

**2017 San Antonio Claude D. Pepper Older Americans Independence
Center Pilot and Exploratory Study Core**

REQUEST FOR APPLICATIONS – PILOT PROJECTS

Application Period Opens: Friday, October 7, 2016

Abstracts Due: Friday, November 11, 2016

Invitations to Submit Full Proposal to be Extended By: Friday, December 9, 2016

Full Proposals Due: Monday, January 16, 2017, 5PM CST

Mission:

The major objective of the San Antonio Claude D. Pepper Older Americans Independence Center's (OAIC) Pilot/ Exploratory Studies Core (PESC) is to promote the overarching goals of the OAIC at the University of Texas Health Science Center at San Antonio (UTHSCSA) -- to develop and validate interventions to enhance healthy aging and mitigate or slow the progression of adverse aging-associated processes and diseases.

The PESC plays a key role in the OAIC's strategy of developing the infrastructure for translating the discoveries on aging interventions made with invertebrate and rodent models to pre-clinical studies and ultimately to human trials.

The PESC will provide merit-based support for rigorously designed pilot studies that test the efficacy, as well as side effect profiles, of promising pharmacologic and non-pharmacologic cell-based (e.g., stem cells, gene therapy) interventions in pre-clinical animal models and early human clinical studies.

What types of pilot studies will the PESC fund? In keeping with the overall emphasis of the OAIC, the PESC will support studies in either marmosets or human subjects, focusing especially on pharmacologic interventions using compounds already in clinical use for other indications. However, we will also consider new molecular entities, stem cell, and gene therapy approaches, and other novel approaches to improving the health and functioning of older people, based upon emerging clinical or basic science research.

We will primarily focus on applications that propose to test a hypothesis embodying the central theme of interventions that may impact favorably on healthspan and/or lifespan, either in marmosets¹ or people. In general, research in marmosets and humans receive the highest priority; while other animal models may be considered, very strong justification for their use must be provided. Additionally, the PESC program will facilitate development and deployment of new techniques, enhance the career development of young investigators, attract new translational and clinical scientists into aging research, and stimulate research in emerging areas of science relevant to the OAIC.

How do the Pilot / Exploratory Studies interact with other OAIC cores?

The primary goal of the PESC is to promote translational studies to test promising aging-modulating interventions identified in lower animals, in either marmosets or humans, in collaboration with the other OAIC Cores. Consequently, integration of the PESC with other components of the OAIC will be achieved through the explicit expectation that the supported projects involve at least one of the other Resource Cores (RCs) – RC1 (Pre-clinical Research and Analytical Pharmacology Core), RC2 (Clinical Research Core), and RC3 (Biostatistics and Data Management Core). Similarly, the PESC will synergize with the Research Career Development Core (RCDC) by placing a high priority on meritorious proposals from OAIC Scholars, and other young investigators interested in studying aging-related interventions.

Eligibility:

Applications may be submitted by principal investigators whose primary faculty appointment is at the University of Texas Health Science Center at San Antonio or at one of our regional affiliates, including the following institutions: San Antonio Military Health System, South Texas Veterans Health Care System; Texas Biomedical Research Institute; University Health System; University of Texas San Antonio; University of Texas School of Public Health–San Antonio and Brownsville Regional Campuses; Texas A&M University at San Antonio; and University of Texas College of Pharmacy.

¹ For marmoset studies, there will be additional project funding opportunities available through Southwest National Primate Research Center for a larger, joint sponsored trial. Details will be issued separately.

Previous PESC pilot project award recipients may apply again, but the new application must be a distinct project or a substantial departure, not a simple extension of the previously funded project.

An individual may submit no more than one project as a Principal Investigator, plus one as a Co-Investigator.

Amount and Term: Requests for funds of up to \$50,000 will be considered for project periods of up to 1 year. Funds are available to fund up to 5 projects, contingent upon the submission of a sufficient number of scientifically meritorious applications. **The expectation is that institutional approvals (INCLUDING Institutional Review Board [IRB] or Institutional Animal Care and Use Committee [IACUC]) will be obtained promptly and projects initiated/ funds disbursed within 60 days of award. If a different timeline is anticipated, address this in the application.**

Budget and Financial Policies:

Awards will be made for a project period of up to one year, starting on or about May 1, 2017. The maximum budget for these one-year awards is \$50,000. Proposals with smaller budgets and for shorter time periods will be considered and reviewed under the same criteria.

Facilities and Administrative (F&A, indirect cost) expenses will not be reimbursed.

Although the PI(s) should be listed in the personnel section of the summary page for all budgets, there is no minimum effort requirement. On a case-by-case basis, we will consider application budgets that include funds to support a total of up to \$7,500 in salary and fringe for the PI(s) and/or faculty-level collaborators². Salary (plus associated fringe benefits) may also be requested for non-faculty support staff, including postdoctoral fellows.

Other allowable expenses include: equipment essential for the project (maximum \$10,000, including computer hardware³); PI or Co-PI travel to

² SA OAIC is also exploring the availability of additional institutional salary support for PIs and collaborators; additional information will be provided to applicants.

³ Equipment purchased with pilot funds is the property of the UTHSCSA, and must be made available for use by qualified members of the UTHSCSA research community.

relevant scientific meetings (maximum \$1,500); consumable laboratory supplies; animal purchase and per diem; core facility fees; consultation fees (maximum \$5,000); computer time; software; publication / presentation expenses; costs related to human subject enrollment and management (listed as “Patient Care Costs” on budget page); and other expenditures that can be justified as being essential for the completion of the project. Account management will be handled within the OAIC. **Investigators proposing clinical research projects should specifically include advertising and patient incentive payments within their budgets, as the Center does not have dedicated funds for these purposes.**

Award Administration:

Principal investigators of funded projects are required to abide by NIH rules and regulations, as well as OAIC policies and procedures.

Support from the OAIC must be acknowledged in all publications and reports generated with pilot project resources.

Evaluation of Progress and Tracking:

Progress reports will be requested six months (brief) and 12 months after the initiation of funding for one-year projects, and at the midpoint and end of shorter term projects. Recipients who fail to submit timely and meaningful progress reports will be deemed ineligible for future funding cycles. Progress reports must include, at a minimum:

- Review of the status of the Specific Aims originally proposed, with discussion of and rationale for any proposed changes.
- Summary of the status of patients enrolled and progress towards accrual goals, if applicable.
- Obstacles or challenges encountered to date, if applicable, and plans to address such problems.

Prerequisites to Expenditures

For projects involving the use of human subjects or vertebrate animals, no expenditures will be permitted until the PESC is provided with a copy of the official letter of approval by the appropriate IRB or IACUC, respectively, and, for human studies, the data safety monitoring plan, if applicable, and NIA prior approval of the project.

Investigators are encouraged to submit IRB and IACUC protocols early in order to avoid significant delays in project initiation. Excessive delays in meeting these regulatory requirements may result in withdrawal of the award. Applicants must also be up to date on compliance with institutional research training and conflict of interest disclosure policies.

Submissions of Abstracts and Invitation to Apply

Applicants should submit an abstract of up to 500 words. The abstract should be accompanied by a cover letter that includes the title of the project and identifies the principal investigator (PI) and co-PI, if any. The abstract and cover letter should be submitted via email to Renee Hill, Center for Healthy Aging Program Manager, at hillr4@uthscsa.edu. The abstract may be submitted starting **Friday, October 7th, 2016 with the final deadline for receipt of abstracts being Friday, November 11 at 5PM.**

The abstracts will be reviewed for responsiveness to the RFA, relevance to OAIC themes and objectives, and potential scientific and clinical impact. Those invited to submit a full proposal will be notified by Friday, December 9; **with applications due by 5 PM on Monday, January 16, 2017.** The application should include a list of 3 to 4 potential reviewers from UTHSCSA and/or the institutions delineated in the “Eligibility” section of this RFA, but not from the same department or research group as the PI.

Before submitting an application, invited investigators proposing a human subject study must consult with the RC2 core for preliminary evaluation of feasibility and necessary regulatory processes, including IRB and data safety monitoring procedures. Investigators may wish to review <http://research.uthscsa.edu/ocr/> for an overview of requirements and to prepare for this consultation.

Invited Investigators proposing a marmoset study must consult with the RC1 core for preliminary evaluation of feasibility, animal availability, and necessary regulatory processes, including IACUC procedures. Investigators may wish to review <http://research.uthscsa.edu/IACUC/> for an overview of requirements and to prepare for this consultation.

Applications submitted without evidence of having consulted with the RC2 or RC1 core, as appropriate, risk adverse scoring during the evaluation

process. The REDCap application form includes space to note the date of your RC2 or RC1 consultation, as appropriate.

Final proposals must be uploaded to <https://redcap.uthscsa.edu/REDCap/surveys/?s=D9J7CH3EX3> by **5PM CST on Monday, January 16th, 2016**.

Proposal components must be uploaded in a single pdf document to include:

- 1-Project Summary
 - 2-Detailed Budget
 - 3-Budget Justification (maximum 1 page)
 - 4-Biographical Sketch for PI (maximum 5 pages); for NIH template, format, and sample see <http://grants.nih.gov/grants/funding/424/index.htm#biosketch>
 - 5-Biographical Sketches for other key personnel (maximum 5 pages each)
 - 6-Research Plan (maximum 4 pages)
 - 7-Literature Citations (maximum 1 page)
 - 8-Letters of support from core directors or Research Imaging Institute are required (if applicable)
 - 9-Letters of collaboration (optional)
 - 10- List of potential reviewers
 - 11- List of any pending or funded pilot applications, either externally or to other internal UT programs, with total budget and dates of funding
- **Appendices are NOT allowed and a Certificate of Proposal is not required by UTHSCSA applicants at this time.
- ***Proposals are expected to use one or more of the OAIC service cores, and, as noted above, contact with the core(s) at the proposal development stage is strongly encouraged.

Applicants will be notified on or before **Monday, February 20, 2017** with either notice of intent to award or notice of denial of an award. Successful applicants are expected to provide notice of IRB or IACUC approval, as applicable, within 60 days or receipt of notice of intent to award. Before funding is awarded, all projects must provide documentation of final IRB and/or IACUC (if applicable) and all other institutional and regulatory approvals, and appropriate data and safety monitoring plans must be in place where applicable.

Review Process and Criteria:

Applications will undergo a two-tiered system of review. The first phase, or scientific review, will be performed by Scientific Review Committees, including appropriate internal UTHSCSA and external content experts and representatives. Scientific merit will be scored by these reviewers based on the following criteria:

- Significance
- Novelty / innovation
- Strength of the study protocol, including:
 - Design
 - Feasibility
 - Preliminary data (to the extent available)
 - Integration with ongoing research
 - Quality of the investigative team
- Contribution to career development of clinical / translational scientists, if applicable
- Responsiveness to PESC objectives of promoting innovative, collaborative, multidisciplinary, pre-clinical and clinical research on interventions designed to impact favorably upon healthy aging and lifespan.
- Likelihood of future NIH or other competitive external funding
- Use and leveraging of OAIC core facilities, including assurance that the project has been discussed with leaders of those cores, including a letter of support from each relevant core director).
- Protection of human subjects and experimental animals

A programmatic review will then be performed by the OAIC leadership team for program relevance and potential public health impact, taking advantage of input from institutional and external advisors. Funding decisions will be based on scientific merit, as well as programmatic considerations, such as breadth and depth of the overall pilot study portfolio.

Questions? Please contact PESC Co-Leader Alfred L. Fisher, MD, PhD at fishera2@uthscsa.edu or Renée Hill, Center for Healthy Aging Program Manager at hillr4@uthscsa.edu.