NICHD Director's Report

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NIH *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

Presentation Overview

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

News from NIH

NIH Strategic Plan

- Dr. Tabak presented the 5-year NIH-wide Strategic Plan during September's Council Meeting
- Goal: To advance mission to support research in pursuit of fundamental knowledge about the nature and behavior of living systems, and the application of that knowledge to extend healthy life and reduce illness and disability
- Sent to Congress mid-December and posted on NIH's website

Overview

- Mission of NIH
- Unique moment of opportunity in biomedical research
- Current NIH-supported research landscape
- Constraints confronting the community in the face of lost purchasing power

Objective 1: Advance Opportunities in Biomedical Research

Fundamental Science

- Foundation for progress
- Consequences often unpredictable
- Technology leaps catalyze advances
- Data science increases impact/efficiency

Health Promotion/Disease Prevention

- Importance of studying healthy individuals
- Advances in early diagnosis/detection
- Evidence-based reduction of health disparities

Treatments/Cures

- Opportunities based on molecular knowledge
- Breakdown of traditional disease boundaries
- Breakthroughs need partnerships, often come from unexpected directions
- Advances in clinical methods stimulate progress

Objective 2: Set Priorities

- Incorporate disease burden as important, but not sole factor
- Foster scientific opportunity; need for nimbleness
- Advance research opportunities presented by rare diseases
- Consider value of permanently eradicating a pandemic risk

Objective 3: Enhance Stewardship

- Recruit/retain outstanding research workforce
- Enhance workforce diversity
- Encourage innovation
- Optimize approaches to inform funding decisions
- Enhance impact through partnerships
- Ensure rigor and reproducibility
- Reduce administrative burden

Objective 4: Excel as a Federal Science Agency by Managing for Results

PMI

- NICHD is actively involved to make sure people of all ages are included in the cohort
- Dr. Josephine Briggs will talk more about PMI later today

PMI Cohort Program Funding Opportunities

Opportunity Name and Number	Deadline
Direct Volunteers Pilot Studies (OT) PM-OT-16-001	December 22, 2015
Communication Support for the Precision Medicine Initiative Research Programs (OT) PM-OT-16-002	December 22, 2015
PMI Cohort Program Biobank(U24) RFA-PM-16-004	February 4, 2016
PMI Cohort Program Coordinating Center (U2C) RFA-PM-16-001	February 17, 2016
PMI Cohort Program Healthcare Provider Organization Enrollment Centers (UG3/UH3) RFA-PM-16-002	February 17, 2016
PMI Cohort Program Participant Technologies Center (U24) RFA-PM-16-003	February 17, 2016

Redirection of National Children Study Funds in FY16: Overview

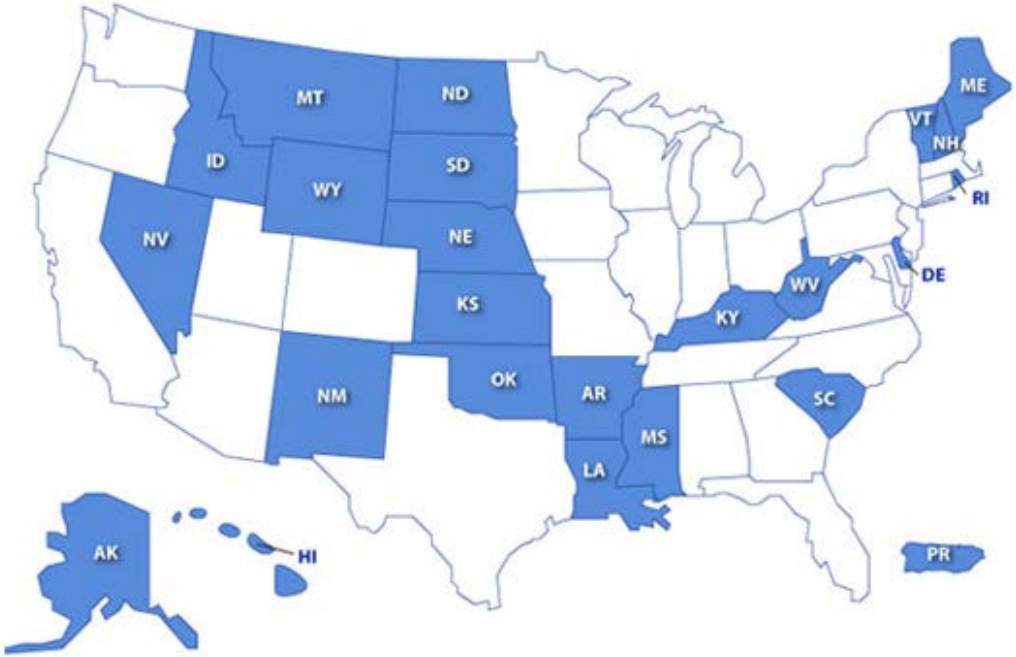
- New name: Environmental influences on Child Health Outcomes (ECHO) program
- Overarching Goal:
  - Leverage extant cohorts to investigate the longitudinal impact of prenatal, perinatal, and postnatal environmental exposures on pediatric health outcomes with high public health impact
- Support multiple synergistic, longitudinal studies by:
  - Using extant cohorts
  - Representing various environmental exposures
  - Sharing standardized research questions
  - Focusing on four key pediatric outcomes

FY16 Plan: Overview (cont.)

- Core Elements (across all longitudinal studies)
  - Demographics
  - Typical early development
  - Epigenetic influences on early childhood development
  - Environmental factors
- Pediatric outcome focus areas
  - Upper and lower airway
  - Obesity
  - Pre-, peri-, and postnatal outcomes
  - Neurodevelopment

IDeA Program

- Institutional Development Award (IDeA program) supports faculty development and research infrastructure enhancement in 23 states & Puerto Rico
  - Enhances competitiveness where NIH success has been historically low
  - Serves unique populatio
    - Rural
    - Medically underserved



IDeA Program: Opportunity

- FY2016, as part of the redirection of National Children's Study funds, NIH plans to create an IDeA States National Pediatric Clinical Trials Network
  - Address access gaps for rural children through a national network for pediatric research embedded at IDeA locations
  - Link existing IDeA state centers with experts in clinical trials

ECHO/IDeA Funding Opportunities

Opportunity Name and Number	Deadline*
Clinical Sites for the IDeA States Pediatric Clinical Trials Network (UG1) RFA-OD-16-001	April 15, 2016
Data Coordinating and Operations Center for the IDeA States Pediatric Clinical Trials Network (U24) RFA-OD-16-002	April 15, 2016
Environmental Influences on Child Health Outcomes: Patient Reported Outcomes Research Resource Center Core (ECHO PRO Core) (U24) RFA-OD-16-003	April 15, 2016
Environmental influences on Child Health Outcomes (ECHO) Pediatric Cohorts (UG3/UH3) RFA-OD-16-004	April 15, 2016
Environmental Influences on Child Health Outcomes (ECHO) Data Analysis Center (U24) RFA-OD-16-005	April 15, 2016
Environmental Influences on Child Health Outcomes (ECHO) Coordinating Center (U2C) RFA-OD-16-006	April 15, 2016
Limited Competition: Exposure Analysis Services for the Environmental Influences on Children's Health Outcomes (ECHO) Program (Admin Supplement) PA-16-046	April 15, 2016

*Letters of intent are due March 15, 2016.

ECHO Information Session

- Webinars about the ECHO funding opportunities:
  - Jan 14, 2016
  - February 1, 2016 2:30-3:30 pm
- To register, visit: www.etouches.com/nih012016

What About NCS Staff?

- NIH provided resume review assistance and training, interview skills training, and instruction on how to navigate USAJOBS
- Some found positions on their own, were reassigned within NICHD, retired; Remaining staff placed in other NIH ICs using existing NIH vacancies and directed reassignments
- In FY16, ~3 program staff will help with the data archive and data clean up

NCS Data and Sample Archive

- NCS Archive will be open to public users within a few months, waiting on OMB clearance
- A second release of additional data and introduction of sample access scheduled for May 2016; third release on October 2016
- Anyone can visit the site or download the NCS Study Description and Guide document

Data Types Available in the NCS Archive by Vanguard Study Phase, Participants, and Time Covered

Note: First data sets planned for release in late 2015 are in bold font. Italicized data sets are planned for release in 2016.

Operational Data | Data collector observations and measurements
Interview Data | Samples housed in repository

Participants covered	Time period of data coverage						
	2009	Jan-Sept 2010	Oct-Dec 2010	2011	2012	2013	2014
IVS participants	**IVS Operational data**						
	IVS Interview data						
	IVS self-administered quetionnaire data						
	Biospecimen & environmental sample collection forms data						
	Physical Measures data						
	Recruitment & Enrollment data (covers participants who were enrolled after September 2010)						
ARS participants			*ARS Recruitment*				
			ARS Retention				
PBS providers and participants						*PBS Provider*	
						PBS Sample Frame	
						PBS Recruitment	
All VS participants			*ARS interview data (also covers IVS and PBS participants)*				
			ARS self-administered questionnaire data & proprietary data collection instruments data				
			ARS data collector observations and measurements				
	VS Fathers						
	VS Baby Index						
	VS Participant Linkage File						
	VS Participant Demographics						
	VS biospecimen and environmental samples (from Sample Repository)						

Key:

VS = Vanguard Study; IVS = Initial Vanguard Study; ARS = Alternate Recruitment Substudy; PBS = Provider Based Sampling

Available Materials on the NCS Archive

- Study visit databases for mother, child, and father participants
- Initial Vanguard Study instruments, detailed data user materials
- Sample inventory, including a summary of biospecimen aliquots and environmental samples
- Study procedures
- Protocol
- Protocol schedule and content of assessments by study visit and phase
- Tools for navigating the protocol and data
- Various reports, including white papers and reports on specific scientific topics, and reports on NCS workshops and events
- The application for accessing the researcher portal
- Frequently Asked Questions for researchers

Gabriela Miller Kids First Pediatric Research (Kids First) FY 2015 Initiative

- PAR-15-259 Discovery of the Genetic Basis of Structural Birth Defects and of Childhood Cancers: Gabriella Miller Kids First Pediatric Research Program (X01)
  - An administrative supplement to an NHGRI-funded sequencing center
  - X01 (Resource Access Award) soliciting for
    - WGS structural birth defects cohorts (trios)
    - childhood cancer cohorts (trios) with a suspected genetic basis
    - samples of treatment-resistant sarcomas (to jumpstart FY16 Precision Medicine Initiative)

Kids First: FY 2015 Cohorts

- Selected cohorts:
  - Rare cancers of the bone or soft tissue
  - Bone tumors that were resistant to drug treatment
  - Cleft lip and cleft palate
  - Developmental disorders of facial nerves, such as those controlling eye movement
  - Congenital Heart Defects
  - Developmental disorders of the chest muscle used for breathing
  - Disorders of Sex Development
- Plan to reissue the call for applications in FY 2016, pending availability of funds

Kids First Solicits Applications for Genome Sequencing Center

- RFA-RM-16-001: Genome Sequencing Center for the Gabriella Miller Kids First Pediatric Research Program (U24)
- The Sequencing Center will generate whole-genome sequence data from childhood cancer and structural birth defects cohorts and these and other clinical data will be included in the data resource.
- Letter of Intent: March 1, 2016
- Applications due: March 31, 2016

NIH-Gates Foundation Collaboration
Areas of Milestone-driven Collaboration

- Infectious Disease
  - HIV/AID, Malaria, TB, HPV/cervical cancers
- Maternal, Newborn, and Child Health
  - Maternal and newborn health, child health and development, pediatric pneumonia and indoor air pollution, contraceptive research
- Emerging initiatives
  - Drug repurposing, point of care diagnostics

Working Groups with NICHD Participation

- Maternal and newborn health
  - Co-chairs: Drs. Jeff Murray and Catherine Spong
  - NICHD staff members: Drs. Catherine Spong, Tonse Raju, Marion Koso-Thomas, Menachem Miodovnik, Uma Reddy, and Paul Albert
- Child health and development
  - Co-chairs: Drs. Dan Marks and Vesna Kutlesic
  - NICHD staff members: Drs. Vesna Kutlesic, Della Hann, Maggie Brewinski Isaacs, Lisa Freund, Sonia Lee, Daniel Raiten

Working Groups with NICHD Participation (continued)

- Pediatric pneumonia and indoor air pollution
  - Co-chairs: Drs. Gail Rodgers, Josh Rosenthal and Linda Lambert
  - NICHD staff members: Drs. Danuta Krotoski and Robert Tamburro
- Contraceptive research
  - Co-chairs: Drs. Dan Hartman and Catherine Spong
  - NICHD staff members: Drs. Catherine Spong, Caroline Signore, Diana Blithe, Stuart Moss, and Susan Newcomer
- HIV/AIDS
  - Co-chairs: Drs. Emilio Emini, Nina Russell and Carl Dieffenbach
  - NICHD staff members: Dr. Rohan Hazra

Accomplishments: Maternal, Newborn, and Child Health

- Data pooling in areas such as fetal growth and child neurocognitive development
- Developed RFAs for development of tools for neurodevelopmental assessment of infants and children in resource-limited settings
- A BMGF Grand Challenge nominated projects to develop new tools and new combinations of interventions to ensure that all children not only survive but also are on a trajectory to live a healthy productive life.
- Workshop in global maternal mortality

Accomplishments: Household Air Pollution

- “Household Air Pollution (HAP) Health Outcomes Trial” RFA issued October 2015, for a multi-country interventional trial to address the NIH-BMGF mutual priority of developing a validated exposure response curve for PM 2.5 and respiratory diseases.
- Support for this trial comes from BMGF, NIH (NHLBI, NIEHS, NCI, NICHD, FIC, CF) and the Global Alliance for Clean Cookstoves (GACC)

Accomplishments: HIV

- Collaboration on the production of HIV envelope proteins, components of vaccine concepts, through joint BMGF-DAIDS HIV Envelope Manufacturing & Analytics Working Group, with two proteins prioritized for production with joint funding (BG505.SOSIP and gp145 protein).
- Continued dialogue on evaluation of broadly neutralizing antibodies (bNAbs) for immunotherapy and immunoprophylaxis; clinical trials ongoing or planned for 3BNC117, 10-1074, PGT121 and VRC01.

News from NICHD

NICHD Non-Human Primate Operations at the Poolesville Facility

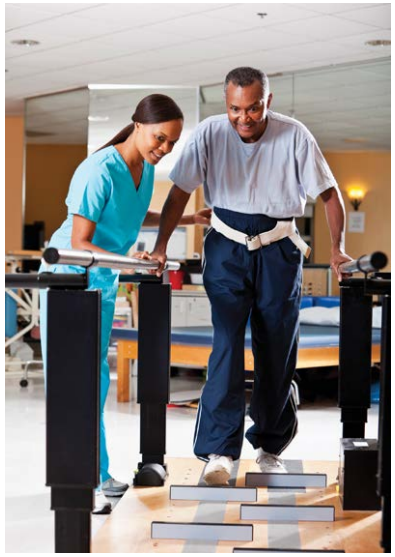
- NICHD intramural research program will phase out operations at the NIH Animal Center in Poolesville, Maryland
- This decision was based on internal programmatic priorities and the desire to optimize research efficiency within the NICHD intramural program.
- NICHD has developed a three-year plan to ensure the orderly closure.
- NICHD will transfer approximately 100 animals per year to other facilities so all animals are transferred by September 30, 2018.

Office of Health Equity Review

- NICHD's Office of the Director underwent a review to examine its function and structure; OHE was included in that review.
- We have undertaken changes in OHE to align it better with the new structure of NICHD, including transferring grants to the Division of Extramural Research. As a result, we are now working to develop the new role of OHE.
- We will be convening a working group of Council to help us identify critical areas of focus and a strategy for moving forward.

NCMRR

- National Center for Medical Rehabilitation Research



NIH Medical Rehabilitation Coordinating Committee

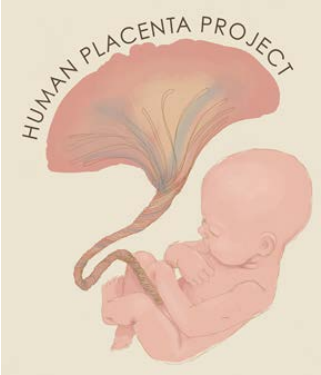
- Developing a comprehensive plan for the conduct and support of rehabilitation research to identify current rehabilitation research activities at NIH, gaps in and opportunities for additional research, and priorities for future research
- Responses were due in December for a *Request for Information (RFI): Inviting Comments and Suggestions on the Priorities specified for the NIH-wide Rehabilitation Research Plan* (NOT-HD-15-032)

Rehabilitation Research at NIH Meeting – Save the Date

- May 25-26, 2016, “Rehabilitation Research at NIH: Moving the Field Forward” on NIH Main Campus, Bethesda, Maryland
- The meeting plans to:
  - address the full scope of the rehabilitation research portfolio at the NIH
  - highlight accomplishments and advances that have resulted from NIH sponsored projects and programs
  - provide the scientific community and the public an opportunity to provide input in the development of the recommendations for the NIH Rehabilitation Research Plan
  - identify gaps and possibilities in rehabilitation research, discuss infrastructure needs, and highlight training and career development opportunities

HPP

Human Placenta Project



Overarching goal:

Understand human placental development, structure, and function in real time

Three RFAs in FY15

- Novel Tools to Assess Human Placental Structure and Function (R01, R21)

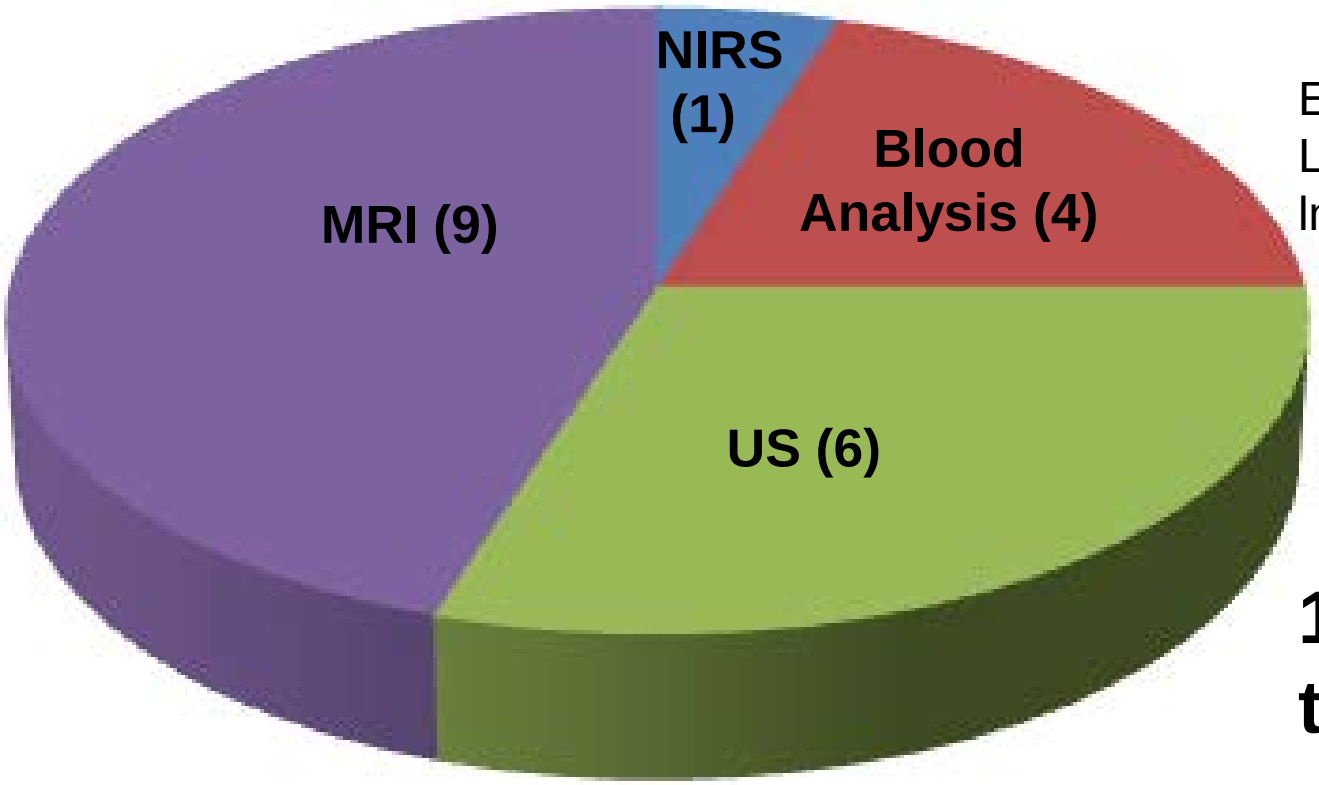
For development of new technology, or novel application of current technology, for studying the placenta in vivo with the ultimate goal of human use across pregnancy. Objective is to push beyond existing paradigms.

- Developing Paradigm-Shifting Innovations for in vivo Human Placental Assessment in Response to Environmental Influences (U01 Cooperative Agreement)

- Formation of interdisciplinary teams to design and develop new or next-generation placental imaging and assessment technologies and methods that will increase our capability to assess human placental structure and function safely in vivo throughout gestation
- Explore the impact of environmental influences on placental structure and function across pregnancy

Distribution of FY15 Projects

Near Infrared Resonance Spectroscopy (assessment of hemodynamic alterations)

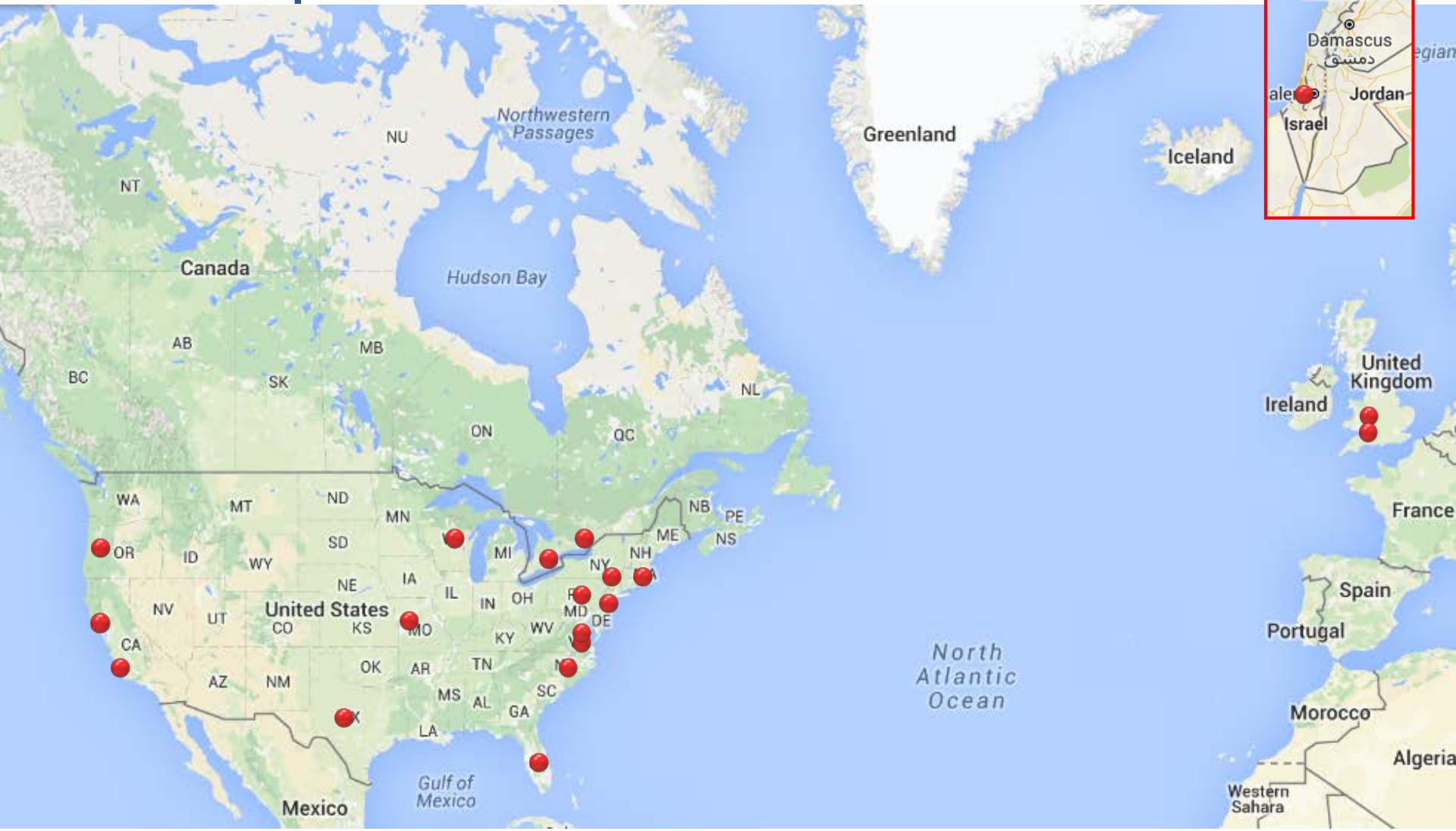


Exosomes, Lipids,miRNA, lncRNA

19 awards totaling ~$46M

Focus on collaboration across disciplines and development of synergy

Widespread Effort



Two RFAs published for FY16

- Using Omics to Define Human Placental Development and Function Across Pregnancy
  - RFA-HD-16-036 (R01)
  - RFA-HD-16-037 (R21)

For research directed at the development of omics profiles reflecting human placental development and function across gestation.

- Applications were due December 18, 2015

3rd Human Placenta Project Meeting

- Save the date:
  April 14-15, 2016 in Bethesda, Maryland
- Focus on imaging, bioinformatics, and technology
- Will have breakout groups and poster session(s)
- Technology demonstrations will be a new activity
- http://www.nichd.nih.gov/research/HPP

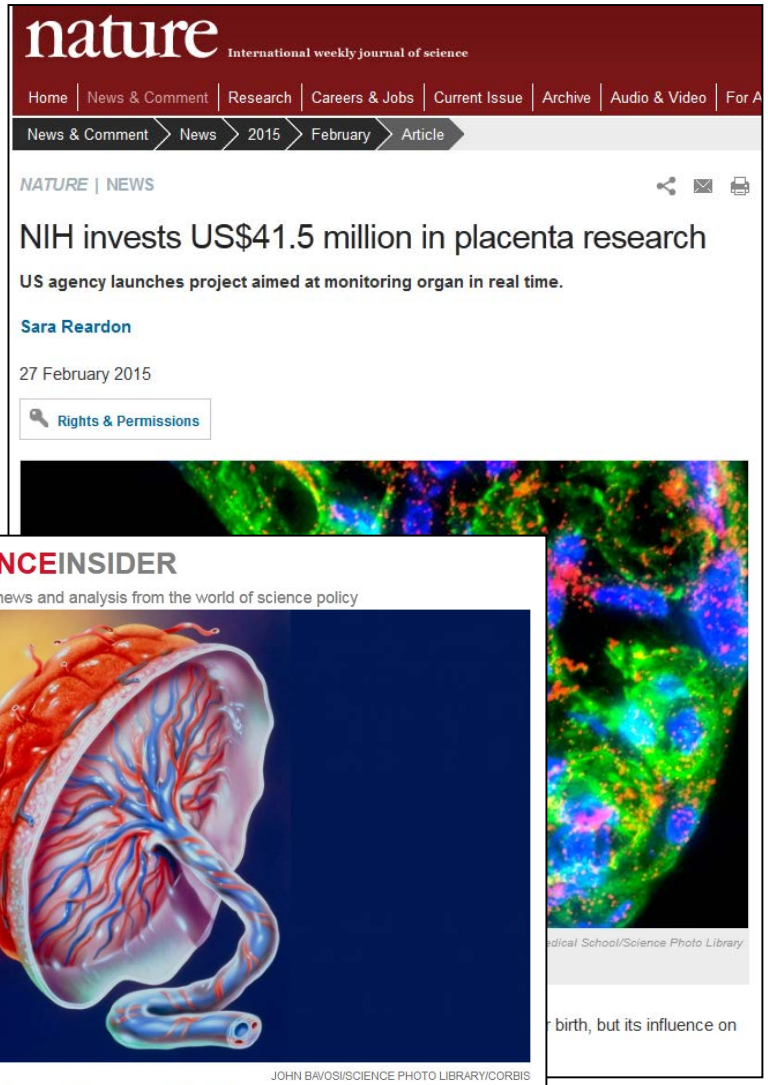
Widespread Interest…

Sept 11-13, 2015 Guangzhou, China

THE INTERNATIONAL SYMPOSIUM OF MATERNAL AND FETAL MEDICINE

CHINA HUMAN PLACENTA PROJECT

Dec 1-2, 2015 India



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NATURE | NEWS

NIH invests US$41.5 million in placenta research

US agency launches project aimed at monitoring organ in real time.

Sara Reardon

27 February 2015

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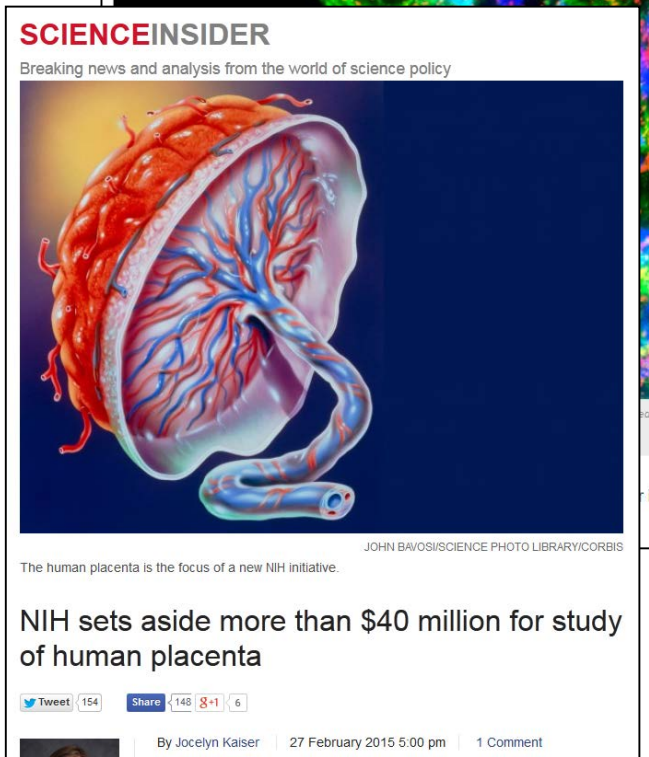
r birth, but its influence on



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The human placenta is the focus of a new NIH initiative.

NIH sets aside more than $40 million for study of human placenta

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By Jocelyn Kaiser 27 February 2015 5:00 pm 1 Comment

PregSource™

Crowdsourcing to Understand Pregnancy

PregSource™

Crowdsourcing to Understand Pregnancy

PregSource™

- A crowd-sourced, interactive, mobile app to:
  - Detail the natural history – and variations - of human pregnancy
  - Provide accurate info about pregnancy from trusted sources
  - Let pregnant women know about opportunities to participate in targeted research
- 20 partner organizations

PregSource™
Crowdsourcing to Understand Pregnancy

PregSource™ Partners

NIH Eunice Kennedy Shriver National Institute of Child Health and Human Development

Society for Women's Health Research

NIH National Center for Complementary and Integrative Health

CDC Centers for Disease Control and Prevention

NIH National Institutes of Health Office of Research on Women's Health

march of dimes

NIH National Heart, Lung, and Blood Institute

Society for Maternal-Fetal Medicine

Lamaze International

NIH National Institute on Minority Health and Health Disparities

The American Academy of Pediatrics

Preeclampsia foundation

NIH National Institute of Environmental Health Sciences

AWHONN Promoting the Health of Women and Newborns

Genetic Alliance

NIH National Institute of Nursing Research

NIH National Institutes of Health Office of Behavioral and Social Sciences Research

U.S. Department of Health and Human Services HRSA Health Resources and Services Administration

American College of Nurse-Midwives

The American College of Obstetricians and Gynecologists 1951 Women's Health Care Physicians

American Society for Reproductive Medicine 1944

Scientific Rationale: Defining Normal Pregnancy

PregSource™
Crowdsourcing to Understand Pregnancy

- Women will provide information about common pregnancy experiences in near-real-time:
  - Sleep
  - Nausea
  - Exercise
  - Weight
  - Medication use
- Answers to these topics will help researchers build a more complete picture of normal pregnancy and develop strategies for improving maternal care

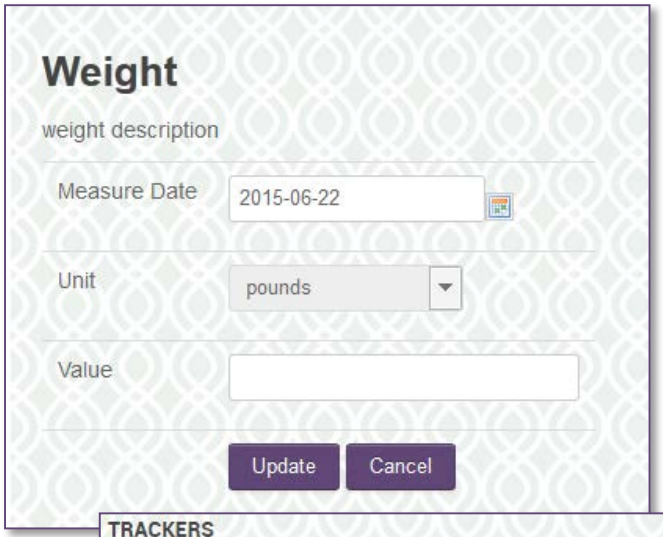
Questionnaires

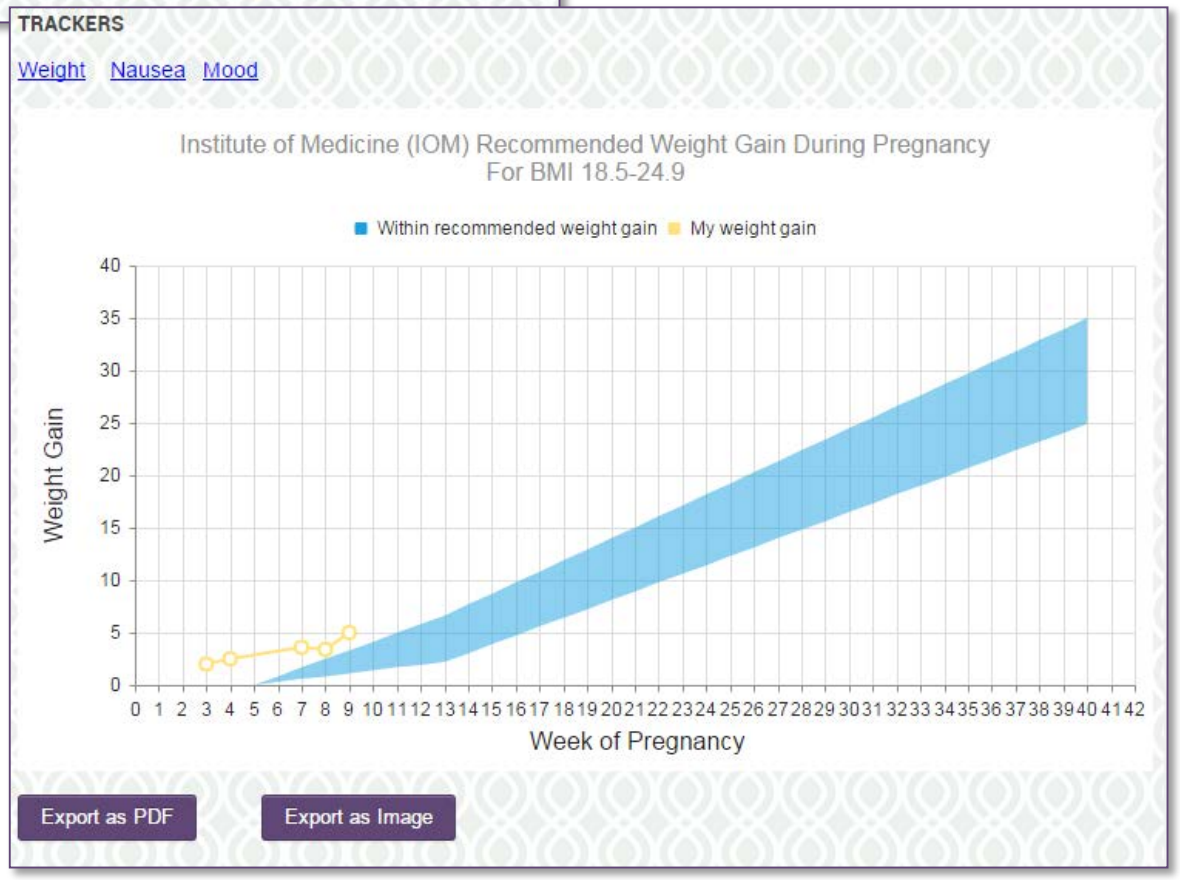
- Weekly educational updates and appropriate reminders to complete questionnaires
- Woman can see aggregate data showing how her responses compare to other participants'
- Pregnancy-related educational information from our Partners will be available in an online Resource Library
- Plan to follow through 6-12 months after delivery

Trackers

Data entered into trackers

View graphically over time



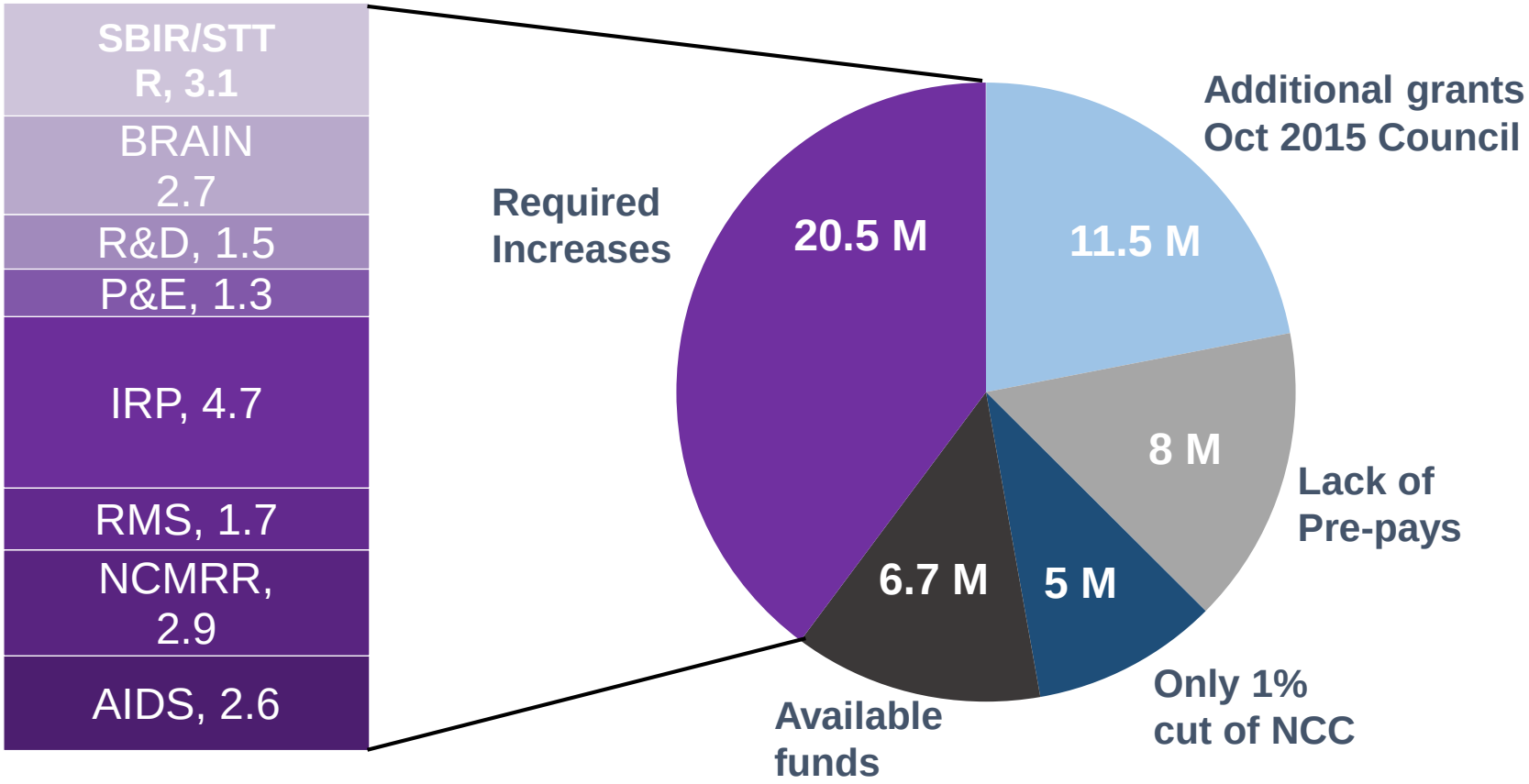


Legislative and Budget Updates

Budget Update

- Congress appropriated $32 billion for NIH (a $2 billion, or 6.6 percent increase over FY 2015 enacted budget)
- Congress appropriated $1.34 billion for NICHD (~4% above last year's total)
- NCMRR budget will be approximately $70 million

$51.4M NICHD FY16 Budget Increase
Where did it go?



Report Language: Anhydramnios

- NICHD will plan a science workshop on the biology, pathophysiology, and clinical aspects of amniotic fluid abnormalities, focusing on mechanisms of production and regulation of amniotic fluid, possible causes of anhydramnios, neonatal outcomes, and early diagnostic and treatment approaches, identifying knowledge gaps for future research.
- Requests an update in the fiscal year 2017 budget request on the timeline for the workshop and its relationship to the Human Placenta Project.

Report Language: Trisomy

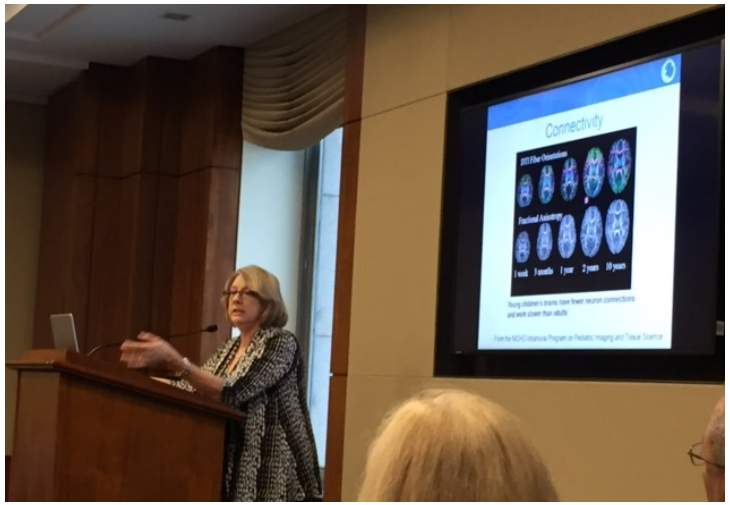
- Encourages the NIH to explore the molecular, cellular, and physiological mechanisms that predestine individuals born with a third copy of human chromosome 21 (trisomy 21) to either live with – or be protected from – a range of diseases that cause nearly 60 percent of deaths today in the U.S.
- Requests that NIH submit a report within one year of enactment of this Act to the Committees on Appropriations of the House of Representatives and the Senate on the feasibility of a multi-year study of children and adults with trisomy 21

Other Report Language

- Training: Calls for an increase in the number of NRSA awards and other training grants that is at least proportional to the general IC increase (3.925 percent) and stipends should increase at least as much as the Federal employee pay raise (~1% for base pay)
- NIH Strategic Plan: Requests update in FY17 budget request on how NIH will use the NIH Strategic Plan “as part of its resource reallocation process” to target cures and better treatments

Legislative Briefing: Understanding the Developing Brain

- Congressional Neuroscience Caucus Briefing on the Developing Brain held on December 1, 2015
- Lisa Freund, Ph.D., Chief of Child Development and Behavior Branch presenting research from Drs. Basser and Pierpaoli
- Frances E. Jensen, MD, former Council member also spoke



Questions?