

High Impact Awards for Clinical and Translational Research

Arkansas Center for Clinical and Translational Research

The Center for Clinical and Translational Research (CCTR) requests applications for the CCTR High Impact Translational Research Awards (HIA). The HIA awards are up to \$150,000 and will provide funding for one year.

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. As part of this, 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:

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

Investigators are encouraged to use any of the above resources as appropriate during development of the pilot application by calling **(501) 614-CCTR (2287)**. The CCTR Navigator will provide assistance in accessing these resources. You may visit www.uams.edu/cctr for a full description of resources available.

In addition to providing research resources, the CCTR also established an innovative group of senior investigators, called *Rainmakers*, to provide guidance and mentoring in proposal development. The CCTR Rainmakers are experienced in the development and direction of multi-disciplinary and translational research projects. Their role in the CCTR are to identify scientists with innovative ideas and help build collaborative translational research teams by matching researcher's skills and interests. Because the Rainmakers are expected to play an important role in enabling research programs to overcome obstacles typically encountered when translating discoveries to practical use, **potential HIA applicants must identify and discuss the project with a Rainmaker sponsor during application development**. The list of Rainmakers is below. **If you have any questions regarding this RFA or assistance in contacting a Rainmaker, please contact Paul Duguid at (501) 319-4513 or email CCTRPilotStudies@uams.edu.**

Below is the full program description and guidelines

Purpose

The Clinical and Translational Pilot Award Program in the CCTR intends to 1) facilitate research innovation and progress, 2) stimulate and solidify research collaborations and 3) to promote high-quality translational research. The CCTR defines translational research as innovative science that moves between the bench, clinic, and community to significantly impact human health. 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 goals of the HIA awards are to assist an investigative team with a discovery that is preparing to translate from the laboratory into a clinical trial, preparing for an initial clinical trial, preparing for expanded implementation in the community, and/or preparing a system to improve healthcare delivery. This award is for translational projects that already receive significant research funding but require funds for specific purposes that are not easily covered by NIH-type grant funding. For example, manufacture and stability analyses of a therapeutic protein for phase 1 safety studies or manufacture of DNA chip with candidate biomarker sequences for diagnosis of orphan diseases in at-risk or under-represented minority populations.

Eligibility

Full-time faculty at UAMS and affiliates (Arkansas Children's Hospital, Arkansas Department of Health, AR Regional Health Education Centers, CAVAHS) are eligible. Preference will be given to well-established multidisciplinary teams of scientists that include multiple Departments (e.g. basic science and clinical Departments), Colleges (e.g. COM and COPH), or UAMS affiliates (e.g. AHEC, ACHRI, and UAMS-affiliated communities).

Application process

Deadline for application submission is 5:00 pm, November 9, 2009. The application must identify a member of the CCTR Rainmaker group (see individuals identified below) who assures that the application aligns with the intent of the RFA and can help access CCTR resources/support as needed. This individual will serve as the "program officer" for the CCTR in the event that the application is selected for funding.

Application packets will be available on the **CCTR website** (<http://www.uams.edu/cctr/novelcore/novelpilots.asp>), should be prepared carefully, and include the following

1. Grant Application cover sheet (Form provided)
2. High Impact Award applications must be able to provide information on all of the following. Answers to these questions will be a **major determinant** of the success of the application:
 - a. Describe how this project will have a transformative impact on human health or healthcare delivery (e.g. prevention, treatment, diagnosis, behavior change, etc) (Form provided)
 - b. Explain how this award will have a significant programmatic impact on the trajectory of your research. (Form provided)
 - c. Describe how successful completion of this project fits into the long-term goals of your research. (Form provided)
3. Biographical sketches of the Principal Investigator and Co-Investigators. (Form provided, 2 page limit, select 10 key references)
4. 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).
5. Proposed Budget and Budget Justification (Forms provided, 2 pages).
6. Research proposal should include the following sections:
 - A. Specific Aims
 - B. Background
 - C. Relevant Preliminary Data and Need for HIA Funds
 - D. Research Design and Methods (Sections A-D, 5 pages)
 - E. Literature Cited (1 page)
 - F. Monitoring plan describing proposed quarterly milestones, individuals responsible for meeting these milestones, and link milestones to overall project timeline. (Form provided)

- G. Future research/development plans, proposed extramural applications, potential intellectual property/conflict of interest issues, private sector interest (1 page limit).
- I. Human subject/Animal welfare information requested by NIH (as appropriate).
- 7. 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 to the CCTR Pilot Grants Program Manager via email at CCTRPilotStudies@uams.edu.

4. 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 or Tahoma 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) or Adobe (.pdf) file format.

5. Application review and award selection

HIA review and selection is multi-tiered process. Applications will be reviewed for significance and scientific/clinical rigor, innovation and feasibility, approach, investigator qualifications, and the impact on the proposed research program. Another level of review will ensure that the proposed project meets the intent of CCTR Pilot Project Awards and aligns with the overall goals of the CCTR itself. Based on these assessments, the PIs for a subset of HIA applications may be invited to present to the Rainmaker group to discuss the multi-disciplinary character of the proposed research and describe the relevant contributions of participating co-investigators to the project. Applications recommended for funding will be presented to the CCTR Steering Committee for final approval.

6. Postaward Monitoring

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

HIA awardees are encouraged to continue meeting with their Rainmaker sponsor to ensure continued progress and discuss potential alternatives/support if obstacles arise. PIs will be required to provide an interim six-month report describing research progress, milestones achieved, and, if necessary, revised milestones and justification. Unless requested differently in the budget justification, HIA funds will be equally divided and credited to the account at 6-month intervals. **Distribution of the second six-month allocation is dependent on meeting the milestones described in the monitoring plan and submission of timely progress reports to the CCTR Grants Program Manager.** A final progress report at the end of the award period is required. Failure to provide a final progress report will result in the PI being ineligible to receive future support from any CCTR grant programs.

PIs should inform the Arkansas CCTR of submitted applications for extramural funding. In addition, all publications of research supported by the CCTR Pilot Grants Program should acknowledge the funding and resource support provided and a copy should be provided to the CCTR Grant Program Manager. 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. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Center for Research Resources, the National Institutes of Health, or the Arkansas Center for Clinical and Translational Research.”

Rainmakers

Michael Owens, PhD (Co-chair), is currently the Director of the Center for Alcohol and Drug Abuse Studies, a Professor of Pharmacology and Toxicology in the College of Medicine, and the *Wilbur D. Mills Endowed Chair* in Alcohol and Drug Abuse Prevention at the University of Arkansas for Medical Sciences (UAMS). His research interests are in translational science, antibody-based medications

development, experimental therapeutics, and drug abuse. 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, NSF, the Office of Naval Technology, and the AAAS. 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.

Warren Bickel, PhD, is Professor at the University of Arkansas for Medical Sciences (UAMS) in the College of Medicine and College of Public Health (COPH) and holds the *Wilbur D. Mills Chair of Alcoholism and Drug Abuse Prevention*. He serves as Director of the UAMS Center for Addiction Research and the COPH's Center for the Study of Tobacco Addiction at UAMS. He serves as Principal Investigator on several NIDA grants, including an NIH Merit Award, and has been continuously funded since 1987. His research interests include the neurobehavioral mechanisms of addiction and therapeutic processes underlying recovery from addiction. His recent research includes the application of behavioral economics to drug dependence with an emphasis on the discounting of the future and the use of information technologies to deliver science-based prevention and treatment.

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 University of Arkansas for Medical Sciences (UAMS) and Staff Surgeon at the Central Arkansas Veterans Healthcare System. He serves as Associate Dean for Research in the UAMS 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.