



# Clinical and Translational Science Institute K12 Mentored Career Development Award Request for Applications for 2025 Letter of Intent Deadline: Friday, November 1, 2024 by 5pm EST

Application Deadline: Monday, December 16, 2024 by 5pm EST

### Overview

The CTSI K12 Mentored Career Development Award (formerly KL2) offered through Wake Forest University 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 K12 Research Scholars will receive:

- 75% salary support for two years\*,
- up to \$25,000/year to support educational and research needs,
- an Individual Development Plan, and
- a multi-disciplinary mentoring team.

K12 Scholars will receive priority access to other CTSI resources including biostatistical and research design support, study coordinator support, and research navigators.

K12 Scholars will become members of the CTSI <u>Translational Research Academy</u> and actively participate in its ongoing and diverse educational, networking, and mentoring opportunities. K12 Scholars will also become members of the K12 Peer-Mentoring Group that meets once a month.

The two-year K12 program award period will start July 1, 2025, and run through June 30, 2027. We expect to fund up to three K12 Research Scholars from Wake Forest University School of Medicine in the Winston-Salem or Charlotte markets.

\*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.

### K12 Informational Meetings

Learn more about the K12 program, the application process, and ask questions at one of the K12 Informational Meetings hosted by K12 Program Director, Dr. David Miller, and K12 Program Co-Director, Dr. Nichole Allred. The WebEx meetings will be on **Thursday, September 5, 2024,** from 4-5pm and **Thursday, September 26, 2024,** from 12-1pm. If you are interested in attending one of these meetings, please register here <u>https://redcap.link/2025K12info</u> and you will receive a WebEx calendar invite within 1-2 business days.

# Eligibility

K12 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).
- Applicants must have a faculty appointment at Wake Forest University School of Medicine in the Winston-Salem or Charlotte markets.
- Applicants must be able to commit to 75% effort for 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 mentored career development award (e.g., K07, K08, K22, K23, K99) that duplicates any of the K12 provisions. However, scholars who successfully secured a K12 position are encouraged to apply for another K award as early as immediately after starting the K12 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, please contact CTSI Director of Education Programs, Susie Newcomb at: <u>snewcomb@wakehealth.edu</u>.

# Translational Research Academy

Independent of the success of your K12 application, you will qualify to be considered for the CTSI <u>Translational</u> <u>Research Academy</u>, a program offering diverse educational, networking, and mentoring opportunities over the course of two academic years. The 90-min long sessions are held virtually twice monthly on Tuesday afternoons. Virtual attendance options available. Indicate your interest in this program on your application form in REDCap.

### **Expectations**

CTSI K12 Scholars must commit a minimum of **75% of full-time professional effort to their research and educational program for at least two years**. K12 Scholars in surgical specialties may have less than 75% of full-time professional effort, but not less than 50%, protected time for this program, if sufficiently justified and programmatically approved.

K12 awardees will become members of the CTSI <u>Translational Research Academy</u>, 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. K12 Scholars will also become members of the K12 Peer-Mentoring Group that meets once a month.

A full mentoring committee meeting is required every 6 months. Continued progress in meeting pre-defined research and educational goals must be demonstrated.

Departments of K12 applicants must agree to support dedicated research effort in the year following CTSI K12 support. K12 Scholars are eligible for the <u>Early Career Faculty Salary Support Program</u> following the K12 award. K12 Scholars are expected to submit applications for externally funded grants to support their research and further career development following the K12. In accordance with NCATS requirements, the academic productivity of K12 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 nontransferable. Scholars who leave the institution will not continue to receive K12 funding from this grant. No K12 funds can be carried over from year 1 to year 2 of the award.

Each year of funding is contingent upon satisfactory participation in the CTSI K12 activities and progress toward the Scholar's individual career goals, and continued support from the Scholar's mentors and department.

#### **NIH Definition of Clinical and Translational Science**

The National Center for Advancing Translational Sciences (NCATS) at the National Institutes of Health (NIH) is transforming the translational science process so that new treatments and cures for disease can be delivered to patients faster. NCATS strives to develop innovations to reduce, remove, or bypass costly and time-consuming bottlenecks in the translational research pipeline in an effort to speed the delivery of new drugs, diagnostics, and medical devices to patients. Translation is the process of turning observations in the laboratory, clinic, and community into interventions that improve the health of individuals and the public — from diagnostics and therapeutics to medical procedures and behavioral changes. Translational science is the field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process. NCATS studies translation on a system-wide level as a scientific and operational problem. The NCATS approach is not to focus on specific diseases, but on what is common among them and the translational science process. NCATS does this by developing new approaches, technologies, resources, and models; demonstrating their usefulness; and disseminating the data, analysis, and methodologies to the community. (Ref: PAR-21-336; see also https://ncats.nih.gov/translation)

### Letter of Intent

All prospective applicants must submit a Letter of Intent (LOI) form prior to the submission of their K12 grant application. The LOI 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 K12 research project
- A 3-5 sentence summary of your proposed research project

The LOI must be submitted electronically through REDCap no later than **November 1, 2024, at 5pm** EST using the following link: <u>https://redcap.link/2025K12LOI</u>.

The LOI is used to estimate reviewers needed for the full applications. The LOI is non-binding and non-scored. 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. Potential applicants are encouraged to read through this entire RFA to determine if they are eligible for the K12 and should read through the <u>K12 Frequently</u> <u>Asked Questions</u> web page.

We will confirm that we received the LOI and provide any feedback, as necessary, regarding eligibility by **November 8, 2024.** 

### **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 K12 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/K12 application, a 1-page response to prior critiques can be included here (recommended).

#### 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 K12 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 Wake Forest University School of Medicine 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 <u>https://school.wakehealth.edu/Education-and-Training/Graduate-Programs/Molecular-Medicine-and-Translational-Science-MS</u>

#### 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. <u>Please download the Non-Fellowship Biographical Sketch Format Page Forms H</u>.

#### **10. NIH Biosketches for all Mentors**

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 K12 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 University School of Medicine and Atrium Health
- Provide resources to ensure project success
- Critically review mentee's scholarship
- Participate in K12 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. For applicants with a base salary greater than \$160,000, the Letter of Support should confirm the department's agreement to cost-share any portion of the applicant's salary that exceeds the \$120,000 annual cap of the K12 award.

Additionally, the letter should indicate a commitment to provide adequate protected research time in the third year for the Scholar to continue their research effort. Under current Wake Forest University School of Medicine policies, K12 scholars are eligible for <u>Early Career Faculty Salary Support</u> in the third year if they have at least 25% of their research 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. Include your full salary (not NIH cap) and latest faculty fringe rate (currently 16%).

Prepare a budget that reflects salary support for 75% effort (plus fringe benefits) for the Scholar. Surgical specialties may have less than 75% of full-time professional effort, but not less than 50% protected time for this program, if sufficiently justified and programmatically approved.

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 (\$160k x 75% = \$120k.) 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

Other Direct Costs: The K12 budget may include funds to support the scholar's research projects and career development activities. Applicants may request a maximum of \$25,000/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. 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 including justification for effort less than 75%.

#### 15. References

#### All files must be uploaded 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 K12 Award

Candidates who are selected for the K12 Award will be required to submit supplemental documents required by NCATS prior to start date of the K12 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.

### K12 Application Deadline

The deadline for receipt of the LOI is:

#### Friday, November 1, 2024, at 5:00 pm EST.

The LOI must be submitted electronically through REDCap using the following link: <u>https://redcap.link/2025K12LOI</u>.

#### The deadline for receipt of CTSI K12 Mentored Career Development application is:

#### Monday, December 16, 2024, 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).

### **Applicant Resources**

All applicants are strongly encouraged to read through the <u>K12 Frequently Asked Questions</u> web page. For any other questions you may have, please contact CTSI Director of Education Programs, Susie Newcomb at <u>snewcomb@wakehealth.edu</u>.

Learn more about the <u>CTSI Scientific Editing Services</u>. To request grant writing and editing assistance, please complete the <u>CTSI Service Request Form</u>.

Requests for biostatistical consultation or grant editing assistance must be submitted no later than November 1, 2024, preferably at an earlier date, to allow time for feedback.

# **Evaluation of Applications**

Applications will be screened for eligibility by K12 Director, David Miller, MD, MS, K12 Co-Director, Nichole Allred, PhD, and CTSI Director of Education Programs, Susie Newcomb, MA, PhD. Eligible applications will receive multiple reviews by Wake Forest University School of Medicine faculty, K12 Core Faculty, and 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 **February 3, 2025.** Top candidates will be invited to present a 10 minute "chalk talk" to the K12 Core Faculty and CTSI Executive Council members scheduled for **March 10, 2025,** from 2-5pm to present their research plan, expected results, and envisioned future directions. The final selection decision will be made by K12 Core Faculty. Finalists will be notified by **March 17, 2025.** 

### Award Date

The K12 Award will begin on July 1, 2025, and end on June 30, 2027, and are depending on accurate and timely submission of supplemental documents required by NIH (at least 30 days prior to start date of the K12 Award). We expect to fund up to three K12 Research Scholars from the Wake Forest University School of Medicine Winston-Salem or Charlotte markets.