













# INSTITUTE FOR TRANSLATIONAL MEDICINE

# REQUEST FOR APPLICATIONS CTSA KL2 Clinical and Translational Scholar Awards

Applications Due by 11:59 pm CST Friday, September 30, 2022

The Institute for Translational Medicine announces funding for CTSA KL2 Clinical and Translational Scholar Awards that provide substantial salary support (up to \$75,000 plus fringe) for faculty-level clinical and translational scientists near the beginning of their investigative careers. Applications are for funding in 2023, with appointments beginning as early as July 1, 2023. Appointments are for two years and we anticipate making 1-3 awards. Eligible candidates may be from any ITM-affiliated institution (UChicago, Rush, Loyola, NorthShore, IIT, Advocate), must hold a doctoral degree and must have a faculty-level appointment during the period of support. Graduate students or post-doctoral trainees are not eligible.

For the purposes of this award, and in agreement with the recommendations of the NIH Director's Panel on Clinical Research, (<a href="http://www.nih.gov/news/crp/97report/index.htm">http://www.nih.gov/news/crp/97report/index.htm</a>), patient-oriented research is defined as research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena for which an investigator directly interacts with human subjects). This area of research includes 1) mechanisms of human disease; 2) therapeutic interventions; 3) clinical trials; and 4) the development of new technologies. Research topics can relate to any aspect of clinical and/or translational research, relevant to any patient population and disease group, and employing any suitable research approach. However, potential relevance to the understanding or treatment of human disease must be demonstrated.

### **OVERVIEW OF THE CTSA KL2 MECHANISM**

CTSA KL2 Scholars are to be relatively new investigators, at the faculty level of Assistant Professor or Instructor, who are committed to a career in clinical and/or translational research. In certain circumstances, Associate Professors can apply if they are newly entering the field of clinical and translational research. The goal of the CTSA KL2 Scholar mechanism is to produce accomplished clinical/translational researchers capable of utilizing the tools of clinical and/or basic research to improve the understanding or treatment of human disease.

#### **ELIGILIBILTY**

U.S. citizen or permanent resident with research or clinical doctoral degree.

For more information visit https://grants.nih.gov/grants/policy/nihgps/HTML5/section 12/12.3.4 citizenship.htm

### **HEALTHY CHICAGO 2025**

Healthy Chicago 2025, launched on September 17, 2020, reflects the work of hundreds of community members and organizations to assess the current status of our communities and organizations and develop approaches

to strengthen neighborhood vitality and system coordination.

Healthy Chicago 2025 Vision: A city where all people and all communities have power, are free from oppression and are strengthened by equitable access to resources, environments and opportunities that promote optimal health and well-being.

As a partner of the CDPH and an institutional citizen of Chicago, the ITM seeks to align its activities and funding support with the goals of Healthy Chicago 2025 to promote optimal health and well-being: KL2 Scholars' Research Projects should align with one of the following Healthy Chicago 2025 priority areas.

https://www.chicago.gov/content/dam/city/depts/cdph/statistics\_and\_reports/HC2025\_917\_FINAL.pdf

#### **EXPECTATIONS OF CTSA KL2 SCHOLARS**

- Candidates are expected to assemble a multidisciplinary mentoring committee of senior advisors/mentors and meet with their mentors regularly.
- All KL2 Scholars are expected to participate in the monthly ITM Clinical Scholar Seminar Series, as well
  as ITM Outcomes Research Workshops or other ITM educational seminars, as appropriate to their
  areas of study.
- A crucial expectation of the awardees is that preliminary data will be developed which will serve as the basis for an NIH grant application (or equivalent) in clinical and/or translational research.
- Awardees will be expected to submit reports on a yearly basis or more frequently as requested by ITM leadership.

#### KL2 SCHOLAR APPLICATION

Applications must be submitted online using the <a href="KL2 Career Development Program Application">KL2 Career Development Program Application</a> (<a href="https://redcap.uchicago.edu/surveys/?s=7W4CWLMD3D">https://redcap.uchicago.edu/surveys/?s=7W4CWLMD3D</a>) by Friday, September 30, 2022 at 11:59:59 pm. Applications will not be accepted after the deadline, so please start early and plan for questions and last-minute submission problems.

Applications must include the following:

- 1. A full curriculum vitae (not an NIH Biosketch).
- A one-page description of candidate's commitment to an academic career in patient-oriented research.
   Include a description of all professional responsibilities and show their relation to the proposed activities on the career award.
- 3. A one-page detailed, structured training plan to be undertaken during the appointment period.
- 4. A seven-page research plan including Specific Aims (1 page) and Research Strategy (6 pages), the latter including Significance, Innovation, Approach, Impact, and Preliminary Studies. In addition (no page restriction), please include Literature Cited and information regarding Human Subjects and Vertebrate Animals as appropriate.
- 5. A brief (250 words or less) statement of how the research project aligns with Healthy Chicago 2025 goals and will help improve health, human and clinical services.
- 6. A brief letter from the Department Chair or Section Leader addressing:
  - a. The candidate's prospects for development into an independently funded clinical/translational scientist;
  - The Department's assurance that at least 75% of the candidate's time will be protected for research career development and devoted to her/his role as a K12 Scholar (at least 50% for surgeons);

- c. Names of the proposed mentors who will constitute a multidisciplinary mentoring committee for the Scholar (a minimum of two disciplines must be represented)
- 7. A brief letter from the candidate's mentors, indicating their commitment to the candidate and endorsement of the candidate's training plan.
- 8. For projects that involve human subjects research, the following documentation must also be included in the application
  - a. While the protocol does not yet have to have IRB approval, the IRB application must have been submitted in AURA. Applicants must list "ISAP" as a reviewing committee in answering question 2.1.2 of your IRB application. The ITM pilot application must list the project's AURA-IRB number. For applications coming from outside the University of Chicago, a copy of the complete IRB application, including all documents, must be submitted.
  - A completed Protection of Human Subjects document, following the instructions in the NIH's Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan (http://grants.nih.gov/grants/funding/424/SupplementalInstructions.pdf).
  - c. List of Eligibility Criteria, including Age Limits
  - d. Inclusion plans for Women, Minorities and Children
  - e. Recruitment and Retention Plan
  - f. Study Timeline
  - g. Targeted Enrollment Table or Inclusion Data Record
  - h. Data and Safety Monitoring Plan
  - i. Proof of Human Subjects Research and Good Clinical Practice training for all study personnel

## Projects that meet the NIH Definition of a Clinical Trial must also submit the following:

- j. Narrative Study Description
- k. Statement of the Primary Purpose of the Study
- I. Description of the Study Interventions
- m. Study Phase
- n. Description of the Intervention Model
- Description of Study Masking/Blinding
- p. Description of Study Allocation/Randomization
- q. Description of Study Outcome Measures
- r. Description of the Study's Statistical Power and Design
- s. Description of the Study Subject Participation Duration
- t. IND/IDE Paperwork or FDA Determination
- u. Dissemination Plan

Projects that are deemed by the IRB to be Exempt must provide a letter of exemption from the IRB, citing the exemption category.

PLEASE NOTE: All applications involving human subjects research must undergo a regulatory review prior to receiving an award. Applicants must have completed an IRB application by the time they submit their pilot application. Failure to provide the requested human subjects research documentation may result in your application being rejected from review.

# All uploaded application documents must be in PDF format, with a minimum ½" margins and 11 pt. Font.

Applications by women, underrepresented minorities, individuals from disadvantaged backgrounds, and individuals with disabilities remain a high priority for funding. The academic and intellectual background,

motivation, and commitment of the candidate to pursue clinical and/or translational research will be evaluated.

The criteria for selecting awardees will include assessment of the candidate's potential, the dedication to clinical and/or translational research, and the degree of support from the Department.

#### **NEED HELP WITH YOUR APPLICATION?**

The ITM offers a 10-week summer workshop to help you write a K application. Led by senior investigators and NIH reviewers, the ITM's K Writing Workshop meets for ninety minutes each week and provides hands-on help with how to best organize and write a K application. Workshop participants actually work on their applications during the course and receive targeted, constructive feedback on their drafts.

Visit the <u>ITM Website</u> (<u>https://chicagoitm.org/itm-university-of-chicago-grant-writing-feedback-for-researchers/</u>) for more information or to enroll.

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