

Overview Information

Funding Opportunity Title	VCU Wright Center K12 Mentored Career Development Award Request for Applications
Funding Opportunity Purpose	The Wright Regional Center for Clinical and Translational Science (CCTS) calls for applicants for the K12 Mentored Career Development Grant. There is a national need to increase the clinical and translational research workforce – to prepare our future research leaders to address healthcare challenges. A key step in this process is providing early-career investigators with the support and skill sets required to translate their research discoveries into clinical treatments. The K12 Mentored Career Development Award at VCU (previously the KL2) is open to any assistant professor engaged in clinical or translational research or science, who has less than five years of service in that role at the time of appointment. The K12 award provides talented junior faculty investigators with mentored, research-intensive experience in a multidisciplinary setting. It enables the development of future leaders in clinical and translational research. Late-stage postdoctoral researchers who <u>are</u> transitioning to faculty positions will be considered on a case-by-case basis. The K12 Award is a 2-3-year award (contingent on satisfactory progress) funded and administered by the National Institutes of Health's (NIH) National Center for Advancing Translational Science (NCATS) and the Wright Center. The Wright Regional Center CCTS seeks proposals that address scientific questions consistent with our mission to fund research across the Translational Spectrum while utilizing Translational Principles to advance translational progress.
<u>Key Dates</u> Funding Announcement	February 21, 2025
LOI Due	March 3, 2025
Completed K12 Application	April 7, 2025
Finalists' presentation and interviews	April 21-25, 2025
Award start date	May 2025

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Table of Contents

Section I. Funding Opportunity Description.....	3
Purpose.....	3
Selection Process.....	3
Benefits.....	3
Expectations.....	3
Section II. Eligibility Information.....	6
Section III: Application and Submission Information.....	7
Letter of Intent.....	7
Full Application.....	7
K12 Application Components:.....	9
Personal Statement – 1 Page Max.....	9
Career Development Plan – 2 Page Max.....	9
Research Plan – 7 Page Max.....	9
Biosketch.....	10
CV.....	10
Reference Letter.....	10
Letter of Support.....	10
Primary Mentor Biosketch.....	10
Section IV: Application Review Information.....	10
Section V. NIH/NCATS Prior Approval.....	11
Section VI. Award Administration Information.....	12
Award Requirements.....	12
Section VII. Wright Center K12 Program Contacts.....	13

Section I. Funding Opportunity Description

Purpose

The award is designed to benefit a wide spectrum of clinical or translational researchers and scientists. The award provides salary support to ensure protected time for mentored research and didactic training in clinical/translational research across various project topics and academic areas. The program aims to equip three (3) early career investigators to advance from mentored to independent researchers funded by an NIH R01 award, an individual K award, or equivalent.

Selection Process

K12 Scholars will be selected based on a competitive application process, with the following key review considerations determining funding:

- The transdisciplinary/translational science and quality of the research project
- The qualifications of the applicant
- The experience of the mentorship team
- The quality of the training plan

A review panel will make recommendations to the Wright Center, which will approve funding for one K12 scholar. All applicants will receive reviewer comments on their applications.

Please note the following requirements:

- To be considered, all applicants must submit the required Letter of Intent form by noon on March 3, 2025, via Redcap.
- Applicants invited to complete a full application must complete all sections of the application. Applications are due by noon on April 7, 2025, via Redcap.
- No late LOI or applications will be accepted.

Benefits

- Provides partial salary support, research funding, and protected time for conducting research, reducing the financial pressures on scholars.
- Structured career development activities, including courses, webinars, and training sessions, to help scholars enhance their skills and knowledge.
- Access to experienced mentors who provide guidance, support, and advice on research projects, career paths, and professional development.
- Helps in preparing scholars for the next steps in their careers, whether that be securing an independent research position, transitioning to individual K or R01 funding, or other professional advancements.

Expectations

- Each K12 Scholar is required to meet with the Wright Center K12 leadership four times a year to discuss program progress and goals for the coming year, which include research questions, publications, grant applications, and leadership. Mentors are required to attend at least two meetings.
- Each K12 Scholar is required to assess their clinical and translational skills development yearly. The skills self-assessment is due every January. The skills assessment and subsequent reflection will support the drafting and updating of an Individual Development Plan (IDP) that each scholar is required to maintain.

- Scholars are expected to maintain and use their IDPs at the biannual review meeting with K12 leadership. IDPs must be reviewed and signed by a primary mentor. Scholars are also expected to complete other surveys and assessments as requested by the Wright Center staff.
- Scholars are expected to dedicate their protected time to research.
- Scholars are required to complete the following set of courses to ensure that they gain a core set of competencies.
 - CCTR 520: Fundamentals of Research Regulation
 - CCTR 630: Design Implications in Clinical Trials
 - CCTR 640: Team Science
 - CCTR 690: Research Seminars in Clinical and Translational Science
 - OVPR 601: Scientific Integrity or
 - OVPR 602: Responsible Scientific Conduct or
 - OVPR 603: Responsible Conduct of Research
 - (Optional) WRLD 302: Communicating Across Cultures or Communication Strategies in Health Services

*Completion will allow one to receive a Post-baccalaureate Certificate in Clinical Research
- Scholar are required to attend the following conferences at least once during their award:
 - The annual **Association for Clinical and Translational Science (ACTS)** meeting. Scholars are required to attend this translational science meeting at least once during the award. In addition to attending, scholars must submit an abstract for consideration.
 - The **Research Conference in the respective field of study.**
 - Wright Center Annual Research Day
- Scholars are required to participate in the following workshops and learning opportunities at least once during their award:
 - **Scholar as Reviewer.** Scholars will participate as reviewers in the Wright Center mock study section program.
 - **Mentorship Training.** Scholars will gain the skills needed to be effective mentors and mentees.
 - **Online CITI Training**
- Scholars are required to conduct presentations to support gaining competence in communicating about science.
 - **Discovery Dialogue Series:** At least once during their appointment, K12 Scholars must present their research to a general audience.
 - **Research-in-progress presentation to the K12 Internal Advisory Committee:** Once a year, K12 Scholars present their progress, research, and career trajectory to the K12 Oversight Committee. Mentors are **required** to attend. Scholars will be assessed and provided feedback to incorporate into their yearly Individual Development Plan.
 - **Scholar Exchange:** Scholars will present their research to a partner CTSA hub as part of the K12 Visiting Scholar Series at least once during the award.

- Each K12 Scholar is to submit a grant application to the NIH by the end of year one or the beginning of year two. Intramural and other smaller external funding opportunities are encouraged as well.
- Mandatory Participation in the Wright Center mock study section program before grant submission.
- Regularly meet with mentor/mentor team to discuss research progress, and career goals, and receive guidance and feedback.
- K12 Scholars are expected to cite the Wright Center's K12 grant (K12TR004364) during their award period and comply with NIH Public Access Policy in submitting their publications. [Read more here.](#)

Section II. Eligibility Information

We aim to have representation of candidates across the clinical and translational spectrum and from [underrepresented populations](#). K12 Scholars come from a robust and diverse pool of junior faculty within the translational workforce at VCU. The pipeline includes several feeder programs, such as T32 programs, the Department of Internal Medicine's Rising Scholars program, and the Wright Center's Emerging Scholars program.

To be eligible to apply for Wright Center's K12 Mentored Career Development Program, applicants must:

- Have a full-time faculty position (current or offered) in one of the schools or colleges at VCU, or partnering institutions, at the **assistant professor** rank.
- Late-stage postdoctoral fellows who anticipate transitioning to faculty positions who anticipate transitioning to faculty positions will be considered case by case.
- Have a terminal degree in a discipline applicable to clinical and translational research. These degrees include but are not limited to:
 - M.D., Ph.D., M.D.-Ph.D., Pharm.D., D.O., D.D.S., O.D., Psy.D., D.M.D.
- Be a U.S. citizen or lawful permanent resident. Permanent residents must have a U.S. Permanent Resident Card or other verification of their legal status as a permanent resident at the time of application. Individuals on temporary or student visas are not eligible.
- Have an ongoing program of research – that is, be pursuing a clinical and translational research project.
- Have a current and established primary mentor relationship.
- Commit to two years in the program. During this time, at least 75 percent (9 months) of the scholar's full-time professional effort must be devoted to the K12 Program. Candidates in surgical subspecialties are required to dedicate at least 50% (6 months). The remainder of the scholar's time may be devoted to other clinical or academic pursuits that are consistent with developing a career as an independent clinical researcher.
- NOT have a pending application for any other Public Health Service (PHS) agency's mentored career development award (K07, K08, K22, K23, etc.) that duplicates any of the provisions of the K component, at the time of their appointment.
- NOT be a former or current PD/PI on any NIH research project grant (this does not include NIH small grants (R03)) or equivalent non-PHS, peer-reviewed grants that are over \$100,000 direct costs per year, or project leaders on sub-projects of program project (P01) or center grants (P50).
- NOT be the recipient of an R01, P or U54 award. The applicant cannot have been a principal investigator on an NIH R01 award or on a sub-project of a program project (P01), center (P50, P60 or U54) or other equivalent research award. Applicants may have had support on a National Research Service Award grant (F or T series), NIH small grant (R03), exploratory developmental (R21), or SBIR, STTR (R43, R44 grants).

Section III: Application and Submission Information

The two-phased application process consists of a Letter of Intent (LOI) and a Full Application. Please note a LOI is required for this application process. Top candidates will be invited to submit a full application. All submitted LOI's and applications will be scored by the K12 program Internal Review Committee using the NIH 1-9 score system (with 1 being exceptional and 9 being poor.)

Letter of Intent

The required LOI must be submitted through REDCap at the link found in the announcement and hyperlinked web address. All letters of Intent must be submitted through the online process by **12:00 PM on March 3rd**. No late Letters of Intent will be accepted. **All attachments must be in PDF Format.**

The LOI form requires you to:

- Provide a short description of the research you will conduct as a K12 scholar or upload a well-developed rough draft of your specific aims
- Describe the Mentor-Mentee relationship (person, length of time working together, other mentors, plans for independence)
- Describe why participation in this career development program will help you to become a successful independent investigator.
- Upload the most recent copy of your CV
- List of all past, current, and pending research funding

The LOI will be used to assess your eligibility as well as inform the reviewers of your preparedness to be a K12 scholar.

All applicants will be notified if they will proceed or not proceed with the full application. If you have any questions or concerns, please contact the Program Manager, Brad Williams at williamsb12@vcu.edu.

Full Application

The required Full Application must be submitted through REDCap through the invited link that will be sent to the top-scored LOIs. All applications must be completed fully on REDCap by **12:00 PM on April 7th**. No late applications will be accepted. **All attachments must be in PDF Format.**

The application requires the following information:

- Personal Information (ERA commons username, ORCID)
- Current University Employment Information
- Personal Statement (One Page Maximum)
- Career Development Plan (Two Pages Maximum) –
 - Outline of 5-year goals. Please include a timeline (figure or table)
 - Identify the gaps in your training that you intend to fill in this program
 - How will this program and your proposed mentor(s) will help fill those gaps?
 - How will you meet the NIH requirements for training in responsible conduct of research? (see

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-055.html> for more information).

- Research Plan (Seven Pages Maximum) – Specific Aims (One Page Maximum), Significance, Innovation, Approach, Preliminary/supportive data.
 - Specific Aims (One Page Maximum)
 - Significance, Innovation, Approach (6 Page Max)
 - Significance of the problem. State how the proposed project will improve scientific knowledge and/or change the field of study; what will be the (short- or long-term) impact of the research on human health; what will be the long-term impact of the proposed research on health inequities.
 - Innovation by explaining how the proposed project challenges current practice or creates a novel approach to the problem.
 - Approach by describing the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project, noting in particular how it is clinical and/or translational. Discuss potential problems, and alternative strategies, and include a list of milestones/benchmarks for success anticipated to achieve the aims. For materials and methods, highlight powerful non-routine approaches, summarize routine approaches, and address statistical approaches.
 - Must include a statement on inclusion of NIH Rigor and Reproducibility Guidelines,
 - A timeline for your proposed work within the 2-year funding period (table or figure)
 - References to Scientific Literature (Not Included in Page Limits)
- NIH Formatted Biosketches (to be uploaded to the Application): Applicant and Primary Mentor. NIH – Biosketch Template <https://www.ncbi.nlm.nih.gov/sciencv/>
- CV -Including Funding History
- Reference Letter from an individual (previous mentor or other professional associate, but not your proposal primary mentor) who can speak to your research/scientific qualifications.
- Letter of support from your proposed primary mentor. The Letters should acknowledge awareness and support of the project and address the role and qualifications of the mentor for the project.
- Primary mentor Biosketch and CV
- Letter of support from your department chair including a statement agreeing to provide 75% protected time for the duration of the award period.

Section IV: Application Review Information

Each application will be read by two reviewers. Applications will receive an Overall Score (NIH 1-9 scale). Individual components will also be scored 1-9.

The overall impact will reflect an evaluation of the trainee, the mentoring team, the training plan, and the proposed research. All are equally weighted, and the reviewers will assess the overall fit of the components together.

Section V. NIH/NCATS Prior Approval

Prior approval of all research subject to review by the IRB or IACUC is required by the National Institutes of Health National Center for Advancing Translational Science, which funds the VCU Wright Center. Full applications identified as meritorious for funding through comprehensive review will be subject to NIH prior approval before the release of funds.

Documentation for this federal review will be collected from applicants and submitted after acceptance of the award if selected for funding. Information provided in the human subjects research and/or vertebrate animals research sections will be used to assemble the prior approval documentation. Depending on your research, additional information may be required. Wright Center staff will reach out to applicants selected for funding as soon as a signed letter of offer is received to work with potential K12 scholars to collect all necessary documentation. Once submitted to the NIH, the prior approval process takes approximately 1 to 2 months to complete. Therefore, the sooner the packet is submitted, the more likely NIH approval will be received by the announced start date of the K12.

A protocol approved by the appropriate review board (IRB, IACUC) is required before a prior approval submission to NCATS can be made. Therefore, the sooner your project receives the appropriate regulatory approval at VCU, the sooner it can be submitted to NIH for prior approval. Regulatory approval before submission of the K12 application is highly recommended.

Suppose your project is subject to prior approval. In that case, part of the required documentation is that all study team members have obtained CITI training or equivalent training in human research protection, as well as GCP training. If the project involves the use of animals, all study team members must obtain the relevant animal use training. Applicants should ensure that all research team members have completed and are up to date in their required training, as incomplete records will delay submitting the prior approval application. See the Office of Responsible Research Practices website for study team training requirements.

If the NIH/NCATS declines prior approval, the Wright Center cannot support the project.

Section VI. Award Administration Information

A formal Letter of Offer will be provided to the applicant. A completed and signed Award Acceptance Letter is required before the start date.

Award Requirements

- The NIH requires individuals supported by the K12 to have ORCID IDs (Open Researcher and Contributor Identifiers) beginning in FY 2020. You may acquire your ORCID here: <https://orcid.org/>
- Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest.
- Any clinical trial supported by this grant will have an NCATS approved DSM plan or DSM Board, as appropriate, and the researcher will comply with that plan.
- Clinical trials beyond the end of Phase IIA cannot be supported by this grant.
- If this award provides support for one or more clinical trials, by law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration System Information Website.
- All foreign activities must be cleared through the NIH foreign component tracking system.
- The Statement of Appointment form (PHS 2271) will be submitted for the awardee by CCTS staff each year at the time of appointment through xTrain, and the awardee will comply with any requests for action or information related to xTrain appointment in a timely manner.
- This award is issued in accordance with, and is subject to, the conditions set forth in PAR-18-464 "Institutional Clinical and Translational Science Award (U54)," which are hereby incorporated by reference as special terms and conditions of this award. This RFA may be accessed at: < <https://grants.nih.gov/grants/guide/pa-files/PAR-18-464.html> >
- • This award is issued in accordance with, and is subject to, the conditions set forth in the NIH grants policy statement as of the date of this letter and subsequent updates. By accepting an award, you agree to comply with the requirements in the NIH Grants Policy Statement except where the notice of award states otherwise. See: <https://grants.nih.gov/policy/nihgps/index.htm#>

Section VII. Wright Center K12 Program Contacts

Faculty Development Program Manager

If you have any questions regarding this RFA, please contact:

Brad Williams, MSPH

K12 Program Manager

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Please click on the following link to schedule a meeting with me at your convenience: <https://calendly.com/williamsb12/>

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