



Clinical and Translational Science Institute KL2 Mentored Career Development Award Request for Applications

Extended Deadline: Due Monday, December 9, 2019 by 5:00pm

OVERVIEW

The CTSI KL2 Mentored Career Development Award provides 2 years of support for early-career research faculty from Wake Forest School of Medicine to build clinical and translational research skills and competencies under the guidance of skilled multi-disciplinary mentoring teams, within the context of a learning healthcare system and rapidly evolving academic research environment.

CTSI KL2 Research Scholars will receive:

- 75% salary support for two years,
- up to \$35,000/year to support educational and research needs,
- an Individual Development Plan, and
- a multi-disciplinary mentoring team.

KL2 scholars engaged in clinical work are allowed to devote less than 75 percent effort, but not less than 50 percent effort, to the KL2 program. Scholars will become members of the CTSI Translational Research Academy and actively and regularly participate in its ongoing and diverse educational, networking, and mentoring opportunities. Scholars will receive priority access to other CTSI resources including biostatistical and research design support, study coordinator support, and Research Navigators.

We expect to fund two KL2 Research Scholars in 2020.

The expected **start date** for the 2020-2022 KL2 program is **July 1, 2020**.

In September, there will be two information sessions on the KL2 program and application process. These meetings are optional. If you are interested, please sign up here: <https://is.gd/2020KL2info>

ELIGIBILITY

KL2 awards support mentored research career development for clinical investigators who have recently completed professional training and who are commencing basic, translational and/or clinical research.

Applicants must be U.S. citizens, noncitizen nationals, or legal permanent U.S. residents. Applicants must have a research or health professional doctoral degree (e.g. MD, PhD, DO, DVM) or its equivalent. Applicants should be early career faculty (Instructor/Assistant Professor level). Individuals at the Associate Professor level will be considered if they are transitioning from a clinically intensive to a research-intensive pathway. Clinical faculty from

all health professions (nursing, pharmacy, veterinary medicine) are encouraged to apply. Women and underrepresented minorities are encouraged to apply.

At the time of their appointments, scholars must not have a pending application for any other PHS-mentored career development award (e.g. K07, K08, K22, K23) that duplicates any of the KL2 provisions.

Former or current PDs/PIs on any NIH research project grant or equivalent non-PHS peer-reviewed grant with over \$100,000 direct costs per year, or project leaders on sub-projects of program project (P01) or center grants (P50) are NOT eligible to participate as scholars. [This does not include NIH small grants (R03), exploratory Developmental (R21) or SBIR, STTR (R43, R44 grants)].

Applicants must be tenure-track faculty and cannot be in a contingent faculty status.

For questions on eligibility, contact **Claudia Olivier**, colivier@wakehealth.edu.

Independent of the success of your KL2 application, you will qualify to be considered for the CTSI Translational Research Academy, an 18-month program offering diverse educational, networking, and mentoring opportunities. Sessions are held twice monthly, 75 minutes each. You will be able to indicate your interest in this program on your application form (REDCap).

EXPECTATIONS

CTSI KL2 Research Scholars must commit **a minimum of 75% of full-time effort to their research and educational program for at least two years**. KL2 scholars in clinical specialties are allowed to devote less than 75 percent effort, but not less than 50 percent. Awardees will be members of the CTSI Translational Research Academy, a program of formal and informal educational opportunities and research support services designed to promote the careers of promising early-career clinical and translational researchers. Scholars will develop competencies in general research skills, academic career development, and scientific leadership. Education opportunities of special importance to the learning healthcare system will be provided in areas such as team science, innovation/entrepreneurship, biomedical informatics, and implementation & dissemination science. Continued progress in meeting pre-defined research and educational goals must be demonstrated.

Departments of KL2 applicants must agree to support dedicated research effort in the year following CTSI support. At the end of their participation, KL2 Scholars will be expected to submit applications for externally funded grants to support their research and further career development. In accordance with NCATS requirements, the academic productivity of KL2 Scholars will be tracked for a period of 15 years.

This is an institutional career development award granted to WFUHS, and it is non-transferable; scholars who leave WFUHS will not be able to continue receiving KL2 funding from WFUHS.

Each year of funding is contingent upon satisfactory participation in the CTSI KL2 activities and progress toward the scholar's individual career goals, and continued support from the Scholar's mentors and department.

APPLICATION

The application must include:

- A. **Background and Career Goals** for the applicant (1 page)
- B. **Educational Plan** for the applicant (2-3 pages)
- C. **Letter of Support** from the applicant's Section Head (if applicable), Department Chair, and/or Center or Institute Director
- D. **Letters of Recommendation** from two faculty which speak to the applicant's potential to become a leader in clinical/translational research
- E. **CV** for the applicant
- F. **NIH Biosketch** for the applicant
- G. **CVs** for all mentors (clearly specify primary mentor)
- H. A **Letter of Support** from the proposed primary mentor
- I. **Research Plan**: Summary of the proposed clinical or translational research project (5 pages maximum)
- J. **References**
- K. **Budget** requesting funding for each year of support
- L. **Budget Justification** for proposed budget

Application Details

A. Candidate's Background and Career Goals (1 page)

Provide details on the applicant's educational and professional background and future career goals.

B. Educational Plan (2-3 pages)

Describe proposed educational activities and discuss how these will facilitate the conduct of the proposed research and the development of desired research, leadership, and career development competencies. Options can include, but are not limited to, formal degree programs, selected graduate courses, experiential internships, short courses, conferences, online courses, and self-study.

Applicants who do not hold a research degree are strongly encouraged to enroll in a formal program. Applicants who are not selecting participation in a formal degree program should justify the merits of the proposed educational plan in lieu of the research degree, and their training should be described in the KL2 application.

The Educational Plan should be formulated to enhance the Scholar's competencies in the following domains:

- Critical thinking and research question formulation
- Biostatistics and study design

- Responsible conduct of research and regulatory environment
- Research implementation
- Scientific communication
- Proposal preparation
- Community engagement and cultural diversity
- Biomedical informatics
- Team science and team leadership
- Research in the Learning Health System context

Details and application deadlines for two WFSM degree programs focused on translational research are available as follows:

- 1) Clinical and Population Translational Sciences
<https://www.phs.wakehealth.edu/public/edu.cfm>
- 2) Molecular Medicine and Translational Science
<https://school.wakehealth.edu/Education-and-Training/Graduate-Programs/Molecular-Medicine-and-Translational-Science-MS>

C. Letter of Support from the applicant's Section Head (if applicable), Department Chair, and/or Center or Institute Director

Letter(s) must agree to protect 75% of the applicant's time, if the grant is awarded. (KL2 scholars engaged in clinical work are allowed to devote less than 75 percent effort to the KL2 program, but not less than 50 percent during the two years of the award period.) Additionally, there should be a commitment to provide adequate protected research time in the third year for the Scholar to continue his/her research effort.

D. Two (2) Letters of Recommendation from faculty

Letters need to speak to the candidate's potential to become a leader in clinical/translational research. Letters can be from internal and external faculty.

E. CV for the Applicant

F. NIH Biosketch for the Applicant – Template and instructions can be downloaded here:

<https://grants.nih.gov/grants/forms/biosketch.htm>

Please use format for non-fellowship with expiration date of 3/31/2020.

G. CV for the Primary Mentor – CV should convey mentor's track record and independent research funding sufficient to provide the mentee with specialized resources and an environment necessary to complete the proposed project.

H. A Letter of Support from the proposed primary mentor(s) which delineates their prior experience in research mentoring, commitment to the mentee as well as the outlined mentee career development goals, and

endorsement of the proposed educational plan. The mentor's letter should convey the commitment to meet KL2 mentor expectations. These include to:

- work in the mentee's long-term interest
- meet frequently (at least every other week)
- serve as an internal advocate
- help mentee network outside of Wake Forest
- provide resources to ensure project success
- critically review mentee's scholarship
- participate in KL2 mentoring team meetings
- participate in mentor development activities

I. *Research Plan* that summarizes the clinical or translational research project to be conducted (5 pages maximum)

This project should address a problem of compelling clinical or translational relevance, ideally from a multidisciplinary perspective. The Research Plan should include:

- **Specific Aims**
- **Background and Rationale** – including significance of the problem to be studied
- **Approach**
- Identification of a **Primary Mentor** (or mentors) and his/her role(s) in the project
- **Specific Plans** to extend the proposed work via external funding

J. *References*

K. *Budget requesting funding for each year of support*

Using the budget template provided in the online application (REDCap), prepare a budget that reflects salary support for 75% effort (plus fringe benefits) for the Scholar. (Note: For Scholars engaged in clinical specialties, the protected effort can be less than 75 percent effort, but not less than 50 percent).

Additionally, the budget includes a maximum of up to \$35,000/year in research/educational support funds for years 1 and 2 (e.g. for supplies, travel, tuition, or other non-salary support).

Salary support for other individuals is not covered by this award.

L. *Budget Justification.*

Provide a justification for all requested budget items.

Other Documents:

PLEASE NOTE: Candidates who are selected to advance in the review process will be required to submit supplemental documents required by NCATS prior to funding the KL2. These include:

- IRB or IACUC protocol for the proposed research project (approval can be pending)
- Informed Consent document, if applicable
- Human Subjects section, if applicable
- Clinical Trial information, as indicated (Investigator's Brochure, package insert, IND or IDE documentation, IND exemption, or IDE waiver)
- Inclusion Plan for Women, Minorities, and Children, if applicable
- Targeted Enrollment Table or Inclusion Data Record, if applicable
- Data and Safety Monitoring Plan (DSMP) and Board (DSMB), if applicable
- Date of most recent CITI certification and other education in the protection of human subjects.

Additional details about the required documents will be provided as indicated.

The DEADLINE for receipt of CTSI KL2 Mentored Career Development Scholar applications is:

Monday, December 9, 2019 by 5:00pm.

Proposals must be submitted electronically through REDCap using the following link:

<https://is.gd/2020KL2apply>

Incomplete application packages will be returned without review.

All applicants are encouraged to meet with Claudia Olivier, PhD, CTSI Education Program Director, prior to the submission to discuss proposed educational plans and review information about resources available through the CTSI, including Biostatistical consultation and editing services.

We encourage you to reach out to **Claudia Olivier**, colivier@wakehealth.edu or 336-716-9895 about your intent to apply and for questions about the CTSI KL2 Mentored Career Development Scholar program.

For assistance with grant writing and editing, please contact Indra Newman, inewman@wakehealth.edu or 336-713-1073.

NIH DEFINITIONS OF CLINICAL AND TRANSLATIONAL RESEARCH

Clinical Research is patient-oriented research conducted with human participants (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Studies may focus on mechanisms of human disease, therapeutic interventions, clinical trials, or the development of new technologies to prevent, detect, diagnose, or treat disease. Other clinical research explores outcomes, such as quality of life, and use of health services. Clinical research studies include epidemiological studies (study of the numbers of people and patterns of a disease or condition in a population), observational studies (in which individuals are observed and their outcomes are measured by the investigators), and clinical trials (in which the participants are assigned by the investigator to a treatment or other intervention, and their outcomes are measured).

Translational Research includes two areas of translation. One is the process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in humans. The second

area of translation concerns research aimed at enhancing the adoption of best practices in the community. Cost-effectiveness of prevention and treatment strategies is also an important part of translational science.

(Ref: PMC2829707, PMID: [20182120](#))

EVALUATION OF APPLICATIONS

Applications will be screened for eligibility by Dr. David Miller, Director of the CTSI Mentored Career Development Program. Eligible applications will be reviewed by the KL2 Core Faculty and external reviewers.

Applicants will be evaluated on:

- Past academic performance and research productivity
- Proposed project's scientific merit, feasibility, and clinical/translational impact
- Potential of the project to lead to successful extramural grant applications
- Educational plan's coverage of core competencies
- Strength and commitment of the proposed primary mentor(s)
- Commitment of the department to the applicant's scholarly and professional development

Applicants will be scored according to the 9-point NIH scale (1 = exceptional; 9 = poor)

https://grants.nih.gov/grants/policy/review/rev_prep/scoring.htm

Top candidates will be invited to present a "chalk talk" to the KL2 Core Faculty and CTSI Executive Council members outlining their research plan, expected results, and possible future directions.

Applicants continuing to the next level of review will be notified of the outcome of their applications by **January 17, 2020**. Candidates for chalk talks will be notified by **January 17, 2020**. The final selection decision will be made by KL2 Core Faculty.

AWARD DATE

Awards will begin on **July 1, 2020** and end on **June 30, 2022**. We expect to grant two awards, depending on the quality of applications received.