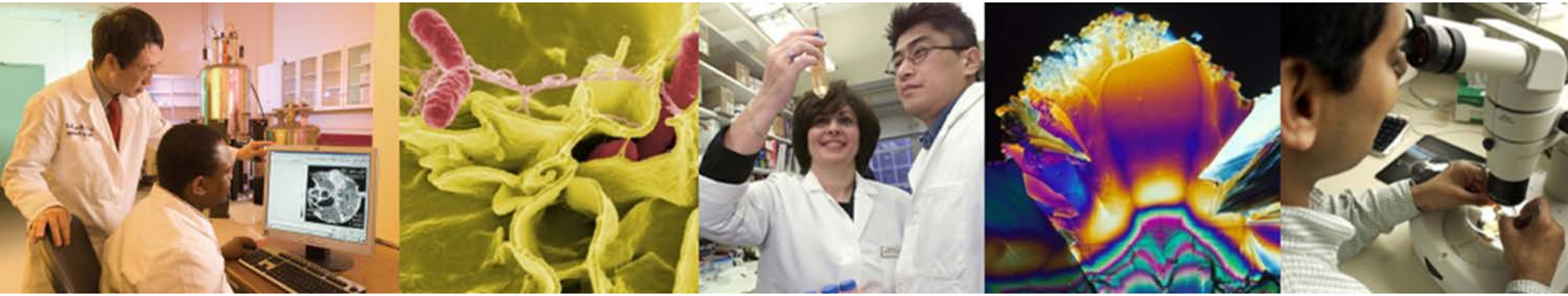
Environmental influences on Child Health Outcomes (ECHO) Program

Funding Opportunity Announcements Webinar

January 14, 2016



Lawrence A. Tabak, DDS, PhD
Principal Deputy Director, NIH
Department of Health and Human Services

Janine Austin Clayton, MD
NIH Associate Director for Research on Women's Health
Director, Office of Research on Women's Health, NIH
Department of Health and Human Services

ECHO Program: Overview

- **Overarching Goal**
  - Investigate the longitudinal impact of pre-, peri-, and postnatal environmental exposures on pediatric development and health outcomes with high public health impact through leverage of extant cohorts and other available resources
- **Core Elements to be Collected From all Participants**
  - Demographics
  - Typical early health and development descriptors
    - Optional Sub-Element: Microbiome
  - Genetic influences on early childhood health and development
    - Optional Sub-Element: Epigenetics
  - Environmental exposures (e.g., behavioral, biological, chemical, social)
  - Patient/Person (parent and child) Reported Outcomes (PROs)

ECHO Plan: Overview (cont'd)

- **Pediatric Health Outcome Focus Areas**
  - Upper and lower airway
  - Obesity
  - Pre-, peri-, and postnatal outcomes
  - Neurodevelopment
- **Additional Opportunity**
  - Create an IDeA States 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 Plan: Potential Research Questions that Could be Addressed

- What are the specific relative contributions of genetic and environmental (behavioral, biological, chemical, social, etc.) influences on child health?
- What factors render individuals or populations subjected to the same exposures as resilient or susceptible to disease? Do these differ over time, and by sex/gender, race/ethnicity, and/or SES?
- What are the inflection points at which the body's normal physiologic homeostasis becomes dysregulated, leading to chronic disease(s)?
- What are the molecular and behavioral mechanisms involved in maintaining a healthy weight across the lifespan?
- What are the genetic, biomarker, and environmental predictors of risk for the key focus areas of childhood outcomes?

ECHO Program Elements

- Extant Pediatric Cohorts
- Coordinating Center (CC)
- Data Analysis Center (DAC)
- PRO Core – leveraging PEPR (started in FY15 with NCS funds)
- CHEAR Core – leveraging CHEAR (started in FY15 with NCS funds)
- Genetics Core

- IDeA States Pediatric Clinical Trials Network
  - IDeA Clinical Sites
  - IDeA Data Coordinating and Operations Center (DCOC)

ECHO Program Element: Extant Cohorts [RFA-OD-16-004]

- **Characteristics of cohorts (not limited to):**
  - Cohorts initiated in pregnancy or post-partum that continue to follow offspring outcomes
  - Cohorts that ended data collection on pregnant women and offspring, but can demonstrate the capability to recontact
  - Cohorts that are currently recruiting and/or assessing pregnant or post-partum women and their offspring
- **Additional items that may be considered by applicants:**
  - EHRs are encouraged, but not required
  - Basic mechanistic studies that can only be done using human cohorts are encouraged
- **Two phases:** UG3/UH3
- **Anticipated Combined Cohort Size:** ~50,000

ECHO Program Element: Coordinating Center [RFA-OD-16-006]

- Responsible for:
  - Administrative coordination, training, and communication
  - Developing standard Core Elements
  - Coordinating statistical analysis with DAC/CHEAR/PRO Cores
  - Assisting DAC administratively
  - Developing and implementing policies (e.g., data sharing)
  - Coordinating with existing bio-repositories
  - Administering the Opportunities and Infrastructure Fund
  - Coordinating the functions of the Steering Committee and the External Scientific Board
- 4 Components
- Applicants are encouraged to apply for the CC and DAC

ECHO Program Element: Data Analysis Center [RFA-OD-16-005]

- Responsible for:
  - Developing and applying novel analytic methods for combining and analyzing existing and new longitudinal data from disparate extant cohorts
  - Data quality control and assurance, and validation
  - Conducting multi-level analyses on pooled consortium data
  - Bioinformatics and statistical analysis with the help of the CC to coordinate with the CHEAR, PRO, and Genetics Cores
  - Building and maintaining data dictionaries and databases
  - Developing a data sharing, security, and dissemination plan
- Applicants are encouraged to apply for the CC and DAC

ECHO Program Element: PRO Core [RFA-OD-16-003]

- Responsible for:
  - Providing expertise in selecting, developing, and validating PROs
  - Updating existing and validating emerging child PROs
  - Assisting with the incorporation of PROs into study design (i.e., Core Elements)
  - Coordinating the mode of administration
  - Performing initial quality control and assessment of PRO data
  - Assisting the DAC with PRO data analysis, where applicable
  - Integrating Validation of Pediatric Patient Reported Outcomes in Chronic Diseases (PEPR) derived knowledge and resources with the ECHO PRO Core

ECHO Program Element: CHEAR Core [PA-16-046]

- Expand upon an existing resource – Children's Health Exposure Analysis Resource (CHEAR)
  - Network of laboratory hubs supporting comprehensive exposure analysis of biological samples
- Responsible for:
  - Conducting targeted and untargeted analysis of stored and prospectively collected biological samples
  - Providing statistical and data flow support and coordination with the DAC
  - Assisting with the incorporation of exposure assessment into study design (i.e., Core Elements)
  - Coordinating workflow with the CC and DAC

ECHO Program Element: Genetics Core

- Responsible for:
  - Coordinating the standardized collection and measurement of genetic samples for SNP-chip analysis through state-of-the-art techniques
  - Collaborating with the CC and DAC on data workflow
  - To be released in FY17

ECHO Program Element: IDeA Clinical Sites and DCOC [RFA-OD-16-001/002]

IDeA Clinical Sites

- Expand pediatric clinical trials initiated by other entities
- Studies initiated within the Network are encouraged
- Local teams will receive training on conducting trials
- Open to IDeA States awardees

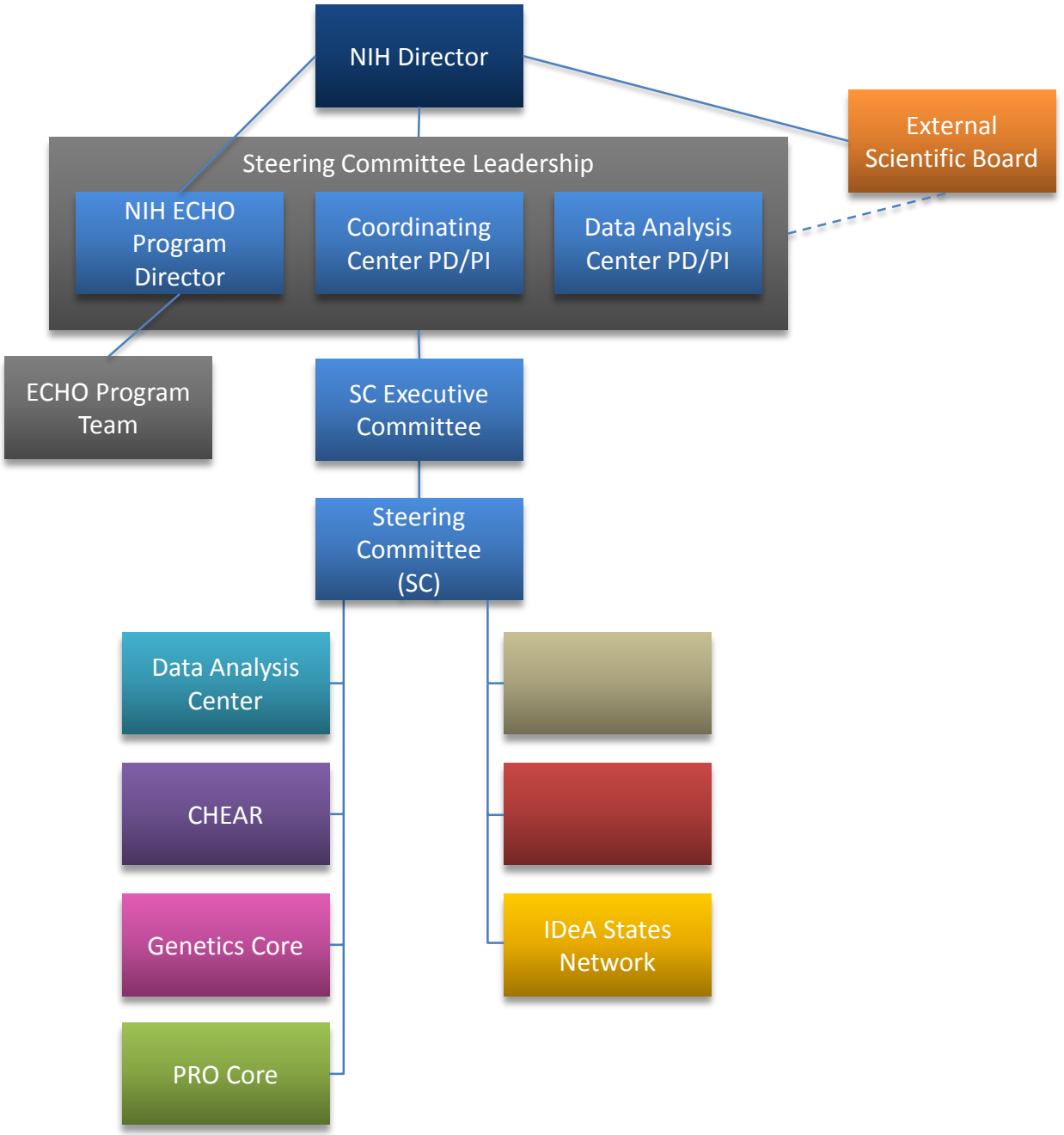
IDeA DCOC

- Point of contact, and oversight and training responsibilities
- Function as an informatics, data coordinating, and operations center for clinical trial implementation
- Funding for capitation fees and expenses
- Steering Committee
- Open to organizations with an IDeA state awardee partner

ECHO Program Elements: IDeA States Pediatric Clinical Trials Network

- Linkage to ECHO
  - Prioritize research investigating the four ECHO Focus Areas
  - Prospective data collection encouraged to address the ECHO Core Elements
  - Representatives on ECHO Steering Committee and subcommittees

Structure and Governance



ECHO Program Timeline

Action	Timeframe
Call with HHS	***July 10th***
Meet with stakeholder groups to solicit input	***July***
Stakeholder Roundtables	July 14-15
Conduct webinars	***July 22, 27, 29***
Craft and analyze RFI	***July***
Release/Publish RFI	July 13
Analyze RFI	Early August
Craft RFA concept/plan	***By 9/1/15***
Present concept for clearance by Council of Councils	***9/1/2015***
Craft FOAs	***September - October 2015***
All FOAs with OER for review	***11/1/2015***
Publish notices, if necessary	December-15
RFAs published in the Guide	***December 2015***
Applications due	***4/15/2016***
Peer review of applications	***Summer 2016***
Council review of applications completed	***9/30/2016***