USC-Yale Roybal Center for Behavioral Interventions in Aging Request for Proposals Letter of Intent due January 10, 2025

The <u>USC-Yale Roybal Center for Behavioral Interventions in Aging</u> seeks proposals for research projects that study mechanisms of behavior change and involve randomized controlled trials (RCTs) (**see LOI guidance and application found <u>HERE</u>**.) For the upcoming year, we will support 2 projects with a maximum direct cost of \$200,000 per project that, if approved for funding by the National Institute on Aging (NIA), would receive funding during the period of June 1, 2025, through May 31, 2026. Although a 12-month timeline is typical for these projects, we will consider longer timelines of up to 18 months. Eligible projects will propose to study a health outcome or behavior that promotes a better health outcome and must be adequately statistically powered to detect meaningful treatment effects.

Proposals will be evaluated for research design, innovation, feasibility, scalability, and timeliness using the following <u>Proposal Evaluation Criteria</u>. Projects must propose to test mechanisms of behavior change (factors that mediate or moderate an effect) that can inform scalable interventions with the potential to improve health-related outcomes from midlife to older adults. Projects must specify the development stage according to the <u>NIH Stage Model for Behavioral Intervention Development</u>.

Responsiveness criteria:

1. Projects must include an evaluation of mechanisms of behavior change.

Proposals should focus on careful testing of mechanism-driven interventions to contribute to an understanding of causal drivers and/or mediators (psychological processes that explain *how* an intervention leads to change) and moderators (factors that influence the magnitude or probability of behavior change) to help identify how an intervention works, for whom, and in which contexts, helping to identify heterogeneous subgroup effects or variations on intervention design.

This includes intervention and study designs that apply and test specific principles of behavioral economics to improve individual or institutional decisions and processes. Examples include investigating the ways in which defaults help to address causal drivers of health disparities; how different choice architectures impact decision support tools; and messenger effects on the promotion of preventive care.

2. Projects must be an NIH-defined clinical trial

To be an NIH-defined clinical trial that studies mechanisms, the answers to the following four questions must be "**YES**":

- 1. Does the study involve human participants?
- 2. Are the participants prospectively assigned to an intervention?
- 3. Is the study designed to evaluate the effect of the intervention on the participants?
- 4. Is the effect being evaluated a health-related biomedical or behavioral outcome?

Studies must be prospective to be eligible for support. The project must comply with all <u>NIH clinical trial</u> <u>policies</u>.

3. Projects must address health-related behavior

Participants are encouraged to propose trials at their own institutions or coordinate with our partner organizations, the *Roybal Implementation Network*, which includes Contra Costa Health, Geisinger Health, Keck Medicine of USC, Northwestern Medicine, and Yale University. Potential topics of interest for RCTs identified by our partner sites include (but are not limited to):

- Preventable readmissions
- Equity of care
- Care transitions
- Addressing social determinants of health or health-related social needs
- Prescribing/Deprescribing/Polypharmacy
- Vaccination
- Operational optimization (throughput, no-show, scheduling)
- Preventive screening
- Overuse/inappropriate use of emergency medicine
- Advanced care planning
- Medication adherence
- Social services
- Overuse of diagnostic services
- Mobility/Fall prevention (inpatient and outpatient)
- Mood metrics (depression screening)
- Advanced care at home

The sustainability and scalability of intervention modalities will be considered, including using email, SMS, phone, clinical decision support, dashboards, and existing programs that are aligned with operational resources and priorities.

4. Proposed projects must have adequate statistical power to test mechanisms of behavior change and/or efficacy of the intervention.

Proposals must include a power calculation to demonstrate that the study design can adequately answer the research questions, test the proposed hypotheses, and provide interpretable results.

Next steps / How to apply:

- <u>This Fall:</u> The USC-Yale Roybal Center team is available to discuss proposal ideas or answer related questions from potential applicants. Please email knight@usc.edu to schedule a time.
- By Friday, January 10, 2025: Submit a brief description of your project using the LOI guidance and application found <u>HERE</u>.
- By Friday, January 31, 2025: We will tell you if you are invited to submit a full application.
- By Friday, March 7, 2025: Using templates and instructions we will provide, submit your Specific Aims,
 2-page Research Design, Human Subjects Questionnaire, Planned Inclusion Enrollment Report(s),
 Budget, Biosketch, and Other Support.
- <u>During March 2025:</u> Review and approve your Human Subjects System record, which we will help to draft. Complete applicable USC-Yale Roybal Center and NIH administrative requirements.
- <u>Summer 2025:</u> We will learn if your study has been approved by the NIH. Depending on the risks associated with your study, the NIH may require your study to receive Data & Safety Monitoring Board (DSMB) and/or Safety Officer (SO) approval before recruitment can begin.
- For as long as your study continues: Update us quarterly on your progress and be available for Center meetings as needed. If applicable, update the DSMB and/or SO periodically and submit monthly enrollment data to NIA. Help us to maintain your CROMS, ClinicalTrials.gov and Human Subjects System records.