Pre-Application Webinar for ECHO Coordinating Center (U2C) RFA-OD-22-021

Scientific/Research Contact: Susan A. Laessig, M.S. Ph.D., DABT Email: susan.laessig@nih.gov NIHKidsandEnvironment@nih.gov





Agenda

- ECHO Overview
- ECHO Coordinating Center (U2C) (Clinical Trial Not Allowed) <u>RFA-OD-22-021</u>
 - 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





ECHO Overview – please view the ECHO Overview webinar



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: <u>Draft ECHO Cohort Data and Biospecimen Collection Protocol</u>)
- Centralized data capture, e.g., REDCap Central
- No Cohort Study Site-specific analyses or science
- Commitment to Diversity, Equity, Inclusion, and Accessibility



Essential Information

- It is essential that applicants for ECHO Funding Opportunity Announcements (FOAs) 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.
- All FOAs and other relevant information/resources are available on the <u>NIH</u> <u>ECHO website</u>.





FOA Presentations

See Presentations for each ECHO FOA on the <u>NIH ECHO website</u>:

1. ECHO Overview

- 2. Pregnancy Cohort Study Sites (UG3/UH3) <u>RFA-OD-22-017</u>
- 3. Limited Competition: Pregnancy and Pediatric Cohort Study Sites (UG3/UH3) RFA-OD-22-018
- 4. Limited Competition: Cohort Study Sites for Regiatric Follow Up (UG3/UH3) RFA-OD-22-019
- 5. Laboratory Core (U24) <u>RFA-OD-22-016</u>
- 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 Coordinating Center (U2C) (Clinical Trial Not Allowed) RFA-OD-22-021



U2C Mechanism

Cooperative Agreement: A support mechanism used when there will be substantial Federal scientific or programmatic involvement.

U2C = Resource-Related Research Multi-Component Projects and Centers Cooperative Agreements

- To support multi-component research resource projects and centers that will enhance the capability of resources to serve biomedical research.
- Substantial federal programmatic staff involvement is intended to assist investigators during performance of the research activities, as defined in the terms and conditions of the award.



Section I: Funding Opportunity Description

The ECHO Coordinating Center will provide comprehensive operational leadership and an organizational infrastructure to manage and coordinate all ECHO Cohort activities.

The Coordinating Center's main roles are to:

- 1) Provide oversight and effective project management for all aspects of the ECHO Cohort consortium
- 2) Support multiple ECHO Cohort committees and serve as the centralized ECHO Cohort communications center
- 3) Administer the Opportunities and Innovation Fund

This FOA will not support management of the ECHO Biorepository, which is a function of the ECHO Laboratory Core (see RFA-OD-22-016)



Section I: Funding Opportunity Description 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 intends to fund one award, corresponding to a total of up to \$14,000,000 total costs for fiscal year 2023. 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.



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 <u>NIH Grants Policy Statement</u>, are allowed.
- Applicant organizations may submit more than one application, provided that each application is scientifically distinct.



Section IV: Application and Submission Information

- It is critical that applicants follow the Multi-Project (M) Instructions in the <u>SF424</u> (<u>R&R</u>) <u>Application Guide</u>, except where instructed in this funding opportunity announcement to do otherwise.
- Applicants for the Coordinating Center may also apply to another ECHO Cohort Core or Center FOA. Each application to a FOA should be self-contained and not overlap in scope or budget. Applicants to an ECHO Core or Center cannot apply to an ECHO Cohort Study Site FOA.
- In lieu of the standard Research Strategy sub-sections (Significance, Innovation, and Approach), applicants must address specific sub-sections that are described in the RFA; this is applicable to all the Coordinating Center components.
- However, applications must highlight aspects of the proposed activities that speak to the significance and innovation of the approach.



Section IV: Application and Submission Information 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 Program Director(s)/Principal Investigator(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 NIH staff to estimate the potential review workload and plan the review.
- Send the letter of intent to:
 - Susan A. Laessig, Ph.D
 - Email: susan.laessig@nih.gov



Section IV: Application and Submission Information Multi-Component Structure of ECHO Coordinating Center (U2C)

Available Component Types	Research Strategy / Program Plan Page Limits
Overall Component	6
Coordinating Center Administrative Core	6
Oversight and Project Management	12
Committee Support and Communications Component	12
Opportunities and Innovation Fund Component	12
National Institutes of Health	

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

Section IV: Application and Submission Information Overall Component

- When preparing your application, use Component Type 'Overall'.
- Budget: May include allowable costs for PEDP implementation
- Specific Aims: Address how the ECHO Coordinating Center will provide overall management and coordination of the ECHO Cohort consortium to achieve its overall goal
- Research Strategy: Describe proposed plans for organization and staffing of the Coordinating Center
 - Include the information listed in the Overall Component- Research Strategy under Section IV: Application and Submission Information
 - If applying as a renewal, the applicant should document their progress during the first seven years in the ECHO Cohort consortium (FY2016-2022)



Section IV: Application and Submission Information 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: Application and Submission Information Administrative Core

- When preparing your application, use Component Type 'Coordinating Center Administrative Core'.
- **Budget:** Include support for key staff to attend 2 consortium meetings per year in the Bethesda, MD area
- Specific Aims: Briefly describe the overall Specific Aims of the proposed Core
- **Research Strategy**: Describe the internal administrative structure of the proposed ECHO Coordinating Center.
 - Include the information listed in the Administrative Core- Research Strategy under Section IV: Application and Submission Information



Section IV: Application and Submission Information Oversight and Project Management Component

- When preparing your application, use Component Type 'Oversight and Project Management Component.'
- **Budget**: Consider budgeting for support of a single, standardized Protocol and comprehensive Project Management.
- Specific Aims: Briefly describe the overal Specific Aims of the proposed Oversight and Project Management Component.
- **Research Strategy**: Describe the approach for innovatively addressing the scope of activities for overall oversight and project management. Include proposed plans for supporting development of the ECHO Cohort Protocol and monitoring of data and biospecimen collection at all study sites.
 - Include the information listed in the Oversight and Project Management Component- Research Strategy under Section IV: Application and Submission Information



Section IV: Application and Submission Information Committee Support and Communications Component

- When preparing your application, use Component Type 'Committee Support and Communications Component.'
- Budget: Budget forms appropriate for the specific component
- Specific Aims: Briefly describe the overall Specific Aims of the proposed Committee Support and Communications Component.
- **Research Strategy:** Describe proposed plans for support of the functions of ECHO Committees and plans to support communications among all ECHO Cohort Study Sites, Cores, and Centers, and NIH, between ECHO and the broader scientific community, and between ECHO and the public.
 - Include the information listed in the Oversight and Project Management Component- Research Strategy under Section IV: Application and Submission Information



Section IV: Application and Submission Information Opportunities and Innovation Fund Component

- When preparing your application, use Component Type 'Opportunities and Innovation Fund Component.'
- **Budget**: Costs associated with administration of the OIF. Estimated award of \$2,400,000 in direct costs per year for up to 12 new studies of 2-year duration per study in years 2-6.
- **Specific Aims**: Briefly describe the overall Specific Aims of the proposed Opportunities and Innovation Fund Component.
- **Research Strategy**: Describe proposed plans for the management of the ECHO Opportunities and Innovation Fund, a fund to promote the development of early career scientists, support innovative projects that introduce new research, tools, and technologies in the ECHO Cohort consortium, and promote collaborations that support the goals of the ECHO Cohort consortium.
 - Include the information listed in the Oversight and Project Management Component- Research Strategy under Section IV: Application and Submission Information

Section V. Application Review Information

 Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s) 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

- Please send questions to:
 - -<u>Susan.Laessig@nih.gov</u>
 - -<u>NIHKidsandEnvironment@od.nih.gov</u>
 - -Put RFA number in the subject line

• NIH will answer submitted questions in the FAQs on the NIH ECHO website: https://www.nih.gov/echo/funding





ECHO

Environmental influences on Child Health Outcomes

A program supported by the NIH in the NIH Office of the Director