Funding Announcement
Columbia Roybal Center for Fearless Behavior Change Request for Applications
Application Deadline: Monday, December 1st, 2025

Overview:
Each year, millions of Americans who experience serious health events such as heart attacks, strokes, or cancer diagnoses develop severe anxiety, depression, and even PTSD. All too often, these individuals do not follow recommendations for health behaviors such as exercise, diet, or taking medications even though they are essential to recovery and prognosis. The **Columbia Roybal Center for Fearless Behavior Change,** funded through the National Institute on Aging (NIA), is dedicated to advancing behavioral interventions that reduce psychological distress and improve health behaviors in these patients, with the ultimate goal of advancing effective behavioral interventions with the potential to be routinely implemented into clinical practice.

We are excited to announce our call for proposals to conduct randomized clinical trials (RCTs) that test behavioral interventions. These trials should test interventions that are designed to **reduce psychological distress and/or improve health behaviors in midlife and older adults who have suffered serious health events. Studies that test implementation strategies for increasing the uptake of effective behavioral interventions into practice will also be eligible**. Interventions should be designed with consideration of mechanisms of behavior change and potential to advance interventions toward implementation. Relevant study populations include, but are not limited to, patients with stroke, myocardial infarction, cardiac arrest, COPD, heart failure, respiratory failure, or recent diagnosis of cancer or end-stage renal disease. Relevant behavioral outcomes include, but are not limited to, measures of quality of life or psychological distress such as depression, anxiety, or PTSD and of health behaviors such as medication adherence, physical activity, or sleep.

Applicants must demonstrate how they will follow the **mechanism-driven approach** to intervention development promoted by the Science of Behavior Change (https://commonfund.nih.gov/behaviorchange). This involves testing the effect of the intervention not only on the target health behavior (e.g., medication adherence or physical activity), but also on the proximal mechanism that explains how the intervention works (e.g., reducing fear of recurrent cardiovascular events). Applicants are also expected to explain how the current trial will advance the intervention along the NIH Stage Model and what the next step in intervention development will be if they are successful. (See NIH Stage Model for nomenclature onstage of behavioral intervention development:).

Early-stage studies that are limited to assessing the feasibility of behavioral interventions (i.e., Stage I on the NIH Stage Model) are not eligible.

Award amount:
Up to $300,000 in total costs over a two-year period, contingent on institutional IC rates. The second year of funding will be dependent on achieving milestones from Year 1.

Investigators will also receive support from the Columbia Roybal Center with finalizing the study protocol including selecting robust measures of behavioral mechanisms and health behaviors (e.g., actigraphy, electronic pill bottles); consultations on data management and analysis; planning for data and safety monitoring; and advice on integrating implementation outcomes into their research plan. Investigators will also gain mentorship from experienced behavioral trialists involved in the Columbia Roybal Center as well as opportunities for disseminating their study findings. Applicants are also encouraged to inquire about the possibility of applying for co-funding from other Centers in the Roybal Network.

Duration: Up to two years, with an anticipated project period **June 01, 2026 – May 31, 2028**.

Number of awards:
Up to 1 award per year.

Eligibility:
Applicants can be post-doctoral research fellows or faculty of any rank but must show evidence of being able to complete the trial within two years. Early stage investigators are particularly encouraged to apply. Applicants are **not** required to be affiliated with Columbia University; however, all applicants must be directly affiliated with a domestic, US-based institution. This project only supports US-based components and institutions.

Letter of Intent (LOI):
Submission of a 1-page LOI, though not required, is strongly encouraged. Submissions will receive feedback on whether the proposal is aligned with this funding announcement. To receive feedback, LOIs must be submitted by **Friday, October 31, 2025** to rmc2203@cumc.columbia.edu.

Application Deadline:
Applications are now being accepted. Applications must be submitted by **Monday, December 1, 2025**.

Trial Selection:
Applicants will be notified of the outcome of their application by **Friday, January 30, 2026**. All submissions will receive written feedback from the review committee. Applications that are not selected may resubmit their application the following year. Selected projects will then coordinate with the Roybal research team to formally submit a proposal for broader NIH approval, with an anticipated project period of **June 01, 2026 – May 31, 2028**, pending NIA and IRB approval.

Application Process Overview:
Applicants will be required to submit a 3-page research strategy describing the significance, innovation, approach, and expertise of the study team, statistical analysis plan, preliminary budget, and biosketches of all co-investigators.

Review Process:
Reviewers, including patient stakeholders, will score proposals from 1-9 for overall impact, broadly mirroring the NIH approach to grant review. Reviewers will judge each application on the basis of significance, innovation, expertise of the applicant and formation of multidisciplinary teams inclusive of patient stakeholders, rigor of the scientific approach including its consideration of mechanisms of behavior change, likelihood that study activities can be completed on time, potential impact on public health, potential to lead to subsequent funding, and alignment with goals of the Columbia Roybal Center. Early-stage investigator status will be viewed favorably when prioritizing applications for funding.

At least 2 independent reviews will be obtained for each proposal. A “study section” will be convened in January 2026 at which the top ranked proposals will be discussed. One proposal will be selected for funding in the upcoming year.

For any questions about the application process and format, please contact Columbia Roybal Center Project Manager, Robin Cumella at rmc2203@cumc.columbia.edu.

To learn more about the NIA’s Roybal Center Initiative, please visit:
https://www.nia.nih.gov/research/dbsr/edward-r-roybal-centers-translational-research-behavioral-and-social-sciences-aging

Application Instructions:
The Columbia Roybal Center of Fearless Behavior Change will accept and consider all applications; however, early investigators will receive special consideration. Project(s) will receive up to $300,000 total costs over a two-year duration, contingent on institutional IC rates. Applicants are **not** required to be affiliated with Columbia University; however, all applicants and components must be directly affiliated with a domestic, US-based institution. This project only supports US-based components and institutions.

RCT Application Template

Please provide us with the following information:

1. **Title Page** (1 page)
    a. Provide the RCT study title
    b. Provide contact information, including name, academic credentials, role on the proposal, address, email, and phone number, for the Principal Investigator and any co-investigators, collaborators, stakeholders, and/or consultants
    c. State the Stage of Intervention Development according to NIH Stage Model of Behavioral Intervention Development https://www.nia.nih.gov/research/dbsr/nih-stage-model-behavioral-intervention-development)
    d. State the target patient population (e.g., survivors of acute myocardial infarction)
    e. State the target behavioral mechanism and the measure used to measure this mechanism (e.g., fear of recurrent heart attack)
    f. State the targeted outcomes (s) (e.g., depression, PTSD, cardiac medication adherence)
    g. Provide a brief synopsis of the proposal (250 words or less)

2. **Specific Aims & Research Design** (3 pages maximum)
    This section should not exceed three (3) single-spaced, typed pages (provide at least one-half inch margins (½") - top, bottom, left, and right - for all pages; 11- or 12-point font required; excluding references. It should include:
    a. Description of the public health problem that the intervention will address (.5 page)
    b. Rationale for the intervention to be tested. The rationale should include a brief review of the evidence in support of the behavioral mechanism that the intervention is designed to target. (1 page). Stage V trials should include the generalizable evidence to practice gap, summary of barriers and facilitators, theory-informed strategy development, and mechanisms by which the strategy may be targeting outcomes.
    c. Description of the study design including eligibility, recruitment, consent, randomization (if applicable), description of intervention and control (if applicable), and key measures including of the proposed behavioral mechanism(s) of action. The description of the study design should include an explanation for the stage of intervention development (1 page)
    d. Long-term goals, including plans for the next stage of intervention development depending on study outcomes and possible funding opportunities to support the next step (.5 page)

3. **Study Timeline** (1 page)
    a. This should include timeline for achieving milestones for submitting IRB, accruing first patient, 50% of the sample, 100% of the sample, completing follow-up assessments, and analyzing data relevant to the primary outcome(s)

4. **Public health impact statement** (0.5 page maximum)
    a. Description of plans to engage a multidisciplinary team of scientists and stakeholders with lived experience in the design, conduct, or dissemination of the trial
    b. Articulate plans to recruit and retain a representative sample of individuals impacted by this health event.

5. **Statistical Design and Power** (2 pages maximum)
    a. State the statistical hypotheses of the proposal.
    b. State the primary and secondary outcomes
    c. Describe the analysis plans for the primary and secondary endpoints as well as any exploratory or descriptive analyses, including whether there will be any interim analyses or subgroup analyses
    d. Describe the rationale for the targeted sample size and power estimates. Of note, studies are expected to be powered to test the efficacy of behavioral interventions
    e. Describe the statistical plan for assessing the influence of the intervention on the proposed mechanism(s) of behavior change

6. **References** (No page limit)

7. **Budget** (.5 page)
    a. Budget justification with itemized list of expenses and total amounts.

    Note: *The maximal award is in the sum of $300,000, total costs, contingent on institutional IC rates, over 2 years. Your detailed budget should directly support your protocol. Each item must be justified in the budget justification section of the application form. This trial can fund faculty salary. Other expenses may include technologist/staff salary, fringe, supplies or research-related services. Please contact Tyla Yurgel at ty2267@cumc.columbia.edu with any budgetary questions. Please calculate any salaries using your institution's fringe rate.*

8. **NIH Biosketches** (5 page maximum per biosketch)
    Please include an NIH-style biosketch for each investigator, including collaborators and/or consultants, with personal statements tailored to the application. Importantly, please ensure biosketches adhere to the ***new*** **format required after 1/25/2022. Please ensure you have an eRA commons ID listed on your biosketch**. Updated Biosketch resources, including FAQs and sample Biosketch format pages can be found here: https://grants.nih.gov/grants/forms/biosketch.htm

9. **Other Requirements**
    a. A member of the research team must commit to attending the annual Columbia Roybal Center Retreat and study progress meetings with the Roybal team (typically once every 2 weeks).
    b. A member of the research team must commit to submitting current enrollment and screening data in CROMS* on the 15th of every month the trial is active as required by the NIA.
    c. A member of the research team must commit to maintaining an accurate and up-to-date ClinicalTrials.gov entry for the trial, including submission of results no more than 365 days after the trial's primary completion date.

*CROMS is the National Institute on Aging (NIA)'s Clinical Research Operations Management System, designed to provide NIA staff and grantees with real-time tracking, reporting, and management of clinical research enrollment data, study documents, and activities.

Submit Your Application
To submit your application, please attach all documents as PDF files and email them to Robin Cumella at rmc2203@cumc.columbia.edu using the subject line: **Columbia Roybal Behavioral RCT Trial Application Submission**.