

Frequently Asked Questions

Clinical Sites for the Environmental influences on Child Health Outcomes (ECHO) IDeA States Pediatric Clinical Trials Network - 3 (UG1 Clinical Trial Required) RFA-OD-24-008

Eligibility

**1. The RFA says that “...ECHO ISPCTN Clinical Site and DCOC applicants may propose collaborations.”
With whom may 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. May we have more than one collaborating partner?

Yes. Applicants may propose more than one collaborating partner.

Principal Investigator/Multiple Principal Investigator Qualification

4. The RFA requires the inclusion of at least one board-certified pediatrician. Does a pediatrician who is board-certified from a non-IDeA State qualify to serve as a contact Program Director/Principal Investigator or a Multiple Principal Investigator?

Yes. For this RFA, the NIH requires that the contact PD/PI or the MPI (or both) be a board-certified pediatrician(s), irrespective of the state from which the individual obtained the certification.

Research Coordinator Qualifications

5. If we cannot find a research nurse coordinator for a full-time position, may we propose to name more than one research coordinator, making sure at least one of them is a research nurse coordinator?

Yes. For this RFA, the budget may support the salary and fringe benefits of one research nurse coordinator to focus solely on ECHO ISPCTN projects at a minimum of 12 person months per year for each of the five years of the award. As an alternative to supporting a single research nurse coordinator at 12 person months per year, the applicant may propose to support one research nurse coordinator at a minimum of 6 person months per year; plus an experienced, non-nurse research coordinator at a minimum of 6 months per year; for each of the five award years. Applicants may also include in the budget request additional part-time research coordinators as needed to develop or implement ECHO ISPCTN trials.

Early Stage Investigators

6. Who qualifies as an Early Stage Investigator (ESI)?

The [NIH Early Stage Investigator Policy](#) defines the term ‘Early Stage Investigator.’

7. How many Early Stage Investigators (ESIs) can we propose?

Applications must propose one or two ESIs (as defined by the [NIH Early Stage Investigator Policy](#)) as key persons for at least the first award year. If at any point during the award cycle, an ESI or other individual included in the budget are no longer contributing efforts toward the key ECHO ISPCTN goals of developing, conducting, disseminating, or overseeing network trials commensurate with their level of funding, the PD/PI(s) must adjust the award budget to reflect those individuals' actual efforts and request pre-approval for changes to the budget from the ECHO ISPCTN program official.

8. May we include an individual as an Early Stage Investigator who is not yet at our institution, but will later join our institution?

Yes. Please be sure to include the individual's NIH Biosketch along with other details you would include for any ESI. Please clearly state when the individual is anticipated to join your institution.

9. May we have investigators with an interest in pediatric clinical trials from other disciplines?

Yes. You can propose any qualified individual(s) as co-investigator(s) if the individual's expertise matches the role in which they will be serving in your research program.

10. Are we required to propose a senior professional development leader?

No. Applicants do not have to name or budget for a Senior Faculty Development Leader. PD/PI(s) may designate an additional senior faculty member to provide support to early stage investigators if the individual has expertise in both clinical trials research and in mentorship.

11. May we add salary support for a senior mentor from a non-IDeA state to our budget?

Yes. To enhance research expertise and potential to build capacity to include needed expertise, applicants may consider collaborating with other components or investigators within their own state or in other IDeA or non-IDeA states. The NIH will support a minimum of 75% of total costs to institutions within IDeA states.

Clinical Trial Proposal

12. May we propose a trial previously submitted to ECHO ISPCTN or another NIH Institute or Center that was not funded?

Renewal applicants can submit brief concept proposals that were previously submitted for consideration to the ECHO ISPCTN during a previous cycle that were not funded. Likewise, applicants are allowed to submit clinical trial proposals previously submitted to other NIH entities that were not funded.

Budget

13. May we split Early Stage Investigator budget (1.8 FTE) among more than 2 persons per year? What if one ESI leaves after 2 years, can we hire someone new?

Please note that the RFA-OD-24-008 reads, "Salary and fringe benefits for the time and effort for one or two early stage investigators...Should such individuals leave earlier, the PI/MPI can plan on replacing with suitably qualified ESI(s) after discussing with their eligibility with the NIH program official."

14. How are we allowed to split 1.8 FTE for Project Director/Principal Investigator (PI/PD) if we are proposing Multiple Principal Investigators (MPIs)?

A minimum of 1.8 person months overall for PD/PI(s) is required in each of the five award years. This can be split between two individuals (one designated the contact PI and the other the MPI). Divide time and effort between the Contact PI and MPI, so that the total is no less than 1.8 person months per year for each of the five years. The proportional breakdown could depend upon division of tasks among the Contact PI and MPI. Describe this in the budget justification section of the application. For more

information, please visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the [SF424 \(R&R\) Application Guide](#).

15. May we propose one contact Principal Investigator and more than one Multiple Principal Investigators?

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

16. For an individual to be named Early Stage Investigator, should the person meet the criteria at the start of the grant?

Information from the Education section of a PI's eRA Commons profile included in the application is used to determine ESI eligibility based on completion date of their terminal research degree or the completion date of post-graduate clinical training. The system notes ESI eligibility in the PI profile.