Frequently Asked Questions

Data Coordinating and Operations Center for the ECHO IDeA States Pediatric Clinical Trials Network - 3 (U24 Clinical Trial Required—Infrastructure)

RFA-OD-24-009

Eligibility

1. The RFA says that "…. ECHO ISPCTN Clinical Site and DCOC applicants may propose collaborations." With whom can we collaborate?

Applicants may consider collaborating with other components or investigators within their own state or in other IDeA or non-IDeA states.

2. Are there any budgetary restrictions when a collaboration is proposed?

Yes. The NIH will support a minimum of 75% of total costs to institutions within IDeA States.

3. Can we have more than one collaborating partner?

Yes. Applicants may propose more than one collaborating partner.

4. Can we propose one contact Principal Investigator and more than one Multiple Principal Investigator?

Yes. Applicants may propose one contact PI and more than one MPI.

NEW: Updated April 2, 2024

PLEASE NOTE: **The NIH has released a Notice of Change (NOT) for this funding opportunity.**
This notice changes **the application receipt date** and the **budget** for RFA-OD-24-009.

Please see NOT-OD-24-094 for changes to the RFA.

- Application receipt Date changed from April 15, 2024, to June 14, 2024
- Award budget text changed to reflect changes to the DCOC direct costs for Core Infrastructure Costs in addition to capitation costs for Protocol-Specific Costs distributed to clinical sites for trial related activities.
    - 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.
    - 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

The NIH has issued the following NEW FAQ related to this Notice of Change.

5. Please clarify what are the costs that must be in the "core" DCOC costs, and what are permissible in the capitation dollars.

Besides those noted in the RFA, the NIH considers the following DCOC core costs:

- IRB support
- Safety monitoring
- Electronic trial infrastructure (electronic data capture, e-Regulatory systems/Trial Master File; etc.)
- Non-DCOC personnel costs: Leadership Committee, Steering Committee chair, DSMB / PRC stipends

Permissible in capitation:

- Study-specific monitoring
- Study-specific supplies (some examples: recruitment materials; intervention materials such as the filters, monitors, drugs and placebos; study-specific laboratory supplies)
- Study specific community advisory group costs
- Study-specific medical monitoring costs beyond the standard safety expectations.
- IND/IDE submission costs
- Study-specific trial expertise: protocol chair, consultants (e.g., neuroradiologists to interpret MRIs), and other experts with justification.