REQUEST FOR APPLICATIONS (RFA)

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

Pre-K Discovery Scholars Program

• $50,000 research funds
• 50% time committed to research and research career development
• Two-year mentored career development
• Underrepresented in Medicine (health sciences research) Assistant Professor with salaried appointment (in rank ≤ 4 years), primary mentor, and biostatistician
• Weekly (Wednesdays, 1:15pm) K Scholar Multidisciplinary Seminar Series with BIRCWH (Women’s Health K12) programs, CTSI Pre-K Scholars, and Individual K awardees
• Individualized educational and training plan
• Application due Wednesday, April 29 (11:59pm)
• Interviews for highly rated applicants held June 2020
• Award announced June 2020
• Start date September 1, 2020
• Up to 4 awards will be issued for this RFA

1. NATURE AND PURPOSE OF THIS RFA

The Pre-K Discovery Scholars Program is designed to provide mentorship, oversight, and pilot funds to junior faculty underrepresented in medicine (health sciences research). In addition, it is an opportunity to take courses relevant to an individual’s career development needs. For those without the relevant formal coursework, the newly created Certificate in Clinical Research equivalent or coursework in the MS in Clinical Research will be required. Funds for these courses will be provided by CTSI-Ed in addition to the $50,000 award. This two-year program aims to place junior investigators on the path to be competitive for NIH K awards. This RFA will be issued every year. Success of this program will be judged by the number of scholars who go on to secure NIH K awards (including the intramural KL2) grants in the short term, and subsequently, NIH R01, and R01 equivalent funding in the long term in clinical and translational research.
2. CRITERIA FOR FUNDING

Awardees will be selected based on the following criteria:

1. United States citizens and permanent residents
2. Individual from group identified as underrepresented in the biomedical, clinical, behavioral and social sciences (Blacks or African Americans, Hispanics or Latinos, American Indians or Alaska Natives, Native Hawaiians and other Pacific Islanders)
3. Conduct human relevant clinical and/or translational research
4. Have a clinical doctorate, PhD or its equivalent (MD, PhD, DO, DDS, DVM, OD, DC, PharmD, DNP)
5. Be Assistant Professor in rank ≤ 4 years and have the potential to establish their own funded research programs in clinical/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 at 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.
6. Application must identify a primary mentor (ideally with the rank of Professor, but Associate Professors will be allowed in certain cases), and a biostatistician as a secondary mentor. The primary mentor will co-sign the application indicating they have read the application agreeing to serve as a mentor. For questions, contact Michelle Lamere (Assistant Director, CTSI-Ed) at mlamere@umn.edu or 612-624-0619. The CTSI-Ed program is directed by David Ingbar, MD.
7. Not be, or have been, a principal investigator on an R01, R29 or subproject of a Program Project (P01), Center Grant (P30, P60, U54), mentored career development grants (K-series), or other equivalent research grant awards or career development awards such as those from ACS, ADA, AHA, etc. at the time of the application. Those serving as PI of an NIH R03 and/or R21 grant are eligible to apply for this Pre-K grant.
8. Commitment to a minimum of 2 years of research, with a minimum of 50% protected time.
9. Participants are required to submit a K award application within the first 12 months of their support.

3. REQUIREMENTS

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<tr>
<th></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 Pre-K Program.</td>
<td>Required</td>
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<tr>
<td>With your mentoring team each year, address components of your career development plan:</td>
<td>Required</td>
<td>Required</td>
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<tr>
<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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</table>
Submit an abstract to and attend the annual Clinical and Translational Science conference, held in the spring each year in Washington, DC. At the minimum you are expected to attend the conference in year 1 or year 2. It is strongly encouraged for you to attend both years.

Complete the Certificate in Clinical Research (or other formal coursework with written approval from Dr. Ingbar) by end of second year. Tuition will be covered by CTSI.

Apply for NIH K-award funding within first 12 months of support.

Submit minimum of 2 peer-reviewed manuscripts within first 18 months.

Attend at least 75% of the required weekly K Scholar Multidisciplinary Seminar Series on Wednesday afternoons.

**For Coordinate Campus Applicants:** the 75% attendance policy for the K Scholar Multidisciplinary Seminar Series will remain in place for coordinate campus scholars, as it does for all scholars. Scholars must attend at least 50% of the scheduled seminars in-person and the other 25% via video link.

Present research at the annual CTSI Poster Session and Reception.

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.

Participate in annual committee progress review meetings.

Submit six-month and annual reports of progress.

Complete Hogan Leadership Forecast Series Assessments (1-hour debrief and coaching session with Michelle Lamere, MPA, ACC.

Complete Wellbeing and Resilience for Health Professionals online training course.

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<td>Complete the Certificate in Clinical Research (or other formal coursework with written approval from Dr. Ingbar) by end of second year. Tuition will be covered by CTSI.</td>
<td>Enroll and begin taking classes</td>
<td>Complete by end of year 2</td>
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**4. FUNDING**

1. $50,000 in pilot funds for technical assistance or supplies to assist in obtaining data
2. Funds for formal coursework, up to the completion of the Certificate in Clinical Research or other approved courses
3. 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). 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 (graduate students or technicians). Travel is limited to the $2,000 provided as travel funds, unless otherwise approved by program.

5. SELECTION CRITERIA

Scholars:
1. A 2-year career development and training plan with support of a primary mentor, and mentoring team
2. Multidisciplinary nature of mentoring team (i.e., primary and secondary mentors must be from different disciplines – any questions, please contact Dr. Ingbar (ingba001@umn.edu)
3. Long-term career plan with milestones for later evaluation by advisory committee
4. Research study including hypothesis to be tested, aims, significance, innovation, translation plan, incorporation of Biostatistical analysis and potential for building a career
5. Plans for interacting with mentors
6. Previous research and academic experience
7. Passion for research and contemplated career trajectory
8. After formal review of the applications, the top rated applicants will be interviewed by CTSI-Ed leadership and final decisions will be made based upon a combination of the grant review score, the interview and having balance and diversity in the program.

Department:
1. Commitment of 50% protected time for the scholar
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 Research Education, Training, and Career Development
mlamere@umn.edu
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 their 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 the application. 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.

**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>
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<td>Research Proposal to include:</td>
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<tr>
<td></td>
<td>• Project Title</td>
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<td></td>
<td>• State clear and testable hypothesis</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><strong>3</strong></td>
<td>Career Development Plan to include:</td>
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<td>Describe a 3-year career development plan with a timeline and objectives that will advance your career goals. Present a systematic plan to obtain the necessary educational background, research experiences and skills, and mentoring necessary to launch an independent career in clinical/translational research. Describe your proposed research project.</td>
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<td>• Describe how the educational plan you propose supplements your previous educational background</td>
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<td>• What other professional development activities will you engage in instead of or in addition to formal coursework</td>
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• Describe why an interdisciplinary approach is necessary
• Give the title of your research plan, specific aims, and hypotheses, if relevant (briefly restated from section 2). Describe how the project fits into the context of current literature on the topic
• Give an outline of other projects or studies you plan to pursue over the two years of Pre-K funding and what you will do one year after completion of the award
• Describe why interdisciplinary approaches and mentorship are critical to your research area. Describe what you intend to learn from each proposed mentor as well as how the mentors will interact with you as a team (i.e. meeting schedule, format, etc…)

4 Statistical Support Plan (attached)

5 **Budget:** use NIH budget template (PHS 398) 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 Pre-K webpage.

Up to 5 pages

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 all three documents and upload in one document

9 Department/Division Head Form (attached)

Upload document

10 Mentor Letter (attached)

Up to 2 pages

11 Primary Mentor Form (attached)

Upload document

12 Primary Mentor NIH Biosketch/Other Support

Upload document(s)

13 Biostatistical Mentor Form (attached)

Upload document

14 Biostatistician NIH Biosketch/Other Support

Upload document

15 Letters of support and biosketches from all collaborators

Upload document(s)

16 Mentor-Mentee Compact with Primary Mentor (and co-Primary Mentor, if applicable) Available for download at [https://z.umn.edu/prek](https://z.umn.edu/prek)

Upload document(s)

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 BERD 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 Pre-K 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#VOze0nzF9u0
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, in rank for ≤ 4 years. Protected time for research at 50% will be available for the duration of the 2-year award, and I will be taking required courses. I understand the CTSI will provide $50,000 in research funds and carryforward is not allowed. Continued availability of funds is dependent on adequate yearly progress of scholar.

___________________________________  ____________________________________
Signature of Division Head Name of Division Head

___________________________________  ____________________________________
Signature of Department Head Name of Department 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 (maximum 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 within the first 12 months of this award (maximum 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 (maximum 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 and approve the statistical aspects of the proposal
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.

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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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____________________________________________________________________
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