

Translational Research Pilot Grant Opportunity

Request for Full Application (RFA)

January 3, 2024

The UAMS Translational Research Institute (TRI) invites applications for pilot grants. The mission of TRI is to develop new and novel approaches that will measurably address the complex health challenges of rural and underrepresented populations. For this Request for Applications (RFA), TRI seeks proposals that employ translational approaches to healthcare issues that particularly affect rural individuals and/or that directly examine or impact rural health. Specifically, TRI is accepting applications that will employ novel approaches in or address any of the following focus areas: 1) Health concerns and challenges of rural and underrepresented populations, 2) Implementation science to incorporate new research findings into the health care system, including rural practices, 3) Biomedical informatics approaches that examine unique state data resources or 4) Community and/or stakeholder-partnered research currently attending the CBPR Scholars Program.

Priority will be given to projects that generate critical data to improve competitiveness for future extramural funding. Projects at all levels of the translational spectrum will be considered, but priority will be given to projects that meet an immediate translational need or that 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 \$25,000 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 be completed within a one-year project period.

Eligibility

Eligible participants 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 Instructor or above; and must be a US citizen or permanent resident.

Letter of Intent (LOI) Submission Process

LOIs are solicited broadly from UAMS and related campuses including CAVHS, ACH, and UAMS Northwest. All applicants are required to use our online application system to enter their basic information and upload a one and a half page Letter of Intent (LOI). The cover page and LOI must be completed by 5:00 pm, February 16, 2024, through Apply. Contact Crystal Sparks at 501-526-8730 if you have any questions. Instructions for how to make an account in Apply.

Letter of Intent (LOI) Format

Acceptable fonts are Arial, Tahoma, or Calibri with a font size of 11 pt. Figure and Table legends may use a smaller font but no smaller than 9 pt. Please use appropriate headings in preparing your proposal. The LOI 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.
- Approach Briefly describe the scientific approach used to address the research question.
- 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, and date of submission) that will be targeted.

LOI Review and Selection

The LOI review committee will consist of UAMS senior faculty and staff. Each LOI will be reviewed based on the criteria listed above. A subgroup of applications will be invited to submit a full application. We anticipate selecting approximately 6-8 LOIs for invitations to submit a full proposal.

The LOI review and selection committee will prioritize projects that include translational research approaches, that align with one or more of the focus areas of this RFA, and that have a high likelihood 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 Pl's current state of professional development. Successful LOIs will address these factors in addition to the specific future funding mechanisms that will be targeted.

Application Process

If you are invited to submit a full application, you should receive a link in the email with this RFA that requests your full application, to be submitted via Apply's submission system. Contact Crystal Sparks at CSparks@uams.edu with any questions. The submission deadline is 5:00 PM, April 10, 2024.

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 merged into a single PDF file.

Application Content & Instructions

A complete application will include the following components uploaded into <u>Apply</u>. 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 and other significant contributors (please use the latest NIH format found at NIH format)
- 3. BERD and CIRC consult summary or waiver saying the consult is not needed.
- 4. Prepare a two-page lay summary of the Research Plan; in this summary minimize jargon and promote readability at a nonscientific lay level. Prepare a 5-minute lay video that explains your proposed project to a general audience. Allowable video formats are .avi, .mp4, .mov, .wav, .mp3, YouTube, or Vimeo.
- 5. Other Support (PHS 398) for the PI. Please refer to other support document instructions for additional information.
- 6. Proposed <u>budget</u> and <u>budget justification</u>, and email from Crystal Sparks certifying budget review (see the Budget section below).
- 7. Research Plan. Research Plan should include the following sections:
 - **Sections A-E are limited to no more than 5 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.

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.
- 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. Plan for Extramural Funding

• Describe your specific plan for obtaining extramural funding. This should include what this project will provide with regard to the type of grant that will be targeted. Applicants are encouraged to name specific funding mechanisms if they have been identified.

F. Literature Cited

G. Timeline/Milestones

- Provide a timeline with expected milestones for the proposed study; propose only what can be accomplished within **ONE YEAR.** <u>Milestone Template.</u>
- 8. Letter of Support from PI's department chair.
 - Submit a letter from your department chair supporting your research and release time for this project.
 - For PI applicants at the level of Instructor, please include in your departmental letter confirmation that you are not in a temporary position, and the department intends to develop you as a full-time faculty member.
- 9. Projects must be submitted to the relevant research regulatory body (IRB and/or IACUC) for approval by April 10, 2024, and must receive full approval, if applicable, before June 1, 2024. 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 uploaded to your account in Apply.

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.

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

IRB and/or IACUC approvals uploaded into apply by March 29, 2024. The expected start date for all projects is ~July 1, 2024, after prior approval has been obtained. All projects must be completed within one calendar year. Extensions on pilot grants will not be permitted.

Note that 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 PRMC before they can be submitted to the IRB. The applicant must ensure that they identify the correct procedures for their department and prepare their required paperwork with sufficient time to meet the April 10, 2024, deadline. TRI staff can assist with these processes, and we encourage applicants to reach out if they need assistance.

Budget

All projects are required to have their budgets reviewed by Crystal Sparks, TRI Assistant Director of Programs, for budgeting and allowable costs. These consultations are free to pilot program applicants and serve as great resources for strengthening proposals and research design. Please refer to the <u>Budget Instructions</u> for additional details.

A detailed budget for this ONE-year study is required for invited full applications. As an intramural award, the

Translational Pilot Grant Opportunity will **NOT** support salary for faculty on these pilot 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.

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 Pilot Awards Frequently Asked Questions (FAQ) page for updated information regarding any questions you may have.

For the budget review, applicants should send their draft budget and budget justification to Crystal via email (CSparks@uams.edu) before March 20, 2024, at 11:59 pm, to ensure enough time for review. Once your budget has been reviewed and deemed properly filled out with all expenses allowable, you will receive an email from Crystal 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.

Pre-Award

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 Pilot Grant Opportunity. All projects invited to submit a full application are required to consult with the following TRI groups: 1) Biostatistics, Epidemiology, and Research Design (BERD) group concerning design and statistical approaches; 2) Comprehensive Informatics Resource Center (CIRC), for informatics approaches and needs; and 3) TRI Program Manager with respect to budgeting and allowable costs. These consultations are free to pilot program applicants and serve as great resources for strengthening proposals and research design.

Application Review and Award Selection

Full applications will undergo review by two scientific experts and one community member. The community members comment on the feasibility, impact, and relevance of the research to the local community at large. One of our goals is to integrate community reviewer perspectives into shaping our translational research agenda and helping researchers communicate to the local public about research occurring at UAMS. Community reviewers will read, score, and discuss the applications.

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 (multidisciplinary, team-based science is given priority), 4) Innovation, 5) Approach, and 6) Plan for Extramural Funding. Based on these assessments, applications will receive a score and funding recommendation. Applications recommended for funding will be presented to the TRI Pilot Administrative Council for final funding decisions.

Applications receiving the highest priority will be presented to the TRI Leadership for final approval.

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 ~July 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 NIH Notice of Information: NOT-OD-15-129, NOT-TR-21-026, and NOT-TR-23-007.

Awardee Responsibilities

The TRI Pilot 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 will 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 TRI staff every three months and will provide a written progress report for discussion at six and twelve months (final report) as well as annually thereafter for at least the 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 <u>"Services"</u> tab for more detailed information). To access these services, please use the <u>TRI</u> Portal.

Timeline

LOI Due Date February 16, 2024 (5:00 PM)

Full Applications Invited ~February 22, 2024

BERD Consultations February 22, 2024 – March 20, 2024 CIRC Consultations February 22, 2024 – March 20, 2024

Budget Review March 20, 2024

Proof of Regulatory Submission Due April 10, 2024 (5:00 PM)
Full Application Due April 10, 2024 (5:00 PM)
Lay Videos Due April 10, 2024 (5:00 PM)

Study Section April 25, 2024

Awardees Announced Week of April 30, 2024

Regulatory Approval, if applicable June 1, 2024

Start Date for Projects Once prior approval is granted, ~July 1, 2024

Please contact Paul Duguid (by <u>email</u>) if you have any questions about the Translational Pilot Grant Opportunity or the application process.