

## Collaborative Clinical and Translational Science Pilot Program

### Funding Opportunity Announcement

March 18, 2024

The UAMS Translational Research Institute (TRI) invites applications for the Collaborative Clinical and Translational Science Pilot Program (CTSP2). Our mission is to develop and test translational science innovations that will drive real-world solutions to enhance health equity for rural and underrepresented populations. For this Funding Opportunity Announcement (FOA), TRI seeks proposals that employ translational approaches to address the health challenges of rural and/or underrepresented populations. Specifically, TRI is accepting applications that will employ novel team approaches to address any of the following focus areas:

- Health concerns and challenges of rural and underrepresented populations
- Implementation science to incorporate new research findings into the health care system, including rural settings
- Biomedical informatics approaches, including artificial intelligence to improve disease diagnosis or prevention
- Community and/or stakeholder-partnered research
- Public health emergencies/emerging priority needs
- Lifespan research.

The purpose of this FOA is to **establish team approaches in translational science among mid-level and senior faculty in durable collaborations** and generate data to advance to extramural funding. This FOA requires that projects include one or more principles of Translational Science (TS) as defined by the National Center for the Advancement of Translational Science (NCATS). Unlike translational research, which is concerned with traversing a particular step of the translational process for a specific target or disease, translational science seeks to overcome longstanding, general challenges of translational research. We encourage you to learn more about translational science principles [on the NCATS website](#). In addition, we recommend reading [these three papers](#), and additional information can be found [on TRI's website](#). All applicants are highly encouraged to talk with CTSP2 Directors (Mathias Brochhausen, PhD, and Shelley Crary, MD) to ensure that your proposal is incorporating a translational science approach. Consistent with the vision of NCATS, CTSP2 will provide the opportunity for TS teams to develop innovations, demonstrate their effectiveness or impact, and disseminate discoveries to the CTSA network.

The overall purpose of this FOA is to support projects that generate critical data to improve competitiveness for future extramural funding. Projects at all levels of the translational spectrum will be considered; but all proposed projects must demonstrate one or more translational science principles; and priority will be given to projects that meet an immediate translational need or can be incorporated into clinical practice in the short term. Projects with the potential to develop into future multi-site studies will be given special consideration. These awards will not support projects that are minor offshoots of ongoing research by existing teams. Likewise, these awards will not support bridge funding to previously funded investigators.

Budgets up to \$50,000 for a one-year project will be considered. A review of the budget will be part of the funding decision, and all projects must be scaled to feasibly be completed within a one-year project period. **NCATS will not allow extensions** beyond a 12-month project period. Awardees will be provided with ongoing review and guidance to support project completion within the timeline. **All projects under this FOA must be complete by 6/30/2025.**

#### Eligibility

Contact PI should have a terminal degree; must be full-time faculty at UAMS, UAMS-NW, ACH/ACRI, or CAVHS who hold non-temporary positions at the rank of Associate Professor or above; must be a US citizen or permanent resident. Other

PIs/team members may be faculty at the rank of Instructor or above or project leads from community organizations. Proposals must include a team-based collaboration with other faculty or community groups/organizations. Multiple PIs (MPI) are encouraged, and a plan describing how team members will work together with a description of the division of responsibilities across the team must be included in the proposal (MPI plan).

### **Management Oversight Committee (MOC)**

CTSP2 awards will be overseen by a Management Oversight Committee (MOC) to provide ongoing review of progress and to ensure that awardees benefit from TRI's available resources. The MOC will meet quarterly with CTSP2 awardees to review research progress and provide recommendations/support to projects that are not meeting study timelines. When needed, additional faculty or staff will join these meetings to ensure that awardees have a broad array of resources to complete their projects. Awardees will submit quarterly progress reports to the MOC prior to meeting.

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### **Letter of Application (LOA) Submission Process**

LOAs are solicited broadly from UAMS and related campuses including CAVHS, ACRI, and UAMS - Northwest. All applicants are required to use TRI's online application system, [Apply](#), to enter their basic information and upload a 2-page Letter of Application. The cover page and LOA must be completed by 5:00 pm, May 13, 2024. Contact [Hailey Rogers](#) at 501-526-0363 if you have any questions. Here are [instructions](#) for how to make an account in Apply.

### **Letter of Application (LOA) Format**

Acceptable fonts are Arial, Tahoma, or Calibri with a font size of 11 pt. Figure and Table legends should be no smaller than 9 pt. Please use appropriate headings in preparing your proposal. The LOA must provide information on each of the following points, which will be major factors in scoring and selecting invitations to submit a full proposal:

- Project Summary - summarize the project and the importance of the proposed research at a level easily understood by diverse scientific disciplines.
- Potential impact on health/healthcare.
- Clearly state which of the focus areas your proposal addressed.
- Clearly state how your proposal addresses Translational Science by describing a barrier that the project will overcome, a gap that the project will close, and a description of how the project can be generalized to benefit future research or researchers.
- Approach - briefly describe the scientific approach used to address the research question.
- Plan for future extramural funding - describe your specific plan for obtaining future extramural funding. The plan should include how this project will provide data supporting future extramural funding proposals, including the type of grant (R01, R21, etc), FOA/agency, proposed project length, and date of submission targeted.

### **LOA Review and Selection**

The LOA review committee will consist of UAMS senior faculty, staff, and community members. Each LOA will be reviewed based on the criteria listed above. Based on the outcome of the LOI review, applicants will be invited to submit a full application.

The LOA review and selection committee will prioritize projects that include team-based translational science approaches, that align with one or more of the focus areas of this FOA, and that have a high likelihood and a clearly stated plan to obtain future extramural funding. The likelihood of future funding from extramural sources is strongly influenced by training, environment, and productivity (e.g., peer-reviewed publications) that are appropriate for the PI's current state of professional development. Successful LOAs will address these factors in addition to the specific future funding mechanisms that will be targeted.

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### **Full Application Process**

If you are invited to submit a full application, you should receive a link in the email with this FOA that requests your full application, to be submitted via the [Apply](#) submission system. Contact [Hailey Rogers](#) with any questions. **The submission deadline is 5:00 PM, July 1, 2024.**

## Pre-Application Consults

All projects invited to submit a full application are required to consult with the following TRI groups: 1) CTSP2 Directors to discuss integration of translational science; 2) Biostatistics, Epidemiology, and Research Design (BERD) group concerning design and statistical approaches; 3) Comprehensive Informatics Resource Center (CIRC), for informatics approaches and needs; 3) Community and Stakeholder Engagement (CSE) core for dissemination planning and engagement support; and 4) Paul Duguid, TRI Director of Research Programs with respect to budgeting and allowable costs. These consultations are free to CTSP2 applicants and serve as great resources for strengthening proposals and research design. Additionally, all applicants will receive assistance to facilitate IRB/IACUC approval if needed. Please submit a request through the [TRI Portal](#). Be sure to indicate on the request form that you are an applicant for TRI's CTSP2 Opportunity.

## Proposal Format

Proposals should be typed, single-spaced with 0.5 in. margins. Acceptable fonts are Arial, Tahoma, or Calibri with a font size of no less than 11 pt. Figure and Table legends may use a smaller font, but no font smaller than 9 pt. is allowed to ensure readability. Please use appropriate headings in preparing your proposal. All application documents must be uploaded as a PDF. Please follow the directions for each task in [Apply](#) to upload your application materials.

## Application Content & Instructions

A complete application will include the following components uploaded into [Apply](#). Applications should be prepared carefully. The applicant is responsible for the readability of the entire application.

The application should include the following:

1. Scientific Abstract
2. Biographical sketches of the Principal Investigator(s) and other significant contributors on the team (please use the latest [NIH format](#)).
3. BERD and CIRC consult summary or waiver saying the consult is not needed.
4. Documentation of attendance at CSE and CTSP2 Director consults provided by [Hailey Rogers](#), CTSP2 Program Manager.
5. Prepare a two-page lay summary of the Research Plan; in this summary, minimize jargon and promote readability at a nonscientific lay level.
6. Prepare a ~5-minute lay video that explains your proposed project to a general audience. Allowable video formats are .avi, .mp4, .mov, .wav, .mp3, or YouTube.
7. [Other Support \(PHS 398\) for the contact PI and any other faculty PIs](#). Please refer to other support document [instructions](#) for additional information.
8. Proposed [budget](#) and [budget justification](#), and email from [Paul Duguid](#), Director of Research Programs, certifying budget review (see the Budget section below).
9. Research Plan. Research Plan should include the following sections:

**\*\*Sections A-F are limited to no more than 6 pages total.**

### A. Overall Impact and Significance

- Discuss the significance of this project in terms of innovation and impact on human health.
- Explain the potential for high impact, the importance of the problem, and critical barriers.
- Explain how the proposed project will improve scientific knowledge/practice for health challenges of special populations.
  - Describe the next steps in the research agenda if the proposed aims are achieved.
  - Provide justification and/or evidence that the research question(s) and aims are important from the perspectives/priorities of multiple stakeholders.
  - Explain which of the focus areas your proposal addresses and specify the Translational Science principles included in your approach.

### B. Innovation

- Describe any novel theoretical concepts, approaches, or methodologies, as well as any novel

instrumentation or interventions to be developed or applied in a novel way; describe any advantages over existing methods, instrumentation, or interventions.

- Explain any novel refinements, improvements, or applications of theoretical concepts, approaches, methods, instrumentation, or interventions.

#### C. Specific Aims

- State the specific aims to address the research question.

#### D. Approach

- Describe the overall strategy, methods, and analyses to be used to accomplish the specific aims of the project. Specifically describe how the data will be collected, analyzed, and interpreted. Describe resource sharing plans if appropriate.
- Discuss potential problems, alternative strategies, and milestones for success in achieving the aims.
- Delineate the roles and responsibilities of the team, including an MPI plan if applicable.
- Describe your specific plan for how project findings can be implemented more broadly.
- If the project is in the early stages of development, describe any strategies to establish feasibility. Address the management of any high-risk aspects of the proposed work.
- Describe how the project will solidify new multi-disciplinary research collaborations.
- Describe plans for disseminating and/or commercializing the findings. Awardees will be required to present their study results to a stakeholder group within 1 year of award completion.

#### E. Translational Science Principle

- Describe the translational science aspect of the proposal. Please demonstrate how your project will align with one or more principles of translational science as described above (see linked resources) and how an aspect of your project will support translational science.

#### F. Plan for Extramural Funding

- Plan for Extramural Funding - describe your specific plan for obtaining extramural funding. The plan should include what this project will provide regarding the likelihood of the type of grant (including proposed project length, agency/FOA, and date of submission) that will be targeted.

#### G. Literature Cited

#### H. Timeline/Milestones

- Provide a timeline with expected milestones for the proposed study; propose only what can be accomplished within **11-MONTHS**. [Milestone Template](#).

#### 10. Letter of Support from PI's department chair.

- Submit a letter from the department chair(s) of the contact PI and any other PIs supporting your research and release time for this project.
- For MPIs other than the contact PI at the level of Instructor, please include in a departmental letter confirmation that you are not in a temporary position, and the department intends to develop you as a full-time faculty member.
- If your project includes community organizations or groups, please include a letter of support from the identified community organization(s) that includes the organizational support for their role on the project.

#### 11. Projects must be submitted to the relevant research regulatory body (IRB/IACUC) for approval by June 15, 2024, and must receive full approval, if applicable, before a Notice of Award can be released. **Projects exempt from IRB submission must provide an official letter from the IRB stating that the proposed research has been determined as non-human subjects research.** Proof of IRB and/or IACUC submission OR a non-human subjects determination letter should be emailed to [Hailey Rogers](#) by the deadline.

**Receipt of a human subjects research determination request DOES NOT satisfy the requirement for proof of IRB submission.** Proof of IRB submission is satisfied by: 1) a non-human subjects determination letter, or 2) proof from CLARA that your request for IRB review has been submitted.

Some departments and/or institutes may require pre-reviews *before submitting* to the IRB. For example, all **cancer-related studies** must be approved by the Disease Oriented Committee and PRMC in the Cancer Institute before they can

be officially awarded. Applicants can learn more about this process [on the Cancer Institute website](#). The applicant must ensure that they identify the correct procedures for their department and prepare their required paperwork with sufficient time to meet the June 15, 2024 deadline. TRI staff can assist with these processes, and we encourage applicants to reach out if they need assistance.

For projects that incorporate animal research, please submit a copy of an email from IACUC certifying that your request has been submitted for review.

The earliest start date for all projects is ~August 1, 2024, after prior approval has been obtained. All project work and expenditures must be completed within 11 months. Extensions on CTSP2 grants will not be permitted. TRI will schedule check in meetings to assist with completion of projects on this abbreviated 11-month timeline.

### **Budget**

All projects are required to have their budgets reviewed by [Paul Duguid](#), TRI Director of Research Programs, for budgeting and allowable costs. Please refer to the [Budget Instructions](#) for additional details.

A detailed budget is required for invited full applications. As an intramural award, the CTSP2 will **NOT** support salary for faculty on these studies. These awards may support salaries for non-faculty research and support staff. Staff must be included in the budget, including full-time, post-doctoral faculty who are engaged in research. Major equipment/supplies and travel must be detailed in the budget and essential to the completion of the project. TRI nursing or coordinator support that is required for the conduct of the study must be included in the budget. Non-faculty personnel should be listed on the budget with their roles, effort, and requested salary included. All budgets should represent direct costs only; indirect costs are not allowed and are not charged to the pilot budget.

**Please note**, due to rules regarding effort reporting and budgeting, TRI does **not allow co-investigators on pilot awards**. All additional faculty should be listed as other significant contributors without mention of specific effort and no requested salary. Non-faculty personnel should be listed on the budget with their roles, effort, and requested salary included. All budgets should represent direct costs only; indirect costs are not allowed and are not charged to the pilot budget.

The requested salary and benefits should be consistent with the amount of effort committed. The project should be scaled to the resources available. Any equipment or computers required for the study must be justified according to the cost principles for educational institutions described in [OMB Circular Uniform Guidance](#). You may visit the TRI CTSP2 Awards [Frequently Asked Questions \(FAQ\)](#) page for updated information regarding any questions you may have.

Applicants should send their draft budget and budget justification to [Paul Duguid](#) before June 5, 2024, at 11:59 pm, to ensure enough time for review. Once your budget has been reviewed and any questions or corrections addressed, you will receive an email with stating that your budget is cleared for submission. Please upload a copy of this email along with your budget documents in the Budget Justification section.

### **Application Review and Award Selection**

Full applications will undergo review by at least two scientific experts and one community member. Full applications will be peer-reviewed for scientific and technical merit using the NIH-based review system. This system includes **1) Significance, 2) Impact, 3) Investigator, 4) Innovation, 5) Approach, and 6) Plan for Extramural Funding**. In addition, proposals will be assessed on how well the project aligns with one or more of the TRI focus areas and how the project integrates translational science principles to address common research barriers. Based on these assessments, applications will receive a score and funding recommendation. Applications recommended for funding will be presented to the TRI CTSP2 Administrative Council for final funding decisions.

A summary statement that evaluates the strengths and weaknesses of the application will be provided to the PI whether the project was funded or not.

### **NCATS Review of Awardees**

Per NIH guidance, each recommended application that involves human subjects research and are supported with CTSA grant funding must receive prior approval. We anticipate project start dates of ~August 1, 2024, but the Notice of Award may not be issued by TRI, nor any work on human subjects projects begin, until the NCATS prior approval notification is

received. For more information about the prior approval process, please refer [to the NCATS website](#). TRI staff will assist you with the Prior Approval process, as applicable.

### **Awardee Responsibilities**

The TRI CTSP2 Awards come with responsibilities on the part of the PI. Each PI that is funded will receive a Memorandum of Understanding (MOU). Please review the MOU thoroughly to understand your responsibilities as an awardee. Failure to adhere to the awardee's responsibilities may result in the suspension of the project, and the PI being ineligible to receive future support from any TRI program.

### **Post-Award Monitoring**

PIs will meet with the MOC every three months and will provide a written progress report for discussion prior to each meeting. In addition, PIs will provide a final report once the project is completed for closeout and agrees to provide updates as requested thereafter for at least two years following the project completion date. Depending on the progress in achieving appropriate milestones, the PI may be required to submit additional progress reports.

### **Resources and Services**

An array of resources and services are available through TRI to assist with project development or study conduct (See the "[Services](#)" tab for more detailed information). To access these services, please use the [TRI Portal](#).

### **Timeline**

LOA Due Date	May 13, 2024
Full Applications Invited	May 17, 2024
CTSP2 Faculty Director Consult	May 17 – June 10, 2024
BERD Consultations	May 17 – June 10, 2024
CIRC Consultations	May 17 – June 10, 2024
Budget Submitted for Review	June 5, 2024
Proof of Regulatory Submission Due via email	June 15, 2024
Full Application Due	July 1, 2024
Lay Videos Due	July 1, 2024
Study Section	~July 19, 2024
Awardees Announced	~July 26, 2024
Regulatory Approval, if applicable	ASAP
Earliest Start Date for Projects	August 1, 2024

Please contact [Paul Duguid](#) or [Hailey Rogers](#) if you have any questions about this FOA or the application process.