

The UAMS Translational Research Institute (TRI) is pleased to invite applications for the 2025 K12 Career Development Award (K12). The K12 Program provides support for early career faculty who are committed to an academic career in multidisciplinary clinical or translational science. The K12 Program is a two-year program of intensive training in clinical and translational science, combining an innovative educational program with strong mentorship.

Program Description

The K12 Program is a core element of TRI's efforts to develop a thriving translational science ecosystem that catalyzes discoveries into health solutions for rural and underrepresented populations. Our mission is to develop new knowledge and approaches that will measurably address the complex health challenges of rural and underrepresented populations. The K12 program aims to increase the quality and quantity of translational scientists conducting innovative research on health issues that impact residents of Arkansas and the U.S.

The awards are designed to support the career development of junior faculty who are committed to a research career in clinical and translational science. The K12 is a two-year program that provides intensive training and mentorship to assist them in becoming independent scientists. This highly competitive program is geared towards promising junior faculty who have a demonstrated record of high achievement and a clear vision of their career goals. Scholars are selected using a rigorous, multi-stage application process.

K12 scholars are funded by the Clinical and Translational Science Award (CTSA) Program and will receive salary support up to \$118,000 (including fringe) per year. Scholars are required to dedicate a minimum of 75% effort to the program; therefore, the sponsoring department or college may be required to supplement support to meet the salary requirement. Salary supplementation may be from a variety of sources, but must be in accordance with NIH Grants Policy on Research and Career Development Awards.

Up to \$25,000 of non-PI salary support will be provided per year, which can be used for research, tuition, travel expenses (including the ACTS national conference in the spring), educational materials in support of the scholar's career development plan, or other costs related to the research project.

NCATS Definitions

Translation: The process of turning observations in the laboratory, clinic, and community into interventions that improve the health of individuals and communities – from diagnostics, preventions, and treatments to medical procedures and behavioral changes.

Translational Science (TS): 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. TRI recommends these three papers to learn more about Translational Science.

Translational Research (TR): The endeavor to traverse a particular step of the translational process for a particular target or disease.

K12 Award Components

The K12 Program has three main components: mentorship; a career development plan (CDP); and a research project.

Mentorship: Strong mentorship is a critical component of the K12 Program. Each scholar will form a mentor committee with a primary mentor and up to 3 additional mentors. The primary mentor commits to the scholar's successful career development and supervises their research project. The scholar and primary



mentor consult regularly at an agreed upon frequency in a mentor-mentee agreement during the 2-year program.

An ideal primary mentor has expertise in the scholar's area of research, a strong record of extramural research funding, a history of successful mentoring, and sufficient available time to oversee the scholar's research and career development. Primary mentors are required to participate in mentorship training, quarterly meetings with the program directors, and mentee evaluations.

Each of the other 1-3 members of the mentoring committee plays a unique and complementary role in supporting the scholar's research and career development. They have complementary expertise and can assist the scholar in learning techniques and skills. At least one member of the mentoring team should be from a different department, division, and/or discipline than the scholar. Awardees supported by the Winthrop P. Rockefeller Cancer Institute have at least one faculty member from the institute on their mentoring committee. Scholars may also receive consultation and focused mentorship from other subject matter experts.

Career Development Plan (CDP): The CDP should serve as a blueprint or map that articulates the activities and milestones on the scholar's path to becoming an independent researcher. The CDP outlines the scholar's goals and the role the K12 Program plays in meeting them. The CDP gives specific timelines for all the scholar's K12 activities and identifies the personalized training and education plan to gain the needed skills, knowledge, and experience to advance to the next step in their career. Scholars may participate in the many seminars, workshops, and programs TRI offers. The CDP may include planned participation in lab meetings or journal clubs, attendance at research conferences, formal coursework on clinical and translational science topics, participation in additional training experiences in clinical or basic science (either at UAMS or externally), and/or informal educational activities such as guided readings or workshops. Scholars are expected to submit an extramural career development K grant or an independent research R grant by the first quarter of the second year. The CDP should identify which specific grant application the scholar will submit during the first quarter of the second year and explain how the current research plan supports that submission. The CDP further defines the mentor/mentee relationships required during the program.

Research Project: Scholars conduct a clinical or translational science project that is supervised by their primary mentor. The research project is designed as a pilot project to set the stage for an individual, external K-award application or to establish the foundation for an R-award application. The research project must be feasible within the available K12 funds and the CDP timeline. The research project should be aligned with the CDP such that it allows the scholar to demonstrate newly learned techniques and skills. It also should provide an opportunity to collaborate and publish with mentors.

Program Requirements:

Scholar Expectations: Scholars in the K12 Program are required to participate in certain activities. Failure to adhere to the responsibilities may result in suspension of the project and ineligibility for future support from any TRI program. Requirements include:

- Committing to the required two-year program. K12 scholars are not allowed to relinquish or terminate their K12 participation early. For example, scholars cannot accept a Project Lead position on a Centers of Biomedical Research Excellence (COBRE) award until after their 2-year K12 program completion.
- Attending an in-person orientation meeting. Date/time will be announced following the notice to selected scholars.
- Submitting a Mentor-Mentee Agreement specifying expectations between scholars and mentors, including meeting frequency, resources provided, and other expectations of the mentor relationship.
- Completing a Core Competency Self-Assessment to identify and prioritize training and educational activities.



- Providing mentorship evaluations.
- Attending K12 Training and Education seminars and meetings, including monthly Research Fundamentals seminars, Work in Progress meetings, Quarterly K12 Directors' meetings, and other activities related to translational science.
- Participating in the Annual Association for Clinical and Translational Science (ACTS) Conference.
- Participating in the Annual TRI Research Day by presenting a poster or oral presentation.
- Completing TRI-sponsored communication training
- Completing NIH-required Responsible Conduct of Research (RCR) Training.
- Publishing manuscripts in peer-reviewed journals (at least 5 by end of year two). We anticipate that
 most K12 scholars will have considerably more than 5 publications.
- Submit an extramural career development or R-level grant by the first quarter of the second year of the award (Y2Q1).
- Completing CSE 101: Training in Community and Stakeholder Engagement course.
- Completing a dissemination plan for the study results.
- Fully expensing the award within 2 years.

Mentor Expectations:

- Attending a mandatory mentorship training program (for primary mentors)
- Completing the Mentorship Competency Assessment
- Submitting evaluations of their mentee
- Attending regular meetings with mentee
- Attending quarterly meetings with program directors and the primary mentor (other mentors may attend as needed.)
- Completing a mentor-mentee agreement
- Attend Center for the Improvement of Mentored Experiences in Research Training (CIMER)

Scholars must submit reports and respond to data requests including:

- Quarterly reporting of progress on planned research tasks, career development activities, and mentorship meetings.
- A Final research report, a final expenditure report, and an updated CV are due within 60 days following the close of the grant term.
- Program evaluation interviews and surveys.
- Surveys of post-K12 career and academic accomplishments for up to 15 years following completion date.

Additional Expectations:

TRI Acknowledgments: Scholars must acknowledge the support of TRI in any news releases, articles, presentations, or manuscripts during or as a result of participation in the program. Notification must be provided to TRI.

Citation language: "Research reported in this publication was supported by the National Center for Advancing Translational Sciences of the National Institutes of Health under award number K12 TR004924. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health."

Changes in Scope: Changes in the scope of work, scholar's effort, mentor changes, and budget changes ≥ 25% of the approved budget must be submitted in writing to the TRI Administration and will be reflected in a revised Notice of Award provided to the scholar, and some changes may require subsequent approval by



NCATS. Scholars are committing to the two-year program. In the case of an extraordinary event, the scholar must notify TRI in writing if they are unable to complete the project and must terminate the award.

Eligibility requirements

- A terminal degree in a health discipline applicable to clinical or translational research. These degrees include, but are not limited to, MD, PhD, PharmD, DNP, DrPH, DO, DPT, OTD, etc.
- U.S. citizenship or status as a non-citizen national or permanent resident. Individuals on temporary or student visas are not eligible.
- Full-time faculty at UAMS, Arkansas Children's Research Institute, or the Central Arkansas Veterans Healthcare System at the rank of Instructor or Assistant Professor at the time of the K12 award.
- Ability to devote 75% professional effort to the program for two years. (In very rare instances, exceptions are approved by NIH for physicians in certain clinical specialties, but not less than 50%)
- Support of a mentoring team approved by the program.
- Approval of the applicant's department chair.
- Applicants are not allowed to have served as principal investigator on an NIH R01, a project leader
 of a program project (P01) or center (P50, P60, U54) grant, have a career development grant
 (K23, K08, K01, CDA), a VA Merit Award, or another equivalent grant award.
- Applicants must not have an individual NIH K award under review with NIH.
- Applicants who are dually employed by UAMS and the Central Arkansas Veterans Healthcare System (CAVHS) may be restricted from receiving a K12 scholar award, depending upon the extent of commitment (percent effort) to the CAVHS.

The TRI Mentored Research Career Development Scholars Program welcomes and encourages underrepresented and minority individuals, individuals with disabilities, and individuals from NIH-defined disadvantaged backgrounds to apply. https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html



Important Dates

Item:	Date/Timeframe:
Informational Session	October 15, 2024, 11:30 am – 12:30 pm
Informational Session	October 28, 2024, 4:30 pm – 5:30 pm
Individualized Support	November 4, 2024 - March 3, 2025
K12 Application Development – Dr. Schootman Session 1	November 4, 2024, 1:30 pm – 3:00 pm
K12 Application Development – Dr. Schootman Session 2	November 12, 2024, 1:30 pm – 3:00 pm
Letters of Application Due	December 16, 2024, 3:00 pm
Invitation to Submit Full Applications	December 20, 2024
Community and Stakeholder Engagement (CSE) Group Consultation	January 28, 2025, 2:00 pm – 3:00 pm
Community and Stakeholder Engagement (CSE) Group Consultation	February 7, 2025, 10:00 am – 11:00 am
Comprehensive Informatics Resource Center (CIRC)/ Biostatistics, Epidemiology, and Research Design (BERD) Consultations Completed	February 13, 2025, 5:00 pm
Budget and Justification Due for TRI Review	February 13, 2025, 5:00 pm
Projects must be submitted to the IRB and/or the relevant regulatory body for approval	February 13, 2025, by 5:00 pm.
 Proof Regulatory Submission Due (IRB, IACUC, IBC). Attach proof of submission or non-human subjects research determination. For projects that involve animal research, submit a copy of an email from IACUC certifying that your request has been submitted for review. Cancer-related projects please visit the <u>Cancer Clinical Research Pre-Review Approval website</u> to learn more about the Cancer Institute Disease Oriented Committees (DOC) and Protocol Review and Monitoring Committee (PRMC) 	Proof of all submissions/protocols due March 3, 2025, 5:00 pm
Applications Due	March 3, 2025, 5:00 pm
Application Review	March 7 – March 27, 2025
Review Session	April 2, 2025
Potential Awardee Interviews with Directors	April 4-24, 2025
Awardees Notified	First week of May
Prior Approval Documents Due to the TRI Research Quality Officer, when applicable	June 2, 2025, 5:00 pm
Project Award Dates	July 1, 2025 - June 30, 2027



Selection Process

Scholars are selected using a highly competitive process that includes the submission of a Letter of Application (LOA), Full Application, and Interview. LOAs are reviewed by TRI program faculty, and full applications are invited. Full applications are independently peer-reviewed by a multidisciplinary study section panel. All applicants will receive reviewer comments. Please see below for detailed instructions of the application components and processes.

Letter of Application

Applicants must submit a Letter of Application (LOA) no later than 3:00 pm, December 16, 2024, through the TRI's <u>Apply Grant Application</u> system. Applicants are required to establish an account with <u>Apply</u> to submit their application. Please refer to the <u>instructions</u> on how to make an account in <u>Apply</u>. Contact <u>Crystal Sparks</u> at 501-526-8730 if you have any questions. LOAs will be evaluated by the program leadership to determine if the applicant is eligible and appropriate for the K12 program. **Applicants will only be invited to submit a Full Application if their LOA demonstrates that they could feasibly submit a competitive full application**. Reviewers will consider the qualifications of the applicant, the strength of the mentorship team, and the career development plan. LOAs that lack a meaningful Career Development Plan will not be viewed favorably.

The LOA submission must include:

- A 3-page narrative that includes:
 - Career Development Plan Summary that describes short (K12 award) and long-term (beyond the K12 award) career goals and how the K12 program will help the scholar achieve them. This summary should articulate planned "next steps" after the K12 program and how the planned training and research activities align with it. Provide a high-level timeline for accomplishments during the two years.
 - Mentoring Plan Summary that identifies the primary mentor and up to 3 other members of the mentoring committee. This summary should describe each mentor's specific role in training and research activities. Briefly describe their expertise, affiliations, and qualifications. Explain the frequency of planned meetings and what support they have committed to provide.
 - Research Specific Aims (no more than 1 page) that also describe the project's innovation and potential impact on human health.
 - Translational Science Impact and Innovation that explains the significance of the project and career development as it relates to Translational Science. It is expected that the K12 award will develop the scholar to be an active member of the translational science workforce.

The LOA should have 0.5-inch margins and be no longer than three pages. Acceptable fonts are Arial, Tahoma, or Calibri with a font size of 11 point. Figures and Tables may use a smaller font, but no smaller than 9 point.

In addition to the narrative LOA, applicants will upload:

- o **Biosketches** for the applicant and each mentor entered as part of the mentoring committee using the current NIH format.
- o **Primary Mentor Statement** as a 1-page letter from the mentor that describes their mentoring experience and their role in mentoring the applicant. The letter should indicate the mentor's availability to meet with the scholar and any resources or support the mentor plans to provide.
- Current CV for the applicant.

All documents must be uploaded as PDFs in the TRI's grant submission system, *Apply*. The full LOA application package will include:



- LOA Cover Page Form (complete in the Apply system)
- Mentoring Committee Form (complete in the Apply system)
- LOA Narrative (PDF to upload in the Apply system)
- o NIH Biosketches (PDF to upload in the *Apply* system)
- Primary Mentor Letter (PDF to upload in the Apply system)
- Applicant's CV (PDF to upload in the Apply system)

LOA applications must be submitted in Apply no later than 3:00 pm, December 16, 2024.

Full Application:

Selected applicants will receive an invitation to submit a full application that includes a link to *Apply*. Full applications are due March 3, 2025, by 3:00 pm.

Required Pre-Application Consultations

Combined BERD/CIRC Consultation: Scholars are required to have a joint consultation with Biostatistics, Epidemiology, and Research Design (BERD) for study design and the Comprehensive Informatics Resource Center (CIRC) I for statistical approaches and informatics approaches. TRI K12 staff will assist you with requesting the BERD and CIRC consults through the TRI portal. A summary of the consultations will be uploaded in *Apply* for verification by February 13, 2025, by 3:00 pm.

CSE Consultation: Scholars are required to have a consultation with Community and Stakeholder Engagement (CSE) to identify appropriate community audiences. TRI K12 staff will assist you in registering for a CSE consult. An email confirmation of attendance will be uploaded in *Apply* for verification by February 13, 2025, by 5:00 pm.

The invitation to submit a full application will provide specific instructions. Applicants will need to fill out forms in *Apply* and upload documents such as the research plan, budget, and biosketches. Below is a full list of application materials for invited applications.

The following is an outline of the full application requirements.

- 1. Demographic and contact information
- 2. Biosketch for applicant, and each mentor using the current NIH format.
- 3. Applicant and mentorship team Other Support documents.
- 4. Completed <u>Table A</u> a detailed report on each proposed mentor's post-doctoral mentees over the last 10 years.
- 5. Career Development and Mentoring Plans. See suggestions on the development of a good CDMP.
 - Five-page maximum.
 - Should reflect that the entire mentorship team has contributed to the plan's development.
 - Brief summary of accomplishments and career path to date. This should include a critical selfappraisal of training needs and a description of how the mentor and mentoring committee will meet these needs.
 - Description of overall career goals, both short-term (K12 award) and long-term (beyond the K12 award). The Career Development and Mentoring Plans should address how the scholar will focus on Translational Science and apply translational science principles in their career.
 - Identification of specific learning and training goals with an explanation of how each experience
 will contribute to the path to becoming an independent researcher and how it will add to
 previous training and experiences. Planned activities should include specific didactic
 coursework and, if appropriate, plans to pursue an MS, MPH, PhD, or Graduate Certificate in
 Clinical and Translational Sciences (CTS). Applicants no longer requiring formal career
 development/research training are not appropriate Applicants for this award.
 - The Mentoring Plan should provide more detail than the summary in the LOA. It should include



details on planned communication methods, meeting frequency, and how conflicting advice will be managed. It should further describe the primary mentor's qualifications to serve in that role, each mentor's background and expertise with clearly defined roles, and how they will contribute to the applicant's growth as a researcher or the Applicant's research project. The mentoring plan should address meeting frequency and content.

- 6. Research Plan (five pages maximum) that explicitly explains how the research project aligns with future goals and other training activities. The first page of the Research Plan is the Aims page. The plan should describe the significance of the proposal in terms of scientific advancement and its contribution to the career development plan. A brief overview of the methodology must contain sufficient detail to demonstrate feasibility. A detailed timeline must include the alignment of project tasks with manuscript and grant preparations.
- 7. Letters of Recommendation, which should include:
 - Letter from the Primary Mentor: This letter should detail his/her support of and commitment to the proposed research and training plan. This letter must include the mentor's assessment of the Applicant's qualifications, in particular motivation and potential for future success. The letter should address the role and expertise of each member of the mentoring committee, a mentormentee meeting schedule, and confirm that adequate space, facilities, and resources will be made available for the successful completion of the project. The letter should describe how the proposed research fits into the mentor's research program, including a description of the mentee's specific role in the research. This letter should not exceed three pages. It should contain specific commitments to provide support and resources described in the application.
 - Letter of recommendation from other members of the mentoring team. Each letter should not
 exceed two pages. The letter should describe the mentor's unique role on the mentorship team
 and the career development plan. The letter should confirm any commitments of support and
 resources described in the application.
 - Letter of recommendation from the chair of the Applicant's department/division or dean of the Applicant's college. This should include assurances that research and career development activities will account for at least 75% of the scholar's time and that other responsibilities will be restricted to no more than 25% of the scholar's time. The letter should also comment on plans for further career development of the Applicant after the end of the K12 Scholar Award and should address the applicant's motivation and likelihood of becoming an independent investigator. This letter should not exceed two pages.
 - Letter of financial acknowledgement. This letter is to be signed by both the department chair and
 financial administrator stating that a financial analysis has been completed and that they are both
 aware of the financial impact to the department. The letter must include an acknowledgement
 that any equipment purchased with program funds becomes the property of the TRI at the end
 of the award.

8. A budget and budget justification

- A budget should be provided for both year one and year two, separately.
- All applicants must have their budgets reviewed by TRI.
- Applicants should send their draft budget and justification to Nik Berardi via email by February 13, 2025, by 5:00 pm. to ensure enough time for review.
- Once the budget has been reviewed and is properly filled out with all expenses allowable, the TRI Director of Business Operations will provide an email stating that the budget is cleared for submission. Please include that email in the application after the budget justification.
- The budget must include funds to travel to the ACTS Translational Science Meeting every March/April.



- Note that any TRI biostatistics, nursing, or coordinator support that is required to conduct the study must be included within the budget.
- Any equipment required for the project must be justified. Computers and other office supplies are not allowed.
- 9. Proof of required pre-application consultations. This can be a PDF upload of a consultation summary provided by the consults.
- 10. Proof of appropriate regulatory submission.
 - Projects must be submitted to the IRB and/or the relevant regulatory body for approval by February 13, 2025, by 5:00 pm.
 - Attach proof of submission or non-human subjects research determination.
 - For projects that involve animal research, submit a copy of an email from IACUC certifying that your request has been submitted for review.
 - If applicable, Cancer Institute Disease Oriented Committees (DOC) and Protocol Review and Monitoring Committee (PRMC) approvals.

Review Process and Criteria

- Applications will be independently peer-reviewed by a multi-disciplinary panel of UAMS affiliated researchers. Written reviews are based on NIH K-application review criteria. An NIH-style study section will be conducted.
- Proposals will be evaluated based on 1) applicant qualifications; 2) career development plan; 3) mentors and mentoring plan; 4) research plan; and 5) environment and institutional commitment
- Note: the research plan will be evaluated on how well the timing, tasks, and scope align with the career development plan and the planned training activities.
- Applications with the highest priority scores will be recommended for funding.

Interviews: K12 Program Leaders may conduct interviews with top potential applicants from the study section discussion. Applicants will be invited to interviews between April 4-24, 2025. The interviews are brief (approximately 30 minutes) and are not meant to be evaluative. The interviews provide an opportunity to clarify concerns or questions raised in the study section, to answer the applicant's questions, and to observe strengths that may not have been noticed in the written application.

Final Selection

K12 and TRI Leadership will make the final selection of scholars based on recommendations from the review committee and institutional priorities. We anticipate offering 4 to 10 awards with funding from NCATS and institutional funds.

Required Pre-Reviews and Approvals

All projects selected for funding must complete all regulatory approval processes prior to study initiation. Documentation of IRB or IACUC approval must be submitted to TRI Program Administration.

NCATS Prior Approval: Before research projects can begin, applications meeting the NIH definition of Human Subjects Research will require scientific review and approval by NCATS. Awardees are required to submit all requested Prior Approval documents to the TRI Director of Quality Management no later than June 3, 2025.

More information will be provided to awardees upon notification of the award.

Cancer Related Studies: Cancer-related projects must receive approval through the Cancer Institute Disease Oriented Committees (DOC) and Protocol Review and Monitoring Committee (PRMC) before initiating the study. Please visit the Cancer Clinical Research Pre-Review Approval website to learn more about the process. You can contact Nia Indelicato with any questions about the DOC and PRMC process.

TRI Program staff are available to answer questions and notify applicants of any relevant requirements as part of the invitation to submit a full application.



Official Notice of Award: Following all necessary regulatory approvals and official NCATS approval or notification, TRI will issue the official Notice of Award, which will provide the project period, accounting information, contacts, and rules and restrictions, and the study can begin. Any changes to scope, budget, personnel, etc. will not be considered active until the scholar has notified TRI in writing of the requested changes, submitted any required reports or documentation, and received a revised Notice of Award that reflects the change(s).

TRI Mentored Research Career Development Scholars Program Contacts

If you have any questions regarding this RFA, please contact <u>Crystal Sparks</u>. For more information about the TRI Career Development Scholars Program, you may contact the following or review the <u>TRI K12 site</u>.

Program Administration

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