



Overview Information

Funding Opportunity Title	<i>PCCTSDP K12 Scholar Award</i>
Awarding Organization	University of Utah
Federal Prime Sponsor	<i>Eunice Kennedy Shriver</i> National Institute of Child Health and Human Development (NICHD)
Federal Award Number	K12HD047349
Activity Code	K12 Training Program
Summary of the Funding Opportunity Purpose	The Pediatric Critical Care and Trauma Scientist Development Program (PCCTSDP) is a national faculty training program that develops successful pediatric critical care and pediatric trauma physician scientists. The PCCTSDP goal is to increase the number of highly trained, successfully funded, and sustainable pediatric critical care and pediatric trauma physician scientists who do research to enhance the scientific understanding, clinical management, and long term outcomes of critical illness and trauma in children. The PCCTSDP is funded by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) to select the most outstanding junior faculty candidates for sustained training as PCCTSDP Scholars in excellent research settings throughout the United States.

Key Dates

Application Due Date	October 1, 2020
Merit Review	November 5-8, 2020
Earliest Start Date	January 1, 2021

Section I. Funding Opportunity Description

Pediatric critical care and pediatric trauma surgery are important subspecialties in medicine. Critical care physicians and pediatric trauma surgeons provide intensive care to children with critical or unstable conditions. Because pediatric trauma and critical care is a high-risk and time-consuming field, the fellowship training is clinically intense and often does not allow for adequate development of physician scientists. The field needs translational researchers, those who can move clinical problems into the laboratory and incorporate scientific findings into bedside care. This type of research requires physician scientists who maintain a sound research career in addition to providing excellent clinical care.

The PCCTSDP is a national training program for outstanding young pediatric critical care and pediatric trauma surgery faculty, and training opportunities are distributed among different institutions throughout the United States. It provides financial support for the best young faculty to train in the most outstanding research settings. The training program consists of local training and mentorship that will occur at the institution at which the training is located. In addition, the PCCTSDP provides supra-institutional mentorship for the scholars and mentors in the program.

The PCCTSDP requires five years of commitment and participation from PCCTSDP Scholars and their institutions. During Phase I, the PCCTSDP will provide funding (see below) for the individual as he or she pursues intense research training.

The Pediatric Critical Care and Trauma Scientist Development Program (PCCTSDP) is administered through the University of Utah School of Medicine. Governance of the program is provided by the National Advisory Committee (NAC). The NAC is composed of outstanding scientists and leaders in pediatric critical care and trauma surgery. The NAC provides oversight for the program, selects applicants for funding as PCCTSDP Scholars, and provides mentorship for PCCTSDP Scholars.

Potential applicants may identify outstanding mentors from their own institutions, or by contacting the PCCTSDP Program Director for advice. The program provides an annual PCCTSDP retreat to facilitate interaction with the NAC members and site visits to assure quality of the training environment for each scholar.

Phase I

Phase I lasts up to two years (in exceptional circumstances, three years may be possible). During this period, the Scholar will:

- Pursue intense training in a mentored laboratory or clinical research setting.
- Develop a short and long-term career development plan, including plan for future research activities.
- Meet with the National Advisory Committee at the annual PCCTSDP retreat where research protection, progress, and challenges are discussed.

Development Plan

The development plan must be outlined in the application for funding. The Scholar must be protected from clinical and administrative responsibilities so that a minimum of 75% time is protected and dedicated to research training.

Evaluation

During Phase I, members of the National Advisory Committee will site visit each training institution and verify that the Scholar is being provided with the institutional commitment described in the scholar's application and the department chairs endorsement letter. Renewal for two years, and in exceptional circumstances, three years, is dependent on satisfactory progress of the scholar.

Annual Retreat

Phase I Scholars will attend the annual PCCTSDP retreat, travel expenses are to be included in the Scholar's proposed budget.

Phase II

During Phase II, Scholars must be:

- Supported by their institution, preferably with extramural funding such as K08 or K23 NIH awards.
- Protected from clinical and administrative responsibilities at least 50% of their time, according to the RFA for this program.

Institutions must protect Phase II Scholars for a minimum of 50% regardless of their funding status, and are strongly encouraged to protect Phase II Scholars for 75% of their time, reflecting our goal that these scholars will be supported by K awards. It is important to note that protection of Scholars for the duration of five years must be a firm commitment of the sponsoring Department and must be acknowledged in a letter from the Department Chair during the application process.

Annual Retreat

Phase II Scholars will attend the annual PCCTSDP retreat, and discuss their long-term career development with the National Advisory Committee at these annual retreats. Travel expenses must be borne by the sponsoring Department.

Training Activities

PCCTSDP provides value added to the training of pediatric critical care scientists by acting in a complementary manner to the local institution. Activities of value to the PCCTSDP Scholar include the following:

- Assistance with original application, by the Program Director
- Interviews and interactions with National Advisory Committee members
- Assistance with preparation of extramural grant proposals
- Site visits of Phase I Scholar training institutions to verify training environment
- Participation at the annual PCCTSDP retreat

Assistance with Original Application

Applicants may contact the Program Director, who can provide assistance in contacting potential mentors, and provide helpful input into career development ideas and research proposals. The Program Director will not assist with writing applications, but can provide helpful advice to applicants because she does not play a role in selection of PCCTSDP Scholars. Selection of Scholars is the responsibility of the National Advisory Committee.

Interviews and Interactions

Interaction with the leaders and outstanding scientists who comprise the National Advisory Committee is a major benefit to participants in the PCCTSDP. These interactions include interviews of applicants during the selection process, scientific interaction at the annual retreat, discussion of the applicants' and Scholars' academic and research development plans, and presentation of selected faculty development topics by committee faculty and guest speakers. In addition, the committee may convey expectations to each applicant and Scholar, particularly with respect to the timeline for seeking the next level of research funding.

Preparation of Extramural Grant Proposals

Phase I scholars will begin early preparation of K08 or K23 proposals for submission to the NIH. The PCCTSDP will help provide structure to this timeline by interactions between the National Advisory Committee and the Scholar, both at the annual retreat and throughout the year. Phase I Scholars should write a two to three page draft outline of a K08 or K23 proposal or, in rare instances, an R01 proposal, by the end of the first 12 to 15 months in the program. This draft may be submitted to the PCCTSDP and then disseminated to National Advisory Committee members for constructive feedback. This activity is optional but highly recommended.

At least eight weeks prior to the NIH submission deadline, the Scholar should send a nearly complete draft of the specific aims, career development and approach sections and the PCCTSDP may do a mock review, providing pink sheets back to the Scholar and mentor in ample time for the Scholar to improve the proposal based on those comments. If the National Advisory Committee does not have appropriate expertise to provide this review, expertise will be solicited. In this manner, the Scholar will have an opportunity to obtain an initial, external, rigorous scientific evaluation for their proposal in time to not waste a cycle in the NIH peer review process. If a Scholar achieves K award funding, then the Scholar will automatically transfer into Phase II.

Site Visits

The Program Director or a designee from the National Advisory Committee will site visit each training institution on an annual basis during Phase I training. During these site visits, the Program Director or National Advisory Committee member will meet with the Scholar, the training mentor, the critical care or surgical Division Chief, and the Pediatric or Surgery Department Chair, depending on the specialty of the Scholar. The Program Director will verify that the institution is meeting its obligations to the Scholar as outlined in the original application submitted by the Scholar.

External Mentorship for PCCTSDP Scholars

The program provides external mentorship to PCCTSDP Scholars as outlined in the Training Activities on the Program page. In addition, Scholars will be expected to seek extramural funding between 15 and 18 months into training. National Advisory Committee (NAC) members may provide an external peer review to these

proposals as they are prepared for submission to funding agencies. This is available if the Scholar contacts the Program Director.

The committee will also provide mentorship during the K12 application process.

Section II. Scholar Selection

Candidate Criteria

The candidate must have demonstrable potential to be an excellent physician scientist, whose research interests are likely to improve long-term outcomes and quality of life for children who sustain critical illness or traumatic injury. The candidate must make a five-year commitment to the training plan, and there must be institutional commitment to the scholar. Letters of recommendation are required and must support the exceptional caliber of the candidate.

Mentor Criteria

The mentor should be an established clinical or basic scientist with a track record of extramural funding, preferably from NIH, who has expertise in training junior faculty in the research setting. A tabular presentation of previous trainees (date of training, current academic position, grants awarded, publications) may be included and will not be credited against the page limit of the application. The mentor statement should describe the mentoring plan in detail, including time commitment and coherence with the academic goals of the trainee.

Research Plan Criteria

The research plan should demonstrate the ability of the candidate to consider a scientific problem, develop a hypothesis-driven proposal, outline a research design, and describe the implementation. The research plan must address human subjects or vertebrate animal issues, as applicable. The research plan will form the major agenda for discussion when the National Advisory Committee interviews the applicant at the annual retreat. The applicant should demonstrate a good understanding of the research problem and be prepared to discuss the ideas formally with the committee during the interview.

Selection Process

Each candidate's application will be reviewed by three members of the National Advisory Committee. The application will be presented and discussed at the Committee's internal study section during the retreat. New Scholars will be chosen at the study section. All applicants will receive written comments from the study section to help them with future applications.

Section III. Award Information

Scholar Salary Support	The PCCTSDP K12 will provide salary support up to \$75,000 plus fringe benefits during Phase I . The total salary/benefits requested <i>must</i> be based on a fulltime, 12-month faculty appointment. The K12 Scholar Award requires the candidate to devote a minimum of 75% FTE (9 person months) to conducting their career development related research.
Tuition Costs	The PCCTSDP K12 will provide limited tuition support for specific training opportunities (up to \$4,500 per year during Phase I).
Travel Costs	The PCCTSDP K12 will provide travel funds for the annual PCCTSDP retreat and appropriate scientific meetings (up to \$3,500 per year during Phase I).

Other Direct Costs	<p>The PCCTSDP K12 will provide research development support for the award recipient up to \$10,000 per year during Phase I. These costs may be used for the following expenses: research expenses, such as supplies, books, service fees, and technical personnel; and statistical services including personnel and computer time. <i>Unallowable costs</i> include clerical and administrative salaries, office supplies, telephone costs, postage, and membership dues.</p> <p>The PCCTSDP K12 Award follows the stipulations laid out in the NIH Grants Policy Statement. Scholars should assure they exercise proper stewardship over funds and that costs charged to the award are allowable, allocable, reasonable, necessary, and consistently applied regardless of the source of funds.</p>
Indirect Costs	<p>Indirect expenses will be provided to training institutions at 8% of all direct costs except tuition, which is not eligible for indirect expense reimbursement.</p>

Section IV. Submission Information

The PCCTSDP K12 requires all applicants to adhere to the following instructions when preparing their application. Failure to adhere to instructions may result in administrative rejection of the application.

Recommended Supplemental Instructions: As appropriate, the PCCTSDP recommends applicants utilize the most recent version of the [NIH SF424 \(R&R\) Application Packages Career Development Instructions](#) when completing the application.

The entire proposal will be submitted as one, combined PDF via email to the Program Director, Dr. Heather Keenan (heather.keenan@hsc.utah.edu), with the Subject Line reading “**PCCTSDP Application – PI LAST NAME**”.

The electronic application is due October 1, 2020. Please do not send a paper copy unless necessary.

University of Utah
 Pediatric Critical Care - PCCTSDP
 ATTN: Heather Keenan
 295 Chipeta Way
 Salt Lake City, UT 84108

All Letters of Referee must be sent electronically directly from the Referee to Dr. Heather Keenan (heather.keenan@hsc.utah.edu) by October 1, 2020 with the Subject Line reading “**PCCTSDP Referee Letter – PI LAST NAME**”.

Section V. Application Instructions

Referee Letters

[NIH guidelines](#) stipulate that you must include 3-5 reference letters. The letters should be from individuals not directly involved in the application but who are familiar with the applicant's qualifications, training, and interests. These letters are to be either physically mailed or electronically emailed by the Referee to the Program Director (Dr. Heather Keenan).

Application Content

1. Cover Letter
2. [PHS 398](#) Form Page 1: Face Page
3. [PHS 398](#) Form Page 2: Summary, Relevance, Project/Performance Sites, Senior/Key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells
4. [PHS 398](#) Form Page 3: Research Grant Table of Contents
5. Candidate Biographical Sketch (*5 page limit*)
6. Mentor(s) Biographical Sketch(es) (*5 page limit each*)
7. Mentor(s) Other Support Forms
8. Other Senior/Key Personnel Biographical Sketch(es) (*5 page limit each*)
9. Facilities and Other Resources
10. Equipment
11. [PHS 398](#) Form Page 4: Detailed Budget for Initial Budget Period
12. [PHS 398](#) Form Page 5: Budget for Entire Proposed Project Period
13. [PHS 398](#) Checklist Form Page
14. Budget Justification
15. Research Career Development Plan (*included in the 12 page limit*)
16. Specific Aims (*1 page limit*)
17. Research Strategy (*included in the 12 page limit*)
18. Training in the Responsible Conduct of Research (*1 page limit*)
19. Plans and Statements of Mentor(s) (*6 page limit*)
20. Letters of Support (*6 page limit*)
21. Description of Institutional Environment (*1 page limit*)
22. Institutional Commitment to Candidate's Research Career Development (*1 page limit*)
23. Vertebrate Animals
24. Select Agent Research
25. Consortium/Contractual Arrangements
26. Resource Sharing Plan
27. Authentication of Key Biological/Chemical Resources Plan
28. [PHS](#) Human Subjects and Clinical Trials Information Form
 - a. Inclusion of Women, Minorities & Children
 - b. Recruitment & Retention Plan
 - c. Study Timeline
 - d. Inclusion Enrollment Report Form
 - e. Protection of Human Subjects
 - f. Single IRB Plan
 - g. Data and Safety Monitoring Plan (clinical trial only)
 - h. Overall Structure of the Study Team (clinical trial only)
 - i. Statistical Design and Power (clinical trial only)
 - j. FDA – Regulated Intervention (clinical trial only)
 - k. Dissemination Plan (clinical trial only)
29. Bibliography

Section VI. Program Contacts

Scientific/Research Contact

Heather Keenan, MD, PhD, MPH
Program Director, PCCTSDP K12
Email: heather.keenan@hsc.utah.edu

Administrative Contact

Randi Willey
Program Coordinator, PCCTSDP K12
Phone: 801-587-7609; Email: Ped-K12@hsc.utah.edu