

CRECD Program, Phase II Master of Science in Clinical Research Program

Application Package

Phase II-Mentored Clinical and Translational Research Scholars Program

- Program Description
- Eligibility Criteria
- Application Guidelines
- Submission Date
- Selection/Review Criteria
- Application Form - Cover Page

Phase II- Mentored Clinical and Translational Research Scholars (Program

Program Description

Purpose

The goal of the Phase II (CRECD) CRECD Program is to support career development for junior faculty from a wide variety of disciplines (M.D. or Ph.D.-level junior faculty) at Morehouse School of Medicine (MSM) to become independent, established and ethical clinical and/or translational research investigators. Trainees accepted into the program will receive salary support to enable them to spend at least 75% of their professional time (50% is allowed for trainees from surgery or surgical subspecialties) on clinical and/or translational research training; a technical budget; and salary support for their lead mentor. Didactic training is provided through the Master of Science in Clinical Research [MSCR] program and mentored training under the direction of an established and successful clinical investigator at one of the collaborating institutions. Support in the program for junior faculty trainees will be provided for up to two years and is based on performance in the program.

Source of Support

Funding for the Phase II Program comes from the CRECD Award received by the Master of Science in Clinical Research Program at MSM.

Background

A limitation for many junior faculty with high potential to become clinical and/or translational research investigators is the lack of salary support and protected time to pursue research training including didactic training provided by the MSCR. The Phase II Program provides additional opportunities and support to train junior faculty members to enter careers in clinical investigation. The Phase II Program provides the opportunity to build upon the resources of the ACTSI and other established programs in supporting junior faculty members who want to establish a successful clinical and/or translational research career. The Phase II program provides the opportunity for didactic training (in large part through the MSCR program) and also requires that the trainee have an established and successful lead mentor who could provide further guidance and training for those pursuing careers in clinical and/or translational investigation.

Training Programs

The CRECD Phase II Program provides an opportunity and the resources for junior faculty at MSM and to have a large amount of protected time (75%) to pursue clinical and/or translational research training. This includes didactic training (through the MSCR program) and a mentored clinical research program under the direction of an established clinical and/or translational investigator.

Training Support

Junior faculty trainees accepted into the Phase II (CRECD) Program must devote a minimum of 75% professional effort to clinical and/or translational research training (the only exception to this is a minimum of 50% effort for trainees from surgery or the surgical subspecialties). Salary support reflecting effort will be provided by the CRECD Phase II Program (as well as the costs to cover fringe benefits on that salary). Salary support is based on the trainee's current institutional

salary. The maximum salary support that the CRECD program can provide is \$80,000 per year (plus fringe benefits). The salary support provides protected time for trainees to obtain clinical and/or translational research training. Support will be provided for up to two years. Ongoing support is contingent upon the trainee making adequate progress in the program. In addition to salary support, limited funds per year will be provided to each trainee for a technical budget. These funds must be used to pay for MSCR tuition while the trainee is in the MSCR program and can also be used for other research related needs including research supplies, equipment, non-faculty research staff salary support, and travel to national meetings or to receive additional specialized training. Up to 5% salary support (plus fringe benefits support on that salary) is provided to the Lead Mentor for junior faculty trainees accepted into the MCTRS Program.

Mentors

Each junior faculty trainee must identify a lead mentor who is an established clinical and/or translational investigator at one of the collaborating institutions. A letter of support from the lead mentor indicating their willingness and desire to serve as the trainee's lead mentor should be included in the candidate's application. All trainees must have mentored clinical and/or translational research training under the direction of their lead mentor. The lead mentor will provide guidance and mentoring to the trainee while in they are in the program. Mentors should be established and successful clinical and/or translational investigators. Generally this means that the lead investigator must be a NIH or federally-funded investigator.

Additional Information

An investigator initiated, hypothesis driven proposal with specific aims will be developed by each trainee. This will be initially outlined in the application submitted by candidates for the program and will be further refined after enrollment in the CRECD Phase II Program. Progress towards those aims will be updated in required semi-annual reports. It is anticipated that the clinical or translational research project that the trainee is working on under the guidance of their lead mentor will provide the data to be analyzed for their mentored thesis which is required to receive the MSCR degree. Clinical and/or translational research will begin during the first year of the program. Much of the trainee's time in the first year will be devoted to didactic studies (i.e., first year of MSCR curriculum). In the second year of the MCTRS Program, a large proportion of the trainee's time will be devoted to working on their clinical and/or translational research project under the guidance of their mentor and the MSCR thesis. The MCTRS Program will provide additional support as well through ongoing functions such as journal club, colloquiums and special seminars (often in collaboration with the MSCR program or other ACTSI components). The importance of interdisciplinary research will be emphasized in these additional colloquiums and seminars. Each trainee must submit an NIH K23 Mentored Patient-Oriented Research Career Development Award or equivalent NIH K award (e.g., K01, K08) grant application by the end of their first year of KL2 funding.

Eligibility Criteria

Junior faculty members who hold a M.D. or D.O. degree, M.D./Ph.D degrees, or Ph.D. degree at University, Morehouse School of Medicine, and at the rank of Instructor or Assistant Professor are eligible to apply to the program. Individuals who have accepted a faculty appointment at any of the three collaborating institutions may also apply if they will be on Morehouse School of Medicine or faculty at the date of receipt of the award (e.g., June 1 or July 1, 2008). **Faculty appointments cannot be dependent upon receipt of this award.** Junior faculty physician candidates should have completed training in a specialty and/or subspecialty and be board eligible or certified. Non-physician candidates must have a PhD. Candidates must be committed to a career in clinical investigation (clinical and/or translational research) and be willing to commit in writing to serve on the faculty of an academic institution pursuing clinical and/or translational research for each year of support received through the CRECD Phase II Program.

As per NIH guidelines, candidates must be a U.S. citizen or permanent U.S. resident. Individuals on temporary or student visas are not eligible. Faculty candidates who are or have been former principal investigators on NIH individual mentored career awards (e.g., K12, K23, FIRST awards [R29], research projects [R01], subprojects of program project [P01] or center grants [P50] or the equivalent) are not eligible for this program. Minorities and women are encouraged to apply to the CRECD Phase II Program.

Requirements of the applicants and awardees accepted into the program are as follows.

The candidate must:

- 1) Be a full time junior faculty member Morehouse School of Medicine, (Instructor or Assistant Professor or equivalent level) at the time of receipt of the award.
- 2) Indicate a strong interest in pursuing an academic career in clinical and/or translational research.
- 3) Agree to commit in writing to serve at least one year on the faculty at an academic institution pursuing clinical and/or translational investigation for each year of support provided by the CRECD Phase II Program (the goal would be for the trainee to spend a career in clinical investigation but this pledge emphasizes the importance of identifying persons interested in pursuing a career as a clinical investigator).
- 4) Be nominated by the candidate's Department Chair (and Division Director if applicable); the Chair must guarantee in writing in the nomination letter that a minimum of 75% of the junior faculty member's professional time will be protected to pursue clinical and/or translational research training if the candidate is accepted into the CRECD Phase II Program (an exception is made for a minimum of 50% effort for trainees from surgery or the surgical subspecialties).
- 5) Identify an established, Morehouse School of Medicine, or faculty lead mentor who meets approval criteria discussed above. Additional faculty members may serve as co-mentors or Advisory Committee members but there must be a single lead mentor.
- 6) Submit a completed application that includes a **Research and Training Plan** (as described in the Application Section; the maximum page limit for the Research and Training Plan is 15 single spaced pages). The proposal should also include a budget on how to allocate technical support which is provided in addition to the salary support (in year 1 adequate funds must be appropriated to cover MSCR tuition). Details on the tuition costs can be obtained from Jacquelyn Ali, MSA (jali@msm.edu).
- 7) Have the lead mentor submit a letter indicating their willingness to serve a mentor, potential of the candidate, and their plans for enhancing the research capability of the candidate. Letters of support from co-mentors or Advisory Committee members are also recommended.
- 8) Be a U.S. citizen or permanent resident and meet all other NIH eligibility criteria (e.g., no prior or current NIH career development awards dedicated to training clinical and/or translational researchers [i.e., K23]; has not been PI currently or previously on R01, R29, P01, or P50 NIH grants).
- 9) Agree in writing to abide by the rules and regulations of the CRECD Phase II Program. These include: a) provide semi-annual written progress reports; b) agree to provide the Program Director with updated information following completion of the program on career progress, academic position, publications, funding, etc.; c) agree to meet with the Program Director and co-Program Director on an every 6 month basis to assess progress while in the program; d) agree to complete the MSCR program; and e) agree to submit a NIH K23 or other appropriate application (e.g., K01, K08) as requested by the program (e.g., within the first year in the program).

Application Guidelines

The CRECD Phase II Program junior faculty candidates should submit an application that includes the following components and information:

- 1) **Abstract: 1 page (maximum) summary** of the proposed research project and clinical and/or translational research training goals and activities (single-spaced, 1 inch margins).
- 2) **Research and Training Plan** (15 pages maximum, single-spaced). This section should include the candidate's specific aims and goals in the CRECD Phase II Program, including a hypothesis driven clinical and/or translational research proposal that they would develop under the guidance of their Lead Mentor (Research Plan) as well as plans for didactic and mentored clinical research training (Training Plan). The **Training Plan** should indicate the candidate's background and career goals and should also describe the faculty member at , Morehouse, or who would serve as the lead mentor as well as planned schedule of interactions between the trainee and the lead mentor (be specific and indicate frequency of meetings, types of interactions, etc). Any co-mentors or Advisory Committee members should also be mentioned. A multi-disciplinary Advisory Committee and meeting plan with the mentee is encouraged. The Lead Mentor should be an established and successful clinical investigator as previously described. Applicants should also include detailed information on what proportion of their time would be devoted to clinical and/or teaching activities and what these activities and responsibilities would be if accepted into the CRECD Phase II Program.

The entire Research and Training Plan should be a **maximum of 15 single spaced** pages. Use an Arial typeface and a font size of 11 points or larger with at least 0.5 inch margins. For the specific research proposal, it is suggested to use the NIH PHS 398 format, including a section on Hypothesis and Specific Aims; Background and Significance; Preliminary Data (if any, preliminary data is not required); Research Design and Methods; Biostatistics (can be included in the Methods section); and Data Safety and Monitoring Plan (if applicable).

(NOTE: maximum of 15-pages single-spaced for Research and Training Plan; a suggested format is 5 pages for the training component and 10 pages for the research plan).

- 3) **Literature Citations.** Literature cited should be listed on a separate page in a standard bibliographic format following the research and training plan (this does not count against the 15 page maximum length of the Research and Training Plan).
- 4) **Budget.** A line item budget (salary and fringe benefits [25.6% of salary requested]), percent effort (i.e., 75% except for trainees from the surgical subspecialties where a minimum of 50% is required), and allocation of the technical budget (up to \$12,000 per year) should be included for the first two years in the program. A budget justification (**2 pages maximum**) should also be included. Further details on MSCR tuition costs can be obtained by contacting Jacquelyn Ali, MSA (jali@msm.edu or 404-752-1780).
- 5) **Letters of support** from the applicant's Lead Mentor, Co-mentors/Advisory Committee and Department Chair must be included. The letter from the Department Chair must guarantee that the applicant will have the protected time (a minimum of 75%) to carry out clinical and/or translational research training if accepted into the CRECD Phase II Program. The Lead Mentor's letter should indicate the willingness to serve as a mentor for the candidate, their assessment of the applicant, prior trainees they have mentored, a brief summary of the applicant's research proposal and a brief summary of their plans for mentoring the applicant.

- 6) **Cover letter from the applicant.** The cover letter should indicate the applicant's rank (e.g., Instructor, Assistant Professor or equivalent) at Morehouse School of Medicine or as well as the name of the applicant's lead mentor. The candidate should also indicate their interest in pursuing a career in clinical and/or translational investigation and agree to serve at least one year on the faculty of an academic institution pursuing clinical and/or translational research for each year of support from the program. The applicant should also indicate that they will agree to abide by the rules of the program (e.g., meet with the Program Director on an every 6 month basis to review progress, submit semi-annual progress reports, cite the CRECD grant on all publications, keep the Program updated on publications and receipt of funding during and after completion of the program, plan to complete the MSCR program, submit a NIH K23 or equivalent application within 1 year of joining the program, etc).

- 7) **CRECD Phase II Program Application Form Cover Page.** The two page application form Cover Page should also be completed and be the first pages of the application package that is submitted. **This cover page can be found at the end of this application package.**

- 8) **Biosketch.** A NIH-style biosketch (4-page version) for the applicant, the Lead Mentor, and any co-mentors should be included in the application package.

- 9) **Other Support.** The PHS "Other support" form should be completed for both the Lead Mentor and applicant. Information on current funding as well as prior funding should be included. This form can be downloaded the NIH website (<http://grants1.nih.gov/grants/funding/phs398/phs398.html>).

Submission Date

The deadline for receipt of completed applications is **June 1, at 5 p.m.** The original and one electronic copy of the completed application package should be sent to Jacquelyn Ali, MSA, MSCR Program Office, Morehouse School of Medicine, 720 Westview Dr. SW, MRC Bldg, Room S-07, Atlanta, GA 30310, (404) 752-1780 (jali@msm.edu).

Selection/Review Criteria

The selection process will be carried out under the direction of the MSCR Program Committee. The goal of this program is to select candidates who with proper career development and clinical and/or translational research training have potential to become independently funded, successful and ethical clinical investigators. Decisions will be based on the strength of the application submitted by the prospective trainee including the hypothesis driven research proposal and training plan, the potential of the applicant for a successful career in clinical investigation, the success and track record of the Lead Mentor in mentoring previous junior faculty members and other trainees, diversity issues, and availability of adequate resources through the award. Decisions of the Review Committee are final. Potential applicants are strongly encouraged to discuss their plans with Dr. Alexander Quarshie at MSM (aquarshie@msm.edu). Dr. Quarshie can also be reached by contacting Jacquelyn Ali, MSA at 404-752-1780 or jali@msm.edu.

Plan for Recruitment and Retention of Underrepresented Minorities, Women and those with Disabilities.

The CRECD Program is committed to meeting the NIH/NCRR goal and that of Morehouse School of Medicine to increase the participation of women and individuals from ethnic or racial groups underrepresented in the biomedical and behavioral sciences. Applications from women and minority candidates are encouraged. In addition, accommodations will be made to assist any individuals with disabilities so those persons with disabilities who are qualified applicants for this program can complete the program.

Acknowledgments

All publications derived from work supported by the CRECD Program must acknowledge the CRECD. The CRECD Program Office should be given reprints of abstracts and publications resulting from this funding.

Submission dates

Applications are due on June 1, 2009 by 5 p.m. It is anticipated funding and participation for those applicants accepted into the program may begin in July or August 2009.

Submission Instructions. Please submit an original and 5 copies of the entire application as well as an electronic copy as described above.

Deliver to: Jacquelyn Ali, MSA
MSCR Program Office
Morehouse School of Medicine
720 Westview Dr. SW
MRC Bldg, Room S-07
Atlanta, GA 30310
(404)752-1780

Questions:

Address questions to the Morehouse School of Medicine KL2 co-director Alexander Quarshie, M.D., (404)752-8681, (aquarshie@msm.edu) or the MSCR Program Manager, Jacquelyn Ali, MSA, (404)752-1780 (jali@msm.edu).

APPLICATION FORM

CRECD Phase II PROGRAM

COVER PAGE

Application for the CRECD Phase II Program

Applicant's Full Name and

Degree(s): _____

Current Title: Instructor Assistant Professor other _____

University: _____

School, Department, and Division: _____

Address, including ZIP: _____

Office Telephone: _____ FAX: _____

E-Mail Address: _____

Project

Title: _____

_____ Funding Requested in Year 1: \$ _____

Lead Mentor:

(name & degree(s))	Department	Division	School/University)
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Co-Mentor (if applicable):

(name & degree(s))	Department	Division	School/University)
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Co-Mentor (if applicable):

(name & degree(s))	Department	Division	School/University)
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Co-Mentor:

name & degree(s)	Department	Division	School/University)
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Signatures:	Full Name (typed or printed)	Signature
Candidate	_____	_____
Lead Mentor	_____	_____
Co-Mentors (if applicable)		
Advisory Committee		
Members	_____	_____
	_____	_____
	_____	_____
Division Director (If applicable)	_____	_____
Department Chair	_____	_____

CRECD, Phase II Program

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Atlanta, GA 30310-1495
Phone: (404) 752-1780 FAX: (404) 756-8815