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 geared towards developing your R01 proposal
- Must be an assistant professor (in rank 7 years or less) or associate professor (in rank 4 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 February 18, 2019
- Up to 4 awards will be issued for this RFA
- Applications due 11:59 p.m. on April 29, 2020
- Interviews for highly rated applicants will be held in June 2020
- Start date September 1, 2020

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/or R01 equivalent funding for clinical and translational research. The K-R01 program is directed by Esam El-Fakahany, PhD.

Applications from underrepresented populations are strongly encouraged and are welcome to seek assistance in their applications by contacting Michelle Lamere, MPA, ACC at mlamere@umn.edu.

2. ELIGIBILITY CRITERIA

Awardees will be selected based on the following criteria:
- United States citizen and permanent residents
- Conduct human-relevant clinical and/or translational research
- Have a clinical doctorate, PhD, or equivalent
- Be an Assistant Professor in rank ≤ 7 years or Associate Professor in rank ≤ 4 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, Research Assistant Professor 9403R, Associate Professor 9402, Clinical Associate Professor 9402C, or Research Associate Professor 9402R) 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, Hennepin Healthcare, 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) or successfully concluded a K award on or after February 18, 2019.
- Application must identify a primary mentor (ideally at Professor rank, but Associate Professors allowed in certain cases with adequate justification) and a biostatistician as a secondary mentor. A tertiary mentor may be added if needed to complement the research expertise of the primary mentor. The primary mentor will co-sign the application indicating they have read the application and agree to mentoring requirements. 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.

For questions, contact Michelle Lamere, MPA, ACC (Assistant Director, CTSI-Ed) at mlamere@umn.edu or 612-624-0619.

### 3. PROGRAM REQUIREMENTS

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<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>
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<td>With your mentoring team each year, address components of your career development plan:</td>
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<td>1. Develop your career vision and career mission.</td>
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<td>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.</td>
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<td>3. Identify what strategies (e.g. experiences, training, etc.) will facilitate objective achievement and how experiences and training will be acquired.</td>
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<td>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.</td>
<td>Required in yr 1 or 2</td>
<td>Required in yr 1 or 2</td>
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<td>Participate in the Proposal Preparation Program (P³) led by Dr. Anne-Marie Weber Main, unless specifically exempted by Dr. El-Fakahany. Required only if awardees have not previously attended the program.</td>
<td>Required in yr 1 or 2</td>
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<td>Participate in a mock study section at either the annual ACTS Translational Science Conference or the UMN Translational Research Retreat.</td>
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<td>Submit NIH R01-award or R01 equivalent funding within first 18 months of support.</td>
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<td>First half of the year</td>
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<td>Participate in the bi-annual CTSI Translational Research Retreat</td>
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<td>Attend at least 75% of the required monthly specialized Career Development Lunches, led by Dr. Esam El-Fakahany.</td>
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<td>Present research at the annual CTSI Poster Session and Reception held in fall</td>
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<td>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.</td>
<td>At least twice a year</td>
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<td>Submit six-month Report of Progress and attend annual Committee Review Meeting</td>
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<tr>
<td>Complete Hogan Leadership Forecast Series Assessments (1-hour debrief and coaching session with Michelle Lamere, MPA, ACC)</td>
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<tr>
<td>Complete Wellbeing and Resilience for Health Professionals online training course.</td>
<td>Required in yr 1 or 2</td>
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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. In general, funds should be primarily used for supplies and support of research personnel (effort for biostatistician, graduate students and/or technicians). Small equipment purchases that are directly required for the research are appropriate (i.e. < $5,000 in total). Travel to research meetings or training and tuition/fees for courses is also permitted.

5. SELECTION CRITERIA

Scholars:
1. Previous research and academic experience
2. Passion for research and potential for career trajectory in clinical or translational research
3. Quality of planned research study including hypothesis to be tested, aims, significance, innovation, translation plan, incorporation of Biostatistical analysis
4. Clinical relevance, potential for future funding, and reasonableness of project
5. Goals and ambitions fit with the K-R01 program
6. Training experience of mentors
7. Multidisciplinary nature of the primary and tertiary mentors (if applicable)
8. Plans for interacting with mentors

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 research 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, including placement of past trainees

Secondary Mentor - Biostatistician:
1. Experience with study design and statistical analysis of clinical or translational research projects
2. Plans for interaction and career development of scholars
3. Previous and current mentoring experience and success, including placement of past trainees
4. Listing of NIH funding record (current and past)

Tertiary Mentor (if applicable):
4. Experience with research theme proposed by the candidate
7. Plans for interaction and career development of scholars
8. Previous and current mentoring experience and success, including placement of past trainees
5. 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 | 612-624-0619
7. 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. If you are already working with a faculty-level biostats or informatics mentor you do not need to contact BDAC, but your biostats mentor must complete the biostats support plan.

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 that scholars schedule at the beginning of the application process to facilitate scheduling of a meeting. See the attached Statistical Support Plan form for instructions.

Submission information will be provided via email to those who were invited to submit a full application.

Complete and submit an online application and upload all required documents by 11:59 p.m on Wednesday, April 29, 2020. The submission site will automatically close at 12:00 a.m. Late or partially completed applications will not be accepted.

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

<table>
<thead>
<tr>
<th>APPLICATION COMPONENTS</th>
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<tbody>
<tr>
<td>Formatting instructions: All typed documents must be Arial 11 pt font, ½ inch margins, single-spaced, PDFs</td>
</tr>
<tr>
<td>1 CTSI Scholar Application Information</td>
</tr>
<tr>
<td>2 RESUBMISSIONS: Include an introduction that summarizes substantial additions, deletions, and changes to the application. Also respond to the issues and criticism raised in the reviewer comments. (include copy of reviewers’ comments)</td>
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<tr>
<td>2 Prologue describing progress to-date on K- award and why additional funds will likely result in a funded R01</td>
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<td>3 Research Proposal to include:  ● Project Title  ● Aims  ● Significance  ● Innovation  ● Approach  ● Analysis Plan  ● 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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<tr>
<td>4 Statistical Support Plan (attached)</td>
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<tr>
<td>5 Budget: use NIH budget template for each year of the grant and provide a short justification narrative. Be sure to budget for required ACTS conference travel and effort for a biostatistician. Template can be found on K-R01 webpage.</td>
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</table>
| 6 | Human subject or animal protection information (attached)  
If applicable, follow instructions for documenting human and animal protection for the purposes of this application. Form must be completed and included for each application even if response is “not applicable.” | Upload document(s) |
| 7 | Initial start-up plan: Briefly describe the specific steps you will take in the first three months of the award to operationalize your research project. | Write and submit ~3-5 sentences |
| 8 | CV/NIH Biosketch/Other Support  
• CV should not exceed 4 pages  
• Include manuscripts In Press and Submitted (no abstracts)  
• Include submitted and pending grant applications (specify direct dollar amount of the grant, your role, and percentage of effort) | Combine and upload in one document |
| 9 | Department/Division Head Form (attached) | Upload document |
| 10 | One support letter from primary mentor, cosigned by biostatistician and tertiary mentor (if applicable) (attached) | Up to 2 pages |
| 11 | Primary Mentor Form | Upload document |
| 12 | Primary Mentor NIH Biosketch/Other Support | Upload document(s) |
| 13 | Biostatistician Mentor Form | Upload document |
| 14 | Biostatistician NIH Biosketch/Other Support | Upload document |
| 15 | Tertiary Mentor NIH Biosketch/Other Support (if applicable) | Upload document(s) |
| 16 | Tertiary Mentor Form (if applicable) | Upload document |
| 17 | Any additional/supporting documents  
*Examples: Additional mentors (if applicable) NIH Biosketch/Other Support and support letter(s) or Letters of support from collaborators (if applicable)* | Upload document(s) |
STATISTICAL SUPPORT PLAN

INSTRUCTIONS

All applicants are required to contact the CTSI Biostatistical Design and Analysis Center 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 BDAC consultant will determine together the level of statistical support required by the project and the amount, if any, applicants need to budget in the proposal. This statistical support plan below must be included in the application. If you are already working with a faculty-level biostats or informatics mentor you do not need to contact BDAC, but your biostats mentor must complete the biostats support plan.

INSTRUCTIONS

1. Go to the CTR Portal, 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:
Melissa Hansen
Research Navigator
ctsi@umn.edu
(612) 626-2318
STATISTICAL SUPPORT PLAN
(Use additional pages as necessary)

This statistical support plan must be included in your application

Name of K to R01 Applicant: ________________________________________________

Name of BDAC Consultant or Biostatistical/Informatics Mentor: ____________________________

_____________________________________________________
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:
Human and animal protection documentation for CTSI-Ed career development applications

Protections for Human Subjects

If your research involves human subjects please indicate whether you (or your mentor) have an IRB-approved or IRB-exempted protocol. For each relevant protocol please provide the following information: Protocol Number; P.I.; Title; and Exemption date (if applicable) or Approval Dates. You must be named as an approved investigator on the protocol(s). Indicate if you have a submitted or pending IRB protocol, (and include the relevant information, as below).

If additional human subjects research is proposed, pending or planned, that is not included in a currently IRB-approved or IRB-exempted protocol, then please state whether you expect the IRB to exempt this research and which exemption applies. State whether the research meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, and please specify: 1) the justification for the exemption, 2) human subjects characteristics and involvement, and 3) sources of biological materials and data used in the research. For research that you do not expect the IRB to exempt under 45 CFR Part 46, please provide justification for involvement of human subjects and describe the proposed protections from research risk relating to their participation according to the following five review criteria: 1) types and magnitude of risk to subjects, 2) nature and adequacy of protection against risks, 3) potential benefits of participation to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials. If you believe that your human subjects research may involve vulnerable populations, please state the nature of the potential vulnerability and protections that will be included.

For additional information, please refer to the NIH Human Subjects Protection and Inclusion Guidelines (http://grants.nih.gov/grants/peer/guidelines_general/Human_Subjects_Protection_and_Inclusion.pdf)

Inclusion of Women, Minorities, and Children

When the proposed project involves human clinical research, please describe the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. NIH Human Subjects Protection and Inclusion Guidelines state in part, “Public Law 103-43 requires that women and minorities be included in all clinical research studies, as appropriate for the scientific goals of the work proposed…. NIH policy also states that children (defined as persons under the age of 21) be included in human subjects research supported by NIH unless an acceptable justification for their exclusion is provided.”

If children are included as research subjects, please address the nature and adequacy of human subjects protections under federal rules. Please see NIH, Grants & Funding, Inclusion of Children Policy Implementation, http://grants.nih.gov/grants/funding/children/children.htm, including the link to 45 CFR 46, Additional Protections for Children Involved as Subjects in Research.

Vertebrate Animals

If your research involves vertebrate animals, please indicate whether you (or your mentor) have an IACUC-approved protocol. For each relevant protocol please provide the following information: Protocol Number; P.I.; Title; and Approval Dates. You must be named as an approved investigator on the protocol(s).

The committee will evaluate 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 on review of the Vertebrate Animals section, please refer to the NIH Worksheet for Review of the Vertebrate Animal Section (http://grants.nih.gov/grants/olaw/VASchecklist.pdf)

**University of Minnesota Research Policies & Resources**

The University of Minnesota has extensive policies, procedures, and resources on human subjects protection and on animal care and use in research. Demonstrating compliance is an important part of any application for research funding. You are responsible for determining applicable policy and showing compliance. For more information, see Office of Vice President for Research, Research Resources, with links, at http://www.research.umn.edu/forresearchers/resources.html#V0ze0nzF9u0
DEAN AND DEPARTMENT/DIVISION HEAD STATEMENT

(2 pages maximum)

Scholar Name:___________________________________________________________

Department/Division Head Name:__________________________________________

School:_________________ Department:_____________ Division:_____________

Proposed Mentoring Team

Name (Primary Mentor):____________________________________________________

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
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

Tertiary Mentor (if applicable) (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>
<th>Name of Mentor</th>
<th>School</th>
<th>Department</th>
<th>Area of Expertise</th>
<th>Current NIH funding</th>
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</thead>
<tbody>
<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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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).

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

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Mentor Signature
TERTIARY MENTOR FORM (if applicable)

(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.

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</table>

____________________________________________________________________

Mentor Signature