

Arkansas Center for Clinical and Translational Research

CCTR Pilot Award for Innovative Clinical and Translational Research

INSTRUCTIONS FOR INVITED APPLICATIONS ONLY

The Arkansas Center for Clinical and Translational Research (CCTR) at UAMS invites applications for the CCTR Pilot Research Awards. The Pilot Research Awards are up to \$50,000 and will provide funding for one year. Awards are eligible for a one-year, competing continuation.

Purpose

The overall goal of the CCTR is to transform the pace, effectiveness, and quality of translational research among UAMS and its partners, resulting in better health for all Arkansans. The Clinical and Translational Pilot Research Awards of the CCTR intend to 1) facilitate research innovation and progress, 2) stimulate and solidify research collaborations and 3) promote high-quality translational research. The CCTR defines **translational science** as that which transforms scientific discoveries arising from laboratory, clinical, or population studies into clinical applications to reduce disease incidence, morbidity, and mortality. We conceptualize translational research as occurring on a bi-directional continuum of T1 through T4 research that addresses human health questions and creates human health interventions.

- **T1** research jump-starts the process of translation of bench research to the patient bedside, generally in a limited fashion. This is where basic science discoveries directly related to human health, case study/pilot clinical research, and Phase 1 and 2 clinical trials usually occur.
- **T2** expands that sphere of discovery to larger patient populations in Phase 3 and 4 clinical trials, observational studies, or survey research in target populations. New discoveries can result in need for more translational research in basic sciences (T2→T1) or influence T3 research (T2→T3).
- **T3**, the practice-oriented stage of translational science, uses dissemination and implementation research to answer such questions as: Is treatment X actually being used in the community-at-large, and if not, why not? The identification of new clinical questions, barriers, and gaps in care related to treatment X are the focus at this stage.
- If **T1→T3** studies reach their goals and data indicate efficacious practices or results, new policy or outcomes research is engendered in **T4**. Do existing laws or policies for insurance reimbursement allow equal access or implementation of treatment X to target populations? Is treatment X more effective or of equal effectiveness than other standard of care practices?

The 2011 Pilot Studies will target specific focus areas that reflect UAMS strengths and research priorities established by the NCRR, UAMS, and the CCTR. Applicants will be asked to identify which focus area(s) their project addresses.

Award programs are intended to support novel research studies; these awards will not support projects that are minor offshoots of ongoing research by a funded investigator or provide bridge funding to previously funded investigators.

The Pilot Research Award is intended to provide the data necessary to **quickly advance to extramural funding**, solidify collaborations poised to advance translational research, and support investigators preparing to translate research findings into clinical trials, community implementation, and/or improvements in healthcare delivery. Special emphasis is placed on studies to apply for extramural research funding. These awards aim to support translational studies focused on accelerating research discovery in health-related sciences and improving healthcare and community health.

Eligibility

Full-time faculty at UAMS and affiliates (Arkansas Children's Hospital, Arkansas Department of Health, CAVHS) who hold non-temporary positions at the rank of Instructor or above are eligible for these

awards. Individuals at the level of Instructor require a letter from their department chairperson confirming that the individual is not in a temporary position and that the department intends to develop the individual as a faculty member. **Highest priority will be given to investigators likely to obtain extramural funding, those obtaining critical data that will significantly advance their research toward a novel intervention (FDA IND, Phase I trials, community implementation), and those with high potential for a transformative impact on human health or healthcare delivery.**

Application process

The CCTR Pilot Research Awards program invites full applications after the submission of a one-page, pre-proposal summary of the proposed research. The pre-proposal summaries are submitted with a short survey online, are reviewed, and full applications invited from the initial pool.

The 2011 Pilot Studies will target focus areas that reflect UAMS strengths and the Chancellor's research priorities for UAMS. Applicants are asked to identify which focus area(s) best fits their project. The CCTR Pilot Study focus areas include:

- Cancer
- Cardiovascular
- Community Engaged Research
- Neurological Disorders
- Obesity/Diabetes
- Pediatric Research
- Substance Abuse/Addiction
- Telemedicine

Deadline for submission of the invited, full application is **July 19, 2011**. Applicants are encouraged to identify a member of the CCTR Rainmaker group (see individuals identified below) or contact the program administrator for help accessing CCTR and UAMS resources to support proposal or protocol development and conduct of the study.

Application forms will be available on the CCTR website

(<http://www.uams.edu/cctr/novelcore/novelpilots.asp>), should be prepared carefully, and include the following:

1. Biographical sketches of the Principal Investigator and Co-Investigators. (Form provided, 2 page limit, select 10 key references)
2. List for **all** PIs and Co-PIs the current, pending and previous support for past five years (institutional and extramural support). Include: Title, Source, Total amount (direct and indirect costs), Percent effort, Grant period, Major goal(s) and potential overlap with proposed application (Forms provided).
3. Proposed Budget and Budget Justification (Forms provided, 2 pages).
4. **Research proposal should include the following sections:**
 - A. **Specific Aims**
 - B. **Significance**
 - Explain the potential for high impact, importance of the problem and critical barrier to progress in the field that the proposed project addresses.
 - Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
 - Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.
 - C. **Innovation**
 - Explain how the application challenges and seeks to shift current research or clinical practice paradigms.

- Describe any novel theoretical concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used, and any advantage over existing methodologies, instrumentation or intervention(s).
- Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation or interventions.

D. Approach

- Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
- Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
- If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.
- Experimental details should be cited using the Literature Cited section and need not be detailed in the Approach.
- Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised.

(Sections A-D, 5 pages)

E. Literature Cited (1 page)

F. Monitoring plan

- Describe proposed quarterly milestones, individuals responsible for meeting these milestones, and link milestones to overall project timeline. (Form provided)

G. Human subject/Animal welfare information requested by NIH (as appropriate);

5. Letter(s) from Department/Division Chairs supporting application and confirming release time for participating PI and Co-Is.

Application and supporting documents should be submitted online. Invitees will be provided the upload site address at the time their invitation is extended. Please contact Paul Duguid at pduguid@uams.edu or 501-319-4513 with any questions you may have.

Proposal format

Proposals should be typed, single spaced with .5 inch margins, and no longer than five pages for sections A-D. Acceptable fonts are Arial, Tahoma, or Calibri with a font size of 11pt. Figure and Table legends may use smaller font, but no smaller than 9pt. Please use appropriate headings in preparing your proposal. All submissions should be prepared with word processing software and be submitted in a Word (.doc) file format.

Budget

A detailed budget is required for all invited full applications. The CCTR requires that study budgets be carefully reviewed **prior** to submission by a department administrator. The department administrator must provide an electronic signature approving the budget when the proposal is submitted. Invited PIs may contact Susan Leon (leonsusanb@uams.edu) or Renee Raines (crraines@uams.edu) for review and assistance with Pilot Research Award budgets prior to submitting. As an intramural award, **the CCTR Pilot Research Awards will NOT support salary for faculty (PI, Co-I) on these studies.** These awards will support salary for all research (excluding PI and Co-Is) and support staff listed in the budget, including full time, post doctoral faculty who are engaged in research. If you are requesting biostatistical support for the **conduct** of your study, the CCTR places a cap on the allowable effort of 3% (5.2 hours/month). **All pilot studies are eligible for a statistical consult pre-submission at no cost.** Please contact the program administrator if you have questions.

All budgets should represent direct costs only; indirect costs are not allowed. All key personnel, percent effort, major equipment/supplies, travel, etc must be detailed in the budget. Requested salary and benefits should be consistent with the amount of effort committed. The project should be **scaled to the resources available.** The CCTR will allow unpaid collaborators on the study. Allowable travel must be required for the **conduct** of the study. Travel to present at scientific meetings is not allowed. Any

equipment required for the study must be justified; computers and other office supplies are not allowed. You may visit the Pilot Research Awards FAQ page for updated information to questions you may have at http://www.uams.edu/cctr/novelcore/novelpilots_FAQ.asp.

Application review and award selection

The review process proceeds in two phases: an initial pre-proposal from applicants was reviewed to evaluate the translational impact/innovation, investigator qualifications, and the path to independent funding. From these reviews, full applications have been invited, and all full applications will be peer-reviewed for **scientific and technical merit**, for **appropriateness and feasibility** of the budget and for the **potential to obtain extramural funding**. Based on these assessments, applications will receive a score and funding recommendation. The budget review will affect the overall score of the application, and budgetary revisions may be required prior to funding. Applications recommended for funding will be presented to the CCTR Cabinet for final approval.

As part of our overall goal, the CCTR aims to support faculty in the development and conduct of translational research. The CCTR can provide an array of resources to assist with study design, proposal development, and conducting the study itself. These resources include the following:

- Study coordination services and regulatory support (protocol development, regulatory review and submissions, IRB, etc)
- Processing laboratory and nursing services
- Data safety and monitoring services
- Biostatistical support, including design, analysis, and manuscript preparation
- Epidemiological support and consultation
- Ethics consultation
- Biomedical informatics access and support
- Participant recruitment
- Behavioral research methods and support
- Community engagement
- Education and career development

Investigators are encouraged to access any of the above resources as appropriate during development of the pilot application by calling (501) 614-CCTR (2287). The CCTR Pilot Study Program Administrator (501-319-4513) can provide assistance in accessing these resources and advise on the guidelines to include them in your study. You may visit www.uams.edu/cctr for a full description of resources available. The above services are provided at no cost to CCTR Pilot Research Awardees. Please contact the CCTR Navigator for information on budgeting for these services for extramural grant proposals.

In addition to these resources, the CCTR can assist investigators in accessing scientific core facilities that provide equipment and expertise in support of translational research. These fee-for-service facilities are listed below:

- Bioluminescent and Fluorescent Imaging
- Biotelemetry
- Digital and Confocal Microscopy
- DNA Damage and Toxicology
- DNA Sequencing
- Experimental Pathology
- Microbiology and Immunology Flow
- Pharmacogenomics
- Proteomics
- Radiological Imaging
- Skeletal Phenotyping
- Tissue Bank

- Transgenic Mouse Core

The CCTR also established an innovative group of senior investigators, called Rainmakers, to provide guidance and mentoring in proposal development. These scientists are from a broad array of disciplines, departments, and colleges and will foster collaborative interactions and support investigators in developing novel research ideas. The list of Rainmakers can be found at the end of this RFA.

If you have any questions regarding this RFA or assistance in contacting a Rainmaker, please contact Paul Duguid at (501) 319-4513 or email pduguid@uams.edu.

Postaward Monitoring

Prior to receiving funds and initiating research activities, the PI must obtain all necessary regulatory approvals (IRB, IACUC, radiation etc) and necessary training certifications for all personnel must be current (HIPAA, laboratory/chemical safety etc).

Rainmakers will continue to be available to support continued progress and discuss potential alternatives/support if obstacles arise. PIs are encouraged to contact Rainmakers as needed during conduct of the study. PIs will be required to provide an interim six-month report describing research progress, milestones achieved, and, if necessary, revised milestones and justification. A progress report at the end of the award period or as requested is required. Failure to provide a final progress report will result in the PI being ineligible to receive future support from any CCTR programs.

PIs should inform the CCTR of submitted applications for extramural funding, INDs, legislative actions, and/or peer-reviewed publications resulting from the CCTR Pilot Research Awards. In addition, all publications of research supported by the CCTR Pilot Research Awards must acknowledge the funding and resource support provided and a copy should be provided to the CCTR Grant Program Manager. Failure to properly acknowledge this support may result in denial of future CCTR funding. The CCTR requests that you use the following language in publications resulting from studies supported by the Arkansas CCTR:

"The project described was supported by Award Number 1UL1RR029884 from the National Center for Research Resources."

Rainmakers

Michael Owens, PhD (Co-chair), is the Director of the Center for Alcohol and Drug Abuse Studies, a Professor of Pharmacology and Toxicology in the College of Medicine, and a Wilbur D. Mills Endowed Chair in Alcohol and Drug Abuse Prevention at UAMS. His research interests are in translational science, antibody-based medications development, experimental therapeutics, and drug abuse with continuous NIH funding since 1986. He has mentored 12 PhD or MD/PhD students and three post-doctoral fellows. He was mentor for a K08 clinician/scientist award and a K25 award. He also served on expert panels at the NIH Small Business Innovative Research Grants program, NIDA, NCI, NSF, the Office of Naval Technology, AAAS and the National Academy of Science. He is a founder and Chief Scientific Officer of InterveXion Therapeutic LLC, a pharmaceutical company utilizing Dr. Owens' monoclonal antibody medications.

Sudhir Shah, MD, FSCP (Co-chair), is the Director of the Division of Nephrology at UAMS and at the Central Arkansas VA. Dr. Shah's major research interest is in the pathophysiology of renal and cardiovascular disease. With a major research interest in the role of oxidants and iron in acute kidney injury and progressive kidney disease, Dr. Shah was the PI of an NIH program project grant and has licensed research technology and methodologies (10 U.S. patents) to a company through UAMS BioVentures. His participation with the FDA resulted in one investigational new drug for a Phase III study to prevent contrast-induced acute renal failure and another for a Phase II study to halt progression of kidney disease. He is also the program director of an NIH T32 training grant.

Mary E. Aitken, MD, MPH, is a Professor of Pediatrics in the College of Medicine, Section Chief of the Center for Applied Research and Evaluation in the Department of Pediatrics, and Medical Director of the Arkansas Children's Hospital Injury Prevention Center. She serves on the Executive Committee for the

Section on Injury, Poison, and Violence Prevention for the American Academy of Pediatrics. Her research interests include prevention of motor vehicle and all-terrain vehicle injury and improving the quality of life for children after injury, particularly traumatic brain injury.

Cornelia Beck, PhD, RN, FAAN, serves as Professor in the Department of Geriatrics, Adjunct Professor of Psychiatry and Behavioral Sciences and Nursing, and holds the Louise Hearne Chair in Dementia & Long-Term Care at the University of Arkansas for Medical Sciences (UAMS). She is Co-Director of the UAMS Hartford Center for Geriatric Nursing Excellence and the UAMS Center for Clinical and Translational Research. Her research interests include strategies to improve best practices in long-term care settings and non-drug interventions to alleviate problem behavior and promote functional performance in persons with dementia. Dr. Beck has served on the Mental Disorders of the Elderly Study Section at NIH and on the National Advisory Council for the NINR; chaired the NIH Nursing Research Study Section; and served on the Medical and Scientific Advisory Council of the Alzheimer's Association.

Marie Chow, PhD, is Professor in the Department of Microbiology and Immunology, College of Medicine at UAMS. She has been the major advisor of eight PhD or MD/PhD students and over 20 post-doctoral fellows. She has mentored more than ten junior faculty in basic science and clinical fields. She has served on the scientific advisory boards of biotechnology companies and as a consultant for pharmaceutical companies, the World Health Organization, and the International Union for Cancer Prevention and Control. Her research interests focus on the molecular mechanisms of viral diseases and understanding host responses to and the role of host susceptibility genes in microbial infections. Her most recent research activities include development of technologies for rapid diagnosis of viral and bacterial infections and understanding the role of RNA interference and microRNA regulation of microbial infections.

Michael Douglas, PhD, is currently Director of UAMS BioVentures and Professor of Biochemistry and Molecular Biology in the College of Medicine at UAMS. His research interests focus on the participation of mitochondria in the growth control circuitry of the cell. His more recent studies address the mechanisms of age-dependent mitochondrial loss of function and how this affects the partitioning of growth regulatory proteins and metabolites between the organelle and other sub cellular compartments. Earlier work established the mechanisms of cytoplasmic protein sorting, organelle protein delivery, and the cellular machinery that participates in the control of protein folding and assembly. He has mentored 9 PhD and 12 post doctoral fellows.

Martin Hauer-Jensen, MD, PhD, is Professor of Pharmaceutical Sciences, Surgery, and Pathology at UAMS and Staff Surgeon at the Central Arkansas Veterans Healthcare System. He serves as Associate Dean for Research in the College of Pharmacy and as Director of the Division of Radiation Health. Dr. Hauer-Jensen's has broad experience in basic, preclinical, and clinical research. His research focus is on determining the mechanisms of and developing strategies to prevent short- and long-term adverse effects of radiation therapy in cancer survivors, as well as on developing effective, non-toxic medical countermeasures against radiological or nuclear threats. His research currently receives funding from the National Cancer Institute (NCI), National Institute of Allergy and Infectious Disease (NIAID), and the Defense Threat Reduction Agency (DTRA). Dr. Hauer-Jensen is a former Chair of the Radiation Study Section of the NIH.

Katharine E. Stewart, PhD, MPH, is the Associate Dean for Academic Affairs and Associate Professor of Health Behavior & Health Education in the College of Public Health at UAMS. She is Director of Education for the Arkansas Center for Minority Health Disparities. Her research focus is in the development of behavioral interventions to reduce health risk behaviors, especially sexual risk behaviors, among vulnerable communities and populations. She is currently funded by NIDA to investigate sexual risk reduction interventions for rural African-American cocaine users who are not in substance abuse treatment. She is currently training two funded pre-doctoral trainees and one funded post-doctoral trainee and has an extensive history of mentoring graduate, doctoral, and post-doctoral trainees in health behavior and disease prevention research.