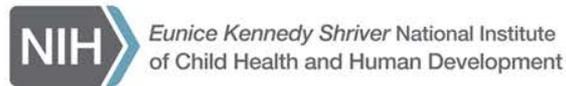


# NICHD Director's Report

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



# Presentation Overview

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



# News from NIH



# Dr. Diana Bianchi Named NICHD Director

- Executive director of the Mother Infant Research Institute
- Vice chair for pediatric research at the Floating Hospital for Children and Tufts Medical Center in Boston
- Natalie V. Zucker Professor of Pediatrics, and Obstetrics and Gynecology at Tufts University School of Medicine
- Start date: November 7, 2016





# Dr. Joshua Gordon Named NIMH Director

- Psychiatrist and neuroscientist
  - Brain plasticity in mouse visual system
  - Disease mutations on behavior
- Associate Professor of Psychiatry at Columbia University Medical Center
- Research Psychiatrist at the New York State Psychiatric Institute
- Associate Director of Columbia University/New York State Psychiatric Institute Adult Psychiatry Residency Program



# NIH Clinical Center

Over the last 15 months a number of changes occurred that will further strengthen NIH's longstanding commitment to patients, staff, and to scientific excellence





# Clinical Center Changes

- ACD Working Group on the Clinical Center (“The Red Team”) made recommendations on reducing risk and promoting patient safety at the NIH Clinical Center
- NIH has taken the following steps:
  - Established a Hospital Board
  - Established an NIH Office of Research Support and Compliance
  - Retained two companies specializing in quality assurance for manufacturing and compounding



# Hospital Board Appointments

- Chairperson: Laura Forese, M.D., executive vice president and chief operating officer at New York-Presbyterian
- Executive Director: Lawrence Tabak, D.D.S., Ph.D., Principal Deputy Director, National Institutes of Health





# Hospital Board Members

- Ellen Berty
- Beatrice Bowie
- Ruth Brinkley, MSN/Adm.
- Brig. Gen. James Burks, MBA, MMAOS
- Carolyn Clancy, M.D.
- Jeanette Erickson, RN, DNP
- Paul O'Neill, M.P.A.
- Peter Pronovost, M.D., Ph.D.
- Richard Shannon, M.D.
- Reed Tuckson, M.D.





# Clinical Center Hospital Board

- Inaugural NIH Clinical Center Research Hospital Board Meeting held on July 15, 2016
- Public meeting, available on [videocast.nih.gov](http://videocast.nih.gov)
- First meeting included welcome and NIH Director's overview, discussed Clinical Center leadership feedback, governance structure, and Chief Executive Officer characteristics
- Upcoming meetings:
  - October 21, 2016
  - January 13, 2017



# New Clinical Center Appointments

- New Chief of Pharmacy, Dr. Majid Tanas recruited from the Oregon Health and Science University
- Dr. Andrew Griffith, NIDCD Scientific Director, will oversee the NIH Office of Research Support and Compliance (ORSC), while a permanent director is recruited





# New Clinical Center Appointments

- Valerie Bonham, J.D., named the deputy of ORSC
- Dr. Bruce Burnett, an expert in regulatory, quality, and preclinical Good Laboratory Practices (GLP) support, joined us from Duke University for a year to help with the ORSC





# Other Clinical Center Staff Changes

- John Gallin, M.D., NIH Associate Director for Clinical Research (ADCR) and Chief Scientific Officer (CSO) for the Clinical Center
  - oversee the scientific review process for all clinical protocols conducted within the NIH Intramural Program;
  - help set priorities for clinical research across ICs at the Clinical Center;
  - oversee the independent research programs of Clinical Center investigators and clinical research training at NIH
  - oversee the strategic planning process for Intramural Clinical Research and develop strategic partnership



# Precision Medicine Initiative® (PMI) Cohort Program

**PRECISION MEDICINE INITIATIVE®  
COHORT PROGRAM**



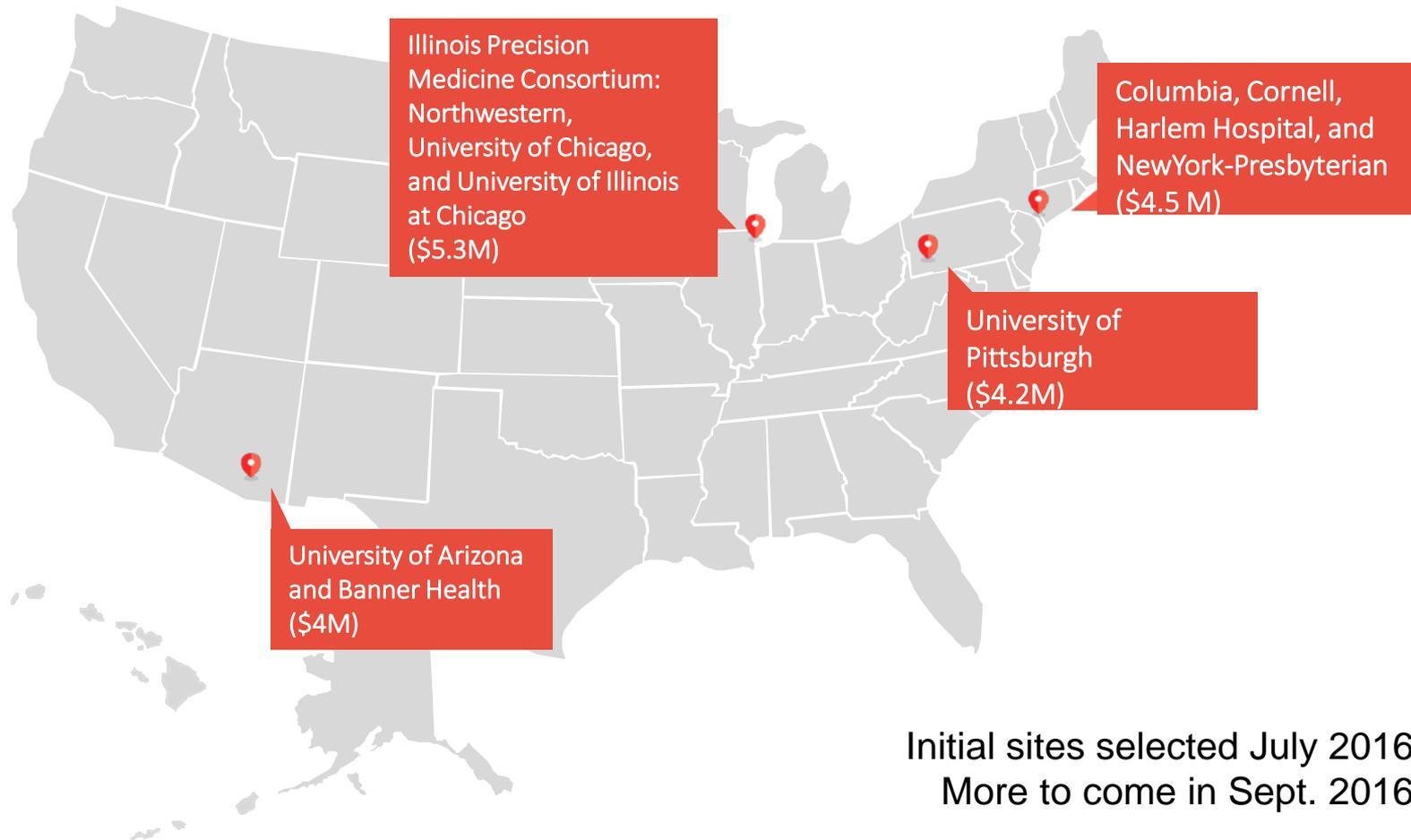


# PMI: Initial Awards for Program Infrastructure

- Data and Research Support Center – \$15.1M
  - Vanderbilt University Medical Center, with the Broad Institute and Verily
- Biobank – \$14.8M
  - Mayo Clinic
- Participant Technologies Center – \$20M
  - Scripps Research Institute, with Vibrent Health
- Health Care Provider Organizations (HPOs)
  - Regional Medical Centers, Community Health Centers (Federally Qualified Health Centers), VA Medical Centers



# HPOs: Regional Medical Centers

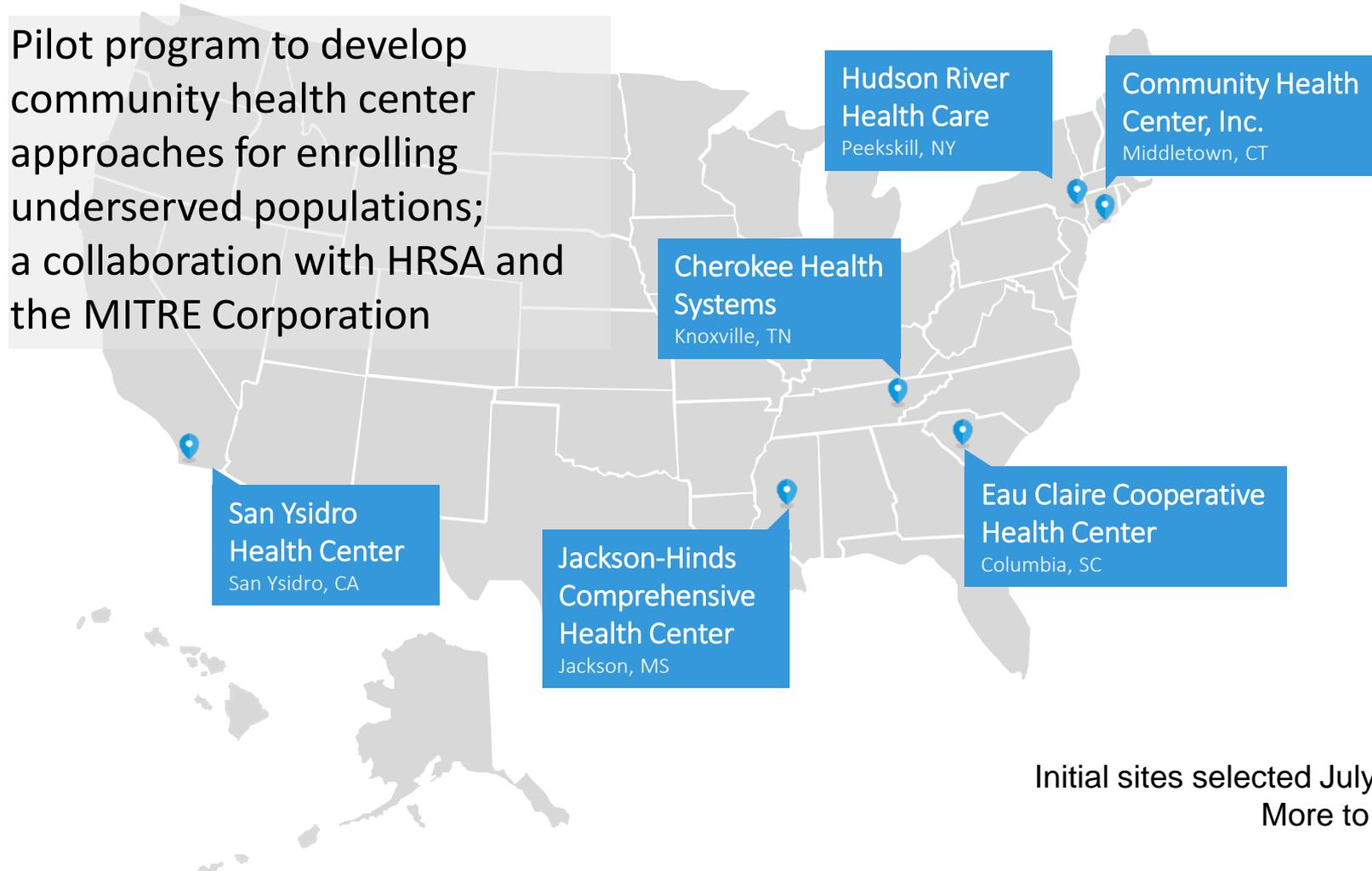


Initial sites selected July 2016  
More to come in Sept. 2016



# HPOs: Federally Qualified Health Center Pilot Sites

Pilot program to develop community health center approaches for enrolling underserved populations; a collaboration with HRSA and the MITRE Corporation



Initial sites selected July 2016  
More to come



# Survey Shows Broad Support for the PMI Cohort Program



- Public opinion survey conducted by the Foundation for the NIH: 2,601 responses analyzed
- 79% supported the program after reading short description
- 54% said they would definitely or probably participate if asked—not predictive of enrollment #'s, but encouraging
- Little variability among demographic groups
- Most important incentive for participation: learning about one's health information



# ECHO/IDeA States Pediatric Clinical Trials Network

- IDeA States Pediatric Clinical Trials Network grants reviewed at August Council session
- Dr. Matthew Gillman will speak today about the Environmental Influences on Child Health Outcomes (ECHO) program
- Will have some exciting news to share about the for IDeA States Pediatric Clinical Trials Network



# News from NICHD



# Funding the Best Science

- Flexibility for discretionary funding
  - Identify priorities more clearly
- Be more strategic about our investments:
  - Mechanisms
  - Number of awards/investigators
  - Large programs
  - Acceptance of large grants
  - > \$1 Million reviews
  - Participation in Funding Opportunity Announcements



## Then

### 2016 Payline

- R01 at 9%-tile
- R01 New Investigator at 12th%
- R03 & R21 at 9th%
- K's at 12PS\*
- F30 at 26PS
- F31 at 12th%
- F32 at 20th%

## Now

### 2016 Payline

- ↑ R01 at 10%-tile
- ↑ R01 New Investigator at 13th%
- ↑ R03 & R21 at 10th%
- ↑ K's at 14PS\*
- ↑ F30 at 29PS
- ↑ F31 at 19th%
- ↑ F32 at 26th%

\* Not K99 which then/now at 22PS



# Branch Funding Priorities Announced

## About NICHD

### Institute Overview

- [Director's Corner](#)
  - [Previous Director's Updates](#)
  - [Podcasts](#)
- [Establishment](#)
- [Laws Governing NICHD's Activities](#)
- [Mission & Scientific Accomplishment](#)
- [NICHD 50th Anniversary](#)
- [Snapshots in NICHD Science 1962-2012](#)

### Organization

### Budget & Appropriations

### Advisory Groups

### FOIA

## Director's Corner

Share this: [f](#) [t](#) [g+](#) [p](#)

### Supporting the Best Science

*Using Priorities to Drive Funding Decisions*



Public health needs and scientific discovery continually evolve, and it is critical for research-funding agencies to remain ahead of the curve. As opportunities arise, agencies must be agile enough to re-prioritize funding and channel resources toward newly defined goals. A good

example of this is NIH's response to the Zika virus outbreak. In February 2016, as Zika began attracting international attention, several NIH institutes, including the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), issued a [funding opportunity](#) designed to accelerate research on the virus and its complications. This rapid funding mechanism enables continuous

## About the Director

Catherine Y. Spong, M.D., assumed the duties of Acting NICHD Director in October 2015, after the retirement of Dr. Alan Guttmacher.

[Read More About the Acting Director](#)

[Subscribe to NICHD Developments](#)

## NICHD Scientific Vision



# Zika Virus Activities

- Grant Awards
- ZIP Cohort Study
- NICHD Outreach and Communications
- Current Statistics for Pregnant Women and Pregnancy Outcomes
- Workshop Focused on the Children





## PAR-16-106 - Rapid Assessment of Zika Virus (ZIKV) Complications (R21)

- Open March 20, 2016 and expires on March 1, 2019
- Applications accepted on a rolling basis, beginning on April 20, 2016

Provides an expedited (rapid) funding mechanism for research on Zika virus (ZIKV) and its complications given the urgent need to determine whether ZIKV infection causes microcephaly and other congenital abnormalities in babies and the potential rapid spread of ZIKV to the United States.



# NIH Funds Zika Virus Study Involving U.S. Olympic Team

- Researchers will monitor potential Zika virus exposure among a subset of athletes, coaches and other U.S. Olympic Committee (USOC) staff attending the 2016 Summer Olympics and Paralympics in Brazil
- Aims to improve understanding of how the virus persists in the body and to identify potential factors that influence the course of infection





# NICHD Intramural Zika Awards

- Drs. Leonid Chernomordik and Joshua Zimmerberg, for their grant, Zika Virus Entry into the Cells: Assays and Mechanisms
- Dr. Leonid Margolis for his grant Pathogenesis and Transmission of Zika Virus in Human Tissue *ex vivo*



# Zika in Infants and Pregnancy (ZIP) Cohort Study

- Multi-site, multi-country prospective observational cohort study
- Primary Goals:
  - Risk of Zika during pregnancy
  - Outcomes of Zika during pregnancy-both symptomatic and asymptomatic infection
  - Fetal and infant outcomes
  - Assess the effect of timing of infection and potential confounders (e.g. environmental factors, co-infections) on outcomes



# ZIP Cohort Study

- 10,000 women in the first trimester
- Women followed monthly until delivery and then 6 weeks postpartum
- Infants evaluated within 48 hours of birth and at 3, 6, and 12 months of age
- Standardized protocol, centralized data collection diagnostic tests (reagents and procedures), diagnostic algorithm
- Supported by NICHD, NIAID, NIEHS Fundacao Oswaldo Cruz-Fiocruz







# ZIP Cohort Study Update

<b>Site Name</b>	<b>Status</b>
Z01: Brazil - Pernambuco	Anticipated start date October, 2016
Z02: Brazil - Salvador	Enrolling
Z04: Brazil - Sao Paulo	Enrolling
Z04: Brazil - Rio de Janeiro	Enrolling
Z05: Colombia – Cali and Medellin	Anticipated start date October 2016
Z06: Guatemala - Amatitlan and Mazatenango	Anticipated start date September 2016
Z07: Nicaragua - Managua	Anticipated start date November 2016
Z08: Puerto Rico - North Karst	Enrolling
Z09: Puerto Rico - San Juan	Enrolling



## Zika Update: NIH Advisory Committee to the Director -

- Update on the Zika outbreak and NIH's activities, including the ZIP cohort study
- [http://acd.od.nih.gov/presentations/062016\\_Spong.pdf](http://acd.od.nih.gov/presentations/062016_Spong.pdf)





# American Museum of Natural History's SciCafe Special Event: Zika: What You Need to Know



Susan Perkins, Ian Lipkin, Cathy Spong, and Jay Varma

Panel talk available online: <https://www.youtube.com/watch?v=SJodZY4bPZc>



# Reddit Science: Ask Me Anything



comments

This post is locked. You won't be able to comment.

## ★ Zika | Child Health and Human Development AMA

Science AMA Series: I'm Catherine Spong—OB/GYN, acting director of pregnancy & children infected in the womb. AMA! [self.science](#)

7 days ago by \* (last edited 6 days ago) [NICHD\\_NIH](#) [National Institute of Child Health and Human Development](#)

Hello reddit! I'm Cathy Spong, and I oversee NIH's Eunice Ken Human Development (NICHD), which supports research on fetal family health; reproductive biology and population issues; and We know that Zika virus causes microcephaly and other serious including miscarriage and stillbirth.

While our attention is rightly focused on vaccine development, spread of Zika, it is also important to acknowledge that people and health care professionals—may be contending with unknow



reddit

CATHERINE SPONG AMA ON REDDIT



**TOTAL REACH**  
12.27 MILLION

**22,553**

USERS CLICKED THROUGH TO READ THEIR ANSWERS



**8,132**  
TOTAL VOTES



# Pregnant Women with Zika Virus Infection

## Pregnant Women with Any Laboratory Evidence of Possible Zika Virus Infection

### US States and the District of Columbia\*

**731**

\*Includes aggregated data reported to the US Zika Pregnancy Registry as of September 8, 2016

### US Territories\*\*

**1,156**

\*\*Includes aggregated data from the US territories reported to the US Zika Pregnancy Registry and data from Puerto Rico reported to the [Zika Active Pregnancy Surveillance System](#) as of September 8, 2016



# Pregnancy Outcomes: Zika Virus

## Pregnancy Outcomes in the United States and the District of Columbia

### Liveborn infants with birth defects\*

18

Includes aggregated data reported to the [US Zika Pregnancy Registry](#) as of September 8, 2016

### Pregnancy losses with birth defects\*\*

5

Includes aggregated data reported to the [US Zika Pregnancy Registry](#) as of September 8, 2016

## Pregnancy Outcomes in the United States Territories

### Liveborn infants with birth defects\*

1

Includes aggregated data from the US territories reported to the [US Zika Pregnancy Registry](#) and data from Puerto Rico reported to the [Zika Active Pregnancy Surveillance System](#) as of September 8, 2016

### Pregnancy losses with birth defects\*\*

1

Includes aggregated data from the US territories reported to the [US Zika Pregnancy Registry](#) and data from Puerto Rico reported to the [Zika Active Pregnancy Surveillance System](#) as of September 8, 2016



# Workshop Focused on the Children

- September 22-23, 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 and outline future research needs
- Information: <https://palladianpartners.cvent.com/ZIKV2016>
- Webcast also available:
  - Day 1: <https://videocast.nih.gov/summary.asp?live=19498&bhcp=1>
  - Day 2: <https://videocast.nih.gov/summary.asp?live=19502&bhcp=1>



*Photo attribution: Agência Brasil*

# NIH Rehabilitation Plan

National Institutes of Health (NIH)  
**Research Plan on  
Rehabilitation**



**MOVING THE FIELD *FORWARD***



National Institutes of Health  
*Turning Discovery Into Health*



# Launch of NIH Medical Rehabilitation Plan

- The Research Plan on Rehabilitation was published on September 14, 2016 with the concurrence of 17 participating Institutes and Centers
- The launch of the plan occurred as part of a White House Office of Disability Policy event on September 15, 2016
- Communication roll out included Capitol Hill and interested organizations





# NIH Medical Rehabilitation Plan

- Includes six areas of research priorities created through consultation with the National Advisory Board for Medical Rehabilitation Research (NABMRR), the NIH Medical Rehabilitation Coordinating Committee, and public input garnered through formal requests and a town hall meeting
  - Rehabilitation through the Lifespan
  - Family and Community
  - Technology and Device Development
  - Research Design and Methodology
  - Translational Research
  - Building Research Capacity
- Performance will be monitored and reported in the May meeting of the NABMRR

## Staff Updates



Dr. Jean Flagg-Newton

Acting Director, OHE  
retiring at the end of  
September

- National Institute of General Medical Sciences
- Fogarty International Center
- Deputy Director and Chief of the Office of Research in the National Center on Minority Health and Health Disparities
  - Implemented the Center's first Centers of Excellence Program and the Research Endowment Program

# NIH Director's Awards



- Lisa Kaeser, Caroline Signore, Robert Tamburro, and David Weinberg for the NCS Redirection/ECHO Working Group
- Eugene Hayunga, Lisa Kaeser, Rosalina Bray, and Sarah Glavin for the NIH-Wide Strategic Plan Working Group
- Michael Weinrich and James Coulombe for the Stimulating Peripheral Activity to Relieve Conditions (SPARC) Working Group
- Yan Li and Chi Hon Lee for the Virtual-Reality Systems Group
- Brenda Hanning for exemplary performance while demonstrating significant leadership, skill and ability in serving as a mentor



# Legislative and Budget Updates



## Legislative Briefings

- On June 14 Dr. Alison Cernich presented at the Women and Traumatic Brain Injury Congressional Briefing
- On June 28 The Friends of the NICHD held a briefing, “Research from A to Zika: How What Happens During Pregnancy Influences Child Health” Spong, Sheffield, Colombo, Cernich presented





# Freedom of Information Act Law

- S. 337 (Cornyn R-TX) signed by the President on June 30 and became **Public Law 114-185**
- Provides the public access to information under the Freedom of Information Act (FOIA), including the right to appeal agencies' decision to withhold information
- Requires Federal agencies to make information disclosable under FOIA available to the public in an electronic, publicly accessible format
- Agencies must make the “raw statistical data” used in each report available in the same format



# Introduced: National Defense Authorization Act (NDAA)

- S. 2943 (McCain R-AR), NDAA must be reauthorized by Congress – two provisions of interest added to this year’s bill:
- Text of S. 800 (Kirk, R-IL), Enhancing the Stature and Visibility of Medical Rehabilitation Research at NIH Act
  - Amend the Public Health Service Act to improve, coordinate and enhance rehabilitation research at the NIH and incorporate The World Health Organization’s definition of medical rehabilitation research
  - Directs the NCMRR Director to develop a research plan, updated every 5 years and to identify existing resources to support research priorities
- Another provision would provide coverage of medically necessary food and vitamins for digestive and inherited metabolic disorders under the TRICARE program (first time explicit coverage mandated)
- NDAA will be voted on after elections



## Introduced: National Pediatric Centers

- S. 3115 (Wicker R-MS), the Pediatric Research Improvement Act of 2016, require NIH to establish a national pediatric research network
- The NIH Director would work with appropriate ICs to establish such a network
- Similar provision included in the H.R. 6, or “Cures” bill that passed the House in July 2015
- The National Pediatric Research Network Act only allowed, did not mandate, the NIH to create this network.



# Budget Update

- Will likely be no budget as we begin Fiscal Year 2017 on October 1st
- Likely to have a Continuing Resolution through December 9<sup>th</sup> (with flat funding)





Questions?