

2021 San Antonio Claude D. Pepper Older Americans Independence Center (OAIC)

Pilot and Exploratory Studies Core (PESC)

**Supplementary Information for Full Proposal Preparation
By Invitation Only**

PESC Mission

The major objective of the Pilot and Exploratory Studies Core (PESC) of the San Antonio Claude D. Pepper Older Americans Independence Center (OAIC) is to promote the overarching goals of the OAIC at the University of Texas Health at San Antonio (UTHSA), namely 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 animal models to pre-clinical studies and ultimately to human trials.

Thus, 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 marmosets and early human clinical studies.

Amount and Terms of the Award:

- Requests for funds of up to \$50,000 will be considered for project periods of up to one year.
- The number of awards to be made is contingent upon the submission of a sufficient number of meritorious applications and availability of funding.
- Institutional approvals (Institutional Review Board [IRB], Institutional Animal Care and Use Committee [IACUC], others as appropriate) must be obtained promptly and projects initiated so that funds can be disbursed within 60 days of award. If a different timeline is anticipated, please address this in the application.

Budget and Financial Policies

- Awards will be made initially for a project period of up to one year, starting on or about June 1, 2021. The maximum budget for these one-year awards is \$50,000.
- Facilities and Administrative expenses will not be reimbursed.
- Salary (plus associated fringe benefits) may be requested only for non-faculty support staff, including postdoctoral fellows. Although the Principal Investigator and co-investigator(s), if any, should be listed in

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the personnel section of the budget summary page, there is no minimum effort requirement.

- Other allowable expenses include: equipment essential for the project (maximum \$10,000, including computer hardware); Principal Investigator or Co-Investigator travel to 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.
- A Certificate of Proposal is not required by UTHSA applicants at the time of application.

Additional Requirements

- Supported projects must involve at least one other Resource Core.
 - RC1 (Pre-clinical Research Core)
 - RC2 (Clinical Research and Pharmacology Core)
 - RC3 (Trial Design and Integrative Informatics Core).
- Studies using marmosets must consult with RC1 leadership to ensure that budgeted funds are adequate for these studies. Contact: Cory Ross, PhD: cross@txbiomed.org
- Investigators proposing clinical research projects must specifically include advertising and patient incentive payments within their budgets, as well as the cost of clinical research unit usage and research nursing support, if applicable. These costs should be determined after consultation with RC2 leadership before proposal submission and reflected in the budget. Contact: Sara Espinoza, MD, RC2 Core Leader: espinozas2@uthscsa.edu
- Studies requiring statistical analysis must consult with RC3 leadership to ensure that budgeted funds are adequate for these studies. Contact: Jonathan Gelfond, MD, PhD: gelfondjal@uthscsa.edu
- Additionally, pilot studies that involve clinical trials (assessment of an intervention in participants) must designate a qualified statistician (from the OAIC Biostatistics Core, or elsewhere) within the proposal, and provide a corresponding letter of support. For randomized trials, the Principal Investigator cannot be designated as the statistician.
- Clinical trials must use REDCap (a web-based application for managing databases) for the collection and data analysis of demographics, adverse events, and efficacy measures. Other clinical studies that request OAIC support in data analysis are also required

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to use REDCap. If the study is awarded funding, then additional institutional requirements for approval and OAIC requirements for registration, safety monitoring, and reporting will apply.

- Investigators must justify fully any equipment expenditures proposed to be made within the final 60 days of the budget period and supply purchases to be made within the final 14 days of the budget period.

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.
- Funds are administered directly within the OAIC.

Evaluation of Progress and Tracking

- Progress reports will be requested six months and 12 months after the initiation of funding and annually thereafter. 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:
 - Brief review of the status of the Specific Aims originally proposed, with discussion of and rationale for any proposed changes.
 - Summary of the status of participant enrollment and progress towards accrual goals, if applicable.
 - Obstacles or challenges encountered to date, if applicable, and plans to address such problems.
 - Manuscripts in progress or submitted as a result of the project.
 - Grant proposals in progress or submitted as a result of the proposal.

Prerequisites to Expenditures:

- For projects involving the use of human subjects, no expenditures will be permitted until the PESC is provided with a copy of the official letter of approval by the appropriate IRB, along with the data safety monitoring plan, if applicable. In addition, prior approval by NIA program officials is required for all projects involving human subjects.
- For projects involving the use of marmosets, no expenditures will be permitted until the PESC is provided with a copy of the official letter of approval by the appropriate IACUC.
- 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.

Submission of Full Proposal and Notification of Decisions

- All application materials must be submitted through the **Survey Monkey Apply (SMA)** platform (<https://apply-uthscsa.smapply.io/>). The funding opportunity at that site is listed as: **Pepper Center (OAIC) Pilot Projects**.
- Based on the RFA responsiveness of the previously submitted Letters of Intent, relevance of the project to OAIC themes and objectives, and potential scientific and clinical impact, selected applicants are being invited to submit a full proposal.
- **Full applications are due in Survey Monkey Apply by 5 PM on Monday, April 5, 2021.**
- **SMA instructions are available at this link:** <https://sapepper.barshop.uthscsa.edu/wp-content/uploads/2018/12/Survey-Monkey-Apply-Login-Instructions.pdf>. **Please use either Chrome or FireFox, as Internet Explorer is known to have problems.**
- Applicants will be notified of funding decisions on or about Monday, **May 10, 2021.**

Proposal components and format

- 1. Enter requested information into SMA electronic forms**
 - a. Project Summary
 - b. Detailed First-Year Budget and Justification
 - c. List of potential reviewers
 - d. List of any pending or funded pilot project applications, by program and title of project
- 2. Upload a single PDF for each of the following items**
 - a. Biographical Sketch for PI (maximum 5 pages); for template see: <https://grants.nih.gov/grants/forms/biosketch.htm>
 - b. Biographical Sketches for other key personnel (maximum 5 pages each). Combine sketches for all into a single PDF.
 - c. Research Plan (maximum 4 pages); include, if applicable, a brief statement of potential project extensions for a second year of support.
 - d. Literature Citations (maximum 1 page)
 - e. Letters of support from OAIC Core Directors (RC1, RC2, and/or RC3). Combine all letters into a single PDF.
 - f. Letters of collaboration (optional)

NOTE: Appendices - NOT ALLOWED

Review Process and Criteria

Applications will undergo a two-tiered review process. The first phase, primarily for scientific merit, will be performed by Scientific Review Committees, including appropriate internal UTHSA and external content experts and representatives. Proposals will be scored 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 Maggie Liang (liangh0@uthscsa.edu) or the PESC Core Leaders (Robert Clark, MD; clarkra@uthscsa.edu and Randy Strong, PhD; strong@uthscsa.edu).