ECHO

Environmental influences on Child Health Outcomes

A program supported by the NIH

in the NIH Office of the Director

Orientation to RFA-OD-24-009 Data Coordinating and Operations Center for the ECHO IDeA States Pediatric Clinical Trials Network - 3 (U24 Clinical Trial Required—Infrastructure)

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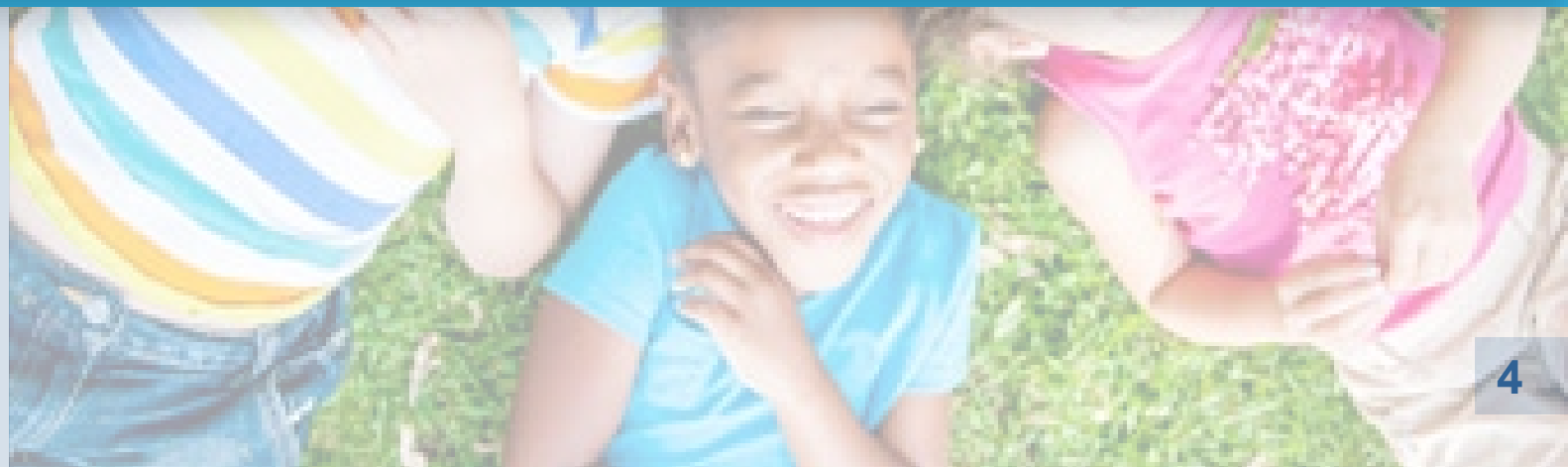
National Institutes of Health
Environmental influences on Child Health Outcomes (ECHO)

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

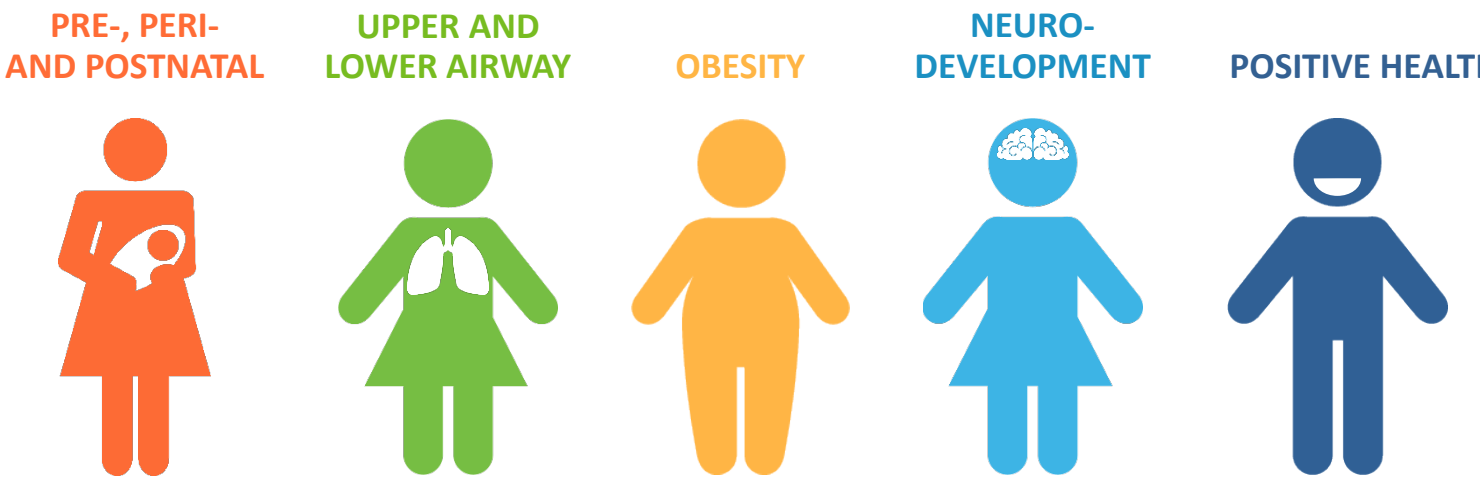
ECHO Program



ECHO Mission

Enhance the health of children for generations to come

ECHO Program Research Focus on Child Health and Development

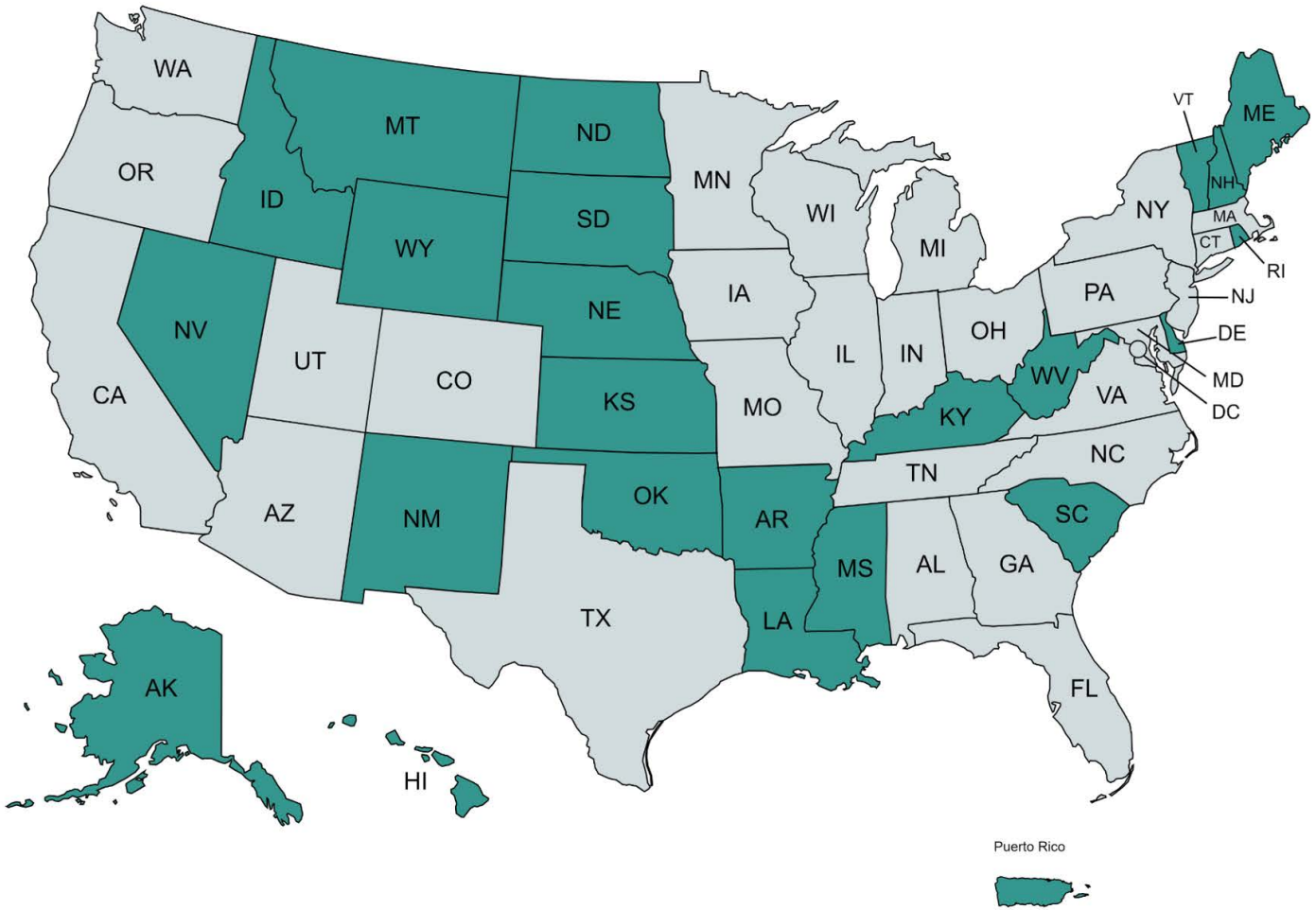


5 key pediatric outcomes with high public health impact

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 program supports faculty development and institutional research infrastructure enhancement in states that have historically received low levels of support from NIH.
- In addition to enhancing the competitiveness of investigators and the research capacities of institutions in the 23 IDeA States plus Puerto Rico, the program serves their unique populations, such as rural and medically underserved communities.



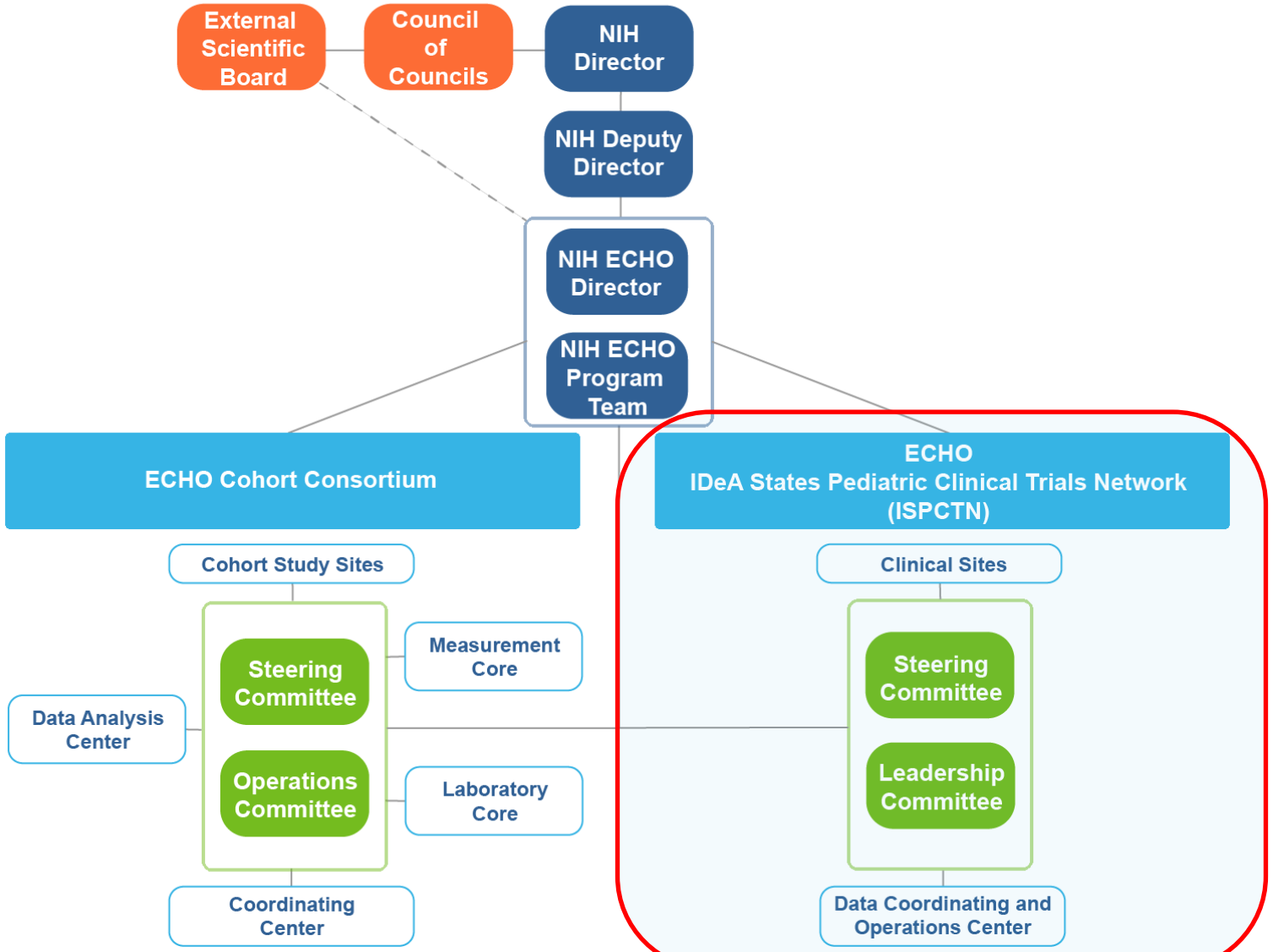
The 23 IDeA States and Puerto Rico

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

Overall goals of ECHO ISPCTN:

- 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 the ISPCTN research processes
  - Enhance diversity, equity, inclusion, and accessibility in workforce and among 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 I:
Funding Opportunity Description

- This NOFO invites applications from entities/institutions in IDeA-eligible states to participate as the Data Coordinating and Operations Center (DCOC) in the ECHO ISPCTN.
- This RFA runs in parallel with companion RFA-OD-24-008 soliciting applications for ECHO ISPCTN Clinical Sites within the IDeA States.
- The DCOC and Clinical Sites together will form the ECHO ISPCTN.

Section I: DCOC Expectations

- Supporting clinical trials:
  - Help ECHO ISPCTN Clinical Sites to develop, conduct, and disseminate findings from multi-center clinical trials, assuring the participation of children living in rural or underserved communities in IDeA States.
- Clinical trial capacity building:
  - Build pediatric clinical trial research capacity in ECHO IDeA States funded by the ECHO ISPCTN.
- Engagement of Communities
  - Engage communities and interested parties to enhance ECHO ISPCTN clinical trial impact, transferability, rigor, and feasibility.
- Administrative and operational support

Section I: DCOC Expectations (2) Supporting Clinical Trials

- Protocol Development: Assisting in clinical trial protocols; their implementation; and biostatistical support including data analyses
- Regulatory: Sponsorship for investigational new drug (IND) and/or investigational device exemption (IDE); coordinating ISPCTN committees: e.g. Data and Safety Monitoring Board (DSMB); single institutional review board (sIRB); and others
- Budgetary: Assisting investigators to develop study budgets; establishing subcontracts; disbursing capitation funds to the sites; monitoring and reporting study budgetary details to the NIH
- Data management: Establishing systems for quality assurance; monitoring study progress, participant safety; adverse events; data on enrollment, retention and diversity; and conducting clinical site visits

Section I: DCOC Expectations (3) Clinical Trial Capacity Building

- Developing and providing core curricula for ECHO ISPCTN investigators
- Focusing the curricula on pediatric topics; clinical trial designs; trial implementations; publication of research findings; and the principles of Good Clinical Practice
- Partnering with existing, experienced clinical trial education providers to leverage expertise and resources to reduce costs and ensure that the network researchers are exposed to high quality content.
- Monitoring the uptake of the curricula by clinical site investigators and adjust the dissemination strategy as needed to ensure widespread participation clinical site investigators and research coordinators.

Section I: DCOC Expectations (4) Engagement of Communities, Participants, and Other Interested Parties

- Support clinical sites to engage community members, nonprofit organizations, and professional societies to strengthen and enhance ECHO ISPCTN clinical trials.
- Support the dissemination of aggregate research products to the lay public and scientific communities by developing a communication plan, so that interested parties can access clinical trial-related information such as protocols, scientific publications, and study summaries.
- Develop communication plans for press releases, newsletters, social media posts, and an ISPCTN-specific website linked to the existing ECHO Program website (echochildren.org).

Section I: DCOC Expectations (5) Administrative and Operational Support

- The DCOC will provide logistical support to ISPCTN committees and working groups to carry out their vital functions.
- The DCOC will provide a dashboard to report progress of the network overall and for each clinical site toward attainment goals, objectives, indicators, and targets (GOIT) developed by the ISPCTN network, including the steering committee, and the ECHO ISPCTN Program Office.
- Other administrative and operational supports are described in the RFA-OD-24-009.

Section II: Award Information

- Funds available and anticipated number of awards:
  - NIH intends to fund 1 award, corresponding to a total of $8,000,000, for fiscal year 2025.
  - Future year amounts will depend on annual appropriations.
- Applicant can request up to $2,000,000 per year in direct costs for Core Infrastructure Costs for the DCOC's roles in supporting and facilitating ECHO ISPCTN operations, completion of ongoing trials, and development and implementation of approximately 5 new clinical trials.

Section II: Award Information (2)

- Core Infrastructure support will also support the DCOC's role in facilitating the work of ECHO ISPCTN committees and oversight bodies.
- In addition, applicants should budget $3,250,000 per year in direct costs for Protocol-Specific Costs for distribution to the ECHO ISPCTN Clinical Sites as capitation fees to conduct clinical trials.
- 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.

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: June 14, 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.

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