ECHO

Environmental influences on Child Health Outcomes

A program supported by the NIH

in the NIH Office of the Director

Orientation to RFA-OD-24-008 Clinical Sites for the Environmental influences on Child Health Outcomes (ECHO) IDeA States Pediatric Clinical Trials Network-3 (UG1 Clinical Trial Required)

Tonse N. K. Raju, MD, DCH
Program Officer
IDeA States Pediatric Clinical Trials Network
Environmental influences on Child Health Outcomes (ECHO) Program
Office of the Director, NIH

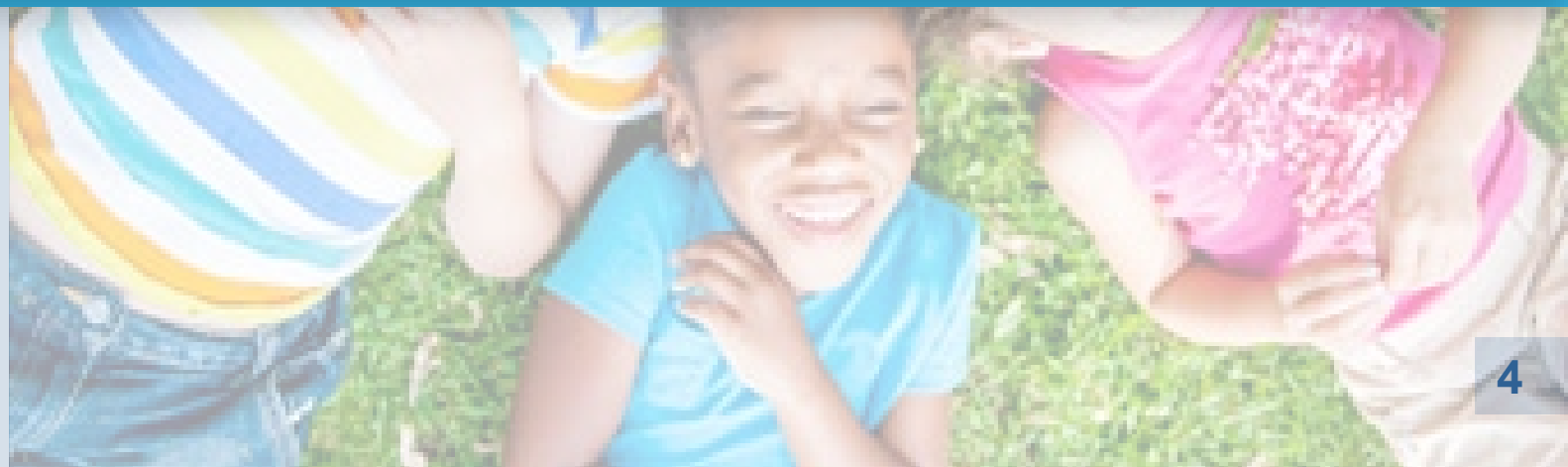
Email: tonse.raju@nih.gov

National Institutes of Health
Environmental influences on Child Health Outcomes (ECHO)

Pre-Application Webinar Purpose

- Overview of:
  - The ECHO Program
  - ECHO IDeA States Pediatric Clinical Trials Network (ISPCTN)
- Orientation to the funding opportunity announcement
- Providing answers to frequently asked questions

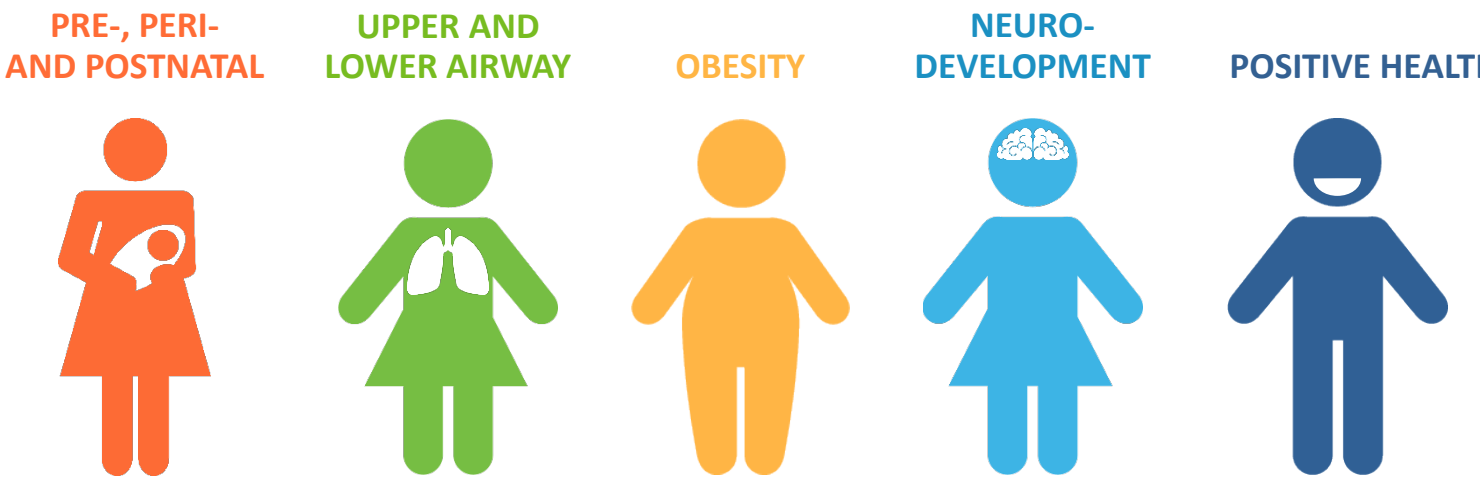
ECHO Program



ECHO Mission

Enhance the health of children for generations to come

ECHO Program Research Focus on Child Health and Development

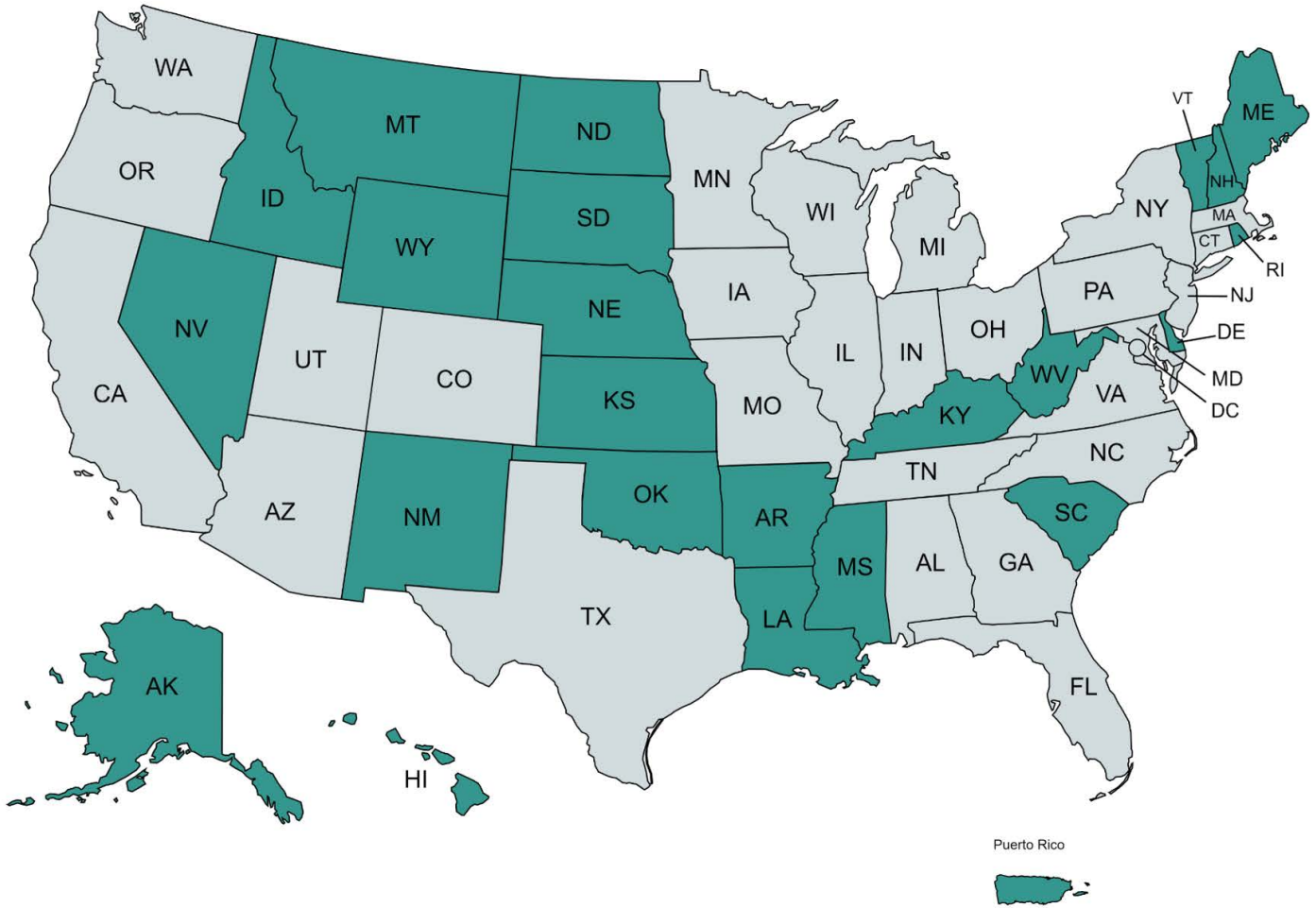


5 key pediatric outcomes with high public health impact

Throughout childhood and adolescence

Institutional Development Award (IDeA) States

- Established by Congressional mandate in 1993, the NIH IDeA program's goal is to broaden the geographic distribution of NIH funding.
- The programs support faculty development and institutional research infrastructure enhancement in IDeA States that have historically received low levels of support from NIH.
- In addition, the programs serve the unique populations in the IDeA States, which are predominantly rural or underserved.



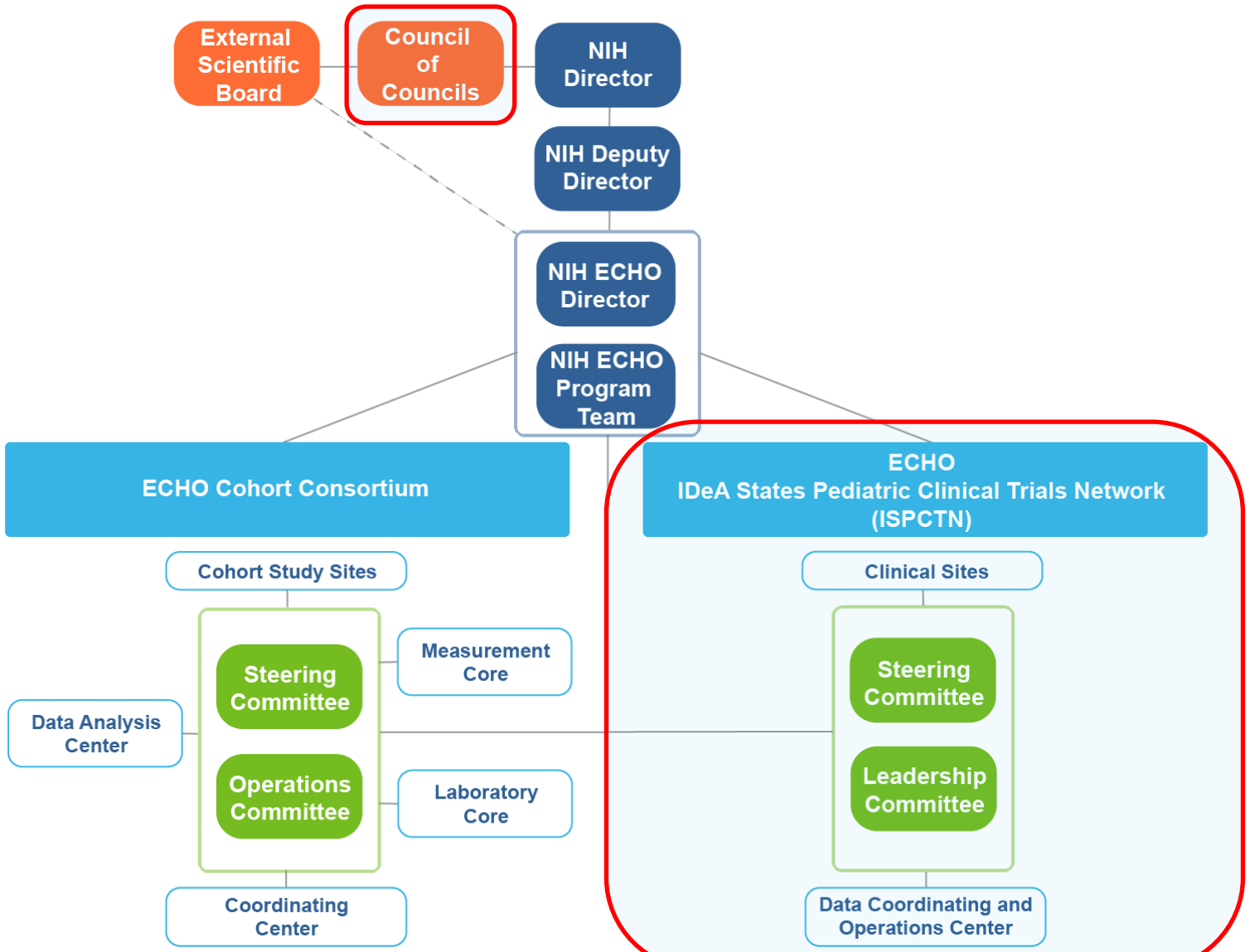
The 23 IDeA States and Puerto Rico

In 2016, NIH Established ECHO IDeA States Pediatric Clinical Trials Network (ISPCTN)

Overall goals:

- Provide children from rural or underserved populations access to state-of-the-art clinical trials
- Build pediatric research capacity within the IDeA States to conduct these trials
- Additional goals
  - Engage communities and interested parties in ECHO ISPCTN research processes
  - Enhance diversity, equity, inclusion, and accessibility in workforce and participants

ECHO PROGRAM ORGANIZATION



ECHO ISPCTN Overall Goals through 2 Cycles

- ECHO ISPCTN overall goals from 1st cycle (2016-2020)
  - Allow children from rural or underserved populations access state-of-the-art clinical trials
  - Build pediatric research capacity within the ECHO ISPCTN-funded IDeA States
- Added in 2nd cycle (2020-2025):
  - Engage communities and interested parties in ECHO ISPCTN research processes
  - Required 1-2 Jr. investigators
- Cross-cutting goals added in 2nd cycle:
  - Enhance diversity, equity, inclusion, and accessibility in workforce and research participation

Section 1:
Funding Opportunity Description (1)

- This RFA invites applications from entities/institutions in IDeA States to participate as clinical Sites in the ECHO ISPCTN.

- This announcement runs in parallel with companion RFA-OD-24-009, soliciting applications for a Data Coordinating and Operations Center (DCOC) within the IDeA States.

- The ECHO ISPCTN Clinical Sites and DCOC together will form the ECHO ISPCTN.

Section I:
Funding Opportunity Description (2)

The clinical sites of the ECHO ISPCTN will:

- Develop, conduct, and disseminate findings from pediatric multicenter clinical trials, assuring the participation of children living in rural or underserved communities located in Institutional Development Award (IDeA) states
- Build pediatric clinical trial network capacity in IDeA states funded by the ECHO ISPCTN
- Engage interested parties such as community members, nonprofit organizations and professional societies to enhance ECHO ISPCTN clinical trial impact, transferability, rigor, and feasibility

Section I:
Funding Opportunity Description (3)

The award will support approximately 5 pediatric clinical trials related to prevention or treatment of conditions in at least 2 of the 5 outcome areas of the ECHO Program, which are:

- pre-, peri-, and postnatal outcomes;
- obesity;
- upper and lower airway;
- neurodevelopment;
- and positive health.

Section II: Award Information:

Available Funds and anticipated number of awards

- NIH intends to fund an estimated 15-20 awards, corresponding to a total of $7,000,000, for fiscal year 2025.
- Future year amounts will depend on annual appropriations.
- The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.

Section II: Award Information (2):

- Award Budget
  - Applicants may request direct cost budgets of up to $300,000 for each of the five years of the award. The application should include a detailed budget for each year of study.

- Award Project Period
  - 5 years

Section III: Eligibility Information

- Institutions of Higher Education
- Nonprofits Other Than Institutions of Higher Education
- For-Profit Organizations
- Local Governments
- Federal Government

Section III: Eligibility Information (2)

- Only 23 IDeA States and Puerto Rico are eligible to respond to this RFA—these are:

  Alaska, Arkansas, Delaware, Hawaii, Idaho, Kansas, Kentucky, Louisiana, Maine, Mississippi, Montana, Nebraska, Nevada, New Hampshire, New Mexico, North Dakota, Oklahoma, Puerto Rico, Rhode Island, South Carolina, South Dakota, Vermont, West Virginia, and Wyoming.

Section III: Eligibility Information (3)

- Program Director/Principal Investigator(s) (PD/PI(s)) from an IDeA State should have skills, knowledge, and resources necessary to carry out the proposed research work
- The PD/PI(s) must be capable of providing both administrative and scientific leadership to the development and implementation of the proposed program.
- At least one PD/PI for the clinical site should be a board-certified pediatrician in an IDeA state.
- PD/PI(s) will supervise the development and conduct of ECHO ISPCTN clinical research at their institution and any partnering performance site.

Partner Institutions

- To enhance research expertise and potential to build capacity to include needed expertise on multi-center clinical trial proposals, ECHO ISPCTN Clinical Site and DCOC applicants may propose collaborations.
- Applicants may consider collaborating with other components or investigators within their own state or in other IDeA or non-IDeA States.
- For Partner Institutions from non-IDeA States, total budget per year should be no more than 25% of the total annual cost awarded to the applicant organization.
- Applicants are encouraged to leverage resources and facilities supported by other NIH programs, such as the IDeA Program-Infrastructure for Clinical and Translational Research (IDeA-CTR) and the Clinical and Translational Science Award (CTSA) Program.

Section IV: Letter of Intent

- A letter of intent is not required; however, such a letter helps NIH Institute/Center staff to estimate review workload and accordingly plan for the review of applications.

- In the letter of intent, please include:
  - Descriptive title of proposed activity
  - PD(s)/PIs contact information
  - Contact information of other key personnel
  - Participating institution(s)
  - Number and title of this RFA

Section IV: Letter of Intent (2)

Address the Letter of Intent to:

Dr. Lisa Steele, PhD
Centers for Scientific Review, MSC 7768
6701 Rockledge Dr
Bethesda, MD, 20892-7768

Work Phone: 301-257-2638
Lisa.steele@nih.gov

Key Dates

- Letter of Intent (optional) Due Date: April 1, 2024
- Application Due Date: April 15, 2024
- Scientific Merit Review: October 2024
- Advisory Council Review: January 2025
- Earliest Estimated Award Date: May 2025
- Earliest Estimated Start Date: June 2025

Some Suggestions for all Applicants

- Please read both funding opportunity announcements for ISPCTN 3rd cycle that have been published:
  - these are
  - RFA-OD-24-008 and
  - RFA-OD-24-009
- Please read both frequently asked questions, or FAQ files available on this website, which are
  - The word file for clinical sites RFA, OD-24-008 and
  - The word file for the Data Coordinating and Operations Center RFA, OD-24-009
- Please see both webinars available on this website, which are one for the clinical sites RFA and the other for the Data Coordinating and Operations Center RFA

Questions

Questions can be sent tonse.raju@nih.gov.

ECHO

Environmental influences on Child Health Outcomes

A program supported by the NIH

in the NIH Office of the Director