Pre-Application Webinar for ECHO Data Analysis Center (U24) RFA-OD-22-022



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Agenda

- ECHO Overview
- ECHO Data Analysis Center (U24) (Clinical Trial Not Allowed) RFA-OD-22-022
 - 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



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 Fediatric 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



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 NIH ECHO website.

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



U24 Mechanism

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

U24 = Resource-Related Research Projects--Cooperative Agreements

- To support research projects contributing to improvement of 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 Data Analysis Center's main roles are to:

- lead, standardize, and integrate ECHO Cohort Protocol data capture, management, and storage through a central data system;
- 2) provide analytic support and expertise necessary to enhance ECHO Cohort scientific productivity; and
- enrich research infrastructure and data science to facilitate broader sharing of ECHO Cohort data and resources with the scientific community.

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 \$14,500,000 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

- 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.

Section IV: Application and Submission Information

- It is critical that applicants follow the Research (R) Instructions in the <u>SF424 (R&R) Application Guide</u>, except where instructed in this funding opportunity announcement to do otherwise.
- Applicants for Data Analysis 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.

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 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:

Christina H. Park, PhD MHS

Email: Parkchris@mail.nih.gov





Section IV: Application and Submission Information Research Plan (limited to 30 pages)

- **Specific Aims**: Describe aims of the proposed Center in achieving the objectives of a data analysis center that support the ECHO Cohort consortium
- **Research Strategy**: Describe the organization of the proposed ECHO Data Analysis Center and an approach to perform the required tasks including:
 - An overall organizational chart
 - A description of overall plans for the governance of the Center
 - A description of the relevant expertise, experience, and capabilities of the applicant organization
 - A well delineated plan for performing tasks under each of the three major responsibility areas of the Data Analysis Center stated under the Objective, <u>Background</u>, and <u>Scope in Section I</u>
 - Plans to provide data for real time tracking of participant enrollment, data and biospecimen collection
 - Plans to develop, maintain, and update data sharing and use agreements between
 Tribal Nations and ECHO to ensure data practices appropriate to Tribal sovereignty
 - Plans for how the proposed Data Analysis Center would follow the <u>NIH</u> and <u>ECHO data sharing and use policies</u>



Section IV: Application and Submission Information Research Plan (limited to 30 pages)

- Research Strategy: Cont'd
 - If applying as a renewal, the applicant should document their progress during the first seven years in the ECHO Cohort consortium (FY2016-2022)
 - Plans for promoting a diverse workforce. The plan should describe in sufficient detail how the Data Analysis Center activities will strengthen its workforce diversity and enhance the diversity of the scientific workforce in children's health (NOT-OD-20-031).
 - If the applicant organization also applies to the ECHO Coordinating Center FOA (<u>RFA-OD-22-021</u>), Measurement Core FOA (<u>RFA-OD-22-020</u>), or Laboratory Core FOA (<u>RFA-OD-22-016</u>), include a discussion of specific advantages offered to ECHO if the applicant organization was to support both the Data Analysis Center in addition to the other ECHO Cohort Center or Core(s).

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

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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:
 - Parkchris@mail.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