I've attached the slides from our update today, the RFA, and the Expanded Concept Proposal form and review criteria. You can listen to our recording here:
https://app.box.com/s/05kxgblcojusx5tjhowe5xx1xrqsiixe

One other question that came in after the meeting re: letters of support is also detailed below.

I've also scheduled FAQ check-ins monthly between now and the due date.

July 21 11 am Central:

Join Zoom Meeting
https://us02web.zoom.us/j/81185063695?pwd=UzJIK0cwa3M4USt4Uk82eGNJK3AvQT09

Meeting ID: 811 8506 3695
Passcode: 226087
One tap mobile
+19292056099,,81185063695#,,,,*226087# US (New York)

August 18 11 am Central:

Join Zoom Meeting
https://us02web.zoom.us/j/86403785927?pwd=aTkxM1FjQ2lLeFg5ZGhpZEdpQ3Fvdz09

Meeting ID: 864 0378 5927
Passcode: 986563
One tap mobile
+13126266799,,86403785927#,,,,*986563# US (Chicago)
+19292056099,,86403785927#,,,,*986563# US (New York)

If you have any questions, email jsnowden@uams.edu or AskDCOC@uams.edu with Junior Pilot in the subject line. I'll update the FAQs in the weekly updates as we go along. Good luck!

Q: One followup – I know you mentioned the **previous LOS would be sufficient**, however I did not submit LOS for the initial concept. I would like to demonstrate for the expanded concept that we have key collaborative partnerships (for example, Kansas AAP, KAFP supports and sees benefit for rural providers/families) to support success – since this was a concern of reviewers. Would it be appropriate to submit LOS at this stage since I did not realize we were able to do this in the previous proposal?

A: I would mention the collaborations that are key to the success of the project in the approach and then add (letter of support available at DCOC). Then just send the letter to jsnowden@uams.edu. Saying the LOS is available addresses the concern that you have support but also doesn't give you a chance to stick anything super glowing about the investigator that might sway a reviewer in a way that disadvantages proposals without a LOS.

ECHO

Environmental influences on Child Health Outcomes

A program supported by the NIH

IDeA States Pediatric Clinical Trials Network

Junior Investigator Pilots

RFA

- Must include a description of the full-scale trial it informs
- Describe need for the pilot and how it informs full scale trial

Timeline

- September 1, 2021: ECP due to DCOC
- September 1-15: Steering Committee review
- September 16: Selection
- October 1, 2021 – August 31, 2022: Jr. Investigators develop protocol; obtain DSMB and PRC approval
- September 1 – August 31, 2024: Implement study

Review Criteria

Uniqueness and Relatedness to ECHO ISPCTN (1-9)	Public health impact and Significance (1-9)	Scientific and technical merit including Approach and Protection of Human Subjects (1-9)	Overall score* (1-9)

Budget

- Development phase (October 1 – August 31, 2022
  - Up to 30% FTE salary support
- Implementation
  - Up to $300K direct costs over two year (NOT PER YEAR)
  - Must include PI salary support (minimum 15%; up to 30%)
  - Does not include DCOC costs
- Formal budget not needed at ECP phase
  - HOWEVER keep the budget limit in mind for your proposed science

DCOC services

- Study coordination
- Central IRB at UAMS
- Regulatory affairs
- Site monitoring
- Statistical support – including protocol development, monitoring of key events (efficacy and safety), stopping rules, report generation (interim, if applicable and final), and manuscript/presentation preparation
- Data management support – including case report form design, data acquisition system development and implementation, generation of analytic datasets; collection and management of remote data collection (e.g. from devices)
- Contractual arrangements with vendors including and not limited to acquisition and management of study product; use of central laboratories; acquisition of equipment
- Reporting to regulatory/regulatory authorities

FAQ

- Letters of support? NO
- Biosketches? NO
- Budget proposals? NO – budget capped per RFA, no formal budget needed now
- Include both the pilot study & trial it informs? YES

Thank You!

ECHO
Environmental influences
on Child Health Outcomes
A program supported by the NIH

IDeA States
Pediatric Network

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.

Contacts:

Carol Blaisdell, MD
Project Officer and Deputy Director of the ECHO Program
Email: Carol.Blaisdell@nih.gov

Alan Simon, MD
Medical Officer, ECHO ISPCTN
Email: Alan.Simon@nih.gov

Jeannette Lee, PhD
MPI, Data Coordinating and Operations Center, ISPCTN
Email: jylee@uams.edu

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.)*

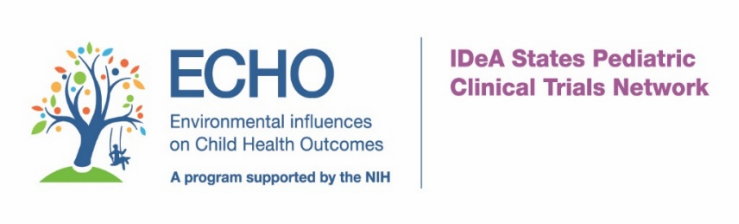
INTERVENTION PLAN: (*Describe intervention (drug, behavioral, other, etc.) in sufficient detail for a reviewer to understand what is proposed)*

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):

REVIEWER(S): _____
ECHO ISPCTN SITE/CONSTITUENCY: _____



ECHO ISPCTN Expanded Concept Proposal (ECP) Review Criteria

The purpose of this review is to provide members of the Steering Committee (SC) with input and insight of an expert in the concept's field of interest to facilitate and guide their evaluation.

Please keep the following in mind while completing this review (see pages 2-4):

- The critique should be comprehensive, diplomatic and constructive
- Reviewers may use references, if applicable, to support their comments and assertions.
- Reviewers must recuse themselves if they have a conflict of interest.
- All materials reviewed are to be kept confidential.
- The Co-Reviewers should not discuss the contents of the Expanded Concept Outline with anyone.

As a reminder here are criteria that are used when reviewing Expanded Concept Proposals:

Public Health Impact and Significance	To what extent: • Is the concept relevant to the treatment, prevention, detection of disease in infants and children? Add value to the field regarding the specific clinical entity? • Does it have the potential to change management of children in rural and medically underserved areas, and if so, how large might the impact be? • Does it address a gap in the literature/field? • Does it have the potential to inform change in clinical practice, public health program, or policy?
Relatedness to ECHO ISPCTN	To what extent does the concept: • Address a clinical area that disproportionately affects children in rural and medically underserved areas? • Target enrollment of rural or underserved pediatric participants? • Focus on an ECHO priority area: pre-, peri- or post-natal outcomes, neurodevelopment, upper or lower airway disease, pediatric obesity, or, positive child health? • Include a moderate to large number of ECHO ISPCTN sites? • Need to be a multi-center trial? • Meet the criteria such that the ECHO ISPCTN is the right venue to conduct this research? • Allow this study to be conducted within the timeframe of the grant funding period?
Scientific Merit	To what extent: • Do the authors have a specific and well-defined research question? • Are the hypotheses scientifically justified and answerable by the proposed study design? • Does the overall study design appropriately address the proposed research question? • Do the pilot/preliminary data justify the proposed study? • Do the authors justify the proposed sample size? • Are the proposed analyses appropriate? Will the study design yield unique outcomes that are not duplicated by previous or currently active clinical trials?
Feasibility	To what extent: • Are the risks to the study population justified based on the risk:benefit ratio? • Are the plans for the intervention feasible (equipment, personnel, testing methods, training, etc.)? • Can the researchers conduct the study within the timeframe of the grant funding period? • Are recruitment plans sufficient to enroll the projected sample size? • Are retention plans sufficient to minimize loss to follow-up? • Are the proposed measurements appropriate to the study question, feasible, and accurate?

REVIEWER(S): _____
ECHO ISPCTN SITE/CONSTITUENCY: _____

Expanded Concept Scoring Rubric

Impact	Score	Descriptor	Categories	
			Public Health Impact and Significance: Direction and Magnitude of Impact; Likelihood of Impact; Distribution of Impact; Strength/Quality of Evidence; Addresses an important problem	**Scientific Merit including Approach and Protection of Human Subjects:** Identification of Strengths and Weaknesses
High	1	Exceptional	High positive impact on many; impact is likely; impacts target population equally; intended impact/significance supported by many strong studies	Exceptionally strong with essentially no weaknesses
	2	Outstanding	High positive impact for some; impact is likely; impacts target population equally or as justifiably expected; intended impact/significance supported by many strong studies	Extremely strong with negligible weaknesses
	3	Excellent	Moderate impact on a medium number; impact is likely; impacts a sub-set of the targeted population; intended impact/significance supported by many strong studies	Very strong with only some minor weaknesses
Medium	4	Very Good	Moderate impact on a medium number; impact is possible; special populations impacted more than total population; intended impact/ significance supported by some good studies	Strong but with numerous minor weaknesses
	5	Good	Moderate impact on a medium number; impact is possible; impact unlikely to benefit the total population; impact/significance supported by some good studies	Strong but with at least one moderate weakness
	6	Satisfactory	Small impact on many; impact is possible; distribution of impact is unknown; intended impact/significance supported by some good studies	Some strengths but also some moderate weaknesses
Low	7	Fair	Strength and direction of impact unknown or no effect; impact is unlikely; distribution of impact is unknown; impact/significance not yet supported by studies, but generally consistent with principles of public health	Some strengths but with at least one major weakness
	8	Marginal		A few strengths and a few major weaknesses
	9	Poor		Very few strengths and numerous major weaknesses

REVIEWER(S): _____
ECHO ISPCTN SITE/CONSTITUENCY: _____

ECHO ISPCTN Expanded Concept Proposal Score Sheet

ECP Writing Group CHAIR/CO-CHAIR(S): _____

Study Title:

Which ECHO ISPCTN priority area(s) is this proposal responsive to:

- ☐ Pre-, peri-, post-natal outcomes
- ☐ Upper and lower airway disease
- ☐ Positive child health
- ☐ Neurodevelopment
- ☐ Pediatric obesity
- ☐ None

Score the scientific and technical merit and public health impact of the concept proposal using the 9-point scoring rubric and document the final scores below.

Uniqueness and Relatedness to ECHO ISPCTN (1-9)	**Public Health Impact and Significance (1-9)**	**Scientific merit including Approach and Protection of Human Subjects (1-9)**	**Overall Impact Score* (1-9)**

*Overall impact score does not have to be an average of the other 2 scores

Comments (optional):
OVERALL:

STRENGTHS:

1.

2.

3.

WEAKNESSES (Identify if these can be addressed/overcome or are they “fatal flaws”):

1.

2.

3.

REVIEWER(S): _____
ECHO ISPCTN SITE/CONSTITUENCY: _____

Any other factors that impact the value (positive or negative), exclusivity, or leverages other resources, to the study population, research team and ECHO ISPCTN:

Feasibility concerns:	☐ NO	☐ YES (identify below)
Will it change clinical practice:	☐ NO	☐ YES (identify below)
Safety/Ethical concerns:	☐ NO	☐ YES (identify below)
Any halting criteria met:	☐ NO	☐ YES (identify below)

REVIEWER(S): _____
ECHO ISPCTN SITE/CONSTITUENCY: _____

ECHO ISPCTN SITE VOTE (ONLY ONE VOTE PER SITE):

☐ APPROVE

☐ APPROVE WITH CONTIGENCIES

☐ REVISE AND RESUBMIT

☐ DO NOT APPROVE

☐ ABSTAIN

ANTICIPATE OUR ECHO ISPCTN SITE WOULD PARTICIPATE:

☐ YES

☐ NO

☐ POSSIBLY

Note: DCOC and NIH may skip this question.

If NO or POSSIBLY, please identify the reason(s):

REVIEWER(S): _____
ECHO ISPCTN SITE: _____

ECHO ISPCTN Expanded Concept Proposal (ECP)
(approximately 6-12 pages)

DATE OF SUBMISSION to SC:

ECP CHAIR/CO-CHAIR(S):
ECHO ISPCTN CHAIR(S):
NON-ECHO ISPCTN CO-CHAIR (if applicable):

STUDY TITLE:

FOCUS GROUP:
☐ Pre-, Peri- and Post-natal
☐ Neurodevelopmental
☐ Upper/Lower Airway
☐ Obesity
☐ Positive Child Health

PUBLIC HEALTH IMPACT: (*Relevance to rural and underserved populations; impact on treatment/prevention/detection of disease in infants/children; address a gap in literature/field; potential to inform change in clinical practice, public health program/policy; why this Network; significance of study*)

CONCEPT PROPOSAL SUMMARY: (*Synopsis and Schema/flow diagram may be used, if appropriate.*)

STUDY EVENT SCHEDULE (make a separate page): For screening, baseline and follow-up visits, indicate the procedures and evaluations that are to be performed. A schedule of evaluations/procedures in chart form may be useful here (an abbreviated example is shown below):

Evaluation/procedures	Screening	Baseline	Week 8	Week 12	Week 16
Medical history	X				
Complete physical	X		X	X	X
Behavioral questionnaire		X	X	X	X
Drug administration		X	X	X	X
CBC with diff	X		X	X	X
Serum chemistry	X		X	X	X

INTRODUCTION: Background, rationale and risk/benefit assessment *(This section should provide the study rationale and supporting preclinical and/or clinical data and also address the*

following: what is the unmet need, why the patient population was chosen, why the intervention was chosen and, how the study results might impact future trials/practice. Preclinical data supporting the proposed study should be presented, and not merely referenced. The background information should be limited to what is relevant to the proposed study and should be presented succinctly but with sufficient detail to enable evaluation by the reviewers. Include pertinent community engagement opportunities.)

STUDY HYPOTHESES: *(Succinctly state the hypothesis)*

OBJECTIVES/Specific Aims: *(List primary and secondary objectives. Ensure that the study design allows for these objectives to be met and that the statistical plan provides an adequate plan to analyze or describe the data for each objective.)*

STUDY DESIGN/Methodology: *(Succinctly describe the general study design and scientific rationale for the design. Provide justification for the intervention(s). If applicable, describe randomization and/or stratification. Define the end of study criteria.)*

STUDY POPULATION/SAMPLE SIZE: *(Clearly identify the population to be studied and how it will include underserved and rural populations. Does this study overlap with any trials that are actively enrolling subjects?)*

ELIGIBILITY CRITERIA*: (Provide inclusion criteria. These should include patient age, clinical characteristics or diagnoses, whether abnormal organ function is permitted, etc. Provide exclusion criteria including but not limited to prior treatment and comorbid conditions. What is the potential for screen failures and how will they be handled? What are the strategies for recruitment and retention?)*

INTERVENTION PLAN:

- For drug interventions,
    - Provide the dose, method of administration, and schedule of each drug, the duration of treatment, the duration of the study, and the duration of follow-up. Indicate if dose titration (escalation or de-escalation) is to occur and the criteria for titration.
    - Provide the study product status (licensed, off label use, test article – under IND, test article – not under IND, unregulated product, standard of care treatment)
    - How will the study product be obtained (e.g. donation, purchased by DCOC)?
    - Describe preparation/handling/storage/accountability (if applicable)
- For behavioral interventions, describe the intervention, its mode of administration, duration of each session if there are multiple sessions, and duration of the intervention across all sessions. Describe training required for these interventions.
- For household interventions, describe the intervention and how it will be administered.
- What measures will be taken to minimize bias? Randomization? Blinding?
- Concomitant therapies? Are any excluded?
- Criteria for study intervention discontinuation?

OUTCOME MEASURES: (*State the outcome measures and how they will be assessed; mechanism for evaluating adherence (compliance) to the intervention (e.g. pill count for drugs.)*

REVIEWER(S): _____
ECHO ISPCTN SITE: _____

SAFETY/ETHICS: (*Describe any potential safety or ethical concerns with the intervention or the study. Define AE's/SAE's and how these will be handled. SUSARS. Risk level. Resources needed? Are there any human subjects' concerns?)*

DATA SAFETY MONITORING PLAN: (*Describe the safety monitoring parameters and plan as well as indications to halt study or withdraw subject from the study.*)

ENDPOINTS AND STATISTICAL CONSIDERATIONS: *(State explicitly the null and alternative hypothesis(es) for the primary objective(s). Also state the sample size and associated type I and type II errors. Provide an analysis plan for both primary and secondary objectives. Include information about which statistical tests will be applied. State the projected accrual rate and ensure that the accrual goals are realistic and achievable with current resources.)*

STUDY TIMELINE: (*Anticipated study initiation and duration of enrollment; period from first patient in to last patient in/out, etc.; time for data analysis/presentation/publication.*)

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

OTHER SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS: (*Clinical monitoring, data handling and record keeping, protocol deviations, and abbreviations, etc.*)

PROPOSED FUNDING SOURCE:

REFERENCES (not included in page limit):

Publication: proposed journal and timeline for publication.