

SIU School of Medicine Clinician-Scientist Program

October 8, 2006

Key dates for FY08 funding:

November 20, 2006	Proposal submission for preliminary review
February 19, 2007	Submission of revised and/or final proposal
April 15, 2007	Approximate date of funding decision
July 1, 2007	Funds become available to initiate award

Introductory comments:

1. The involvement of clinicians in research as an effective method for enhancing research at SIUSM. The Clinician-Scientist Program (CSP) is an approach to facilitating this involvement. However, a key issue in the success of this initiative is whether the clinician-scientist will truly have access to promised protected time for research. Currently, this assurance resides with the department chair or division chief. The assurance of protected time is a key component of program guidelines.
2. Although using CSP funds for salary support may be necessary to ensure protected time (especially in those departments with insufficient resources for providing all of the required salary support), the use of funds for this purpose may prevent the investment of adequate funding for the collection of pilot data. Because the goal is to support the awardee in obtaining extra-mural funding, allocating the budget primarily for research support will enhance program and awardee success for the following reasons: (1) the increased amount of research money allows the awardee to hire a technical staff (postdoctoral fellow, nurse, trained technician) to collect quality preliminary data, (2) the mentor with whom the applicant collaborates can help to train and supervise the technical staff and to maintain continuous research activity even if the clinician can commit only a part of his/her time to research, and (3) the annual progress can be primarily evaluated based on scientific merit, which is more relevant to NIH review criteria, rather than on more subjective factors (e.g., how much of their "protected time" clinician scientists are actually able to use, and how supportive their clinical chairs are).
3. Using the NIH Mentored Clinical Scientist Development Award (K08) (e.g., PA-00-003; <http://grants.nih.gov/grants/guide/pa-files/PA-00-003.html>) as a guide, the RPC subcommittee designed recommendations for the CSP to achieve the following objectives:
 - Select a candidate with significant motivation and potential for successfully obtaining extramural funding.
 - Ensure an appropriate environment (e.g., mentoring, departmental support, facilities, protected time, etc.) to facilitate the success of the candidate selected.
 - Create accountability to ensure benefit from the money invested by making funding after the first year contingent on meeting specific requirements or benchmarks.
4. CSP money that is used to buy protected research time must compensate for lost clinical time and cannot be used to enhance the scientist's overall income. The program will therefore require accounting of clinical RVUs. If the funding used to support the investigator salary exceeds the amount of lost clinical income as determined by lost RVUs, then the CSP will only compensate for the actual loss in clinical income. Money that is budgeted for the protected time but is not used (as reflected in RVUs) will be returned to ADRFA.
5. With regard to protected time for research, 75% effort is required for a K award. However, the subcommittee viewed a 30-60% commitment as more realistic in the current clinical culture at SIUSM. The amount of protected time requested for a CSP award can therefore vary, with justification and explanation, between 30% and 75% effort.

6. In this plan, the subcommittee focused initially on the eligibility criteria and application process. However, funding will not be awarded if none of the proposals are adequately meritorious. A sufficient score will be defined according to traditional CRC scoring (i.e., in general, proposals that score higher than 2 are not viewed as competitive). The ADRFA may request that the chair of the CSP Selection committee also serve on the CRC Allocation committee to guide final funding decisions.
7. Preliminary review of proposals with reviewer comments provided back to the applicants, is encouraged (e.g., submit November 15, receive preliminary review in time to revise and resubmit by February 15, decision made by April 15, and funds available July 1). However, these dates are subject to change based on the final approval date and distribution of the Call for Applications for the CSP and on negotiation with the applicant.
9. Program oversight will reside in two committees: the Selection committee and the Mentoring committee, as follows:

Selection Committee

- The Selection committee will review preliminary applications, review and score final applications, monitor progress based on the reports provided by the Mentoring committee (to include fulfillment of the departmental guaranteed time commitment, availability of resources and support, successful mentoring, and scientific merit reviews provided by CRC).
- The Selection committee will make a recommendation regarding renewal of funded proposals based on the scientific merits provided by CRC and/or NIH, and, if necessary, the annual mentoring evaluation report.
- The Selection committee will provide feedback comments to the Mentoring Committee.
- The Selection Committee will be selected by the Associate Dean for Research as a subcommittee of CRC and/or RPC members. The committee will include the CRC chair, 2 extramurally funded basic scientists and 3 extramurally funded clinician-scientists. "Extramurally funded" is defined as a faculty member who currently or has previously been PI on an NIH funded proposal.
- No committee member should be a potential applicant.
- The Selection Committee may arrange an outside reviewer if necessary.

Mentoring Committee

- This committee includes a primary mentor (and, if necessary or useful, a secondary mentor on-site and/or off-site), and either the department chairman or division chief.
- The primary mentor should have a strong track record of research and NIH funding.
- Utilizing mentors with adequate external funding to ensure the availability of resources and support for the awardee for the next 2 – 3 years is preferred and will be viewed as a strength by the Selection Committee.
- The Mentoring committee will meet every six months, and provide a written summary of progress and recommendations to the awardee and to all members of the Mentoring Committee. These written summaries must also be included with applications for renewal.
- The mentoring committee reports must contain an assessment of whether benchmarks are being met, a statement regarding whether the awardee's research activities are adequately supported in terms of both time and resources, and suggestions or recommendations made by the members.
- The Mentoring committee will be proposed by the candidate and approved by the Selection committee.

Clinical Scientist Program Objective:

- To identify and support the development of outstanding clinician research scientists with significant potential for obtaining funding from NIH.

Clinical Scientist Program Eligibility requirements:

- SIU School of Medicine faculty member (instructors and/or fellows will not be eligible) who has an appointment in a clinical department
- Clinical doctoral degree or its equivalent (e.g., M.D., D.O, etc.)
- Able to spend no less than 30-60% of full-time effort for research for three years (although at least 75% is optimal to reflect requirements of K awards).
- The host department chairman and division chief must guarantee no less than 30% protected time (75% is optimal) for research. How an appropriate reduction in clinical and educational responsibilities will be achieved and how resources (e.g., research space, staff support) will be provided must be explained in the application. Funding will not be approved unless adequate departmental support (time and facilities) is assured to the satisfaction of the Selection Committee and salary support is maintained at a reasonable level.
- No significant budgetary overlap with other extramural salary support.
- Current and/or former principal investigators for an NIH R01 are not eligible.
- Former principal investigators for an NIH R03 or R21 remain eligible.

Clinical Scientist Program Application Process:

The CSP awards will be given for a period of one year (July 1 to June 30). Awards can be extended for an additional two years based on competitive renewal approval.

The application should follow the format of an NIH K08 award. The application should provide the following:

- Abstract summarizing the proposal
- Statement of applicant's career goals (1-2 pages) which should describe long term research goals and how the CSP will meet these goals and lead to extramural funding.
- Applicant's CV (limit to 4 pages).
- Justification of mentoring needs and mentors chosen.
- Statement of detailed mentoring plan that includes the contributions of all the mentors. The plan should explain (1) the role of the mentor in the proposed research plan, (2) role of the mentor in the applicant's career development, (3) overlap with mentor's research, and (4) estimate of a time line for an NIH grant submission.
- NIH-style biographical sketches for all mentors.
- A research proposal (five page limit) to include the following: specific aims, background/significance, preliminary data (if available, but not necessary), research plan, detailed methods, etc. (follow CRC/NIH format).
- Letters of support from Department Chair and Division Chief of the applicant indicating adequate salary support, facilities/space, and guaranteed protected time. Specifically, the letters of support should clearly outline how the candidate will achieve 30 to 60% protected time with the CSP support. For example, will the department/division cover additional salary support, or will the candidate accept lower reimbursement to achieve protected time? The letters should also include other department support available to the candidate.
- Letters of support from primary and secondary mentors.
- Letters of support from the Mentor's Department Chair agreeing to the use of the facilities/space in support of the application.

The application should provide a one-year budget with appropriate justification. The total budget cannot exceed \$80,000. The budget should include candidate salary, research expenditures, and the mentoring budget, as follows:

- Candidate salary. Departmental salary support for the candidate should be explained, with a clear and detailed plan for allocation of time and salary in the budget justification. If candidate salary accounts for more than \$40,000 in the total budget, justification of need is required.
- Research costs (e.g., laboratory supplies, research personnel, patient recruitment costs, etc.)
- Mentoring costs (exclusively for off-site mentor's travel expenditure and consulting fees).
- Training costs (e.g., course work).
- Travel expenditure (e.g., meeting attendance, course attendance).

Annual benchmarks:

The Clinician-Scientist Program awards will be given for a period of one year, and can be extended for an additional two years based on competitive review for scientific merit and Selection Committee recommendation. Successful renewal will require meeting the following benchmarks. However, achieving these benchmarks does not assure continued funding, as the most meritorious CSP applications for that cycle will have priority for funding.

Minimal criteria for competitive renewal for year 2:

- The Selection Committee will make the final recommendation regarding continued funding with input from the CRC (see next bullet).
- The applicant must submit a research proposal with preliminary data and, if available, an NIH critique to CRC in February according to standard CRC processes, but without a budget. This proposal should be identified as a CSP application. The CRC will review the application for scientific merit only. For a successful CSP renewal, the research proposal submitted to the CRC must receive a fundable score (usually lower than 2).
- To support the application, the following materials should be submitted to the Selection Committee no later than April 1.
 - A detailed plan for an NIH submission with time line. This proposal could be an NIH mentored award (K series), R03, R21, etc.
 - A two page progress report prepared by the Mentoring committee on the scientist's progress and problems. For example, inadequate departmental support (time and facility) will be grounds for not approving renewal of the CSP support.
 - A complete budget and justification, including the mentoring budget, for year 2. This budget will include research project costs (see preceding section) and will be reviewed by the CSP Selection committee rather than CRC).
 - Critiques and scores from the CRC.
- The Selection committee will use the CRC scientific merit score as part of the overall review, which will also include a review of the mentoring activities, adequacy of release time, progress report, budget, and overall feasibility of the plan.
- To allow for accountability between CRC and CSP, ADRFA may request that the chair of the CSP Selection committee be a member of the CRC Allocation committee to advise in final funding decision.

Competitive renewal for the year 3:

- The final recommendation regarding continued funding will be made by the Selection committee with input from the CRC.
- At least one manuscript must have been submitted based on data collected with CSP support since beginning the program in year one.
- The applicant must submit the NIH score and critiques for a proposal submitted to NIH for the previous June or October deadlines. (If the NIH submission did not receive a score, the committee may require additional documentation supporting sufficient likelihood of future funding to justify the third year of funding.)

- The applicant must submit a research proposal with preliminary data and the NIH review to CRC in February according to standard CRC processes, but without a budget. This proposal should be identified as a CSP application. The CRC will review for scientific merit only. For a successful CSP renewal, the research proposal submitted to the CRC must receive a fundable score (usually less than 2).
- The following materials should be submitted to the Selection committee no later than April 1.
 - A detailed plan for an NIH submission with time line. This proposal could be an NIH mentored award (K series), R03, R21, etc.
 - A two-page progress report prepared by the Mentoring committee on the scientist's progress and problems. For example, inadequate departmental support (time and facility) will be grounds for not approving renewal of the CSP support.
 - CSP budget and justification for year 3.
 - Critiques and scores from the CRC.
 - A copy of at least one manuscript submitted based on pilot data collected with CSP support.
- The Selection committee will use the CRC scientific merit score as part of the overall review, which will also include a review of the mentoring activities, adequacy of release time, progress report, budget, and overall feasibility of the plan.
- To allow for accountability between CRC and CSP, ADRFA may request that the chair of the CSP Selection committee be a member of the CRC Allocation committee to advise in final funding decision.

Final report:

The awardee will be required to submit a final report that will include a summary of the research progress, a statement of achievement of career goals, and copies of manuscripts of applications for external funding submitted during period of CSP support. The final report should be submitted to the Selection Committee and ADRFA under the signatures of the clinician-scientist and the Mentoring Committee.

Ongoing review of Clinical Scientist Program

The Clinical Scientist Program will be initially implemented as a pilot program. One award will be given during the first year, with possibility of a second based in part on assessment of scientific merit by the CRC. Program operation and success will be closely monitored by the Selection Committee and the RPC. The RPC will re-evaluate the success of the CSP (see below) 2-3 years after its inception. At that time, the CSP may then be modified or canceled depending on the improvement of the research environment in the clinical departments, changes in recruitment policy towards hiring research-oriented clinical faculty, and the outcome of the CSP.

A successful program is defined as one that produces NIH funded clinician researchers, resulting in an increase in indirect funds available to SIUSM comparable to money spent to support the program. The success of the CSP will be monitored by the Associate Dean for Research. Based on this assessment, the ADRFA may request that the RPC subcommittee review guidelines, policies, and requirements at that time. In addition, the subcommittee may elect to reconvene annually to revise guidelines, policies and requirements. Continuation of the CSP will be based on documented success of the program, as defined above.

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