Clinical and Translational Science Institute KL2 Mentored Career Development Award

Request for Applications for 2023

Application Deadline: Monday, December 5, 2022 by 5:00pm

Letter of Intent Deadline: Monday, October 17, 2022 by 5:00pm

Overview

The CTSI KL2 Mentored Career Development Award offered through Wake Forest School of Medicine provides two years of support for early-career faculty involved in translational research to expand their skills and competencies under the guidance of an experienced, multi-disciplinary mentoring team, 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 procedurally intensive clinical work are allowed to devote less than 75% effort, but not less than 50% effort, to the KL2 program. Scholars will become members of the CTSI Translational Research Academy and actively 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.

The two-year KL2 program award period will start July 1, 2023 and run through June 30, 2025. We expect to fund up to two KL2 Research Scholars from the Wake Forest Winston-Salem region and up to one additional KL2 Scholar from the Atrium Health Charlotte region, all with a start date of July 1, 2023.

*Per NIH guidelines, up to $120,000 in salary support is allowed per year for each scholar. Fringe is not included in the $120,000 cap. You can have a base salary up to $160,000 with 75% effort allocated to the grant and still stay within the $120,000 cap ($160,000 x 75% = $120,000.) If your base salary is over $160,000 then the portion that exceeds the $120,000 salary support will be cost-shared to your department.

KL2 Informational Meetings

Join us via WebEx on **Tuesday, August 23, 2022** from 12-1pm or on **Wednesday, September 21, 2022** from 4-5pm to hear from KL2 Program Directors Drs. Dave Miller and Kate Weaver to learn more about the KL2 Program, the application process, and ask questions. If you are interested in attending one of these meetings, please register here: https://redcap.link/2023KL2info and you will receive a WebEx calendar invite within 1-2 business days.

Eligibility

KL2 awards support mentored research career development for 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).
- Atrium Health applicants must have a faculty appointment in the Wake Forest University School of Medicine OR have submitted an application for a faculty appointment.
- Applicants must be able to commit to 2 years of research training.
- 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 appointment, scholars must not be in the research scholar promotion track.
- 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. However, scholars who successfully secured a KL2 position are encouraged to apply for another K award as early as immediately after accepting the KL2 position.
- 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 apply. [Exception: This does not include NIH small grants (R03), exploratory Developmental (R21) or SBIR, STTR (R43, R44 grants)].

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

Translational Research Academy

Independent of the success of your KL2 application, you will qualify to be considered for the CTSI Translational Research Academy, a program offering diverse educational, networking, and mentoring opportunities over the course of two academic years. The 90-min long sessions are held twice monthly on Tuesday afternoons. Virtual attendance options available. Indicate your interest in this program on your application form in 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**. Scholars in procedurally intensive clinical specialties are allowed to devote less

than 75%, but not less than 50% effort to the KL2. 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 Wake Forest University Health Sciences and is non-transferable. Scholars who leave the institution will not continue to receive KL2 funding from this grant.

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.

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)

Letter of Intent

All prospective applicants must submit a Letter of Intent (LOI) form prior to the submission of their KL2 grant application. The Letter of Intent form will require the following:

- Your name, academic title, department, email address, and telephone number
- Primary mentor's name, academic title and department
- Title of proposed KL2 research project
- A 3-5 sentence summary of your proposed research project

The LOI must be submitted electronically through REDCap no later than **October 17, 2022 at 5pm** using the following link**:** https://redcap.link/2023KL2LOI.

The LOI is used to estimate reviewers needed for the full applications. The 3-5 sentence summary of your proposed research project from the LOI will not be included with the full application for reviewers to read during the formal review process. The submission of a LOI does not guarantee the review of a KL2 application. Potential applicants are encouraged to read through this entire RFA to determine if they are eligible for the KL2. We will confirm that we received the LOI and provide any feedback as necessary by **October 31, 2022.**

Application Requirements Summary

1. **Cover Page**
2. **Abstract** (30 lines)
3. **Response to Prior Critiques** (1 page, for resubmissions only)
4. **Background and Career Goals** (1 page)
5. **Educational Plan** (3 pages limit)
6. **Research Plan** (5 pages limit)
7. **Overall Timeline** (1 page)
8. **CV for the Applicant**
9. **NIH Biosketch for the Applicant**
10. **NIH Biosketches for all Mentors**
11. **Letters of Support from all Mentors**
12. **Letter of Support** (From applicant's Department Chair)
13. **Budget**
14. **Budget Justification**
15. **References**

NOTE: Failure to adhere to application guidelines will result in the application being disqualified.

Application Requirements Details

1. Cover Page
The cover page should include: the title of the proposed KL2 research project, applicant's name, credentials, academic title and department along with the name, credentials, academic title and department of each mentor.

2. Abstract (30 lines limit)
The abstract is a concise summary of your proposal that highlights the significance, the hypothesis and major objectives of the project, the procedures to accomplish the objectives, and the potential impact of the work.

3. Response to Prior Critiques (1 page limit, for resubmissions only)

If you are resubmitting a previously submitted KL2 application, a 1 page response to prior critiques can be included here.

4. Background and Career Goals (1 page limit)
Provide details on the applicant's educational and professional background and future career goals.

5. Educational Plan (3 pages limit)
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:

1) Translational and Health System Science
   https://school.wakehealth.edu/Education-and-Training/Graduate-Programs/Translational-Health-System-Science-MS

2) Molecular Medicine and Translational Science
   https://school.wakehealth.edu/Education-and-Training/Graduate-Programs/Molecular-Medicine-and-Translational-Science-MS

6. Research Plan (5 pages maximum)
The Research Plan should summarize the clinical or translational research project to be conducted. 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

7. Overall Timeline (1 page limit)

Timeline should include education, training and research.

8. CV for the Applicant

Applicant's current CV

9. NIH Biosketch for the Applicant

Applicant's NIH Biosketch. The template, instructions and sample biosketch can be downloaded here: https://grants.nih.gov/grants/forms/biosketch.htm

Please download and use the Biographical Sketch Format Page (non-fellowship) - Due Dates on/after January 25, 2022 from the above link.

10. NIH Biosketches for all Mentors

The mentor biosketches should also address the mentors' track record in mentoring. Use the NIH biosketch template listed above. Combine all mentor biosketches into one PDF with the primary mentor's biosketch first.

11. Letters of Support from all Mentors

Letters should delineate prior experience in research mentoring, commitment to the mentee as well as the outlined mentee career development goals, endorsement of the proposed educational plan, and commitment to meet KL2 mentor expectations (including participation in bi-annual mentoring committee meetings). Combine all mentor letters into one PDF with the primary mentor's letter first.

The primary mentor's letter in particular should convey commitment to providing independent research funding sufficient to support the mentee with specialized resources and the environment necessary to complete the proposed project and the following:

- 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 Committee meetings
- Participate in mentor development activities

12. Letter of Support from applicant's Department Chair (or Section Head if applicable)

This letter should be from the applicant's Department Chair or Section Head. It must agree to protect 75% of the applicant's time, if the grant is awarded. KL2 Scholars engaged in procedurally intensive clinical work are allowed to devote less than 75% effort to the KL2 program, but not less than 50% 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 their research effort. Under current Wake Forest School of Medicine policies, KL2 scholars are automatically granted bridge funding in the third year if they have at least 25% of their time covered by extramural grants.

13. Budget

The budget must request funding for each year of support. Download and use the budget template provided after completing the LOI form.

Prepare a budget that reflects salary support for 75% effort (plus fringe benefits) for the Scholar. For Scholars engaged in procedurally intensive clinical specialties, the protected effort can be less than 75% effort, but not less than 50%. Include your full salary (not NIH cap) and latest faculty fringe rate (currently 14%).

Other Direct Costs: The KL2 budget may include funds to support the scholar's research projects and career development activities. Applicants may request a maximum of $35,000/year to cover the following expenses: (a) tuition and fees related to career development; (b) research expenses such as supplies, equipment and technical personnel to supplement those provided by the mentor; (c) up to $2,500 per year for scholar travel to scientific meetings and research training workshops; and (d) statistical services. In addition, mentor support may include up to $10,000 per year associated laboratory or other research-related expenses. Salary support for mentors excluding laboratory- or research-related expenses is not an allowable budget item.

14. Budget Justification

Provide a justification for all requested budget items.

15. References

All uploaded files should be saved as a PDF.

The following required documents should be 11pt Arial font with half inch margins.
1. Cover Page
2. Abstract
3. Response to Prior Critiques
4. Background and Career Goals
5. Education Plan
6. Research Plan
15. References

NOTE: Failure to adhere to application guidelines will result in the application being disqualified.

Other Required Documents if Selected for the KL2 Award

Candidates who are selected for the KL2 Award will be required to submit supplemental documents required by NCATS prior to start date of the KL2 Award. 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 for applicant and primary mentor.

KL2 Application Deadline

The deadline for receipt of CTSI KL2 Mentored Career Development application is:

Monday, December 5, 2022 at 5:00 pm EST.

Applications must be submitted electronically through REDCap using the link that you will receive after submitting your Letter of Intent (LOI).

The deadline for receipt of the LOI is:

Monday, October 17, 2022 at 5:00 pm EST.

The LOI must be submitted electronically through REDCap using the following link:
https://redcap.link/2023KL2LOI.

Applicant Resources

All applicants are encouraged to connect with **Claudia Olivier, PhD, CTSI Education Program Director**, colivier@wakehealth.edu, prior to submission to help address questions about the CTSI KL2 Mentored Career Development Award, discuss proposed educational plans, and review information about resources available through the CTSI, including Biostatistical consultation and Scientific Editing Services.

Learn more about the CTSI Scientific Editing Services by clicking on the link below:
https://ctsi.wakehealth.edu/Service/Proposal-Development-Resources
To request grant writing and editing assistance, please complete this form:
https://redcap.wfubmc.edu/redcap/surveys/index.php?s=PYJWYTREAA

Requests for biostatistical consultation or grant editing assistance must be submitted no later than October 31, 2022, preferably at an earlier date, to allow time for feedback.

Evaluation of Applications

Applications will be screened for eligibility by KL2 Director Dave Miller, MD, MS and KL2 Co-Director Kathryn Weaver, PhD, MPH. Eligible applications will receive multiple reviews by WFSM faculty, KL2 Core Faculty, as well as external reviewers.

Applicants will be evaluated on:
- Past academic performance and research productivity
- Scientific merit, feasibility, and clinical/translational impact of the proposed project
- Potential of the project to lead to successful extramural grant applications
- Educational plan
- Strength and commitment of the proposed mentoring team
- Commitment of the department to the scholarly and professional development of the applicant

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

All applicants will be notified of their application status by **January 20, 2023.** Top candidates will be invited to present a "chalk talk" to the KL2 Core Faculty and CTSI Executive Council members (approximately late February 2023) outlining their research plan, expected results, and envisioned future directions. The final selection decision will be made by KL2 Core Faculty and finalists will be notified by **March 10, 2023.**

Award Date

Awards will begin on **July 1, 2023** and end on **June 30, 2025 and are depending on accurate and timely submission of supplemental documents required by NIH** (at least 30 days prior to start date of the KL2 Award).

We expect to fund up to two KL2 Research Scholars from the Wake Forest Winston-Salem region and up to one additional KL2 Scholar from the Atrium Health Charlotte region, all with a start date of July 1, 2023.