Notice of Award Opportunity
Columbia Roybal Center for Fearless Behavior Change Request for Applications
Application Deadline: Monday, December 16th, 2024

Overview:
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 patients who have experienced serious health events, 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 new call for proposals to fund a randomized clinical trial (RCT) that tests behavioral interventions (NIH Stage II to V). The trial should seek to test interventions that are designed to **reduce psychological distress and/or improve health behaviors in diverse 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 health equity in mind. 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 help advance the intervention along the NIH Stage Model and what the next step in intervention development will be if they are successful.

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 (See **NIH Stage Model** for nomenclature onstage of behavioral intervention development: https://www.nia.nih.gov/research/dbsr/nih-stage-model-behavioral-intervention-development).

Duration: Up to two years.

Award amount:

Up to $300,000 (direct + indirect costs) over two years. The second year of funding will be contingent 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.

Number of awards:
Up to 2 awards per year.

Eligibility:
Applicants can be post-doctoral research fellows or faculty at any rank but must show evidence of being able to complete the trial within two years. Applicants from groups that are underrepresented in behavioral medicine

research are particularly encouraged to apply. Applicants are not required to be affiliated with Columbia University, however, are required to conduct trials in the United States.

Deadlines:
Applications are now being accepted. Applications must be submitted by **Monday, December 16th, 2024**.

Award Selection:
Applicants will be notified of the outcome of their application by **Monday, January 20th, 2025**. All submissions will receive feedback from the review committee. Applications that are not selected may resubmit their application the following year. Selected projects are expected to receive a notice of award in **July 2025**, 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, who include 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 diverse 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 health equity, 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 December 2024 at which the top ranked proposals will be discussed. Up to 2 proposals will be selected for funding in the upcoming year.

Applicants are encouraged, but not required, to attend pre-application office hours with our Center’s directors to ask questions about how to be responsive to the RFP.

Interested applicants may choose to write a brief (no more than one page) Letter of Intent to Co-Directors, Dr. Ian Kronish (ik2293@cumc.columbia.edu) and Dr. Nathalie Moise (nm2562@cumc.columbia.edu) if they wish to schedule a consultation.

For any questions about the scientific content, please contact: Dr. Ian Kronish and Dr. Nathalie Moise, Directors, Columbia Roybal Center, ik2293@columbia.edu (212) 342-1335 and nm2562@cumc.columbia.edu (212) 342-2889.

For any questions about the application process and format, please contact: Robin Cumella, 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. Projects will receive up to $300,000 for a two-year duration, inclusive of direct and indirect costs. Affiliation with Columbia University is not required to apply.

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. **Health equity impact statement** (0.5 page maximum)
    a. Description of plans to engage diverse 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, inclusive of direct and indirect costs, 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 David Hiti at dth2110@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**. 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 the 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: **Roybal Trial Application Submission**.

Please Note: All awarded projects are conditionally selected until appropriate approvals are received including, at minimum, IRB approval. IRB approval is not required at the time of application but is required to receive NIA prior approval. Submission to the IRB must be completed within sixty (60) days of notification of potential funding. Once IRB approval is received, documentation must be submitted to Robin Cumella at rmc2203@cumc.columbia.edu immediately.