

Overview of NIA Roybal Centers

The purpose of the NIA Roybal Centers is to develop behavioral interventions that improve the health and well-being of people as they are aging and the capacity of institutions to adapt to societal aging. Roybal Center resources are intended to conduct pilot studies to create, modify, adapt and test behavioral interventions. Roybal Centers will conduct Stage 0 through IV pilot studies in accordance with the multidirectional, translational [NIH Stage Model](#), to produce potent and implementable principle-driven behavioral interventions. Pilot applications should include studies, in which a principle-driven intervention and the intervention's associated materials are created, refined, adapted, and pilot tested for feasibility, acceptability and efficacy. The goal of the Roybal Centers is to conduct preliminary research to develop potent and scalable principle-driven behavioral interventions, programs, or practices that promote healthy aging at the individual or population level. By establishing an infrastructure organized in accordance with the [NIH Stage Model](#), Roybal Centers will provide the necessary scientific expertise and resources to conduct pilot studies at Stages 0, I, II, III and IV of the translational behavioral intervention development multi-directional pipeline.

The Roybal infrastructure is also intended to facilitate related research proposals outside of the Roybal Center. NIA expects that successful Roybal Center pilot intervention projects will lead to the submission of related translational behavioral intervention development applications for R01s or SBIRs to produce implementable, principle-driven interventions. Pursuit of related NIA research applications that can successfully leverage the expertise, resources and findings of the pilot projects of the Roybal is strongly encouraged. Ideally, translation projects supported through the Roybal program will not only result in benefits to mid-life and older people but will also advance our fundamental understanding of basic scientific questions in the behavioral and social sciences of aging.

Centers are expected to leverage basic behavioral or social science principles throughout the intervention development process, with the aim of creating practical, science-based principle-driven interventions that can be successfully implemented in the real world. This will require expertise at all Stages of the intervention development pipeline, from Stage 0 (basic behavioral or social science) through Stage IV (effectiveness or pragmatic trials), as defined by the [NIH Stage Model](#)).

[The NIH Stage Model of behavioral intervention development](#): The goal of the NIH Stage Model is to create principle-driven and implementable behavioral interventions by structuring intervention development within a translational framework that integrates basic and applied behavioral and social science. The Model describes the full range of behavioral intervention development from basic behavioral science through intervention development, efficacy testing, effectiveness testing, and implementation. It helps to describe where a behavioral intervention is in the developmental pipeline and specifies research activities appropriate for different Stages of behavioral intervention development. ("Behavioral" is defined broadly here, including behavioral, psychological, interpersonal, social, or institutional processes and may be designed for use at the individual, family, dyad, group, community, or health systems level). The NIH Stage Model provides a common language to facilitate discussion of intervention development research by applicants, reviewers, and funders. An examination of the mechanisms of behavior

change ([Science of behavior change](#)) or the principles underlying an intervention is encouraged by the NIH Stage Model in every Stage of behavioral intervention development. Roybal Centers will support Pilot intervention research intended to lay the foundation for independent, larger scale projects. Pilot/preliminary work in the first five Stages of behavioral intervention research may be supported under this FOA:

- **Stage 0** is basic behavioral science relevant to the development of principle-driven behavioral interventions. Basic behavioral science is defined in this announcement as research involving the examination of behavioral, cognitive, affective or social principles (mechanisms or processes) operating at the individual or population level. It may include phenomena operating at any level of analysis (e.g., social, economic, institutional, contextual, interpersonal, behavioral, psychological, neurobiological and/or genetic). It is important to note that questions regarding principles or mechanism of behavior change are relevant at every Stage of the intervention development pipeline and may also be asked in any Stage of intervention development.
- **Stage I** research is where a principle-driven intervention and the intervention's associated materials are created, refined, adapted, and pilot tested for feasibility, acceptability and efficacy.

Stage I in research contexts or in community contexts: Stage I studies may be conducted in research contexts (e.g., in an academic setting where the intervention is administered by an individual working for the researcher) or in community contexts (e.g., in a community setting, such as a home or assisted living facility, where the intervention is administered by an individual in the community), as appropriate

Stage I for the development of associated materials: For interventions that need to be administered by individuals in the community, the development and testing of provider-friendly training materials, and community-friendly procedures for monitoring fidelity for interventionists/ providers in community settings is often necessary prior to progression to Stage III and later Stages. Thus, development of these materials is a critical component of Stage I.

- **Stage II** research is designed to answer the question, "Can this intervention work when administered under ideal conditions, and what is/are the mechanism(s)/ principles(s) of behavior change causing the effect(s)?" Stage II (Traditional Efficacy Testing) research consists of tightly controlled experimental testing (**maximal internal validity**) of promising behavioral or social interventions in research settings, with research-based interventionists/providers. It is expected that Stage II studies will include rigorous methods for ensuring key elements of intervention fidelity.
- **Stage III** research is designed to answer the question, "Can this intervention work when administered under highly controlled conditions in the real world?" Stage III (Efficacy in the "real-world") research consists of the experimental testing of promising behavioral or social interventions in community settings, with community-based interventionists/providers, while maintaining **as high a level of internal validity as possible** under these circumstances. Stage III studies are expected to include rigorous methods for ensuring intervention fidelity and validated procedures for training, developed specifically for use with individuals in a home or community-based setting.

Stage III studies are also encouraged to provide information about the mechanisms or principles of behavior change responsible for any observed effects. (Preliminary

- **Stage IV** research is designed to answer the question, "Can this intervention work when administered under actual conditions in the real world?" Stage IV ("Effectiveness" and "Pragmatic Trials") involves effectiveness testing or pragmatic trials on behavioral interventions that have been shown to have efficacy in earlier Stages. Stage IV research attempts to have **maximal external validity** and is always conducted in community settings, with community-based providers or caregivers.

Behavioral intervention development is rarely a linear process and there is often a need to take advantage of new knowledge from basic or clinical science and return to earlier Stages before proceeding to later Stages to determine the principles underlying the intervention, to improve the potency of an intervention, to streamline the intervention, to develop community-friendly training procedures for the intervention, to develop methods to maximize real-world fidelity, etc. Multiple Stage I studies (sometimes conducted in research settings, but other times conducted in community settings, depending upon the goals) are often needed to lay the groundwork for Stage III and Stage IV studies that can serve as necessary steps toward ultimate implementation. Stage I studies are expected to be the most prevalent type of study within Roybal Centers. Stage II, III, and IV studies may be conducted when justifiable (e.g., prerequisite Stage I work has been completed), and when such research is equivalent in size to Stage I trials. For the purposes of this FOA, Stage I studies and small-scale Stage 0, II, III, and IV studies will be referred to as "pilot" studies. Small-scale Stage II research may be conducted to determine efficacy and mechanisms of behavior change under optimal conditions. Small-scale Stage III research may be conducted to determine real-world efficacy, under maximally controlled conditions. In cases where interventions are highly inexpensive and simple to administer with fidelity (e.g., simple default interventions or technology-based interventions, Stage IV research may be conducted to determine real-world effectiveness, under natural conditions.