

MEDICAL UNIVERSITY OF SOUTH CAROLINA'S

MENTORED CLINICAL SCIENTISTS PROGRAM IN DRUG ABUSE AND ADDICTION FACULTY CAREER DEVELOPMENT NIDA K12 PROGRAM

Principal Investigator: Kathleen T. Brady, MD, PhD Directors: Sudie E. Back, PhD and Robert Malcolm, MD

Program Coordinator: Wendy Muzzy, MRA, MLIS (muzzy@musc.edu)

KEY DATES

Call for Applications:

K12 Applications Due:

Notification of Awards:

Appointment Start Date:

November 3, 2014

March 2, 2015

May 15, 2015

July 1, 2015

KEY INFORMATION

Number of Openings: 1-2
Term: 2-3 years
Effort Requirement: 75% minimum
Type of Research Supported: Clinical Research
Amount of Non-Salary Research Support: \$25,000/year

OVERVIEW

The K12 Career Development Program at the Medical University of South Carolina will support the research career development of junior faculty members who have recently completed clinical training or postdoctoral fellowships, and who have mentorship and a solid plan for training in clinical research relevant to drug abuse and addiction. The K12 Career Development Program at MUSC is funded by the National Institute on Drug Abuse (NIDA).

Scholars will be selected for a career development award to begin **JULY 1, 2015**. Applicants must be on faculty or eligible to join the faculty by this date. Scholars will receive 2-3 years of salary support commensurate with 75% effort per year (see Salary & Time Commitment under "Eligibility") to pursue clinical research.

The program includes a supportive environment, start-up research funds, and access to core faculty who provide expertise and guidance in research design, measurement techniques, study coordination, data management, biostatistical analysis, research dissemination, and grant writing. Applicants should develop a training and research plan in consultation with an eligible mentor (faculty with NIDA research funding and expertise in drug abuse and addiction) and apply according to the instructions outlined below.

ELIGIBILITY

Junior faculty and senior fellows/post-doctoral trainees pending faculty appointment with a doctorate and less than 5 years of research training who are committed to a career in clinical research in drug abuse and addiction. Scholars are scientists with doctoral-level professional degrees who represent a broad range of disciplines, professions, specialties and subspecialties, and who can develop into future leaders of clinical research. Examples include MD, PhD, DO, DDS, DMD, and PharmD. All candidates with clinical doctorates are expected to have completed the specific requirements leading to clinical certification.

<u>Salary & Time Commitment.</u> A minimum of 75% of a Scholar's full-time professional effort (up to \$90,000 per year depending on rank and experience) must be devoted to the program for the training and research activities. The remaining 25% effort can be divided among other research, clinical and teaching activities if these activities are consistent with the proposed goals of the K12 program.

<u>Citizenship.</u> Candidates must be U.S. citizens or non-citizen nationals, or 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. Individuals on temporary or student visas are not eligible for this program.

<u>Prior research experience.</u> At the time support begins, Scholars *may not have served as the principal investigator* (PI) or equivalent on an NIH research project (RO1) or as PI of mentored career development (K-series) grant. Candidates *may not have served as the PI* on an NIH research project grant or equivalent non-PHS peer-reviewed research grant over \$100,000 direct costs per year. Scholars may not hold any other PHS award that duplicates the provisions of this career award. During the period of this award, Scholars are encouraged to apply for, and may accept and hold, independent research grant support.

SCHOLAR SELECTION CRITERIA

The following criteria will be used by the K12 Steering Committee to evaluate applications from Scholar candidates. Top candidates will be interviewed in person.

- Candidate must show evidence of interest in and commitment to clinical research in drug abuse and addiction.
- Candidate must clearly describe short- and long-term career goals. These will help identify applicants whose career goals are in accord with the objectives of the K12 program.
- Applicants must be able to define a specific research question or set of questions to be addressed during the program (see Application Instructions). The significance of the topic, its likelihood of receiving grant support, and the applicant's strength of commitment to the topic will be evaluated. The topic must be consistent with program objectives, specifically including a focus on drug abuse. A Scholar's work during the program should lead to an extended body of research on the chosen topic.
- Applicants as Scholars must devote a minimum of 75% of full-time professional effort (9 person months) to the NIDA K12 Program.
- The mentor's expertise, accessibility, mentorship track record, resources and enthusiasm for the applicant will be taken into account. The primary mentor needs to be a NIDA-funded investigator. In certain situations, Scholars may elect to have a co-mentor who is not a NIDA-funded investigator serve on the mentorship team.

PROGRAM REQUIREMENTS

- 1. **Duration of the Award.** Scholars will receive 2-3 years of salary support at a minimum of 75% effort per year. Each year of funding is contingent on satisfactory participation in K12 activities and progress toward the Scholar's individual career goals, and continued support from the Scholar's mentor and department.
- 2. Career Development Plan. At the time of program entry, a needs assessment will be conducted to develop an individualized program that meets the needs of each Scholar and satisfies the general goals and objectives of the program. While each K12 Scholar will have an individually-tailored career development plan, all will participate in a unified core curriculum designed to address the following six objectives: (1) Increase addiction knowledge base; (2) Provide fundamental clinical research skills; (3) Enhance statistical skills; (4) Enhance research presentation skills; (5) Improve scientific writing skills; and (6) Provide professional development opportunities. Scholars are required to write and submit an NIH-level grant proposal by the second year of K12 support.
- 3. Mentors. Each Scholar appointed to the K12 program must have a primary mentor. All proposed mentors must be: 1) accomplished investigators in the area of drug abuse and addiction, 2) actively involved in federally-funded drug abuse related clinical research, and 3) have a successful record of engendering his or her Scholars' independence as evidenced by Scholars' research productivity and ability to obtain independent research funding. Proposed mentors must have independent NIDA research funding (e.g. R01, P50) or equivalent at the time of the K12 award and be committed to mentoring the Scholar throughout their total period of development under the award. In addition, a primary mentor must be familiar with faculty and resources at MUSC, and have the necessary resources and research staff to support the Scholars' training and research. Mentors will also help to assure that 75% of the Scholar's total work week is protected from clinical and administrative duties, and fully available for the K12 training plan and research activities.

APPLICATION

Completed applications must be submitted online by **5:00 PM on March 2, 2015**, adhering to the instructions provided. Please submit your application at https://redcap.musc.edu/surveys/?s=vrYebjigBH

NIDA K12 PROGRAM APPLICATION INSTRUCTIONS

1) CANDIDATE'S NIH BIOSKETCH

Refer to phs398 instructions located at http://grants2.nih.gov/grants/funding/phs398/phs398.html

2) MENTOR'S NIH BIOSKETCH

Refer to phs398 instructions located at http://grants2.nih.gov/grants/funding/phs398/phs398.html

3) MENTOR STATEMENT AND TRAINEE TABLE

The candidate's primary mentor must complete a Mentor's Statement and Trainee Table. Mentor should be specific about resource commitment to the Scholar's research. If additional mentors or consultants are involved, a letter of support and NIH biosketch must be included from each additional mentor.

4) DEPARTMENT/DIVISION CHAIR STATEMENT

The candidate's Department/Division Chair must provide a statement indicating support of the proposed research.

5) CANDIDATE'S STATEMENT (not to exceed 5 pages)

Using the subheadings listed below, address the following topics while bearing in mind the Scholar Selection Criteria found on page 2 of this document.

Candidate's Background

- Provide evidence of your commitment to a research career in drug abuse.
- Describe your previous research experience, including your role in the project(s).
- Highlight examples of your productivity (e.g., pursuing an original research question, analyzing data, pursuing extramural funding, and presenting or publishing your findings).

Career Goals

- State your short-term and long-term research career goals, including the type of research you plan to conduct and the potential impact your research will have on drug abuse and addiction.
- Explain how participating in the K12 program will prepare you to compete successfully for an NIH grant, such as an R03, R21, or R01.
- Justify the need for protected time afforded through a K12 career development award.

Training Plan

- Explain what additional training you need to achieve your research career development goals in the area of drug abuse and addiction. Identify specific areas where you have deficiencies and describe how you will obtain additional training in each area.
- Provide a timeline of your proposed training plan.
- Describe the role of your mentor. Be specific and refer back to your proposed training and/or research plan whenever possible.

Career Potential

- Explain how you will benefit from the K12 program and how it will contribute to the development of your independent career in drug abuse and addiction.
- Comment on the leadership role(s) you expect to play in your department/division in 5-10 years.

6) ABSTRACT (not to exceed 1 page)

Include Project Title, Key Words, and Research Abstract.

7) RESEARCH PLAN

The applicant should work closely with their mentor on writing the research plan. Propose a line of investigation consistent with program objectives, specifically a focus on clinical investigation relevant to drug abuse and addiction. There should be some relationship between the choice of topic and past or current research activity, although a case can be made for using the program as a transition into a new area. *Organize the Research Plan according to the section headings provided below. Note page limits for each section.*

1. Specific Aims (1 page limit)

State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved.

2. Research Strategy (8 page limit)

Organize the Research Strategy using the instructions provided below. Start each section with the appropriate section heading – Significance, Innovation, or Approach. Include any tables, graphs, figures, diagrams, or charts in this section. If an applicant has multiple Specific Aims, then the applicant may address Significance, Innovation and Approach for each Specific Aim individually, or may address Significance, Innovation and Approach for all of the Specific Aims collectively.

a. Significance

- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
- Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice.
- Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive the field will be changed if the proposed aims are achieved.

b. Innovation

- Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
- Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

c. Approach

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high-risk aspects of the proposed work.
- Address whether minorities and both men and women will be included.

3. Bibliography and References Cited (no page limit)

4. Protection of Human Subjects (no page limit)

If applicable, provide justification for involvement of human subjects for research that involves human subjects. Address the following: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials. For additional information, please refer to

http://grants.nih.gov/grants/peer/guidelines_general/Review_Human_Subjects_20130508.pdf.

5. Vertebrate Animals (no page limit)

If applicable, provide justification for the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information, please refer to http://grants.nih.gov/grants/olaw/VASchecklist.pdf.

8) BUDGET AND JUSTIFICATION

Refer to phs398 instructions located at http://grants2.nih.gov/grants/funding/phs398/phs398.html
Complete a budget and budget justification for research-related expenses (maximum \$25,000) and salary support for Year 01.

Formatting Information

File type: PDF only **Font:** Arial, 11 point

Margins: 0.5"

Paper size: 8 ½" x 11"

Note: Please DO NOT submit any supplementary materials (e.g. appendices) as these will not be reviewed.

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