Pediatric Critical Care Scientist Development Program (PCCSDP)

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1 Background of Program

Pediatric critical care is a relatively new subspecialty, with initial subspecialty board designation and fellowship program certification occurring in the late 1980's. Pediatric critical care is high risk and time consuming; the clinical intensity of fellowship training has not been conducive to adequate development of physician scientists in this specialty. Public recognition of the clinical value of intensivists has increased clinical demand, and this reduces the available time for trained intensivists to devote to research. As a result, careful research of the pathophysiology and treatment of critical illness, with emphasis on long-term outcome, has been very limited. Special needs children represent a large fraction of children requiring critical care, and survival of critically ill children with residual disability or chronic disease has become more common.

To meet these problems, the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) has established the Pediatric Critical Care Scientist Development Program (PCCSDP), administered by the University of Utah School of Medicine. The Program Director is J. Michael Dean, M.D., M.B.A., Professor and Vice Chairman of the Department of Pediatrics. The program selects the most outstanding junior faculty candidates for sustained training as PCCSDP Scholars in excellent research settings throughout the United States. These NIH funded research settings may be clinical or basic science, and may be in any field relevant to pediatric critical care. Translational research, moving clinical problems into the laboratory and incorporating scientific findings into bedside care, requires a physician scientist who maintains a sound research career, in addition to providing clinical care.

The goal of the PCCSDP is to increase the number of highly trained, successfully funded and sustainable pediatric critical care physician scientists, who will do translational research to enhance the scientific understanding, clinical management and rehabilitation of critical illness in children, leading to better long term outcome.

2 Details of Training Program

The PCCSDP is a national program, and training is distributed among different institutions throughout the United States, with the intention of funding the very best young faculty to train in the most outstanding laboratory 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 PCCSDP itself will provide a suprainstitutional level of mentorship for the Scholars in this program.

2.1 Description of Program Support

The PCCSDP requires five years of commitment and participation from PCCSDP Scholars and their institutions. During Phase I, the PCCSDP will provide significant funding (see below) for the individual as he or she pursues intense research training. During Phase II, as the Scholar transitions to an independent investigator, the PCCSDP will provide limited support in the form of participation in the annual PCCSDP retreat.

Phase I will last two to three years. During this period, the Scholar will pursue intense training in a mentored laboratory or clinical research setting. The Scholar will develop a short- and long-term career development plan, including plans for future research activities. This development plan must be outlined in the application for funding, refined upon entry into the program, and evaluated on at least an annual basis. The Scholar must be protected from clinical and administrative responsibilities so that a minimum of 75% time is protected for research training. The Scholar will meet with the National Advisory Committee at the annual PCCSDP retreat, and protection from clinical and administrative responsibilities will be discussed and evaluated. During Phase I, members of the National Advisory Committee will site visit each training institution and will verify that the Scholar is being provided with the institutional commitment described in the Scholar's application and the department chair's endorsement letter. Renewal for two years, and in exceptional circumstances, three years, will be dependent on satisfactory progress of the Scholar.

During Phase I, Scholars may receive up to $75,000, as well as benefits, limited laboratory support for supplies, travel to the annual PCCSDP retreat and to appropriate scientific meetings, and limited tuition support for specific training opportunities. Indirect expenses will be provided to training institutions at 8% of all direct costs except tuition, which is not eligible for indirect expense reimbursement.

During Phase II, Scholars must be supported by their institution, preferably with extramural funding such as K08 or K23 NIH awards. Scholars in Phase II must be protected from clinical and administrative responsibilities at least 50% of their time, according to the RFA for this program. Institutions 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.

Phase II Scholars will attend the annual PCCSDP retreat, and discuss their long-term career development with the National Advisory Committee at these annual retreats. The PCCSDP will provide up to $1,500 for travel to the annual meeting for Phase II Scholars *if funds are available.*

2.2 PCCSDP Training Activities

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

- Program Director assistance with the original PCCSDP application
- 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 PCCSDP retreat

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 he does not play a role in selection of PCCDSP Scholars. Selection of Scholars is the responsibility of the National Advisory Committee, and is described later in this document.

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

Phase I Scholars will begin early preparation of K08 or K23 proposals for submission to the NIH. The PCCSDP will help provide structure to

this timeline through interactions between the National Advisory Committee and the Scholar, both at the annual retreat and throughout the year. Phase I Scholars will 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 – 15 months in the program. This draft may be submitted to the PCCSDP for feedback, and will be disseminated to appropriate National Advisory Committee members for constructive feedback. The Scholar will develop the application for submission to the NIH by 18 months into the PCCSDP, with the goal of obtaining funding by the end of Phase I. At least six weeks prior to the NIH submission deadline, the Scholar may choose to send a nearly complete draft and the PCCSDP will 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, the Program Director will identify ad hoc reviewers to supplement the review. 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. When a Scholar achieves K award funding, then the Scholar will automatically transfer into Phase II.

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 site visitor will meet with the Scholar, the training mentor, the critical care Division Chief, and the pediatric Department Chairman. The site visitor will verify that the institution is meeting its obligations to the Scholar as outlined in the original application submitted by the Scholar.

2.3 Annual PCCSDP Retreat

The PCCSDP will have an annual scientific retreat in October or November of each year, lasting 2 1/2 to 3 days. This year, the retreat will be at The Lodges in Deer Valley October 30 – November 2, 2008. The setting is convenient to the Salt Lake International Airport, but is in a relatively secluded location facilitating interaction among meeting participants in a beautiful environment.

Applicants must attend this retreat as part of the selection process. In exceptional circumstances, the program may be able to provide financial support to help defray applicant travel expenses. Mentors of these applicants are also invited to attend the retreat, at their own institutional expense.

All Phase I Scholars are required and their mentors are invited to attend

the retreat. Scholars who are unable to attend must discuss this with the Program Director (Dr. Dean). The Committee will meet with each Scholar to evaluate progress during the year. Scholars will present their research findings, in 20 - 30 minute talks, to their colleagues, applicants, mentors, and Committee members. This will be an exciting "give and take" session, encouraging the candid exchange of ideas and feedback. Guest speakers will be selected to address specific topics. In retreats that have been held in past years, the Program Director has invited a variety of speakers to address important survival skills such as manuscript preparation, grant writing, identifying funding sources, oral presentations, mock study section, dealing with one's mentor, and learning how to provide mentorship to younger trainees.

3 Program Plan and Organization

The Pediatric Critical Care Scientist Development Program (PCCSDP) is a *national* training program that is administered at the University of Utah School of Medicine. The National Advisory Committee is composed of outstanding scientists and leaders in pediatric critical care. The Committee provides oversight for the program, selects applicants for funding as PCCSDP Scholars, and provides mentorship for PCCSDP Scholars.

The National Advisory Committee will evaluate each application using standard NIH criteria, and each application will be scored. The priority score will not be provided to the applicants, and is only used for internal programmatic purposes. The applications will be funded, in order of priority score, to the limit of available funds. Priority score will depend not only on the science proposed, but also on the qualities of the candidate, mentor, and training plan, which all should reflect the likelihood of success of the candidate.

3.1 PCCSDP Mentors at the Training Institution

The PCCSDP is a *national* program open to outstanding applicants and mentors from throughout the United States. In a traditional K12 or T32 program geographically located at a single institution, the mentors are preselected by the Program Director, and trainees are recruited to that institution to be mentored by these specific scientists. This program is fundamentally different because PCCSDP Scholars will train in laboratories that are geographically dispersed in different institutions. The National Advisory Committee will evaluate the quality of the mentor for each specific Scholar during the peer review process.

While applicants may identify a mentor at the institution where they complete fellowship training, the NIH encourages consideration of training at a different institution. In "Special Requirements, Section E. PCCSD Candidates", the RFA reads "Although remaining at the institution of their fellowship is a possibility for trainees under this award, academic diversity through research training and clinical practice at a different institution should be strongly encouraged." The PCCSDP maintains a national roster of potential mentors, rather than an institutional roster, and the Program Director will assist applicants in contacting mentors. Applicants will be encouraged to discuss opportunities with the Program Director, and will be directed to contact potential mentors prior to developing their application for an award. This mentor roster is used to assist the Program Director and is in no way restrictive — applicants may identify outstanding mentors who are not already on the PCCSDP roster. To date, the majority of Scholars have identified mentors prior to contacting the Program Director.

The PCCSDP will actively recruit skilled, outstanding mentors to be added to this roster, with evaluation and consideration by the National Advisory Committee. We strongly encourage applicants to explore opportunities that are outside their fellowship institutions to gain more diversity with respect to research and clinical aspects of critical care. This grant can enable applicants to secure unusual training and then return to their sponsoring institution.

The criteria for selection of mentors are 1) a record of outstanding scientific accomplishment; 2) a strong record of extramural funding, preferably from NIH; 3) scientific expertise and interests related to pediatric critical care; and 4) demonstrated excellence in mentoring trainees. These criteria are used when adding mentors to the PCCSDP roster, and are applied during peer review of PCCSDP applications. During review of applications, the selection committee will examine the record of the mentor's previous trainees, especially subsequent academic positions, publications, and grant awards. PCCSDP Scholars will provide an annual evaluation of their mentor to the Program Director and National Advisory Committee members.

3.2 Program Mentorship for PCCSDP Scholars

The program will provide external mentorship to PCCSDP Scholars, but this is not intended to intrude on the Scholar's relationship with his or her selected mentor. Obviously, each Scholar will be provided mentorship at their training institution, especially from the research mentor with whom they pursue their scientific training. The PCCSDP will provide external

"suprainstitutional" mentorship by enabling the Scholar to interact closely with the National Advisory Committee members, by having Committee members discuss academic development with each Scholar at the annual PCCSDP retreat (and more frequently via their personal contacts), and by providing site visits from the PCCSDP to the training institution (either by the Program Director or a designated member of the National Advisory Committee). PCCSDP Scholars are expected to seek extramural funding no later than between 15 and 18 months into training, and Committee members will provide an external peer review to these proposals as they are prepared for submission to funding agencies (if desired by the Scholar).

The Committee also provides valuable contact during the application process. Applicants attend the annual PCCSDP retreat, where they are interviewed by members of the Committee, and participate in the scientific portion of the meeting. This provides contact with Committee members, even for applicants who are not funded as Scholars, providing added richness to the value of applying to this program. All applicants are expected to discuss their career development with Committee members, and even unsuccessful applicants derive constructive feedback and benefit from this process.

3.3 Local Institutional Training Activities

The local institution provides the resources and academic protection necessary to achieve the training goals of the Scholar. The peer review selection process is designed to assure that each Scholar will be placed in an outstanding research setting with an experienced mentor, and the annual site visit by the PCCSDP Program Director will help guarantee that the Scholar receives suitable protection and resources from the training institution.

Local training responsibilities include on-going refinement of the Scholar's long-term development plans, assistance with preparing grant applications so that the Scholar can phase into independent investigator status, opportunities to present research in laboratory research meetings, Departmental conferences, and so forth. Journal clubs, didactic training such as might occur in a K30 program, and other educational activities are a local institutional responsibility. These activities will have been described in the Scholar's original application, and the quality of these activities is one of the criteria for selecting an individual for funding.

Each Scholar must receive training in the responsible conduct of research. Scholars should actively participate in the process of obtaining approval from applicable committees, such as the Institutional Review Board (IRB)

or Institutional Animal Care and Use Committee. For Scholars involved in clinical research, the institution should also provide training in Good Clinical Practice (GCP), regulations of the Food and Drug Administration (FDA), and international harmonization efforts.

4 Review Criteria for Scholar Selection

The Committee will evaluate the candidate, the mentor, the institutional environment, and the research plan. 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 injury. The candidate must make a five-year commitment to the training plan. The training plan proposed by the candidate must include appropriate didactic material, training in the responsible conduct of research, and should take advantage of existing programs such as K30 training programs. Letters of recommendation must support the exceptional caliber of the candidate. The *mentor*, even if already included on the PCCSDP roster, must describe the mentoring plan in detail. This includes the mentor's time commitment, and the relationship of the mentor's plan with the academic goals of the trainee. The mentor statement should also describe the laboratory facilities, and provide evidence of expertise in training junior faculty in the research setting. This evidence may include a tabular presentation of previous trainees (date of training, current academic position, grants awarded, publications). Such tables will be excluded from the page limitation on this section of the application. The *institutional environment* must be suitable for a PCCSDP Scholar. Most importantly, there must be institutional commitment to the Scholar, particularly with respect to protection of the Scholar from non-training responsibilities such as teaching, administration, and clinical care. Provision of 75% protection throughout the five years of training is highly encouraged. Opportunity for faculty employment and academic advancement within the institution must be demonstrated. Finally, 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 applicant is expected to write the research plan, but should have discussed the research idea with the mentor proposed in the application. 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 informally with the Committee during the interview.

5 Application Procedure and Contact Information

5.1 Eligibility

PCCSDP Scholars should normally be within five years of completion of fellowship training in pediatric critical care. Interested applicants who completed fellowship training more than five years prior to entering the PCCSDP should contact the Program Director to discuss eligibility before submitting an application.

Individuals who have previously received an NIH K08, K23, or R-type award are not eligible for support under this program. In addition, individuals who are already funded on a faculty K12 program at their institution will *not be considered* for funding under this program.

The NIH language states: "Candidates must be U.S. citizens or noncitizen nationals, or must have been lawfully admitted for permanent residence and possess an Alien Registration Receipt Card (I-151 or I-551) or some other verification of legal admission as a permanent resident. Noncitizen nationals, although not U.S. citizens, owe permanent allegiance to the U.S. They are usually born in lands that are not states but are under U.S. sovereignty, jurisdiction, or administration. Individuals on temporary or student visas are not eligible."

If you have any question about eligibility, please contact the Program Director before submitting an application (or giving up!)

5.2 Structure of the Application

The application to become a PCCSDP Scholar is similar in organization to training award applications such as NIH K08 or K23 applications. Please use the relevant NIH application forms. These applications are used internally by the program, but instructions differ slightly, as follows:

Form Page 1 does not need to be filled out except for the project title and relevant contact information. This form is only used for our internal information purposes. It is not sent to the NIH.

Form Pages 4 and 5 should be filled out. This is contrary to the usual NIH instructions for K awards. The reason for this requirement is to expedite

preparation of a funding subcontract with your institution, in the event your project is funded.

If you are submitting a revised application after having applied to PCCSDP in a previous year, please provide "Additional Information for Revised Applications" as indicated in the NIH instructions.

The page limits for this application are the same as a normal K award. Please note, as in the PHS 398 instructions, the total length of the application may not exceed 25 pages (Item 1, and A-D of Item 4).

The application must include three letters of recommendation (submitted in sealed envelopes), including a letter of commitment by the candidate's Department Chair. The Chair at the mentoring institution must guarantee 75% protection from clinical and administrative duties during Phase I. The Chair at the sponsoring institution must indicate a plan to employ the Scholar with at least 50% (preferably 75%) protection for continued career development during Phase II. In some instances, these institutions will be the same. In this case, the letter from the Chair must guarantee relevant protection for the entire five year program. Here are three examples:

- Applicant is at institution A and will go to institution B for Phase I, with plan to return to institution A for Phase II; intention of faculty appointment and on-going protection from clinical and administrative duties, for a total duration of five years in the PCCSDP, by Chair A required. Endorsement by Chair B must include 75% protection, but does not need to express employment commitment beyond Phase I training period.

- Applicant is at institution A and will pursue Phase I and Phase II training at institution A; commitment for five years for Phase I and Phase II by Chair A required.

- Applicant is at institution A and will go to institution B to pursue Phase I training and will remain at institution B for Phase II; commitment for five years for Phase I and Phase II by Chair B required. Endorsement by Chair A optional.

5.3 Electronic and Hardcopy Application Submission Deadline

The complete hardcopy application, including all forms, letters, narrative, and appendix materials, must be mailed to Dr. Dean and postmarked by October 1, 2008. The narrative materials, including a title and abstract,

must be sent electronically to Dr. Dean at *mike.dean@hsc.utah.edu* with the subject heading "PCCSDP Application" - this subject heading will assure that your application is not lost in a spam filter and is forwarded promptly to Dr. Dean. The electronic version must be received by midnight on October 1, 2008. It is permissible to send the entire grant electronically to Dr. Dean (not just the narrative materials), but physical letters must be received (postmarked by October 1). The electronic materials should be sent as PDF documents.

5.4 Program Director Contact Information

For inquiries about the program, please contact the Program Director at *mike.dean@hsc.utah.edu*. Mentors, program directors, or department chairpersons should indicate "PCCSDP Inquiry" as the subject of the email. Applicants should use the same email address but indicate "PCCSDP Applicant" as the subject of the email. These email subject headings will avoid spam filters and facilitate a rapid response from the Program Director.

6 National Advisory Committee Membership

The National Advisory Committee membership has been selected from established leaders in pediatrics and pediatric critical care and consists of the following individuals in addition to the Program Director:

- Jeffrey Blumer, Ph.D., M.D. Case Western Reserve
- Jeffrey Fineman, M.D. University of California, San Francisco
- Thomas Green, M.D. Northwestern University Medical School
- Jacques Lacroix, M.D. University of Montreal
- Patrick Kochanek, M.D. University of Pittsburgh
- George Lister, M.D. University of Texas, Southwestern Medical School
- M. Michele Mariscalco, M.D. Baylor College of Medicine
- Daniel Notterman, M.D. Princeton University
- Jeffrey Burns, M.D., Society of Critical Care Medicine
- Mary Leih-Lai, M.D., American Academy of Pediatrics

- Carol Nicholson, M.D., Eunice Kennedy Shriver National Institute of Child Health and Development

7 Program Evaluation

The major criteria for success of the PCCSDP include the retention of PCCSDP Scholars in academic positions, outstanding scientific productivity of these new scientists over subsequent years, and the ability of the Scholars to obtain and sustain extramural grant support of their research. These are relatively long-term measurements of performance. Short-term measures of success of the PCCSDP will include presentations at scientific meetings and peer- reviewed publications by PCCSDP Scholars during their training, completion of didactic courses delineated in Scholar training plans, documentation of required training in human subjects protection and research ethics, documentation of academic protection of the Scholars during Phases I and II, and most importantly, submission and funding of K-level or R-level NIH grants. In addition, annual progress reports will be obtained from each Scholar and each mentor. The PCCSDP will obtain follow up information from all Scholars for at least five years after graduation from the program. Scholars must agree prospectively to provide this information to assist with program evaluation.

Applications should be mailed to
J. Michael Dean, M.D., M.B.A.
c/o Sharon Marron (801-587-7572)
Division of Critical Care
Department of Pediatrics
295 Chipeta Way
Salt Lake City, Utah 84158-1220

Deadline: October 1, 2008

Electronic materials should be sent to
mike.dean@hsc.utah.edu