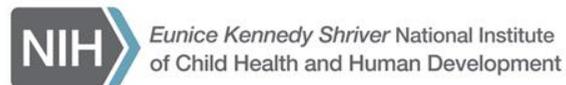


# Director's Report

**Alan E. Guttmacher, M.D.**

National Advisory Child Health and Human Development Council

September 18, 2015





## What's To Come

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



# News from NIH



## NINDS Director Announced

- In June, Walter Koroshetz, M.D., was appointed NINDS Director
- He had served as Acting Director of NINDS since October 2014 and had previously served as NINDS Deputy Director.





## NIH's Office of Behavioral and Social Sciences Research Director Announced

- William (Bill) Riley, Ph.D. was appointed Director of the NIH Office of Behavioral and Social Sciences Research, and Associate Director of NIH for Behavioral and Social Sciences in August.





## Inaugural Director of the NIH Division of Biomedical Research Workforce Programs

- Dr. Kay Lund joined NIH in August as the inaugural director of the Division of Biomedical Research Workforce Programs, a position created in response to the 2012 report of the NIH Biomedical Research Workforce Working Group
- Dr. Lund comes from UNC, where she was the Sarah Graham Kenan Professor of Cell Biology and Physiology, with joint appointments in Pediatrics and Nutrition





## Retirement of Sally Rockey

- Earlier this month, Sally Rockey, Ph.D., retired from her post as NIH Deputy Director for Extramural Research
- She is now the inaugural Director of the Foundation for Food and Agriculture Research





## NIMH Director Thomas Insel to Step Down

- After 13 years as NIMH director, Tom Insel will step down November 1<sup>st</sup>
- Tom will join the Life Sciences team at Alphabet (formerly Google) to lead a new effort focused on mental health
- Bruce Cuthbert, Ph.D., will serve as Acting Director while a national search is conducted





## NICHD Director Alan Guttmacher to Step Down

- In August, Alan Guttmacher, M.D., announced that his last active day at NIH will be September 30<sup>th</sup>
- His next post will be as a cider maker in East Thetford, Vermont





## Back to the Hills of Vermont – More Later





## NICHD Leadership Change

- In August, Alan Guttmacher, M.D., announced that his last active day at NIH will be September 30<sup>th</sup>
- His next post will be as cider maker in East Thetford, Vermont
- **Effective October 1st, Catherine Spong, M.D., Deputy Director, will become the Acting Director of NICHD**





## NIH Strategic Plan

- Dr. Tabak will join us later this morning to discuss this in more detail



## Redirection of NCS Funds FY15

- \$165M appropriated for NCS in FY15
- Congressional language directed NIH to continue to support the mission and goals of the NCS, with flexibility on how to carry this out
- Redirection of NCS resources
  - January 2015: Plan developed and concept cleared
  - February/March 2015: Released FOAs
  - Summer 2015: Applications reviewed
  - September 2015: Awards made



Initiative	IC	Project	Estimated Budget (in millions)
<b>Initiative 1: Develop tools that would enhance studies of environmental influences of pediatric diseases</b>	NIBIB	Pediatric Research using Integrated Sensor Monitoring Systems (PRISMS) [ <a href="#">RFA-EB-15-002</a> , <a href="#">RFA-EB-15-003</a> , <a href="#">RFA-EB-15-004</a> ]	\$28
	NIEHS	Children's Health Exposure Analysis Resource (CHEAR) [ <a href="#">RFA-ES-15-009</a> , <a href="#">RFA-ES-15-010</a> , <a href="#">RFA-ES-15-011</a> ]	\$49.8
	NIAMS	Validation of Pediatric Patient Reported Outcomes in Chronic Diseases (PEPR) Consortium [ <a href="#">RFA-AR-15-014</a> ]	\$12
<b>Initiative 2: Study the influence of environment on in utero development with the goal of identifying the "seeds" of future diseases and conditions</b>	NCATS, NIEHS	Tox21 Developmental Toxicity Program	\$8
	NICHD	Developing Paradigm-Shifting Innovations for in vivo Human Placental Assessment in Response to Environmental Influences [ <a href="#">RFA-HD-15-034</a> ]	\$41.1
<b>Initiative 3: Expand examination of environmental influences on later child development by leveraging extant programs</b>	NIEHS	Collaborative Activities to promote High Dimensional Molecular Analyses in NIEHS-supported Children's Environmental Health Studies [ <a href="#">PA-15-123</a> ]	\$5
<b>Total</b>			<b>\$143.9</b>



# Proposed FY16 Plan: Overview

- A 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



## Proposed FY16 Plan: Overview (cont.)

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



## Proposed FY16 Plan: Overview (cont.)

- Context: The Institutional Development Award (IDeA Program) supports faculty development and research infrastructure enhancement at institutions in 23 states and Puerto Rico



## Proposed FY16 Plan: Overview (cont.)

- Context: The Institutional Development Award (IDeA Program) supports faculty development and research infrastructure enhancement at institutions in 23 states and Puerto Rico
- 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



# Common Rule Notice of Proposed Rule Making

- Proposed revisions to the regulations that govern research
- Available for public comment through the Federal Register website:  
<https://www.federalregister.gov/public-inspection>
- Comments due by December 7



## NIH-BMGF Global Health Meeting

- Held July 8<sup>th</sup>
- Second in a series of meetings that began after Bill Gates visited the NIH in December 2013
- Identified activities for the next 12 months in eight key areas for all of NIH
- Areas of interest to NICHD included: maternal and newborn health, contraceptive research, child health and development, pediatric pneumonia and indoor air pollution, HIV/AIDS



## The Precision Medicine Initiative

- ADC PMI Working Group report released yesterday
- Of note: “the Working Group recommends that the PMI-CP include individuals from all life stages. The Working Group gave special consideration to including children, decisionally impaired adults, and participants who may become incarcerated after enrollment. There are scientific, ethical and policies issues surrounding these populations that warrant further discussion. Therefore, the Working Group recommends that NIH consider the safeguards necessary to ensure the appropriate enrollment, retention, and protection of these groups into the PMI cohort.”



# News from the NICHD



## Welcome Della Hann

- Della M. Hann, Ph.D., is now NICHD's Associate Director for Extramural Research
- Dr. Hann joins us from the NIH Office of Extramural Research, where she has served as deputy director since 2010





# Public Support for MFMU Research Network

- The work of the MFMU was recently recognized by a donor in the San Francisco Bay Area
- Dr. Yasser El-Sayed, a Stanford PI of NICHD's Maternal Fetal Medicine Units Network, was given a \$1 million donation by a grateful patient after helping with her labor and delivery
- Kudos to the MFMU Network!



*Funded by the National  
Institutes of Health*



# HHS Night at the Ball Park





# Intramural Human Placenta Project

- The NICHD Office of the Director awarded a total of \$360,000 to four intramural projects for HPP-related science:
  - Amir Gandjbakhche for *Real Time Oximetry of Anterior Placenta Using Near Infrared Spectroscopy*
  - Sergey Leikin, Peter Basser, and Roberto Romero for *Imaging Extracellular Matrix in Human Placenta*
  - Jennifer Lippincott-Schwartz and Carolyn Ott for *Integrated Cellular Changes Drive Syncytiotrophoblast Differentiation*
  - Erin Wolff for *MRI-Elastography Ultrasound Fusion (MR-eUS fusion) Characterization of Normal and Abnormal Human Placentation*



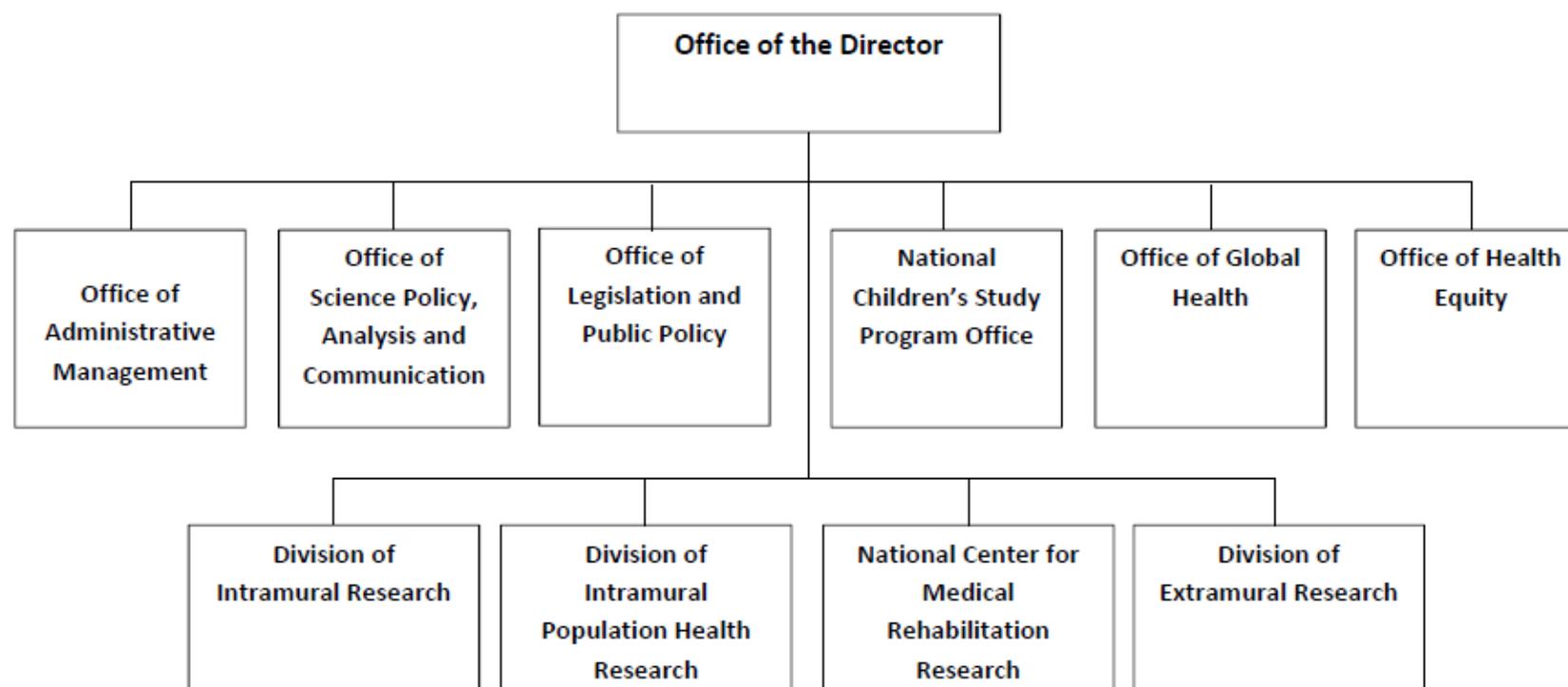


# NICHD Office of the Director Reorganization





# Organization Chart – Before October 1st



## Other Senior Positions:

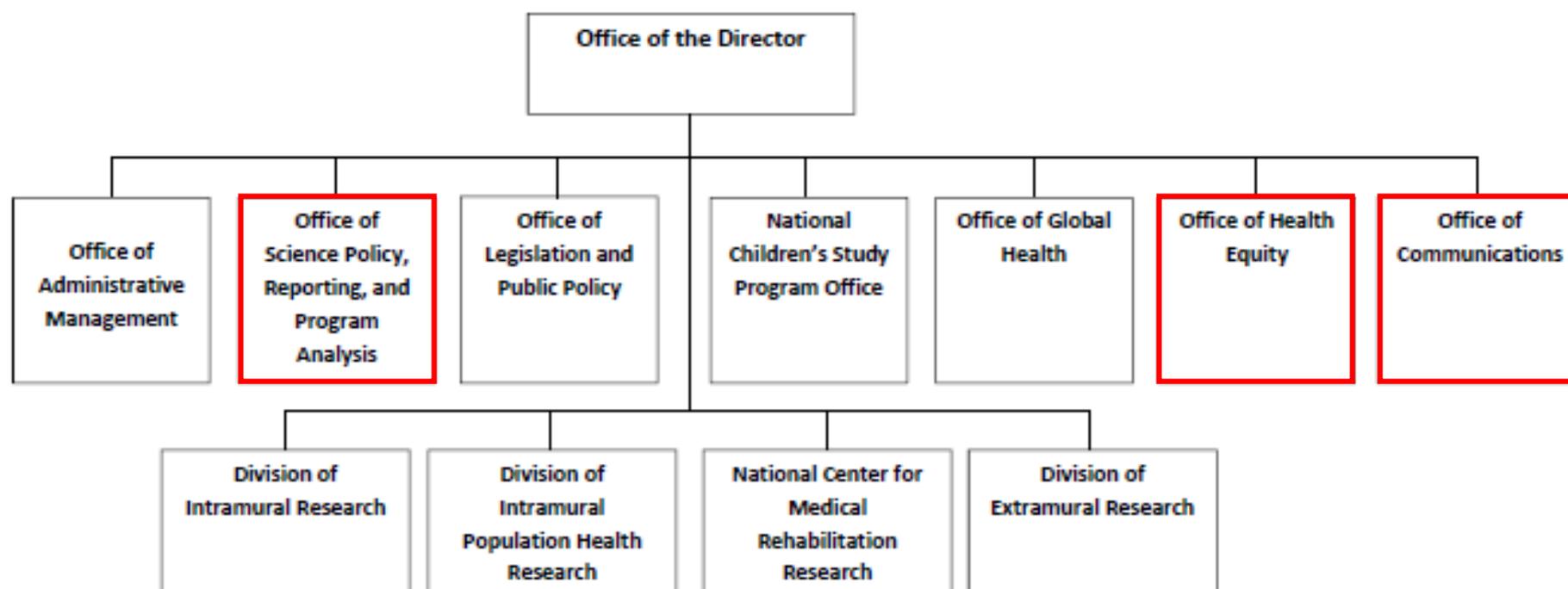
Associate Director for Clinical Research

Associate Director for Prevention

Senior Advisor for Device Development, Biotechnology, and Bioengineering



# Organization Chart – October 1<sup>st</sup> and beyond



Other Senior Positions:

Associate Director for Prevention

Senior Advisor for Device Development, Biotechnology, and Bioengineering

Associate Director for Clinical Research (moved to Division of Extramural Research)



# Legislative and Budget Updates

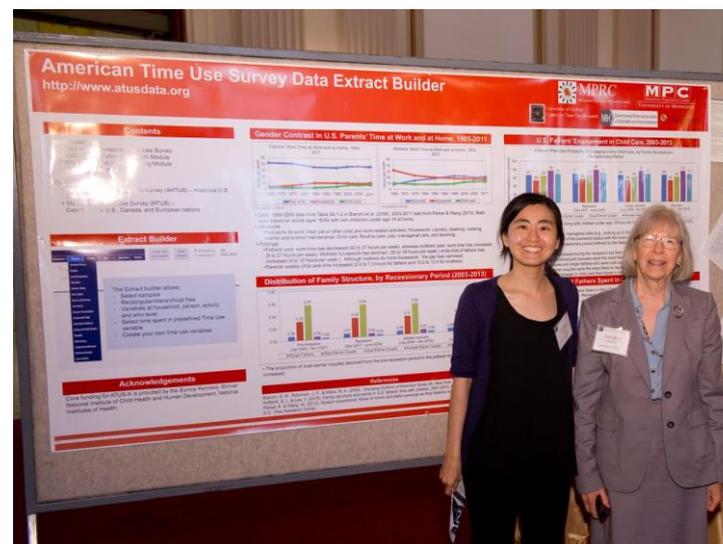
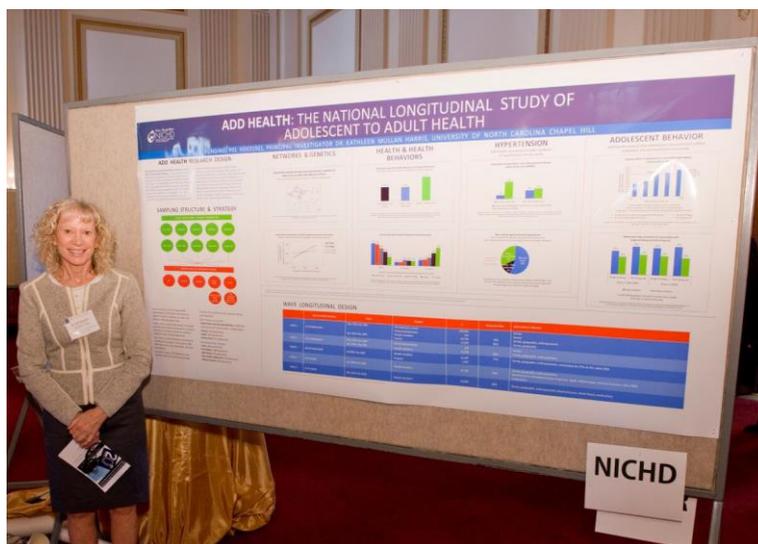


# Newborn Screening Saves Lives Reauthorization Act Guide Notice

- Guide Notice ([NOT-OD-15-127](#)) regarding implementation of the new provision for the Newborn Screening Saves Lives Reauthorization Act
- Requires that federally funded research using newborn dried blood spots collected **on or after March 18, 2015** be considered non-exempt human subjects research and follow the HHS Protection of Human Subjects regulations 45 CFR Part 46. Parental permission is required to use newborn dried blood spots in research.
- For questions, contact Dr. Tiina Urv at NICHD



# NICHD Grantees Present at Hill Poster Session



Kathleen Mullan Harris (UNC) and Sandra Hofferth (Univ. of Maryland) presented their behavioral and social science research at a Capitol Hill event in conjunction with the Office of Behavioral and Social Sciences Research 20<sup>th</sup> anniversary celebration



## 21<sup>st</sup> Century Cures Act – H.R. 6

- July 10: The House passed H.R. 6 (the “21st Century Cures Act”) by a vote of 344-77
- July 13: H.R. 6 was received in the Senate, read twice and referred to the Committee on Health, Education, Labor, and Pensions
- Senate HELP committee plans to introduce a different bill later this calendar year



# Budget Update

- No FY2016 budget yet
- House and Senate committees finished their respective appropriations bills (which differ greatly)
- Without action from Congress, sequestration caps will return in FY2016
- Without a continuing resolution or other action, the government will not be funded beyond September 30...





# The Tight Congressional Calendar

## September

M	T	W	T	F	
	<b>1</b>	<b>2</b>	<b>3</b>		Both chambers out
<b>7</b>	<b>8</b>		<b>10</b>		Both chambers in
<b>14</b>	<b>15</b>	<b>16</b>	<b>17</b>	<b>18</b>	
Rosh Hashanah	Rosh Hashanah ends		Iran deadline		
<b>21</b>	<b>22</b>	<b>23</b>	<b>24</b>	<b>25</b>	
Only Senate in	Yom Kippur begins	Yom Kippur ends	Pope visits		
<b>28</b>	<b>29</b>	<b>30</b>			Senate scheduled to be in on designated holidays
		Funding deadline			



# Questions