

## **2019 San Antonio Claude D. Pepper Older Americans Independence Center Pilot and Exploratory Studies Core**

### **REQUEST FOR APPLICATIONS – PILOT PROJECTS**

#### **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.

Pursuant to this RFA, 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.

#### **What types of pilot studies will the PESC fund?**

- The PESC supports studies in either marmosets or human subjects, focusing especially on pharmacologic interventions using compounds already in clinical use for other indications (i.e., repurposing).
- 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 marmosets or people.
- We 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 and Exploratory Studies interact with other OAIC cores?**

The supported projects must involve at least one of the other OAIC Resource Cores (RCs):

- RC1 (Pre-clinical Research and Analytical Pharmacology Core)
- RC2 (Clinical Research Core)
- 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. Further information about the OAIC and its Cores may be found at: <http://sapepper.barshop.uthscsa.edu/>

#### **Eligibility**

- Applications may be submitted by Principal Investigators whose primary faculty appointment is at University of Texas Health San Antonio or one of the following regional affiliates: 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 Regional Campus; Texas A&M University at San Antonio; and University of Texas College of Pharmacy.

- 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 only one project as a Principal Investigator (PI), but a PI may also serve as a Co-Investigator on a second project.

#### **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.
- A second year of support may be considered, contingent upon the availability of funds, for projects exhibiting unusually strong progress and a compelling rationale for more extended studies.
- 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 for a project period of up to one year, starting on or about May 1, 2019. The maximum budget for these one-year awards is \$50,000. Proposals with smaller budgets will be considered and reviewed under the same criteria.
- Facilities and Administrative expenses will not be reimbursed.
- Salary (plus associated fringe benefits) may be requested for non-faculty support staff, including postdoctoral fellows. Although the Principal Investigator and co-investigator(s), if any, should be listed in the personnel section of the summary page for all budgets, 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.

#### **Additional Requirements**

- Studies using marmosets must consult with RC1 leadership to ensure that budgeted funds are adequate for these studies. Contact: Suzette Tardif, PhD: [stardif@txbiomed.org](mailto:stardif@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](mailto: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](mailto:gelfondjal@uthscsa.edu)
- Additionally, pilot studies that involve clinical trials (assessment of an intervention in participants) must designate a qualified statistician (from the Pepper Center 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 should use REDCap (a web-based application for managing databases) for the collection and data analysis of adverse effects and efficacy measures. Non-interventional clinical studies that request Pepper Center support in data analysis are required to use REDCap. If the study is awarded funding, then additional institutional requirements for approval and Pepper Center requirements for registration, safety monitoring, and reporting will apply.
- In general, equipment expenditures will not be permitted within the final 60 days of the budget period.

#### **Prerequisites to Expenditures:**

- For projects involving the use of human subjects, no expenditures will be permitted until: 1) the PESC is provided with a copy of the official letter of approval by the appropriate IRB; 2) if applicable, a data safety monitoring plan is in place; and 3) the project receives prior approval by National Institute on Aging program officials.
- 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 requirements.

#### **Submission of Letters of Intent and Invitation to Apply**

- All application materials (Letters of Intent and full proposals) must be submitted through the **Survey Monkey Apply** platform (<https://apply-uthscsa.smapply.io/>). The funding opportunity at that site is listed as: **Pepper Center (OAIC) Pilot Projects**.
- **Please use Chrome or FireFox as your browser. Internet Explorer is known to cause problems.**
- Applicants should initially submit a Letter of Intent that includes the title of the project, name and faculty title of the Principal Investigator, plus Co-Investigator(s), if any, and a project abstract of no more than 500 words.
- The deadline for receipt of Letters of Intent is 5 pm, **Friday, December 21, 2018**. 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 **Monday, January 7, 2019**. Further instructions will be provided at that time. **Full applications are due in Survey Monkey Apply by 5 PM on Monday, February 4, 2019.**
- Applicants will be notified of funding decisions on or before Friday, **April 12, 2019**.

**Important dates**

**Letters of Intent due:** December 21, 2018

**Invitations to Submit Full Proposals:** January 7, 2019

**Full Proposals Due:** February 4, 2019

**Notification of Awards:** April, 12, 2019

**Questions?** Please contact Maggie Liang ([liangh0@uthscsa.edu](mailto:liangh0@uthscsa.edu)) or the PESC Core Leaders (Robert Clark, MD; [clarkra@uthscsa.edu](mailto:clarkra@uthscsa.edu) and Randy Strong, PhD; [strong@uthscsa.edu](mailto:strong@uthscsa.edu)).