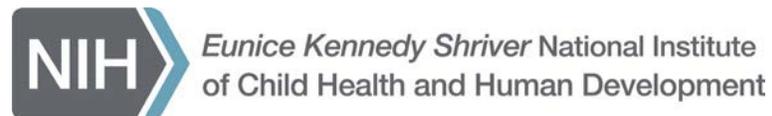


Collaborative Pediatric Critical Care Research Network (CPCCRN)

An Overview of the Funding Opportunity Announcement RFA-HD-21-016
Technical Assistance Webinar



Webinar Basics

- All participants are being muted on entry
- Please type your questions into the “Chat” box – we will have a Q&A session at the end of the prepared presentation
- We will not be unmuting participants during the Q&A session. Questions will be addressed via the chat boxes.
- If you have questions that do not get answered during this session, please submit them by email to tjenkins@mail.nih.gov.
- We will be posting these slides, the recording of this webinar, and FAQs on the website for the Pediatric Trauma and Critical Illness Branch at NICHD: <https://www.nichd.nih.gov/about/org/der/branches/ptcib>



Outline

- Background: CPCCRN History and Changes in Mechanism
- Discussion of Current Funding Opportunity Announcement (FOA): Collaborative Pediatric Critical Care Research Network (PL1, Clinical Trial Required) ([RFA-HD-21-016](#))
- Q & A





Background

About the CPCCRN



- Established April 2005 through a competitive application process using a Request for Applications (RFA)
 - First funding cycle – April 2005: 6 Clinical Sites (U10) and 1 Data Coordinating Center (DCC) (U01)
 - Second funding cycle – December 2009: 7 Clinical Sites (U10) and 1 DCC (U01) [4 renewed sites, 3 new sites]
 - Third funding cycle – December 2014: 7 Clinical Sites (UG1) and 1 DCC (U01) [4 renewed sites, 3 new sites]
 - Fourth funding cycle – April 2021: 7 to 12 Clinical Sites (RL1) and 1 DCC (PL1)



About the CPCCRN (Cont.)



- Dedicated to the investigation of the safety and efficacy of treatment management strategies used for the care of critically ill and injured children
- Network Goals
 - Develop an infrastructure to pursue well-designed collaborative clinical trials and meaningful descriptive studies in pediatric critical care medicine
 - Reduce morbidity and mortality in pediatric critical care illness and injury
 - Provide a framework for the development of the scientific basis of pediatric critical care practice



- Steering Committee (SC): Currently comprised of DCC PI, Clinical Site PIs, Project Scientist, and Independently-Appointed Chair
 - Provides oversight of all publications and presentations
 - Determines the priority given to studies approved by the SC
 - Reviews all study budgets
 - Reviews all studies regarding ethical and regulatory issues
 - Reviews on-going research external, but relevant to, the network
- Single Institutional Review Board (sIRB)
- Data and Safety Monitoring Board (DSMB)
- Family Network Collaborative (FNC)

Principal Investigators (PIs)

Institutional Oversight	Collaboration with NIH	Collaboration with SC	Collaboration with DCC
<ul style="list-style-type: none"> • Institutional Grants Management Office <ul style="list-style-type: none"> • Federal Assurances • Budgets & Financial Arrangements • Hiring Official <ul style="list-style-type: none"> • Research Coordinator • Ensure Appropriate Research Supports in Place <ul style="list-style-type: none"> • Clinical Lab • Clinical Pathology • Research Pharm • Respiration Therapy • Nursing • Communication with IRB • Appointing Alternate PI 	<ul style="list-style-type: none"> • Progress Reports • Project Officer • Grants Management • Publication & Presentation Clearance 	<ul style="list-style-type: none"> • Protocol Development • Data Analysis • Publications (Manuscript Development & Review) • 1 Site = 1 Vote 	<ul style="list-style-type: none"> • Study Monitoring & QA Activities • Reporting Requirements



CPCCRN Completed Projects (from current and past Network cycles)

- **Bereavement and Grief**

- Bereavement Studies: (1) Parent's Perspective; (2) PICU Study; (3) Physician's Perspective; (4) Pilot Study of Framework for Physician-Parent Follow-Up Meetings
- Parent Provider Alliance (PPA)

- **Outcomes**

- Development of a Quantitative Functional Status Scale (FSS) for Pediatric Patients
- Trichotomous Outcome Prediction in Critical Care Study
- Assessment of Health-Related Quality of Life and Functional Outcomes after Pediatric Trauma (TOUCH)
- Informing the Research Agenda for PICUs (IRA)
- PICU Core Outcomes Study (PICU COS)



CPCCRN Completed Projects (from current and past Network cycles) (Cont.)

- **Respiratory/Mechanical Ventilation**

- Acute Respiratory Distress Syndrome (ARDS)
- Critical Asthma Mortality and Morbidity Planning (CAMPS)
- Translating an Adult Ventilator Computer Protocol to Pediatric Critical Care
- Inhaled Nitric Oxide (iNO) in Pediatric Hypoxemic Respiratory Failure



- **Cardiac Arrest**

- Pediatric Intensive Care Quality of CPR (PICqCPR)
- Improving Outcomes from Pediatric Cardiac Arrest (ICU-RESUS)
- Therapeutic Hypothermia After Pediatric Cardiac Arrest (THAPCA) - Vanguard Sites)



CPCCRN Completed Projects (from current and past Network cycles) (Cont.)

- **Intensive Care Clinical Processes and Protocols**

- Bleeding and Thrombosis During ECMO (BATE)
- Pediatric ECMO and Cefepime (PEACE)
- CPCCRN Core Data Project
- Measuring Opioid Tolerance Induced by Fentanyl (MOTIF)
- CPCCRN Central Biorepository
- picuGrid



CPCCRN Completed Projects (from current and past Network cycles) (Cont.)

- **Infection and Sepsis**

- GM-CSF for Immunomodulation Following Trauma (GIFT-1)
- GM-CSF for Reversal of ImmunopAnalysis in pediatriC sEpsis-induced MODS (GRACE)
- Microbiome, Virome, and Host Responses Preceding Ventilator-Associated Pneumonia (VAP)
- Sepsis-induced Red Cell Dysfunction (SiRD)
- Biomarker Phenotyping of Pediatric Sepsis and Multiple Organ Failure (PHENOMS)
- Life After Pediatric Sepsis Evaluation (LAPSE)
- Critical Pertussis
- Critical Illness Stress-induced Immune Suppression (CRISIS) Prevention
- Cortisol Quantification Investigation (CQI)



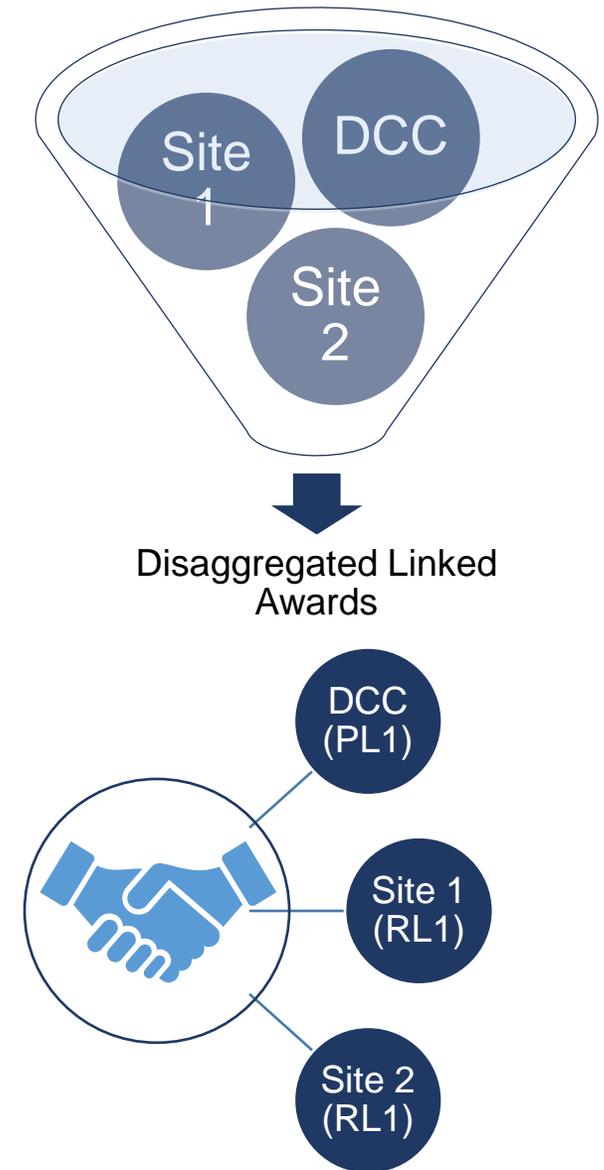
RFA-HD-21-016: CPCCRN DCC & Clinical Sites

- In theory, a “reissue” of the previous CPCCRN RFAs to continue the Network. However...
 - New Mechanism – PL1 – No longer a Cooperative Agreement with NIH
 - PL1 vs. UG1/U01 (previous mechanisms) – New way of selecting Network membership
 - **Previous CPCCRNs** - Institutions submitted application independently to serve as a site or the DCC within the Cooperative Agreement Network.
 - Clinical Sites and DCC selected by NICHD program staff **AFTER** submission and review.
 - Institutions could only submit 1 application.
 - **New CPCCRN** - Institutions seeking to be Clinical Sites &/or the DCC form a partnership and submit a single application to the NIH.
 - Clinical Sites and DCC selected by applicants **BEFORE** submission and review.
 - Institutions may participate in more than one *scientifically-distinct* application submission.



PL1 Application

- DCC and Clinical Site PIs self-select to work together prior to submission
- Submission of DCC and sites together to one RFA to be reviewed as an entity that is clearly linked
 - DCC and sites will be components of a multi-component application.
- Disaggregate sites from DCC at time of award so that DCC and Sites are individual awards but using mechanisms that show they are linked
 - The DCC will retain the PL1 award and the Clinical Sites will be awarded individual RL1 (linked) awards with the PIs named on each award.



What Does “Disaggregation” Mean?

- Once the review is completed, Branch decides which projects/components will be awarded
- Separate record is created for disaggregated projects.
- Grants Management Specialist (GMS) will contact applicants to request necessary updated information from PI and Authorized organizational Representative (AOR) at Clinical Sites
- Individual site RL1 awards are made
- DCC retains PL1 award
- KEY POINT – Disaggregation of site awards must occur **before** the NoA is issued.





Nuts and Bolts of the RFA

SF424 (R&R) Application Guide

- Two words...
 - READ IT
- Three more words...
 - COVER TO COVER
- Do not put your application at a disadvantage because you did not closely read and follow the instructions.
- All instructions in the SF424 must be followed, unless additional instructions are in the FOA. The RFA is the final word on instructions.
- Electronic Application - Apply early to allow time to correct errors.



Application Submission

- Organization must submit to Grants.gov
- Then, applicants must complete the submission process by tracking the status of the application in the eRA Commons
- Paper applications will not be accepted
- Upon receipt, applications will be evaluated for completeness by Center for Scientific Review (CSR) & responsiveness by NICHD.
 - Applications that are incomplete &/or nonresponsive will not be reviewed.



FOA: Helpful Hints

- **Read the RFA cover to cover**

- Highlight all areas that give directions, such as “shall”, “must”, “highly encouraged”, etc. Pay close attention to these directive statements
- Review the requirements for the Research Strategy section and compare side-by-side with the Review Criteria
 - Carefully read the review criteria reviewers will be using to critique your work
 - Compare that to what you prepared in your Research Plan
 - Make sure your descriptions of required information will be understandable to reviewers and allow them to provide critique using the listed review criteria



Key Dates

- Release Date: May 29, 2020
- Letters of Intent Due Date: ~~July 1, 2020~~ **July 31, 2020**
- Application Receipt Date: ~~July 30, 2020~~ **August 31, 2020**
- Peer Review Date: October/November 2020
- Council Review Date: January 2021
- Earliest Anticipated Start Date: April 1, 2021
- Expiration Date: ~~July 31, 2020~~ **September 1, 2020**



Section I: Funding Opportunity

- Funding Opportunity Purpose
 - Initiate/continue a multicenter program to:
 - Investigate safety and efficacy of treatment/management strategies for critically ill/injured children
 - Better understand pathophysiological bases of critical illness/injury
 - Maintain and establish infrastructure required for network of academic centers
 - Research to be performed:
 - Clinical Trial required using rigorous scientific methodology.
 - Additional study(ies) may be included in application if sufficient funds are available within the allotted budget (+/- clinical trial)
 - If desired, awarded Network may develop additional studies, solicit external funding, and conduct such research throughout the 5-year funding cycle (external funding must provide FULL FUNDING for the project, including F&A costs)



How Does NIH Define a Clinical Trial?

*A research study in which one or more **human subjects** are **prospectively assigned** to one or more **interventions** (which may include placebo or other control) to evaluate the effects of those interventions on **health-related biomedical or behavioral outcomes.***

<https://grants.nih.gov/policy/clinical-trials/definition.htm>



Section I: Scope of Work

- Network encouraged to work with other Peds Critical Care investigators within and outside of CPCCRN to conduct studies
 - All studies must go through standard peer review
- Network will be governed by a Steering Committee comprised of site PIs, DCC PI, and independent Chairperson
- Network will provide for a DSMB, sIRB, Family Network Collaborative, and encourage ancillary site collaboration



Section I: Scope of Work (Cont.)

- **High Priority Areas for Study** (required to demonstrate responsiveness)
 - Multiple Organ Dysfunction Syndrome in Children
 - Pediatric Sepsis
 - Pediatric Acute (Critical) Brain Injury
 - Pediatric Acute Respiratory Distress Syndrome
 - Critical Illness in Children with Complex, Chronic Health Conditions
 - ICU Processes, including (but not limited to) cardiopulmonary resuscitation, mechanical ventilation, extracorporeal therapies, etc.
 - Palliative Care in Pediatric Critical Illness
 - Life-Threatening Pediatric Trauma



Section II: Award Information

- Funds Available
 - NICHD intends to commit up to \$4.3 M in FY 2021 to fund 7-12 Clinical Sites and a DCC
- Award Budget
 - Clinical Sites may request a budget for direct costs up to \$175 K/year (up to 5 years)
 - DCC may request a budget for direct costs up to \$900 K/year (up to 5 years)
 - Protocol funds are administered through the DCC and must be budgeted as at least \$700 K/year (up to 5 years)
 - Future year amounts depend on annual appropriations
 - **The total budget (including indirects) must not exceed \$4.3 M/year**



Section III: Eligibility

- Must be based in a multidisciplinary, research-focused PICU(s) in an academically oriented department of pediatric critical care medicine that:
 - Admits both medical and surgical patients
 - Has a minimum of 1,500 annual admissions to the PICU
 - Has the ability to comprehensively follow children for up to 2 years after PICU discharge
- Multiple institutions may apply as a consortium for a single Clinical Site award
- Foreign sites are not eligible to apply



Eligible Individuals

- PI for PL1 application is the PI of the DCC
 - If PL1 is submitted as a multi-PI application, the DCC PI should be the contact PI
 - Minimum requirement for DCC PI(s):
 - Prior experience operating a DCC in multisite studies in past 5 years
 - Experience in planning, developing, and executing pediatric studies, including special consent and IRB procedures for research in critically ill children strongly preferred
 - Ability to assist in designing protocols, data collection systems, including distributed data entry, and capabilities and experience with research performance and data quality control systems
 - Ability to manage and analyze data for several studies concurrently if more than 1 project is submitted in the application
 - Ability to hold and distribute scientific protocol funds to the Clinical Sites, & maintain accounting for funds with regular reporting to NICHD PO and GMS
 - **Should have clinical experience in pediatrics, critical care medicine or preferably both.**



Eligible Individuals (Cont.)

- Minimal Requirements for Clinical Site PI(s)
 - Board-certified pediatric critical care specialists/intensivists (MD/DO).
 - Non-physicians with research doctorate (e.g. PhD) will be considered if able to provide descriptions of training, experience, research, and publication history that demonstrates recognition as academic and clinical pediatric critical care expert
- Individual from underrepresented racial and ethnic groups &/or with disabilities are always encouraged to apply
- Multiple PI (MPI) applications for a Clinical Site
 - Multiple-PI applications are acceptable & must follow instructions in the SF424 guide
 - One PI must be identified as the Contact PI
- Applicant organizations may submit more than one scientifically-distinct application



Section IV: Application and Submission

- Application package
 - Application forms package specific to FOA accessed through ASSIST or institutional system-to-system solution.
- Content/Form
 - Follow the **Multi-Project Instructions** in the SF424 guide, except where instructed in the FOA to do otherwise, and where instructions in the Guide are directly related to Grants.gov downloadable forms used with most NIH FOA.
 - The FOA instructions supersede the SF424 guide in cases where the instructions differ
 - Applications out of compliance may be delayed or not accepted for review.



Letter of Intent

- Not required, not binding, and not part of the application review
- Strongly encouraged because it helps staff estimate review workload to plan review
- **Due – July 31, 2020** to tjenkins@mail.nih.gov
- Must include the following information:
 - Descriptive title of proposed activity
 - Name(s), address(es), and telephone number(s) of the PI(s)
 - Names of other key personnel
 - Participating institutions
 - Number and title of this funding opportunity



Multi-Component Application

- The application should consist of the following components:
 - Overall: Required (includes the Clinical Trial)
 - Data Coordinating Center: Required (only 1)
 - Clinical Sites: Required (minimum of 7 Sites, maximum of 12)
 - Additional Research Projects: Optional/Not Required (minimum 0, maximum 2)



Section IV: Page Limits

- Page Limitations

- Must follow Table of Page Limits in the SF424 Guide and the Table of Page Limits, in addition to these FOA-specific page limitations (for research strategy/program plan page limits)
 - Overall – 12 pages – includes main Clinical Trial
 - Data Coordinating Center 12 pages – 1 site
 - Clinical Sites – 6 pages per Clinical Site applicant (minimum 7 sites, maximum 12 sites)
 - Additional Research Project (OPTIONAL) – 12 pages for each additional project – max 2 projects
- Do NOT use the Appendix to circumvent page limits!



Overall Component

- Follow standard instructions, as well as:
 - “Research & Related Other Project Information (Overall)” section - Other attachments
 - **“CPCCRN Network Organizational Structure”** – diagram and description REQUIRED as PDF
 - Includes DCC, 7-12 Clinical Sites, plus any ancillary sites for subject accrual
 - HINT: No page limits 😊
 - **Populations Available for Clinical Research**
 - Each Clinical Site applicant must describe its pediatric critical care population as directed
 - Must have at least 1,500 admissions per site per year (total may include admissions from ancillary site(s))
 - No more than 30% of admissions may be transfers from other facilities
 - Provide admissions over 2-year period – January 1, 2017 to January 1, 2019
 - **Describe any ongoing or potential clinical studies/trials that may/will limit availability of patients for CPCCRN trials.**



Overall Component (Cont.)

- Project/Performance Site Location – List Primary Site (DCC) only
- Research & Related Senior/Key Person Profile (Overall)
 - Only the PI & any multi-PIs for the entire application
 - All applicant PIs for the DCC and all Clinical Sites must be included
 - DCC PI is the Contact PI
 - Senior/Key Persons for each Clinical Site applicant must be included in that Site's specific section of the application
- Budget (Overall)
 - Only budget info included in Overall is the Estimated Project Funding section of SF424(R&R) Cover



Overall Component: Research Plan

- Specific Aims of the Clinical Trial
 - Describe objectives of trial, including relevant scientific hypotheses and statement of how the research and proposed Network will potentially advance the field and improve care for critically ill children and their families
- Research Strategy:
 - Network Structure and Function
 - Steering Committee, DSMB, FNC, sIRB – Do not duplicate information already provided in attachment
 - Clinical Trial – multisite large-scale clinical trial in high priority area (R01 level)
 - Letters of Support for the clinical trial
 - Resource Sharing Plan



Overall Component: Human Subjects

- Study Record: PHS Human Subjects and Clinical Trials Information
- Study Population Characteristics
 - Study Timeline and Milestones sufficient to evaluate what will be achieved during the 5-year project
- Protection and Monitoring Plans
 - Data and Safety Monitoring Plan
 - Establishment of DSMB
 - Delayed Onset Studies not allowed; Delayed Start Studies are allowed



Data Coordinating Center (DCC) Component

- Research & Related Senior Key
 - PI, and one person designated to direct DCC in absence of the PI
 - Statisticians
 - Clinical Trial Project Coordinators/Managers
 - Programming and analytic staff
 - Data Processing staff
 - Logistics and support staff



Data Coordinating Center (DCC): Budget

- Base budget ***not to exceed*** \$900,000 in direct costs/year, and commensurate with scope of work
 - Meant to cover the operational costs of the DCC
- Protocol “Capitation” funds should be a ***minimum*** of \$700,000/year
 - NIH does not pay F&A on the protocol/capitation award
- Budget minimums and maximums allow applicants to flex dollars depending on cost of clinical trial, and to potentially add additional trials, as funds allow.



Data Coordinating Center (DCC): Research Plan

Research Strategy:

- Evidence of successful past performance
- Academic productivity
- Staffing plan and capabilities
- Capacity and ability to manage data and communications
- Evidence of reporting capabilities
- Logistical and other support services
- On-site and off-site monitoring ability
- Technology transfer, data management and protocol training capabilities
- Administrative and management capabilities
- Special strengths of the PI and/or institution
- Intent to participate

Letters of Support



Clinical Sites Component

- Research & Related Senior/Key Person Profile
 - Clinical Site PI(s)
 - Clinical Research Coordinator(s)
 - Clinical Site(s)
 - Ancillary Site(s)
 - Ancillary Site(s) PI(s)



Clinical Sites: Budget

- Base Budget limited to \$175,000 direct costs
 - May vary depending upon the number of Clinical Site submissions
 - Total budget requests for all Clinical Site applicants must not exceed \$1.25 M in direct costs/year
 - Clinical Sites need not request same amount of funding
- Allowable costs in base budget:
 - Clinical Site PI: Minimum 1.2 person months effort – commensurate with scope of work
 - Clinical Research Coordinator: may request up to 1 FTE – commensurate with scope of work
 - Travel & Supplies
 - Start-up costs for collaborating ancillary clinical sites – commensurate with scope of work
 - Other costs



Clinical Sites: Research Plan

Research Strategy

- Management plan
- Collaboration
- Academic Productivity
- Pediatric Critical Care Staffing and Available Expertise
- Research Staff
- Evidence of Follow-up Capabilities
- Critical Care Data System
- Additional Clinical Capabilities
- Special Strengths of the Clinical Site PI &/or Institution

Letters of Support



Additional Research Project (Optional) Component

- Budget
 - Must fit within the total \$4.3 M allocation for the Network
 - Protocol funds will be distributed by the DCC
- Specific Aims
- Research Strategy
 - Follow instructions in SF424 using NIH/NICHD-appropriate parent FOA - e.g., R01, R21, R03
- Letters of Support
- Resources Sharing Plan
- PHS Human Subjects & Clinical Trials Information, as appropriate





Review Criteria

Application Review

- Applications will be evaluated by a Special Emphasis Panel
 - All applications:
 - May undergo a selection process in which only those applications deemed to have the highest scientific and technical merit will be discussed and assigned an overall impact score
 - Will receive a written critique
 - Overall Review will include 2 categories:
 - Overall structure and function of the proposed Network
 - Common clinical trial required by FOA
 - Proposed clinical trial may include study design, methods, & intervention that are not, by themselves, innovative, but address important questions or unmet needs.
 - Results of clinical trial may indicate that further clinical development of the intervention is unwarranted or lead to new avenues of scientific investigation.



Application Review: Criteria Overview

- Overall Impact (Overall Component)
 - Likelihood of Network and Clinical Trial to exert sustained, powerful influence on the field
- Scored Review Criteria (Overall Component)
 - Significance of both Network and Clinical Trial
 - Investigators – overall evaluation of Network investigators for Network and Clinical Trial
 - Innovation – overall evaluation of Network innovation and innovation of the Clinical Trial
 - Approach
 - Study Design
 - Data Management, Statistical Analysis, and Data & Specimen Storage
 - Environment – overall evaluation of Network DCC, Clinical Sites & Ancillary Sites



Overall Scored Review Criteria: Significance

- Do the Network & clinical trial address important problem/critical barrier to progress in PCC?
 - How will scientific knowledge, technical capability, &/or clinical practice be improved?
- How well does each individual component fit in and contribute to the overall Network?
- Is overall Network likely to successfully complete a rigorous clinical trial (as proposed)?
- Are the scientific rationale and need for a clinical trial to test the proposed hypothesis or intervention well supported in the research plan by preliminary data, clinical &/or preclinical studies, or information in the literature of knowledge of biological mechanisms?
- If the trial focuses on clinical/public health endpoints, is the trial necessary for testing the safety, efficacy, or effectiveness of an intervention that could lead to a change in clinical practice, community behaviors, or health policy?
- For mechanistic, behavioral, physiological, biochemical, or biomedical endpoints, is the trial needed to advance scientific understanding?



Overall Scored Review Criteria: Investigators

- Are the PIs, collaborators, researchers well-suited to the overall Network and clinical trial?
 - If ESI, do they have *appropriate experience and training*? If established, do they demonstrate ongoing record of accomplishments that have advanced PCC?
 - Do the PIs have *complementary & integrated expertise* and are their leadership approach, governance, and organizational structure appropriate for the project?
- Do the PIs have the ability to contribute to the Network as documented by scientific achievements, productivity, stature in their field, and planned activities?
- Do the PIs and their teams have the *knowledge and experience in conducting collaborative multi-site clinical trials in pediatric critical care* and the ability to manage and implement the proposed clinical trial, meeting milestones and timelines?
- Does the application propose a structure that will *optimize the number and distribution of participating investigators*



Overall Scored Review Criteria: Innovation

- Does that application *challenge and seek to shift current research or clinical practice paradigms* by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?
- Is there evidence that the overall Network will be a *source of innovation in scientific design*?
- Does the overall Network propose innovative ways to communicate, allocate resources, promote collaborations, recruit and retain research subjects, or other research activities?
- Does the proposed Clinical Trial offer an innovative approach to conducting multisite pediatric critical care research? Does it hold the *potential to transform care of critically ill or injured children in one of the identified high-priority areas of pediatric critical care*?
- Does the design/research plan include innovative elements, as appropriate, that enhance its sensitivity, potential for information, or potential to advance scientific knowledge or clinical practice?



Overall Scored Review Criteria: Approach

- Are overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the Network and Clinical Trial?
- Does the application adequately address and justify:
 - Study Design, including primary/secondary endpoints, hypotheses, statistical power, ethical issues, data collection, recruitment/retention and inclusion/exclusion of study populations, randomization, etc.
 - Data Management, Statistical Analysis, and Data and Specimen Storage
 - Are planned analyses and statistical approach appropriate for proposed study design?
 - Are procedures for data management and quality control of data adequate at clinical sites, DCC, site labs, etc.?
 - If the Clinical Trial includes biospecimen storage, is there discussion of ownership of data/biospecimens and a succession plan for ownership once federal support is completed.



Overall Scored Review Criteria: Approach (Cont.)

- Does application clearly demonstrate feasibility of the Network organizational structure?
- Does organizational structure have clear lines of authority that allow for efficient implementation of the clinical trial?
- Is there an adequate plan for establishing the Steering Committee, selection of independent Chair, development of SC SOPs, selection/implementation plan for DSMB, and use of a sIRB?
- Is it likely that the Network has the ability to recruit, retain, and follow-up with subjects in a clinical trial? Are appropriate populations available at the Clinical Sites and is there evidence of commitment t(including institutional support and capabilities) to prioritize CPCCRN studies?
- Is there a well-developed and justified overall system for administration and disbursement of capitation funds?



Overall Scored Review Criteria: Environment

- Are the institutional support and scientific environment adequate for the proposed work and will they contribute to the probability of success? Are there unique features of the scientific environment, subject population, or collaborative arrangements that will benefit the project?
- Does the overall Network environment provide adequate high-quality data analytic capacity, database facilities, coordination, and data resources, and are the DCC and Clinical Sites appropriate for the trial?
- Do the applicant institutions have access to diverse subject populations, including racial, ethnic, socioeconomic, and geographic diversity?
- Does the application adequately address the capability and ability to conduct the trial at the proposed sites? Are the plans to add or drop enrollment centers, as needed, appropriate?
- Is there evidence of the ability of the individual sites to enroll the proposed numbers, adhere to the protocol, collect/transmit data accurately and on-time, and operate within the organizational structure?



Overall Additional Review Criteria

- Reviewers will evaluate these items while determining scientific & technical merit, and in providing an overall impact score, *but will not give separate scores* for these items:
 - Study Timeline
 - Is the study timeline described in detail, and is it feasible and well-justified?
 - Does the project incorporate efficiencies and utilize existing resources (e.g. CTSA's, EHRs, etc.) to increase efficiency of participant enrollment and data collection? Are potential challenges and solutions discussed?
 - Protections for Human Subjects
 - Inclusion of Women, Minorities, and Individuals Across the Lifespan
 - Vertebrate Animals
 - Biohazards



Application Review – Component Reviews

- Data Coordinating Center Review
 - Reviewers will provide a single impact score based on criteria listed in FOA (both in DCC section and Overall section)
- Clinical Sites Review
 - Reviewers will provide a single impact score for the sites as a whole based on criteria listed in FOA (both in Clinical Sites section and Overall section)
- Additional Research Project Review
 - Reviewers will provide a single impact score per project based on criteria listed in FOA (both Additional Research Project section and Overall section)



Review and Selection Process

- Appeals will not be accepted for applications submitted to this FOA
- Applications will receive second level of review by NACHHD Council
- The following will be considered in making funding decisions:
 - Scientific & technical merit of the proposed project as determined by scientific peer review
 - Availability of funds
 - Relevance of the proposed project to program priorities
 - Geographic distribution of Clinical Sites
 - Adequacy of the data and resource sharing plan





Frequently Asked Questions (FAQs) **(as of 6/29/20)**

FAQs (1 & 2 of 7)

- **Should current CPCCRN sites submit a renewal application or a new application? Are resubmission applications allowed?**
 - Since the mechanism has significantly changed from the Cooperative Agreement (UG1/U01) to an investigator-led non-Cooperative Agreement grant (PL1), all applicants should submit as new applicants. Resubmission applications are not allowed. This is a one-time-only submission.
- **Can a Clinical Site be made up of more than one institution?**
 - Yes, more than one institution may come together to form a consortium and submit their application as a single site. The institution submitting the application will be considered the lead institution and that PI will serve as the contact PI. If funded, the NIH will issue a single RL1 award to the applicant institution which will administer the award using the traditional subcontract approach to the other collaborating sites. No additional base funds will be provided beyond the base budget maximum request of \$175,000 direct costs per Clinical Site.



FAQs (3 & 4 of 7)

- **I am an appointed study section member with continuous submission privileges. Does that apply to this RFA?**
 - No. Continuous submission only applies to R01s, R21s, and R34s submitted to FOAs using standard due dates. This RFA does not use any of these mechanisms and does not use standard due dates: therefore, applications are not eligible for continuous submission.
- **I recently submitted an R01 on the same topic as our application. Can I include any part of that project in the PL1 application?**
 - No. NIH policy states that you cannot have duplicate or highly overlapping applications under review at the same time. (An application is considered “under review” until the summary statement is issued.)



FAQs (5 & 6 of 7)

- **Will the applications be reviewed in a standing NIH study section?**
 - No. This RFA will be reviewed in a Special Emphasis Panel (SEP) convened by the review staff of the NICHD Scientific Review Branch.
- **The Overall component is supposed to address the Network function and organization, as well as convey the Clinical Trial, but is only allowed 12 pages. How can I fit all that information in 12 pages?**
 - The Network function and organization, etc. should only be discussed in a broad overall description in the Overall section (e.g. one paragraph), with the remaining part of the Overall component dedicated to the clinical trial.
 - The majority of the description of the Network function, organization, communication, etc. should be included as an attachment in the “Research & Related Other Project Information (Overall)” section. There are two (2) required attachments in that section: (1) CPCCRN Network Organizational Structure, and (2) Population Available for Clinical Research.



FAQs (7 of 7)

- **Do we have to submit an Additional Research Project? If we do include one, does it have to be a clinical trial? Can we get additional funds for the Additional Research Project?**
 - Additional Research Projects are optional and not required. If the applicants wish, they may submit up to 2 additional research projects. These additional projects may or may not be clinical trials and/or clinical research. The research plan for such projects should be prepared according to the SF424 Guide instructions for the appropriate NIH/NICHD parent FOA, such as an R01, R21 or R03 application.
 - There are no additional funds available for Additional Research Projects. All costs for such projects must fit within the total PL1 budget of \$4.3 million (total costs).



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