REQUEST FOR APPLICATIONS (RFA)

Research Education, Training and Career Development (CTSI-Ed)

K-R01 Transition to Independence Program

- $50,000 in research funds to be expended over 2 years
- Receive specialized career development
- Must be an assistant professor (in rank 7 years or less) with a primary mentor and biostatistician
- Applicants must have held an active K award for at least one year at the time of application OR successfully concluded a K award on or after July 1, 2017. Up to 5 awards will be issued for this RFA
- Start date November 1, 2018
- Applications due 12:00 p.m. (noon) on October 1, 2018

1. NATURE AND PURPOSE OF THIS RFA
The Clinical and Translational Science Institute (CTSI) K-R01 Transition to Independence Program is designed to support faculty by providing mentorship, oversight, programming, and pilot funds. This two-year program aims to place junior investigators with K awards further on the path toward R01 awards. This RFA will be issued annually. Success of this program will be judged by the number of awardees who move forward to secure NIH R01 grants and R01 equivalent funding for clinical and translational research. Applications from underrepresented populations are strongly encouraged.

2. CRITERIA FOR FUNDING
Awardees will be selected based on the following criteria:
- United States citizen, permanent or non-permanent resident
- Conduct human relevant clinical and/or translational research
- Have a clinical doctorate, PhD, or equivalent
- Be an Assistant Professor in rank ≤ 7 years at time of application and have the potential to establish own funded research programs in clinical and translational science. Applicants must have paid faculty appointments (rank of Assistant Professor 9403, Clinical Assistant Professor 9403C, or Research Assistant Professor 9403R) OR have signed and accepted offer letter from the University of Minnesota at the time of application with a start date before the start of the grant (must provide copy in
application). Eligibility includes affiliated faculty at the VA, HCMC, Regions Hospital, and the Children’s Hospitals of Minnesota. Faculty members holding adjunct appointments are ineligible.

- Have an active K award at the time of application (KL2, BIRCWH, MCC, K12, CHRCDA K12, Independent K award (K23, K07, etc).
- Application must identify a primary mentor (ideally Professor rank, but Associate Professors allowed in certain cases) and a biostatistician as a secondary mentor. Primary mentor will co-sign the application indicating they have read the application and agree to mentoring requirements. For questions, contact Michelle Lamere (Assistant Director, CTSI-Ed) at mlamere@umn.edu or 612-624-0619. The K-R01 program is directed by Esam El-Fakahany, PhD.
- Not be, or have been, a principal investigator on an R01, R29 or subproject of a Program Project (P01), Center Grant (P30, P60, U54), or other equivalent research grant awards or career development awards such as those from ACS, ADA, AHA, etc., at the time of the application.
- Commitment to a minimum of 2 years of research with a minimum of 50% protected time if K-R01 funding extends beyond K award funding.
- Participants are required to submit an R01, or R01 equivalent (e.g., American Heart Association, national American Cancer Society, or national American Diabetes Association) application by the first half of their second year of support.

3. REQUIREMENTS

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Yr 1</th>
<th>Yr 2</th>
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<tbody>
<tr>
<td>Spend a minimum of 50% effort on training, research, and career development activities related to K-R01 Program.</td>
<td>Required</td>
<td>Required</td>
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</table>
| With your mentoring team each year, address components of your career development plan:  
  1. Develop your career vision and career mission.  
  2. Develop a Professional Development Plan for strategic and annual goals with associated near-term objectives, specific objectives, and competencies for the two years. Submit to CTSI-Ed within first two months of funding.  
  3. Identify what strategies (e.g. experiences, training, etc.) will facilitate objective achievement and how experiences and training will be acquired. | Required                    | Required                    |
| Submit an abstract to and attend the annual ACTS Translational Science conference, held in the spring each year in Washington, DC. Required only if awardees have not previously attended the Conference. | Required in yr 1 or 2       | Required in yr 1 or 2       |
| Participate in the Proposal Preparation Program (P^3) led by Dr. Anne-Marie Weber Main, unless specifically exempted by Dr. El-Fakahany. Required only if awardees have not previously attended the program. | Required in yr 1 or 2       | Required in yr 1 or 2       |
Participate in a mock study section at either the annual ACTS Translational Science Conference or the UMN Translational Research Retreat. | Required in yr 1 or 2 | Required in yr 1 or 2 |
---|---|---|
Submit NIH R01-award or R01 equivalent funding within first 18 months of support. | | First half of the year |
Participate in the bi-annual CTSI Translational Research Retreat | Required | Required |
Attend at least 75% of the required monthly specialized Career Development Lunches, led by Dr. Esam El-Fakahany. | Required | Required |
Present research at the annual CTSI Poster Session and Reception held in fall | Required | Required |
Meet at regularly established times with your mentors individually and as a team. Meetings with the full mentoring team must be held, at a minimum, twice a year. Meeting with the primary mentor (substituted at times by a secondary mentor) should be approximately weekly. | At least twice a year | At least twice a year |
Submit six-month Report of Progress and attend annual Committee Review Meeting | Required | Required |
Complete Hogan Leadership Forecast Series Assessments (1-hour debrief and coaching session with Michelle Lamere, MPA, ACC) | Required | |
Complete Wellbeing and Resilience for Health Professionals online training course. | Required in yr 1 or 2 | Required in yr 1 or 2 |

### 4. FUNDING

1. $50,000 over two years in pilot funds for technical assistance or supplies to assist in generating data
2. No carry forward after two years will be allowed

The funds are for the direct support of the research and cannot be used for faculty salaries (except biostatistician effort, travel and equipment). Small equipment purchases that are directly required for the research are appropriate (i.e. < $5,000 in total). In general, funds should be primarily used for supplies and support of research personnel (effort for biostatistician, graduate students and/or technicians).
5. SELECTION CRITERIA

Scholars:
1. Multidisciplinary nature of mentoring team (i.e., primary and secondary mentors must be from different disciplines – any questions, please contact Dr. Esam El-Fakahany.
2. Research study including hypothesis to be tested, aims, significance, innovation, translation plan, incorporation of Biostatistical analysis and potential for building a career
3. Plans for interacting with mentors
4. Previous research and academic experience
5. Passion for research and contemplated career trajectory

Department:
1. Commitment of 50% protected time if K-R01 funding extends beyond K award.
2. Plan for integration of the scholar into the unit’s activities

Primary Mentor:
1. Plan for supporting and facilitating a long-term career path for the candidate
2. Experience with research theme proposed by the candidate
3. Plans for interaction with scholar and integration with mentoring team
4. Listing of NIH funding record (current and past)
5. Clinical or translational research publication record
6. Previous and current mentoring experience and success

Supporting mentor(s):
1. Experience with research theme
2. Plans for interaction and career development of scholars
3. Previous and current mentoring experience and success
4. Listing of NIH funding record (current and past)

6. QUESTIONS

Questions may be directed to:

Michelle Lamere, MPA, ACC
Assistant Director, CTSI-Ed
mlamere@umn.edu
1. APPLICATION AND INSTRUCTIONS

All applicants are required to contact the CTSI Biostatistical Design and Analysis Center (BDAC) for an initial consult, at no charge, with a BDAC faculty biostatistician to review the statistical support needs of the proposal. At the consultation the applicant and a biostatistician consultant will determine together the level of statistical support required by the project and the amount, if any, needed to budget in the proposal. This statistical support plan must be included in applications. It is recommended scholars schedule at the beginning of the application process to ensure a meeting. See the attached Statistical Support Plan form for instructions.

Complete and submit an online application and upload all required documents through the submission link on the website by 12:00 p.m. (noon) on October 1, 2018. The submission site will automatically close at 12:01 p.m. Late or partially completed applications will not be accepted.

Submit application at z.umn.edu/CTSIK-R01.

Complete applications should adhere to the guidelines below and must include:

APPLICATION COMPONENTS

<table>
<thead>
<tr>
<th>Formatting instructions:</th>
<th>All typed documents must be Arial 11 pt font, ½ inch margins, single-spaced, PDFs</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>CTSI Scholar Application Information</td>
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<tr>
<td></td>
<td>Online form</td>
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<td>RESUBMISSIONS: submit a point-by-point response to reviewers’ comments (include copy of reviewer comments)</td>
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<td></td>
<td>Up to 2 pages</td>
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<td>2</td>
<td>Prologue describing progress to-date on K- award and why additional funds will result in a funded R01</td>
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<td>1 page</td>
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<td>3</td>
<td>Research Proposal to include:</td>
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<td>● Project Title</td>
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<td>● Aims</td>
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<td>● Significance</td>
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<td>● Innovation</td>
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<td></td>
<td>● Approach</td>
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<td>● Analysis Plan</td>
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<td>● Translation Plan: A brief description of the translational, clinical or public health impact of your research. Clearly state how a disease or group of diseases will be better diagnosed, treated or prevented, or how the successful completion of your research will improve human health.</td>
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<td>Up to 5 pages, exclusive of references</td>
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<td>4</td>
<td>Statistical Support Plan (attached)</td>
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<td>Up to 3 pages</td>
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<td>7</td>
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</table>
|   | 8 | NIH Biosketch/Other Support  
   ● Include submitted and pending grant applications (specify dollar amount of the grant, your role, and percentage of effort) |
|   | 9 | Curriculum Vitae (current as of date of application submission)  
   *Include manuscripts In Press and Submitted (no abstracts)  
   * Include all current, pending, and previous research funding |
|   | 10 | Department/Division Head Form |
|   | 11 | Primary Mentor NIH Biosketch/Other Support |
|   | 12 | Biostatistician NIH Biosketch/Other Support |
|   | 13 | One support letter from primary mentor, cosigned by biostatistician |
DEAN AND DEPARTMENT/DIVISION HEAD STATEMENT

(2 pages maximum)

Scholar Name:__________________________________________________________

Department/Division Head Name:____________________________________________

School:______________________ Department:___________________ Division:___________

Proposed Mentoring Team

1. Name (Primary Mentor):_____________________________________________________

2. Name Secondary Mentor - Biostatistician:_____________________________________

1. Describe your evaluation of this scholar’s background and potential for a successful academic clinical/translational research career (½ page, single-spaced).

2. Describe how this scholar will become integrated into the research/teaching/clinical service of the unit and describe the scholar’s non-CTSI scholar activities (½ page, single-spaced).

3. Describe your department’s research environment, resources available to the scholar and other researchers within the department that will support the scholar’s efforts (½ page, single-spaced).

In making this application, I understand that the applicant must be an assistant professor at the time of application and have been in rank ≤ 7 years and possess an active K award at the time of application. Protected time for research at 50% will be available for the duration of the 2-year award. I understand the CTSI will provide $50,000 in research funds for 2 years, and carryforward is not allowed. Continued availability of funds is dependent on scholar’s adequate yearly progress.

___________________________________                       __________________________________
Signature of Department/Division Head   Name of Department/Division Head

___________________________________   __________________________________
Signature of Dean                                                             Name of Dean
MENTOR LETTER
(2 pages maximum)

Scholar Name: ______________________________________________________________

1. Describe the team’s evaluation of this scholar’s background and potential for a successful academic clinical/translational research career (maximum ½ page, single-spaced).

2. Describe the intended long-term career path the team envisions for this scholar (½ page, single-spaced).

3. Describe the 2-year timeline with specific mileposts for the clinical scholar’s research and planned submission for a K award, R21, R01, or R01 equivalent in year 2 of this award (½ page, single-spaced).

4. How will the mentoring team support the career development of the scholar and describe the nature, frequency and extent of interaction planned between the team and the clinical scholar during the award period (½ page, single-spaced).

Mentors participating on CTSI-sponsored projects are required to meet with their scholar-mentee regularly, attend the annual CTSI Poster Session, and required to participate in a CTSI-developed mentoring online learning module, in addition to providing data, submitting reports, and attending occasional CTSI events as requested. It is expected that the mentoring team will work closely with the applicant in the development of the application.

Mentor Names and Signatures

Primary Mentor (print name and sign) *By signing this form you are agreeing that you have reviewed the application

Secondary Mentor - Biostatistician (print name and sign) *By signing this form you are agreeing that you have reviewed the application
**PRIMARY MENTOR FORM**

(2 pages maximum)

Scholar Name:___________________________________________________________

Mentor Name:__________________________________   Title:__________________

School:________________ Department:____________________ Division:__________

1. Describe the nature and extent of the interaction planned between you and the scholar during the proposed award period (½ page, single-spaced).

2. Provide a description of your past research experience and current research focus (describe current and past grant funding) (1 page, single-spaced).

3. Provide a list of 5-10 trainees (postdoctoral students and junior faculty) you have advised in the past 10 years in chronological order beginning with the most recent.

<table>
<thead>
<tr>
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<th>Area of Expertise</th>
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<tr>
<td>Name of trainee (status while in training)</td>
<td>Training Period</td>
<td>Degree Sought</td>
<td>Title of Research Project while training with this mentor</td>
<td>Current or last known position</td>
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</table>

Mentor Signature __________________________________________
BIOSTATISTICS MENTOR FORM

(2 pages maximum)

Scholar Name:___________________________________________________________

Mentor Name:__________________________________   Title:__________________

School:________________ Department:____________________ Division:__________

1. Describe the nature and extent of the interaction planned between you and the scholar during the proposed award period (½ page, single-spaced).
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Mentor Signature ________________________________________________
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**INSTRUCTIONS**

1. Go to the CTR Portal, [z.umn.edu/ctsirequest](http://z.umn.edu/ctsirequest), to request a BDAC consultation. You will be asked to log in with your x.500 username and password.
2. Click **New Request**
3. Enter the project title and the PI information. Select **No** for ‘Do you need Scheduling System access?’ Click **Proceed to next step**.
4. Select **Yes I would** from the pop-up menu.
5. Select **Biostatistical and Data Management Support**
6. Answer the remaining questions as completely as you can. In response to the question, 'How will your research be funded?', please choose 'Other' and then enter the name of the career development program in the 'further details' text box.
7. Submit the form upon completion

BDAC meets to assign new requests every Monday. A biostatistician will contact you following that meeting.

**For assistance setting up your consultation contact:**
Rachel Matthes
Biostatistical Design and Analysis Center
[matthes@umn.edu](mailto:matthes@umn.edu)
(612) 626-6032
This statistical support plan must be included in your application

Name of K to R01 Applicant: __________________________________________________________

Name of BDAC Consultant: __________________________________________________________

_______________________________________________                 _______________________
Consultant’s Signature          Date

Statistical Support Plan: Below, describe the level of biostatistics support required by the project and the amount, if any, needed to budget in research proposal. Include name of consultant-recommended biostatistics mentor. To be completed during consultation - handwritten is acceptable.

Recommended Biostatistics Mentor: _________________________________________________

Plan Details, including anticipated costs for budgeting: