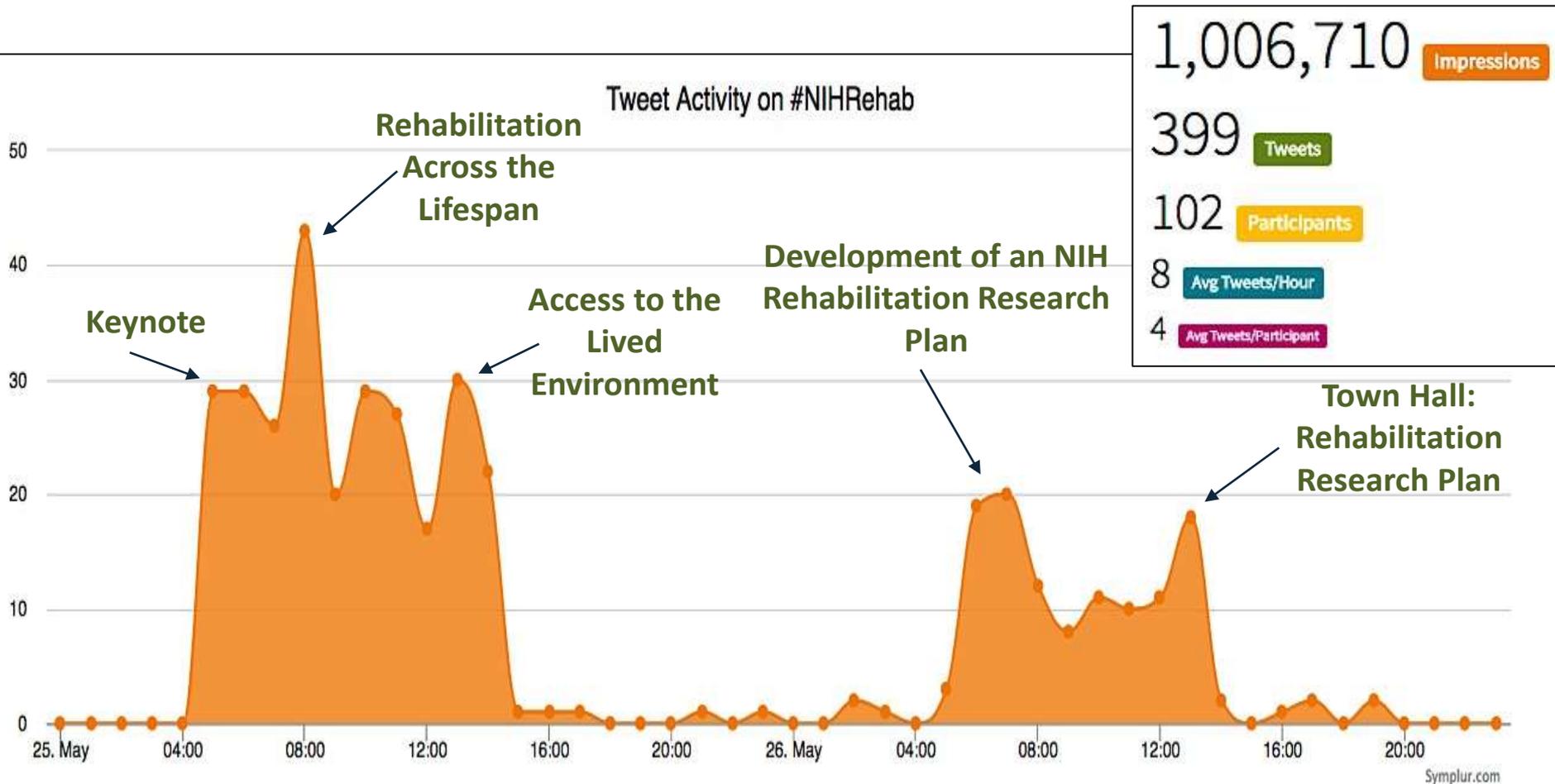


# Rehabilitation Research at NIH: Moving the Field Forward

- May 25 - 26, 2016
- Identified gaps, discussed infrastructure needs, and emphasized training and career development opportunities
- Highly participatory meeting with in person participation through workshops and a town hall and online community with social media
- Meeting now available on videocast
  - <https://videocast.nih.gov/summary.asp?Live=18796&bhcp=1>



# Activity Report for #NIHRehab





# NIH Data Sharing Policy

NOT-OD-03-032

- Requires a data sharing **plan**
- Type of data sharing plans:
- Upon request to the PI
  - Archive
  - Enclave
  - Web

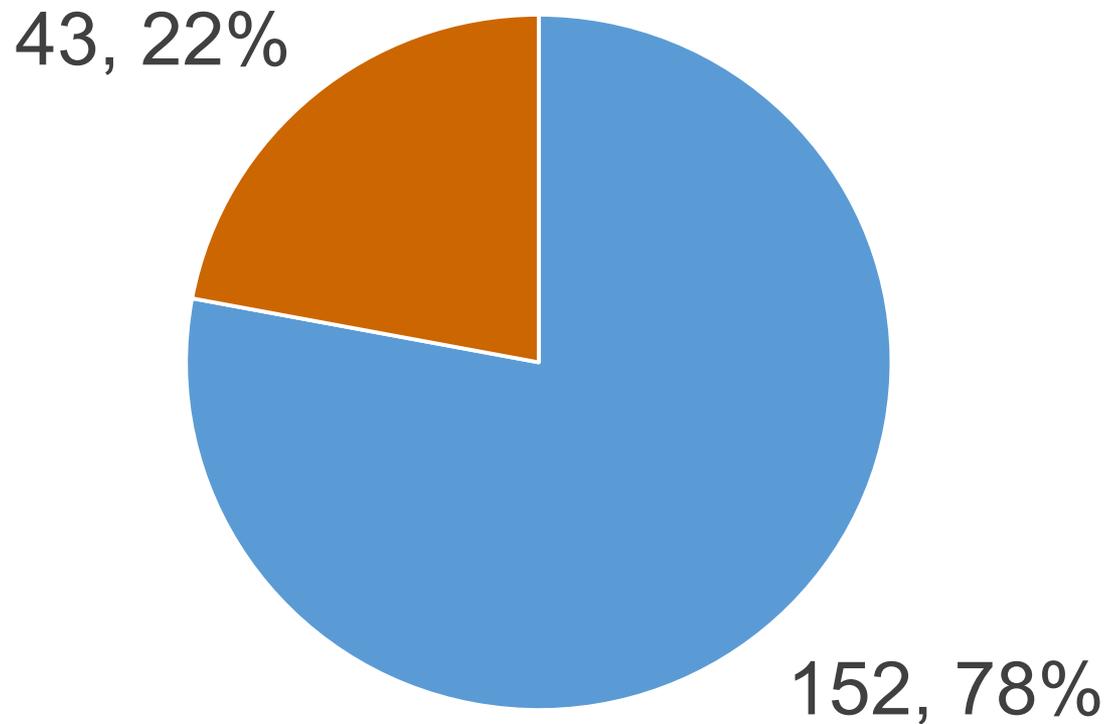


## Evaluation of NICHD Datasharing:

- Selected FY 2009 NICHD funded and administered grants as the universe, to allow for sufficient time for results to be published
- Identified all grants for the policy
- Reviewed original application for all grants and characterized data sharing plan
- Identified “main finding” publication
- Searched for publicly accessible data
- Verified with program staff



## NICHD FY 2009 Applicable Grants, by Inclusion of a Plan Compliant with Policy

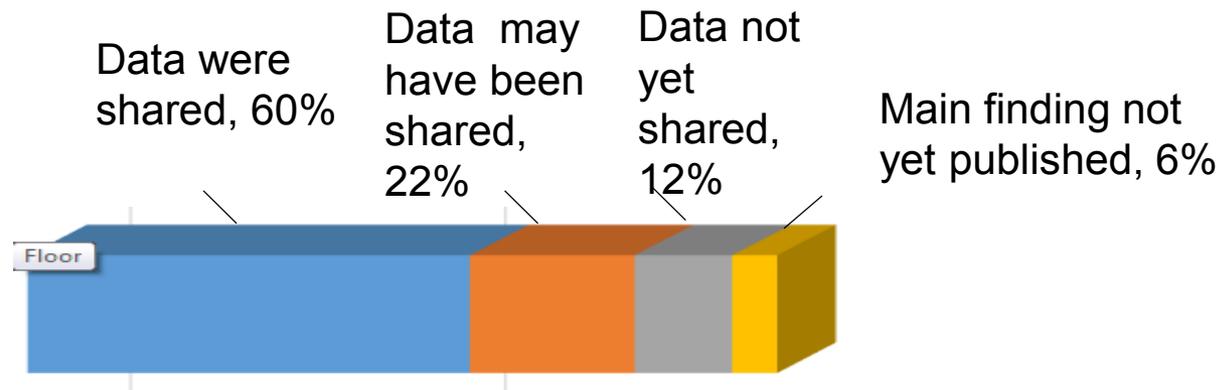


■ plan is compliant   ■ no plan, or plan is not compliant



# Data Sharing Practices

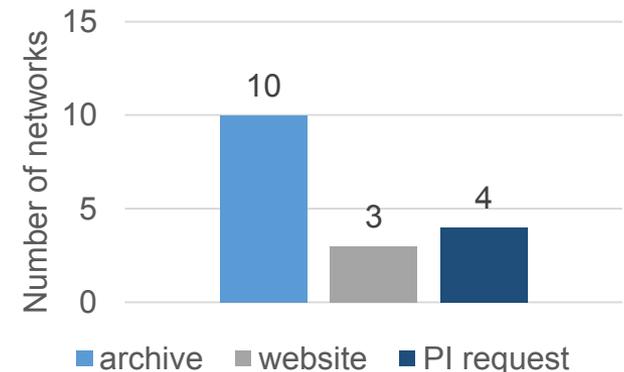
- 99% that planned to use an archive or public web site did
- Some grantees that planned to use PI request, or had no data sharing plan, made data available through an archive or web site
- **Actual** compliance rate with data sharing range from 60 to 88 %
  - Can not verify if PIs made data available upon request
  - For a few studies, main finding not published yet





# Data Sharing Plans for NICHD Clinical Research Networks

- 100% of NICHD's current extramural clinical research networks with completed studies have a data sharing plan that complies with NIH policy
- Of 17 networks, 13 (76%) share completed study data via an archive or public web site, and 4 make data available upon request to the PI



## Summary

### Data Sharing Plans and Practices at NICHD

- At least 78% of NICHD grants had a data sharing plan that met policy requirements
- 100% of clinical networks had data sharing plans
- Over 70% of grants with data sharing plans used a data archive or public web site
- Between 60-82% of grants shared data
- Main findings were published an average of 6-7 years after grant start



# NICHD Data Sharing Resources

- NICHD DASH Website - <https://dash.nichd.nih.gov>
- National Children's Study (NCS) Vanguard Data and Sample Archive and Access System - <https://ncsarchive.s-3.net/bioshare>
- Other NICHD Data Sharing Resources - <https://www.nichd.nih.gov/research/resources/Pages/index.aspx>

## Office of Health Equity Review

- Working group of Council will help us identify critical areas of focus and a strategy for moving forward
- Chaired by Dr. Melissa Gilliam
- Members include Council members and NIH and NICHD staff
- Final report will be presented during September Council



# Office of Health Equity Changes

- Jean Flagg-Newton, Ph.D. is Acting Director of the Office of Health Equity
- Regina James, M.D. now at National Institute of Minority Health and Health Disparities





# 6710 Rockledge

- New home for DER, DIPHR, OD!
- 460 staff
- 15 year lease
- Many thanks to Rodney Rivera



NICHD's New Home

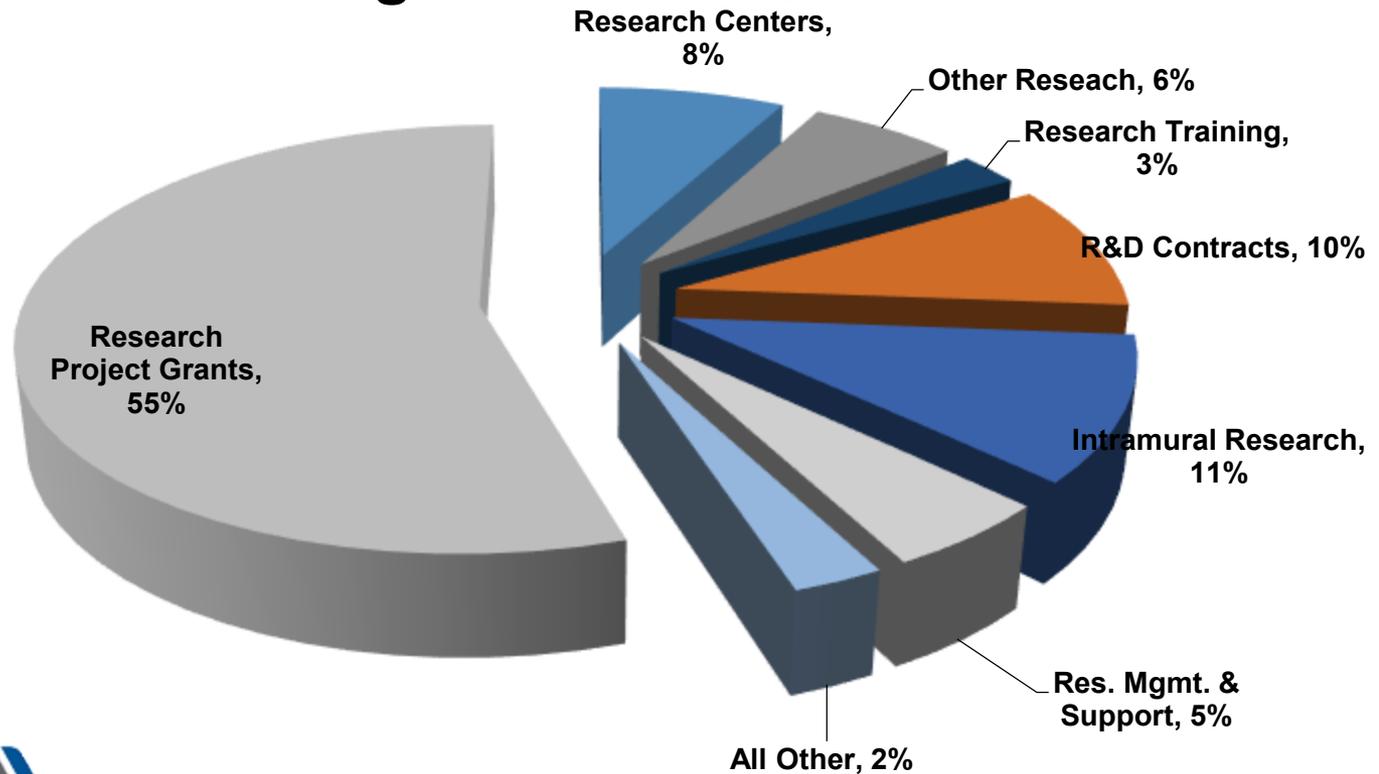


# Legislative and Budget Updates



# FY 2017 PRESIDENT'S BUDGET REQUEST

## NIH Total Program Level - \$33.14 Billion





# President's Proposed Budget for NIH for Fiscal Year 2017

- NIH - \$33.1 billion –
  - Combination of mandatory and discretionary funds
  - Priority areas – Precision Medicine Initiative, BRAIN Initiative, and Cancer Moonshot
- NICHD - \$1.338 billion
- Unknown when a budget will be passed or how close it will be the proposed budget



# Current Appropriations Process

- On June 7, the Senate Subcommittee on Labor-HHS-Education Appropriations reported out a bill proposing funding for agencies for FY 17, including a \$2 billion increase for NIH
- The full committee is taking up the bill this morning
- The House Appropriations Committee has not yet announced when it will take up its version of the bill, or the funding levels that will be included
- If there is a Continuing Resolution, the ceiling still has to agree with the two-year sequestration agreement (less money for FY17 than FY 16)



Questions?