Pre-application Webinar for Limited Competition: ECHO Pregnancy and Pediatric Cohort Study Sites (UG3/UH3) RFA-OD-22-18

S. Sonia Arteaga, PHD
Environmental influences on Child Health Outcomes (ECHO)
Office of the Director, NIH
Sonia.Arteaga@nih.gov
NIHKidsandEnvironment@od.nih.gov

Agenda

- ECHO Overview
- ECHO Pregnancy and Pediatric Cohort Study Sites (UG3/UH3) RFA-OD-22-018
  - Section I. Funding Opportunity Description
  - Section II. Award Information
  - Section III. Eligibility Information
  - Section IV. Application and Submission Information
  - Section V. Application Review Information
  - Section VI. Award Administration Information
- Key Dates
- Questions

Pre-Application Webinar Purpose

- Familiarize the potential applicant with established NIH guidelines and criteria for review;
- Discuss the areas of NIH programmatic emphasis;
- Facilitate the submission of a well-organized application

Essential Information

- It is essential that applicants for this Funding Opportunity Announcements (FOA) familiarize themselves with the companion FOAs, including the goals and requirements for the Cohort Study Sites, Coordinating Center, Data Analysis Center, Measurement Core, and Laboratory Core and how they function together within the ECHO Cohort consortium.
- Read the FOAs carefully. The application instructions and review criteria are aligned with each other, and with the FOA goals, and will be the basis for peer review and programmatic funding decisions.
- All required information is contained in the FOAs. The recorded webinars provide a summary but do not substitute for the FOAs.

FOA Presentations

See Presentations for each ECHO FOA on the NIH ECHO website:

1. ECHO Overview
2. Pregnancy Cohort Study Sites (UG3/UH3) RFA-OD-22-017
3. *Limited Competition:* Pregnancy and Pediatric Cohort Study Sites (UG3/UH3) RFA-OD-22-018
4. *Limited Competition:* Cohort Study Sites for Pediatric Follow Up (UG3/UH3) RFA-OD-22-019
5. Laboratory Core (U24) RFA-OD-22-016
6. Measurement Core (U24) RFA-OD-22-020
7. Coordinating Center (U2C) RFA-OD-22-021
8. Data Analysis Center (U24) RFA-OD-22-022

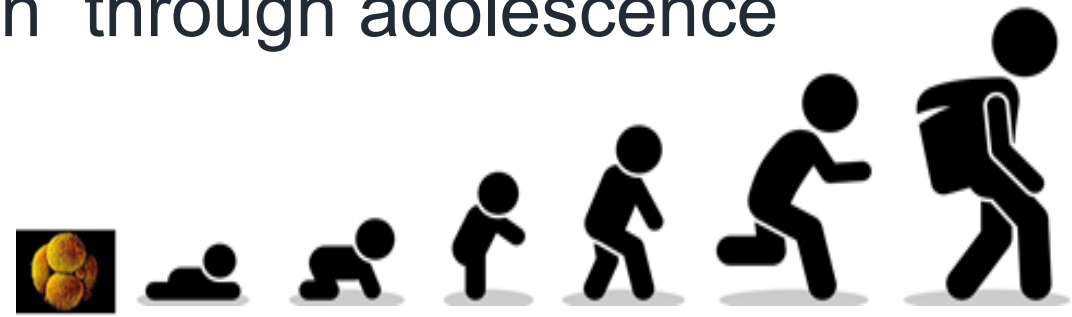
ECHO Overview – please view the ECHO overview webinar

ECHO Overview

Extend and expand the ECHO Cohort in its next phase (FY2023-2029) to further investigate the roles of a broad range of early exposures from society to biology, including the preconception period, on ECHO's five key child health outcomes among diverse populations.

Extend and Expand ECHO Cohort

- Extend reach by following nearly 40,000 existing ECHO children and families
- Expand to include 20,000 women and partners recruited during pregnancy with follow-up of their children
  - Preconception pilot of 10,000 couples at moderate to high probability of subsequent pregnancy
- Combined strategies yield large, diverse cohort from preconception through adolescence



Key Features of ECHO Cohort Consortium

- Team science
  - Mutual respect, cooperation, and collaboration with all consortium members
- Single IRB
- Standardized implementation of ECHO Cohort Protocol (please refer to: Draft ECHO Cohort Data and Biospecimen Collection Protocol)
- Centralized data capture, e.g., REDCap Central
- No Cohort Study Site-specific analyses or science
- Commitment to Diversity, Equity, Inclusion, and Accessibility

ECHO Pregnancy and Pediatric Cohort Study Sites (UG3/UH3) RFA-OD-22-018

Section I: Limited Competition
ECHO Pregnancy and Pediatric Cohort Study Sites Objectives

1. Lead collaborative ECHO Cohort science
2. Follow up existing ECHO Cohort participants
3. Recruit new pregnant participants from diverse populations, their resulting offspring, and, if available, the conceiving partner
4. Develop and implement the ECHO Cohort Preconception Pilot Study
5. Implement the ECHO Cohort Data and Biospecimen Collection Protocol using the ECHO Cohort consortium's central data capture system, e.g., REDCap Central.

Section I: Cohort Study Site

- ECHO Cohort Study Site - an institution at which participant recruitment and follow up takes place at one or multiple locations, e.g., the Cohort Study Site could be a medical system with recruitment taking place at its clinics.

  - If an applicant includes more than one Cohort Study Site in their application, they must justify the multi-site structure and include a project management plan.

Section I: UG3/UH3 Mechanism

- Cooperative Agreement: A support mechanism used when there will be substantial Federal scientific or programmatic involvement.
- UG3/UH3 – milestone driven, involves 2 phases
  - UG3 - The initial milestone-driven developmental phase will last for up to 2 years
  - Award of the UG3 does not guarantee subsequent UH3 funding.
  - NIH ECHO Program staff will administratively review the extent to which each Cohort Study Site meets the criteria for success during the UG3 phase and make final decisions based upon funding availability and Cohort Study Site progress.
  - UH3 – Second phase, lasts five years

Section I: UG3 Criteria for Transitioning to UH3

Including but not limited to:

- Reconsenting existing ECHO Cohort participants,
- Recruiting new pregnant and preconception participants,
- Implementing the ECHO Cohort Protocol to collect requisite data and biospecimens, and
- Producing and disseminating ECHO Cohort science

Section I: UH3

- Funding for the UH3 phase is contingent on successfully meeting the criteria in the UG3 phase.
- Focus on how the applicant will expand
  - development, production, and dissemination of ECHO Cohort science,
  - continue high recruitment and retention rates,
  - continue fidelity to the ECHO Cohort Protocol to collect requisite data and biospecimens

Section I: Draft ECHO Cohort Protocol v3.0

https://dcricollab.dcri.duke.edu/sites/echomaterials/SitePages/Home.aspx

Propose to specialize in at least one exposure area and at least one outcome area.

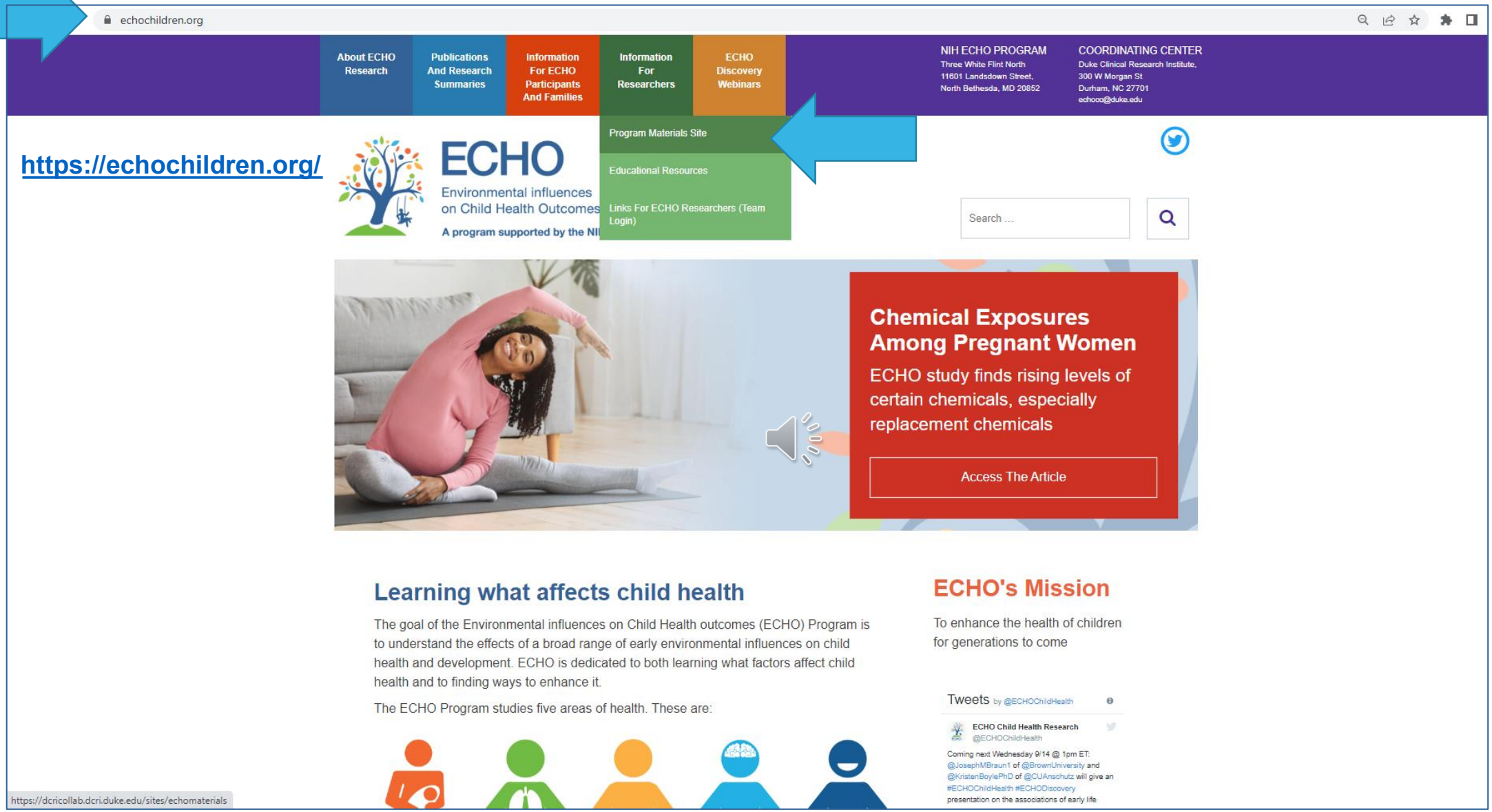
- Specialized exposure areas include: a) Physical & Chemical, e.g., air pollution and household chemicals b) Lifestyle, e.g., nutrition, sleep, and physical activity; or c) Psychosocial, e.g., stress, social support, and discrimination.
- Specialized outcome areas include: pre-, peri- and postnatal, upper and lower airways, obesity, neurodevelopment, and positive health.

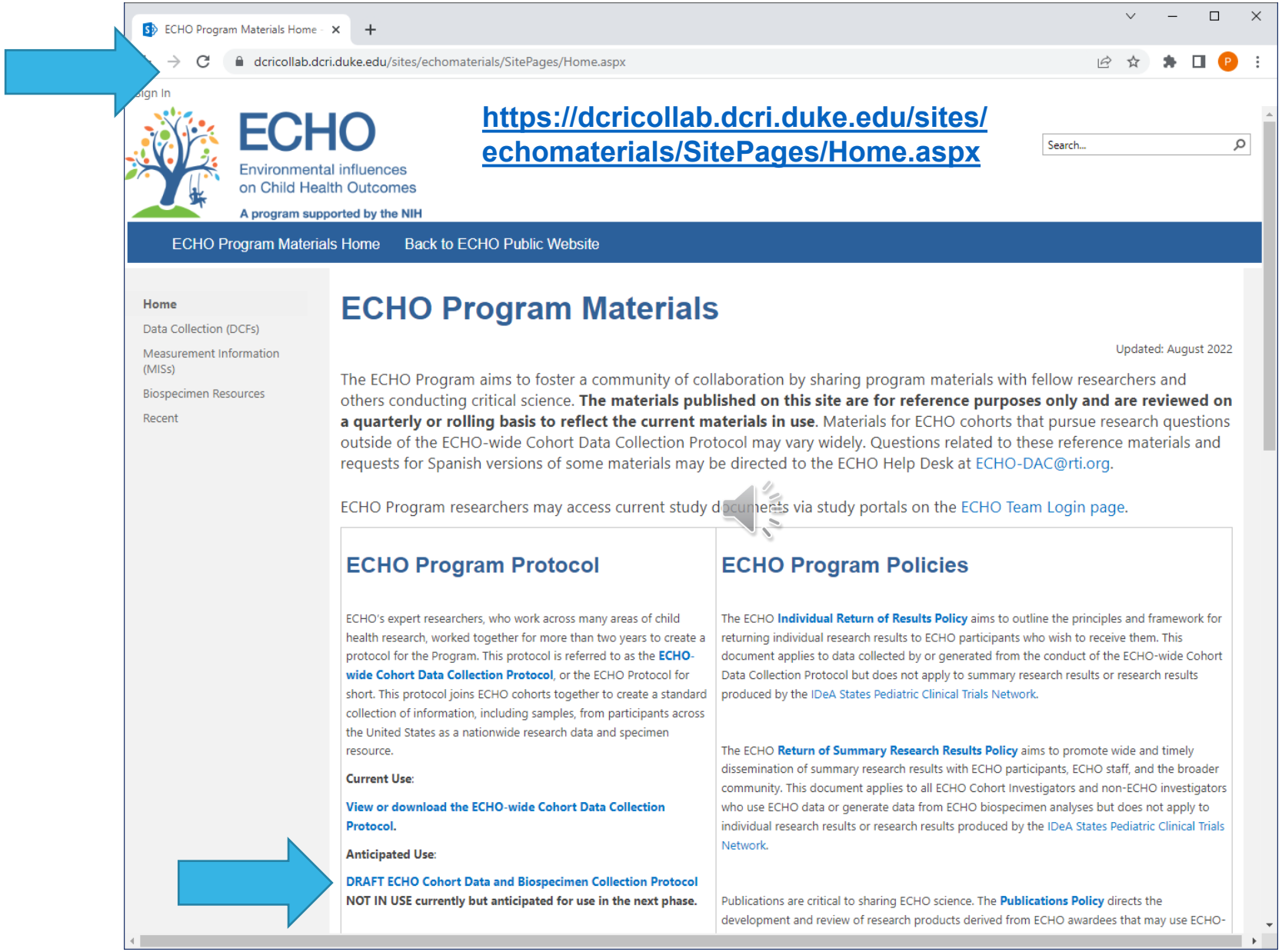
Section I: Draft ECHO Cohort Protocol v3.0

https://dcricollab.dcri.duke.edu/sites/echomaterials/SitePages/Home.aspx

- Aim 2 should incorporate question(s) that leverage proposed specialized exposure and/or specialized outcome areas
- Applicants may choose to propose specialized data elements to support those specific aims.
- Core data element – data element or biospecimen that every Cohort Study Site will collect on every participant. For the purposes of applying to this FOA, consider all elements in the ECHO Draft Protocol v3.0 core.
- Specialized data element - more frequent or more detailed elements than the Core elements. The Steering Committee may add specialized elements to the ECHO Protocol during the UG3 phase.

https://echochildren.org/




ECHO Program Materials Home
dcricollab.dcri.duke.edu/sites/echomaterials/SitePages/Home.aspx
ECHO
Environmental influences on Child Health Outcomes
A program supported by the NIH
https://dcricollab.dcri.duke.edu/sites/echomaterials/SitePages/Home.aspx
Search...
ECHO Program Materials Home
Back to ECHO Public Website
Home
Data Collection (DCFs)
Measurement Information (MISs)
Biospecimen Resources
Recent
ECHO Program Materials
Updated: August 2022
The ECHO Program aims to foster a community of collaboration by sharing program materials with fellow researchers and others conducting critical science. The materials published on this site are for reference purposes only and are reviewed on a quarterly or rolling basis to reflect the current materials in use. Materials for ECHO cohorts that pursue research questions outside of the ECHO-wide Cohort Data Collection Protocol may vary widely. Questions related to these reference materials and requests for Spanish versions of some materials may be directed to the ECHO Help Desk at ECHO-DAC@rti.org.
ECHO Program researchers may access current study documents via study portals on the ECHO Team Login page.
ECHO Program Protocol
ECHO's expert researchers, who work across many areas of child health research, worked together for more than two years to create a protocol for the Program. This protocol is referred to as the ECHO-wide Cohort Data Collection Protocol, or the ECHO Protocol for short. This protocol joins ECHO cohorts together to create a standard collection of information, including samples, from participants across the United States as a nationwide research data and specimen resource.
Current Use:
View or download the ECHO-wide Cohort Data Collection Protocol.
Anticipated Use:
DRAFT ECHO Cohort Data and Biospecimen Collection Protocol
NOT IN USE currently but anticipated for use in the next phase.
ECHO Program Policies
The ECHO Individual Return of Results Policy aims to outline the principles and framework for returning individual research results to ECHO participants who wish to receive them. This document applies to data collected by or generated from the conduct of the ECHO-wide Cohort Data Collection Protocol but does not apply to summary research results or research results produced by the IDeA States Pediatric Clinical Trials Network.
The ECHO Return of Summary Research Results Policy aims to promote wide and timely dissemination of summary research results with ECHO participants, ECHO staff, and the broader community. This document applies to all ECHO Cohort Investigators and non-ECHO investigators who use ECHO data or generate data from ECHO biospecimen analyses but does not apply to individual research results or research results produced by the IDeA States Pediatric Clinical Trials Network.
Publications are critical to sharing ECHO science. The Publications Policy directs the development and review of research products derived from ECHO awardees that may use ECHO-

Plans for Enhancing Diversity

- Plan for Enhancing Diverse Perspectives (PEDP):
  - One-page summary of strategies to advance the scientific and technical merit of the project through expanded inclusivity.
  - Should provide a holistic and integrated view of how enhancing diverse perspectives is viewed and supported throughout the application.
  - Will be evaluated according to multiple review criteria (Significance, Investigator(s), Innovation, Approach, and Environment), and can incorporate elements with relevance to any of these criteria
- For further guidance, FAQs, key elements, and examples, see:

https://braininitiative.nih.gov/about/plan-enhancing-diverse-perspectives-pedp

- NIH will withdraw applications lacking a PEDP attachment without review

Section II: Award Information

- Cooperative Agreement: A support mechanism used when there will be substantial Federal scientific or programmatic involvement.
- Application Types Allowed: New, Renewal

- NIH is restricting renewal applications to UH3 awards made under the previous FOA (RFA-OD-16-004). Subrecipients of UH3 awards made under the previous FOA (RFA-OD-16-004) may submit new applications.

- Applicant PIs may not submit both an application to this ECHO Cohort Study Site FOA (RFA-OD-22-018) and an application to an ECHO Core or Center FOA (RFA-OD-22-016, RFA-OD-22-020, RFA-OD-22-021, and RFA-OD-22-022).

Section II: Award Information

- NIH intends to fund an estimate of 50 Cohort Study Site awards corresponding to a total of up to $117,000,000 for fiscal year 2023 across RFA-OD-22-017, RFA-OD-22-018, and RFA-OD-22-019 Future year amounts will depend on annual appropriations.

- Application budgets are not limited but need to reflect the actual needs of the proposed project.

- The project period is 7 years; the proposed project is 2 years for the first phase (UG3) and 5 years for the second phase (UH3).

Section III: Eligibility Information

- Eligible Organizations:
  - Higher Education Institutions
  - Nonprofits Other Than Institutions of Higher Education
  - For-Profit Organizations
  - Local Governments
  - Federal Governments
- Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply.
- Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.
- Foreign components, as defined in the NIH Grants Policy Statement, **are** allowed.
- Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

Letter of Intent

- Letter of Intent Due Date: October 21, 2022
- Information to include:
  - Descriptive title of proposed activity
  - Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
  - Names of other key personnel
  - Participating institution(s)
  - Number and title of this funding opportunity
- Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.
- Send the letter of intent to:
  - S. Sonia Arteaga, PhD
  - Email: Sonia.Arteaga@nih.gov

Plans for Enhancing Diversity

- Include in an "Other Attachment" a "Plan for Enhancing Diverse Perspectives"
  - One-page summary of strategies to advance the scientific and technical merit of the project through expanded inclusivity.
  - Should provide a holistic and integrated view of how enhancing diverse perspectives is viewed and supported throughout the application.
  - Will be evaluated according to multiple review criteria (Significance, Investigator(s), Innovation, Approach, and Environment), and can incorporate elements with relevance to any of these criteria
- For further guidance, FAQs, key elements, and examples, see:

https://braininitiative.nih.gov/about/plan-enhancing-diverse-perspectives-pedp

- NIH will withdraw applications lacking a PEDP attachment without review

Section IV: Budget

Category 1 – yearly consistent budget

- no more than $375,000 in direct cost per year to support: academic activities, including analysis proposal and manuscript development, ECHO committee work, mentoring, and scientific leadership

- PD(s)/PI(s) must have a minimum of 2.4 person months (20%) per year

- Support for travel to Bethesda MD 2x a year

Section IV: Budget

Category 2 – proportional to number of study participants in proposed plan

- Pregnancy - $1500 per visits, at least two visits during pregnancy including the 1st visit before 20 weeks of completed gestation
  - Preconception (interval between first ECHO pregnancy and subsequent ECHO pregnancy) – direct costs of up to $750 per visit for up to three visits
- Perinatal – direct costs of up to $1,000 for one visit
- Infants – direct costs of up to $1,500 per visit for a total of two visits
- For children 12 months or older, direct costs of up to $750 per visit for one visit per year.

Section IV: Budget

- **Start-up Costs –** up to $100,000

- Applicants may include allowable costs associated with PEDP implementation (as outlined in the Grants Policy Statement section 7: https://grants.nih.gov/grants/policy/nihgps/html5/section_7/7.1_general.htm).

Section IV: Research Plan (30 page limit)
Study Aims

- Aim 1 - incorporate research question(s) that leverage ECHO Cohort Protocol core data elements
- Aim 2 - incorporate question(s) that leverage proposed specialized exposure and/or specialized outcome areas
- Aim 3 - relate to how the ECHO Cohort Study Site will maximize retention of existing participants and ensure adequate recruitment of new pregnant/preconception participants, with emphasis on diversity, and implement the ECHO Cohort Protocol with high fidelity
- Aim 4 - an exploratory aim, incorporate research questions related to preconception exposures and one or more ECHO outcomes

Section IV: Research Plan (30 page limit)
UG3

- UG3 – describe plans for:
  - Using the ECHO Cohort Consortium's central data capture system
  - Using the ECHO Cohort consortium's sIRB
  - Implementing the ECHO Cohort Protocol
  - Publishing ECHO Cohort publications
  - Addressing NIH and ECHO data sharing and use policies
  - Implementing a Diversity, Equity, Inclusion, and Accessibility perspective—consistent with the PEDP
  - Leading and participating in ECHO committees and working groups

Section IV: Research Plan (30 page limit)
UG3 (continued)

- UG3 – describe plans for:
  - Reconsenting participants
  - Estimating sample size of existing ECHO participants
  - Implementing a retention plan

Section IV: Research Plan (30 page limit)
UG3 (continued)

- UG3 – describe plans for:
  - Recruiting pregnant participants beginning before 20 weeks of completed gestation
  - Enrolling the resulting offspring from pregnant participants for follow up in the ECHO Cohort
  - Following up these child participants, including ability to achieve high retention rates.
  - Recruiting the conceiving partner if available.

Section IV: Research Plan (30 page limit)
UG3 (continued)

- UG3 – describe plans for:
  - Determining moderate to high likelihood of a subsequent pregnancy from recruited pregnant ECHO Cohort participants
  - Developing the preconception phase of the ECHO Cohort Protocol within the first year of the funding period
  - Enrolling and following preconception participants for up to three study visits
  - Experience and expertise of staff with recruiting biological parents prior to pregnancy into research studies
  - Implementing the preconception phase of the ECHO Cohort Protocol

Section IV: Research Plan (30 page limit)
UH3

Applicants should describe how they will continue and intensify activities from the UG3 phase, including

- Retaining participants with special emphasis of diverse populations
- Recruiting new pregnant participants
- Recruiting participants at moderate to high likelihood of a subsequent pregnancy into the preconception pilot
- Enrolling children into the ECHO Cohort Protocol
- Recruiting conceiving partner if available
- Completing collection of high-quality data and biospecimens on all participants
- Publishing ECHO Cohort manuscripts
- Leading and participating in ECHO committees and working groups

Section IV: Research Plan (30 page limit)
Progress under previous award

- Enrolled and retained participants into the ECHO Cohort
- Collected data and biospecimens.
- Led and participated in ECHO committees and working groups.
- Published ECHO Cohort science.
- Contribution toward collaborative science.

Section V. Application Review Information

- Applications will be evaluated for scientific and technical merit by an appropriate Scientific Review Group convened by Center for Scientific Review including the general and 'Specific to this FOA' review criteria described in the FOA.

- NIH will consider the following in making funding decisions:
  - Scientific and technical merit of the proposed project as determined by scientific peer review.
  - Availability of funds.
  - Relevance of the proposed project to program priorities, including the PEDP.

Section VI: Award Administration Information

Pay attention to Cooperative Agreement Terms and Conditions described in Section VI:

- PD(‘s)/PI(‘s) responsibilities
- NIH staff programmatic involvement
- Areas of joint responsibility

Key Dates

- Letter of Intent Due Date: October 21, 2022
- Earliest Submission Date: October 21, 2022
- Application Due Date: November 21, 2022
- Scientific Merit Review: February 2023
- Advisory Council Review: May 2023
- Earliest Estimated Award Date: August 1, 2023
- Earliest Estimated Start Date: September 1, 2023

Questions

- Questions can be sent to:
  - Sonia.Arteaga@nih.gov
  - NIHKidsandEnvironment@od.nih.gov
  - Put RFA number in the subject line

- NIH will answer submitted questions in the FAQs on the NIH ECHO website: NIH ECHO Funding Opportunity Announcements

ECHO

Environmental influences on Child Health Outcomes

A program supported by the NIH

in the NIH Office of the Director