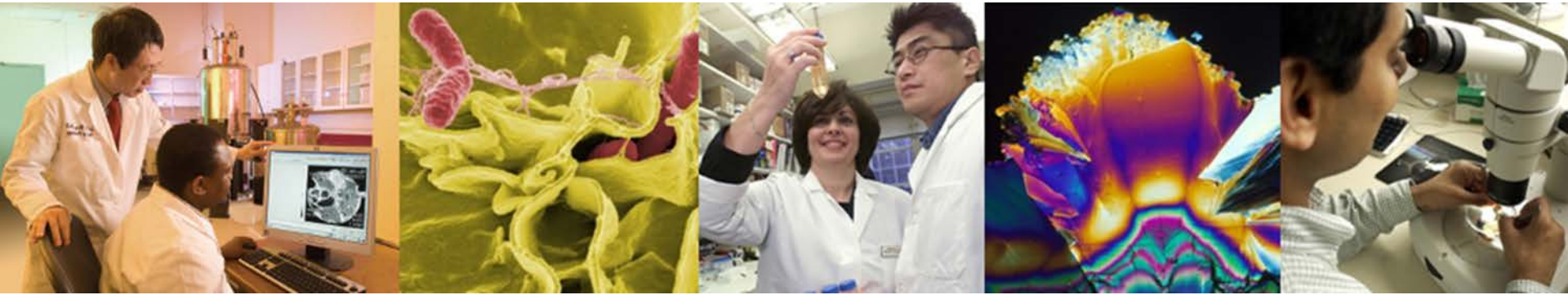


# Redirection of FY16 National Children's Study Funds

*Council of Councils*

*September 1, 2015*



**Lawrence A. Tabak, DDS, PhD**  
Principal Deputy Director, NIH



# Redirection of National Children's Study (NCS) Funds FY15

- \$165M Appropriated for NCS in FY15 Appropriations
- Bill and Report Language direct 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**: Developed a plan
  - **January 30, 2015**: Presented concept clearance to Council of Councils
  - **February/March 2015**: Released FOAs
  - **Summer 2015**: Applications reviewed
  - **September 2015**: Awards to be made

# Update: Redistribution of FY15 NCS Funds

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
	NICHHD	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

- Development Process
- Plan Overview
- Current Efforts

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# Proposed FY16 Plan: Development Process

## ICO Working Group

- 16 ICOs with at least one representative
  - NCI, NHLBI, NIAAA, NIAID, NIAMS, NIBIB, NICHD, NIDA, NIDCR, NIDDK, NIEHS, NIGMS, NIMH, NINDS, OBSSR, ORWH
- Co-led by Dr. Janine Clayton, Director, ORWH
- Helping to develop the details of the plan, coordinate outreach activities, craft the FOAs

# Proposed FY16 Plan: Development Process (cont'd)

- **Stakeholder Roundtables** – July 14, 15
  - Over 20 pediatric, environmental health, epidemiology, and other advocacy groups
- **Webinars** – July 22, 27, 29
  - ~400 participants total
- **RFI** – Closed August 14
  - ~190 responses
- **Summary of Comments**
  - Pregnancy/prenatal time period should be a key feature
  - Include basic research and training
  - Importance of standardizing and harmonizing data
  - Generally positive about IDeA States network
  - Many questions on eligibility of specific cohorts

# Proposed FY16 Plan

- Development Process
- **Plan Overview**
- Current Efforts



# Proposed FY16 Plan: Overview

## ■ **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 variable environmental exposures
  - Sharing standardized research questions
  - Focusing on four key pediatric outcomes

# Proposed FY16 Plan: Overview (cont'd)

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

# Proposed FY16 Plan: Overview (cont'd)

- Ensure that:
  - Recruitment plans are robust enough to address racial and ethnic minority health issues
  - There is a balance between a robust characterization of environmental factors and health related endpoints
- Studies may leverage additional features, such as:
  - Utilizing existing tissue banks collected across pregnancy (e.g., placenta) and data sets by funding additional analyses
  - Serving as a test bed for validating new technologies, tools, and approaches for environmental and pediatric monitoring
  - Using systems approaches to develop multi-variable models to predict disease development
  - Recruit women during subsequent pregnancies to compare outcomes of first and second children

# Proposed FY16 Plan: Overview (cont'd)

- Create an IDeA States National Pediatric Clinical Research 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

# Proposed FY16 Plan

- Development Process
- Plan Overview
- **Current Efforts**

# Current Efforts: Develop Details

- IC staff developing additional plan details
  - Extant Cohorts
  - Coordinating Center
  - Data Analytic Center – Leveraging CHEAR (FY15 resource)
  - IDeA Hubs
  - IDeA Data Coordinating and Operations Center
  - Governance Structure

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# Develop Details: Extant Cohorts

- Responsive datasets include:
  - Existing cohorts of pregnant women
  - Existing high-risk cohorts
  - Existing cohorts that are not high-risk
- Requirements
  - Provide information on available data/samples/cohorts
  - Research plan addressing:
    - Core Elements and Focus Areas
    - Importance for the synthetic cohort
    - How it would inform other Focus Areas
  - Provide evidence the sample/cohort could be re-contacted
  - Participate in prospective data collection efforts



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# Develop Details: Coordinating Center

- Coordinating Center will provide the organizational framework for the management, direction, and coordination of all sites
  - Coordinate interactions of cohort sites and Analytic Center
  - Standardize protocols, train staff, test inter-rater reliability of the Core Elements
  - Work with the Analytic Center to insure data acquisition, protocol, and data analysis pipeline standardization
  - Administrative and Project Management Plans
- Overseen by:
  - **Steering Committee** – NIH program staff, the heads of Coordinating Center, and the PIs of the studies
  - **Scientific Advisory Board** – external experts

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# Develop Details: Data Analytic Center – Leveraging CHEAR

- FY16 Program Needs
  - Data science analytics
  - Laboratory analytics
  - Statistical and informatics analytics
- Children’s Health Exposure Analysis Resource (CHEAR) – a FY15 supported program
  - Network of laboratory hubs supporting comprehensive analytical services to measure environmental exposures
  - Capable of performing comprehensive analysis, targeted and untargeted exposure assessment, and assessment of biological response indicators
  - Establishing data/metadata standards, repository, and statistical support
  - Scalable, adaptable design

# Develop Details: Data Analytic Center – Leveraging CHEAR (cont'd)

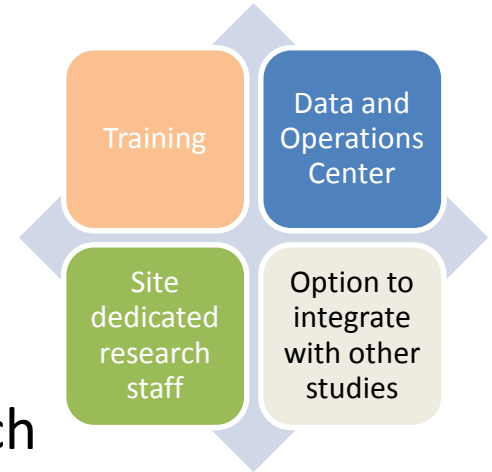
- Options under consideration:
  - CHEAR resources contribute specific expertise on the exposure Core Element, in collaboration with other centers/groups contributing to other Core Elements
  - Establish a separate Data Analytics Center to coordinate and manage the data needs
    - A sustainability plan will be developed as an integral component of the startup activities

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# Develop Details: IDeA Hubs

- Augment pediatric clinical trials initiated by other entities to:
  - Improve access to relevant populations
  - Accelerate overall accrual
  - Support advances in pediatric clinical research
- Focused on, but not limited to, clinical trials
- Local teams will receive specific training on conducting high quality pediatric clinical trials
- Prospective data collection should address the Core Elements
- Encourage research investigating the four Focus Areas
- Studies initiated within the Network will be encouraged
- Open to IDeA States awardees



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# Develop Details: IDeA Data Coordinating and Operations Center

- Multiple functions, including:
  - Function as an informatics, data coordinating, and operations center for clinical trial implementation
  - Funding to cover capitation fees and expenses of collecting data for **trials initiated at the IDeA hubs**
- Steering Committee
  - Composed of an outside chairperson (selected by NIH), PD/PIs from awarded IDeA hubs, PD/PI of Data Coordinating and Operations Center, NIH staff
- Data and Safety Monitoring Board and Advisory Board
- Open to any qualified organization with an IDeA state awardee partner as the lead/co-lead

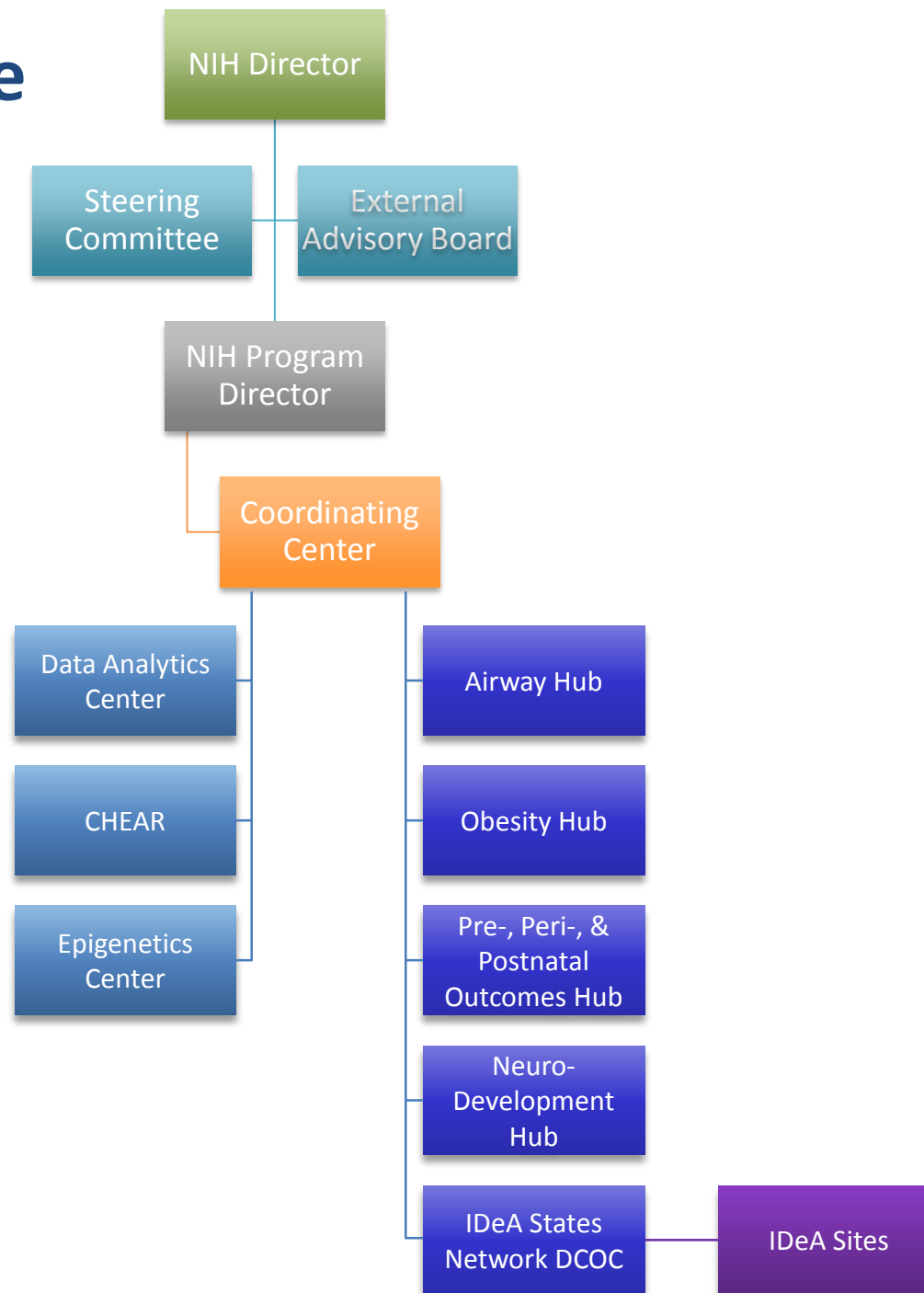
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# Develop Details: Governance Models Under Consideration

- Recruit experienced, full-time, program manager
- Reporting Options
  - Dual report to NIH Director, an ICD Board consisting of relevant ICDs, and an external Board consisting of PIs and independent experts
  - Report to relevant ICD, an ICD Board consisting of relevant ICDs, and an external Board consisting of PIs and independent experts
- Operational Location Options
  - Embed within a relevant IC
  - Embed with OD/DPCPSI

# Draft Structure



# FY16 Plan Timeline

Action	Timeframe
<b><i>Call with HHS</i></b>	<b><i>July 10th</i></b>
<b><i>Meet with stakeholder groups to solicit input</i></b>	<b><i>July</i></b>
Stakeholder Roundtables	July 14-15
<b><i>Conduct webinars</i></b>	<b><i>July 22, 27, 29</i></b>
<b><i>Craft and analyze RFI</i></b>	<b><i>July</i></b>
Release/Publish RFI	July 13
Analyze RFI	Early August
<b><i>Craft RFA concept/plan</i></b>	<b><i>By 9/1/15</i></b>
<b><i>Present concept for clearance by CoC</i></b>	<b><i>9/1/2015</i></b>
<b><i>Craft FOAs</i></b>	<b><i>September - October 2015</i></b>
<b><i>All FOAs with OER for review</i></b>	<b><i>11/1/2015</i></b>
Publish notices, if necessary	December-15
<b><i>RFAs published in the Guide</i></b>	<b><i>January 2016</i></b>
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**Questions?**



# NIH...

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# Turning Discovery Into Health

