

Mentored Clinical/Translational Research Award Program (CTSI Sponsored K12)

The Clinical and Translational Science Institute, is pleased to announce an open competition for a “*Mentored Clinical/Translational Research Award*”. The overall goal of this K12 award is to provide training opportunities for junior faculty working in clinical/translational research to become independent investigators. The specific objectives are to:

- a. Encourage research-oriented junior faculty to develop research skills and gain experience in advanced methods and experimental approaches needed to become independent investigators conducting clinical/translational research; and
- b. Support the career development of junior faculty who have made a commitment to focus on clinical/translational research.

The proposed program will focus on junior faculty with strong potential for careers in clinical-translational (CT) research. The home institution of the successful applicant will provide 75% protected time and \$25,000 in research expenses per year for up to three years of supervised career development activities and mentored clinical-translational research. Applicants must justify the need for a period of mentored research experience and provide a convincing case that the proposed period of support and career development plan will substantially enhance their careers as independent investigators in CT research.

The supervised activities for the K12 scholar are designed around core themes and each clinical-translational research (CTR) scholar will work closely with a mentoring team to apply core curricular themes to his/her own research and career, making each scholar's research the major vehicle for learning. Curriculum design for each trainee is a joint undertaking involving the trainee, his/her mentors, and the K12 program director. The individually tailored curriculum will be based on an assessment of the unique needs and the articulated learning goals and objectives of the scholar, and a performance and evaluation plan for the scholar.

The curriculum is broad in scope, both in terms of opportunities available and length of training. It will involve coursework, including a leadership training course, structured interactions with the Translational Research Units and with the leadership of MCW's multidisciplinary centers, and the opportunity to participate in a multidisciplinary research project under the guidance of a mentor. Each K12 scholar will select existing MCW and partnering institutional resources in order to create a training program, tailored to individual training needs. The expectation is that the K12 curriculum will provide each scholar with sufficient background and experience to lead a multidisciplinary research team.

The scholars will participate on multidisciplinary research teams with their mentors, but should be ready relatively early in their K12 training programs to focus on their mentored research projects and the development of a major grant proposal. During the training period, CTR scholars have opportunities to attend national meetings and to participate on institutional research-related committees, including the IRB, Translational Research Units (TRU, formerly the GCRC) Scientific Review Committee and the Medical College Research Committee.

Specific Requirements

The candidate and mentor are jointly responsible for the preparation of the plan for the career development program in clinical-translational research. Key elements for the award, in addition to information about the applicant candidate, include:

Environment: The candidate and mentor must describe a career development program with an emphasis on clinical-translational research that maximizes the use of relevant research, and educational resources, and qualified faculty as mentors in CT research.

Career Development Program: The award provides support for up to three years, with 75% of the recipient's full-time professional effort devoted to the program. The remainder of the applicant's time should be devoted to other research-related and/or teaching pursuits consistent with the objectives of the award. The candidate is expected to develop knowledge, skills and expertise in CT research relevant to her/his career goals. The candidate should include didactic, laboratory, interdisciplinary and field experiences in their career development plan as needed.

Mentor(s): The candidate must name a primary sponsor/mentor, who, together with the applicant is responsible for the planning, direction, and execution of the program. The mentor should be recognized as an accomplished investigator in the proposed research area and have a track record of success in training independent investigators in CT research. The mentor should have sufficient independent research support to cover the costs of the proposed research project in excess of the allowable costs of this award. Candidates may also nominate co-mentors as appropriate to the goals of the program.

Research Development Support: The research development support costs allowed for this program, up to \$25,000 must be carefully justified annually and must be consistent with the stage of development of the candidate and the proportion of time to be spent in research or career development activities. Salary for ancillary personnel support such as mentors, secretarial and administrative assistants is not allowed.

APPLICATION: The application form pages may be obtained by contacting Sara Goetz, CTSI Administrative Coordinator at sgoetz@mcw.edu or 955-2537. The application is due on July 1st and must address the outlined areas. There is a 15-page limit when addressing the Candidate, Career Development Plan, Training in Responsible Conduct of Research, and Research Plan (see the Table of Contents form page).

I. Candidate

Describe the candidate's commitment to an academic career in CT research. Include a description of all of the candidate's professional responsibilities in the institution and elsewhere and show their relation to the proposed activities on the career development award.

- Discuss prior training and how it relates to the objectives and long-term career plans of the candidate.
- Discuss the candidate's research efforts to this point in his/her research career, including any publications, prior research interests and experience.

- Provide evidence of the candidate's potential to develop into an independent investigator.
- Include a statement that the candidate will commit 75% effort to the CT program and related career development activities.
- The department chair and dean must agree and provide a statement in the application documenting that this 75% percent of time will be protected.
- Letters of reference. Three sealed letters of reference addressing the candidate's potential for a research career in patient-oriented research must be included as part of the application. The letters must be from references other than the designated mentor(s).

II. Career Development Plan

The candidate and the mentor are jointly responsible for the preparation of the career development plan. A timeline is often helpful. The sponsor/mentor may form an advisory committee to assist with the development of the program of study or to monitor the candidate's progress through the career development program.

- Describe a systematic plan: (1) that shows a logical progression from prior research and training experiences to the training and research experiences that will occur during the K12 award period and then to independent investigator status; (2) that justifies the need for further career development to become an independent investigator; and (3) that utilizes the relevant research and educational resources of the institution.
- Describe a training and research plan that is tailored to the individual career development needs and goals of the candidate. The candidate must demonstrate that he/she has received training or will participate in courses such as: data management, epidemiology, study design, hypothesis development, drug development, etc., as well as the legal and ethical issues associated with research on human subjects.
- Describe the professional responsibilities/activities including other research projects) beyond the required 75% effort commitment to the K12 award. Explain how these responsibilities/activities will help ensure career progression to achieve independence as an investigator conducting patient-oriented research.

III. Training in the Responsible Conduct of Research

Applications must include a description of a program to receive formal or informal instruction in scientific integrity or the responsible conduct of research. Applications without plans for instruction in the responsible conduct of research will be considered incomplete. Candidates should consider instruction in the following areas: conflict of interest, responsible authorship, policies for handling misconduct, policies regarding the use of human and animal subjects, and data management. Document prior instruction in, and propose plans to receive, instruction in the responsible conduct of research in terms of subject matter and duration of instruction.

IV. Statement(s) By Mentor(s)/Consultant(s)/Collaborator(s)

- The candidate must name a primary sponsor (or mentor), who, together with the applicant, is responsible for the planning, direction, and execution of the

- The mentor should be recognized as an accomplished investigator in the proposed research area and have a track record of success in training independent investigators.
- The mentor should have sufficient independent research funding to support the proposed research project in excess of the allowable costs of this award.
- The application must include a statement from the mentor(s) providing: 1) information on their research qualifications and previous experience as a research supervisor; 2) a mentoring plan describing the nature of the supervision and mentoring that will occur during the proposed award period and 3) a plan for transitioning the candidate from the mentored phase of their careers to the independent investigator phase during the project period of the award.
- The mentor must agree to provide annual evaluations of the candidate's progress for the duration of the award.
- Similar information must be provided by any co-mentor. If more than one mentor is proposed, the respective areas of expertise and responsibility of each should be described. Co-mentors should clearly describe how they will coordinate the mentoring of the candidate.

Consultant(s)/Collaborator(s): Signed statements must be provided by each consultant/collaborator confirming their participation in the project and describing their specific roles. Collaborators and consultants generally do not need to provide their biographical sketches. However, information should be provided that clearly documents expertise in the proposed area(s) of consulting/collaboration.

V. Environment and Institutional Commitment to the Candidate Candidates who will use the resources within the Translational Research Units (formerly GCRC) during the course of their award should include a letter of agreement from either the TRU program director or the principal investigator as part of the application.

VI. Research Plan

A sound research project that is consistent with the candidate's level of research development and objectives of his/her career development plan must be provided.

The research plan should be organized under the following sections: Specific Aims, Background and Significance, Progress Report/Preliminary Studies, and Research Design and Methods. The candidate should consult with mentor(s) regarding the development of this section.

Studies that involve clinical trials (biomedical and behavioral intervention studies) must include a description of the plan for data and safety monitoring of the research and adverse event reporting to ensure the safety of subjects.

VII. Letters of Reference

Include with the application three sealed letters of reference from well-established scientists addressing the above areas and any other evidence that the candidate has a high potential for becoming an independent investigator in patient-oriented research.

The mentor(s) may also submit letters of reference, but these letters will be considered independently of the three recommendations. All sealed letters of reference should be attached to the face page of the application.

VIII. Budget for the Entire Proposed Period of Support

Within the direct costs limitation for research development support, provide a detailed description with justification for all equipment, supplies and personnel that will be used to help achieve the career development and research objectives of this award.

Submission Process

The application form pages may be obtained by contacting Sara Goetz, CTSI Administrative Coordinator at sgoetz@mcw.edu or 955-2537. CTSI will provide assistance with the organizing and writing of the proposal, upon request. The font used in the application should be no smaller than 11 pt. and the margins should be at least .5" around. Please submit the application to Sara Goetz, Clinical and Translational Science Institute, Mail Stop: MEB, TBRC-CTSI, Medical College of Wisconsin, 8701 Watertown Plank Road, Milwaukee, WI 53226.