REQUEST FOR APPLICATION FOR PILOT STUDIES FROM JUNIOR INVESTIGATORS IN THE IDEA STATES PEDIATRIC CLINICAL TRIALS NETWORK (ISPCTN)

Objective

The purpose of this funding opportunity is to support pilot studies whose results are critical to the design and/or implementation of a full-scale multicenter clinical trial. Thus, the proposed pilot study should clearly address a scientific gap that is required for design or implementation of a larger clinical trial. During the evaluation of applications submitted to this RFA, the Steering Committee will review not only the pilot study/proposal itself, but will also consider the potential public health impact and overall design of the full-scale multicenter clinical trial that would follow the pilot project. Thus, the application should provide a concise description of the larger, full-scale clinical trial, and an explanation of how the results of the pilot study proposed by the junior faculty member will be used to facilitate the development of the full-scale clinical trial. Both the pilot study and planned full-scale trial should address topics within the mission and scope of the IDeA States Pediatric Clinical Trials Network (ISPCTN).

Examples of potential pilot studies that would quality for this program include (and are not limited to) the following:

- Perform studies to determine the appropriate study population, intervention, or outcome.
- Collect information necessary to estimate available populations, attrition rate, or response rate.
- Refine the intervention.
- Test the feasibility of measuring an outcome or implementing an intervention in the field.
- Determine whether adequate adherence to an intervention is achievable.
- Standardize and validate survey instruments.
- Standardize and test effectiveness of training tools.
- Adapt and test a survey instrument or protocol for a population that differs culturally from the population for which the instrument was originally designed.
- Pilot remote acquisition of measurements (e.g. height/weight, spirometry, actigraphy) and participant-generated information (e.g. diary cards, questionnaires)

- Pilot remote acquisition of biological samples from participants that can be submitted to a central lab (e.g. saliva samples, nasal swabs).
- Explore community-informed approaches to understanding and addressing the health care needs of hard-to-reach populations in an interventional clinical trial.

The following table shows the timeframe for each step in the process of review; submission of 3-page initial concept proposals by junior investigators, development of selected expanded concept proposals, development of selected full proposals, and implementation of pilot studies.

December 2020	DCOC releases the RFA to ISPCTN investigators
Jan – Feb 2021	DCOC hosts workshop on pilot studies for junior investigators
April 1, 2021	Jr. investigators submit initial concept proposals to DCOC
April 1-15, 2021	Steering Committee reviews submitted initial concept proposals and selects those for further development into expanded concept proposals
April 16, 2021	DCOC informs jr. investigators on the status of their initial concept proposal (selected or non-selected for further development)
September 1, 2021	Jr. investigators submit expanded concept proposals to DCOC based on the initial concept proposals selected for further development on April 16, 2021
September 1-15, 2021	Steering Committee reviews submitted expanded concept proposals and selects those for further development into full protocols for pilot studies
September 16, 2021	DCOC informs jr. investigators on the status of their expanded concept proposal (selected or non-selected for further development)
For expanded concept proposals selected for development into pilot studies Financial information below.	
October 1, 2021 – August 31, 2022 (Period A)	Jr. investigators develop protocol, and obtain approvals from the Protocol Review Committee (PRC), and Data Safety and Monitoring Board (DSMB), if proposed study involves human subjects research*
September 1 2022 – August 31, 2024 (Period B)	Jr. investigators implement the protocol (enrollment and follow-up of participants), complete closeout functions, and generate manuscript(s) for publication

* As a reminder, for programmatic reasons, the NIH ECHO Program Office may choose not to accept the recommendations of the Steering Committee, PRC or DSMB.

Funding Information

Period A (October 1, 2021 – August 31, 2022): During this period, applicants may request up to a total of 30% FTE salary support for Principal Investigators (PIs) and no less than 15% FTE for a single PI. A maximum of 2 Multiple PIs (MPIs) from different awardee institutions is allowed per application. The only allowed salary support during this period is for PI/MPIs.

Period B (September 1, 2022 - August 31, 2024): Up to $300,000 direct costs for the total duration of up to 2 years (NOT per year) in accordance with the following requirements:

- Up to 30% FTE per year and no less than 15% FTE per year salary support for PI(s). A maximum of 2 MPIs from different awardee institutions is permitted per application.

- Salary support may not be requested for faculty member(s) who serve in the senior faculty development role in an ISPCTN site award.
- Funds may not be requested for services that will be provided by the DCOC which include study coordination across multiple sites, interaction with the central IRB (if required), site monitoring, data management, statistical support, regulatory reporting functions, and database upload to public data repositories in accordance with the NIH requirements for data sharing.
- Travel funds to attend professional scientific meetings are allowed only for the purpose of dissemination of study results from the study funded under this award.

Applicant Eligibility

To be eligible, an investigator must meet one of the following criteria and be at an ISPCTN institution:

- Meets the NIH definition of an early stage investigator; OR
- Is designated as a junior investigator on an ISPCTN site grant.

Note: NIH defines an Early Stage Investigator (ESI) is a Principal Investigator (PI) who has completed his/her terminal research degree or end of post-graduate clinical training, whichever date is later, within the past 10 years and who has not previously competed successfully as PD/PI for a substantial NIH independent research award.

(If a site wishes to submit an application from an investigator that does not meet the criteria described above, the awardee site principal investigator should discuss this matter with the ECHO ISPCTN Project Officer, Dr. Carol Blaisdell).

Each ISPCTN awardee institution is allowed to submit up to one response to this RFA. Junior investigators from ISPCTN institutions are encouraged to collaborate on proposals. At the initial concept stage, junior investigators may submit single-PI proposals, or two junior investigators from different awardee institutions may submit a proposal as multiple PIs. At the expanded concept stage, single-PI junior investigators or 2 PIs (from different awardee institutions) may submit proposals with co-investigators from other awardee institutions.

Application format

NOTE: APPLICATIONS THAT DO NOT ADHERE TO THE PAGE LIMITATIONS AND FORMAT DESCRIBED BELOW WILL NOT BE REVIEWED.

Initial concept proposal

Page Limit: 3 pages (see format below)

Applicants should prepare their initial concept proposals using the attached initial concept template plus a summary of the planned full-scale multicenter clinical trial that follows the attached template. The initial concept proposal should

- include a description (up to 1 page) of the proposed full-scale multicenter clinical trial that the pilot study will inform. The template for this portion of the initial concept proposal is provided below. The description should include
    - the background, gaps in the literature, and motivation for the larger trial,
    - primary research question for the larger trial,

    - clinical or public health impact, and
    - major design features.
- Include a description (up to 2 pages) of the pilot study using the attached initial concept template. The initial concept should also include
    - the research gap and motivation for the pilot study, and
    - how the information from the pilot study will be used in the formulation of the larger trial.

The Steering Committee will evaluate the initial concept proposals using the review criteria for initial protocol concepts. *(Templates for the initial concept proposal descriptions of the full-scale trial and pilot study are below).*

Expanded Concept Proposal

Applicants whose initial protocol concepts are selected in April 2021 for further development into an expanded protocol concept should prepare their expanded protocol concepts using the attached expanded protocol concept template plus a summary of the planned full-scale multicenter clinical trial that follows the attached protocol summary template. Expanded protocol concept proposals should

- include a description the full-scale multicenter clinical trial that the pilot study is intended to inform, and
- describe the need for the pilot study and how information derived from the pilot study will inform the full-scale trial.

The Steering Committee will evaluate the expanded concept proposals using the review criteria for expanded protocol concepts.

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ECHO ISPCTN Initial Concept Proposal – Description of Full-Scale Trial

(Maximum: 1 pages: Any content beyond 1 pages will not be reviewed.)

BACKGROUND, GAPS IN THE LITERATURE, MOTIVATION FOR FULL-SCALE TRIAL (bullet points preferred)

MAIN RESEARCH QUESTION FOR FULL-SCALE TRIAL (include population, setting, number of participants, any relevant demographic characteristics, design, intervention(s) and contract, primary outcome, time frame)

- Example: Among 5-10 year old boys and girls who reside in rural areas, will those randomized to receive a comprehensive informational packet on the benefits of the seasonal influenza vaccine be more likely to get an influenza vaccine than those randomized to receive a one-page fact sheet about the influenza vaccine over a one-year period.

CLINICAL OR PUBLIC HEALTH IMPACT OF FULL-SCALE TRIAL: What clinical practice, public health program, or policy that affects child health would the full-scale clinical trial findings inform? (include relevance to rural and underserved populations, and why this study fits into the ECHO ISPCTN's mission.)

STUDY DESIGN/METHODOLOGY OF FULL-SCALE TRIAL

- Study population (e.g. age, health condition, setting)
- Random allocation (Y/N)
- Intervention(s)
- Projected sample size
- Primary outcome/endpoint
- Feasibility concerns
- Special study needs (e.g. equipment, specialized personnel)

ECHO ISPCTN Initial Concept Proposal – Description of Pilot Study

(Maximum: 2 pages: Any content beyond 2 pages will not be reviewed.)

DATE OF SUBMISSION to DCOC:

CONCEPT PROPOSAL LEADER(S) and awardee institutions:

STUDY TITLE:

BACKGROUND: (*The background information should be limited to the proposed study and should be presented succinctly.)*

PUBLIC HEALTH IMPACT: (*Relevance to rural and underserved populations; significance of study; explain why this is a good study for ECHO ISPCTN.*)

OBJECTIVES/Specific Aims: *(List primary and secondary objectives.)*

STUDY DESIGN/Methodology: *(Succinctly describe the general study design.)*

STUDY POPULATION: *(Clearly identify the population to be studied and how it will include the underserved and rural populations.)*

INTERVENTION PLAN: (*Describe intervention (drug, behavioral, other, etc.) in sufficient detail for a reviewer to understand what is proposed)*

OUTCOME MEASURES: (*State the primary and secondary outcome measures for the study)*

SPECIFIC STUDY NEEDS: (*specific or specialized facilities, equipment, personnel, laboratory capabilities, etc. such as Psychologist, PFT's, NICU, metabolic kitchen, etc.*)

REFERENCES (not included in 2 page limit):