Columbia Roybal Center for Fearless Behavior Change Pilot Award
Application Deadline: December 1st, 2021

Overview:
The **Columbia Roybal Center for Fearless Behavior Change** will fund one-year **pilot studies** relevant to developing **health behavior interventions** in patients who have suffered **acute medical events**. Our prior research has shown that many patients develop **fear-based responses to these traumatic events (e.g., fear of recurrence, heightened distress from internal physiologic stimuli)** that lead to avoidance of the very health behaviors (e.g., exercise, take medications regularly) that are recommended to prevent recurrence. Accordingly, our Center seeks to develop interventions that address these fear-related mechanisms. Relevant study populations include, but are not limited to, patients with stroke, myocardial infarction, cardiac arrest, COPD, heart failure, respiratory failure, or recent diagnosis with cancer or end-stage renal disease. Relevant behavioral outcomes include, but are not limited to, medication adherence, physical activity, sleep, as well as measures of psychological distress and quality of life. Interventions can be delivered in-person or remotely, using telemedicine tools (e.g., video visits, mobile health devices). The goal of the award is to help investigators obtain **preliminary data to support independent grant applications** to the NIH or other extramural sources.

Applicants are strongly encouraged to follow the **experimental medicine 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).

Early-stage studies that are assessing the feasibility of novel behavioral interventions are welcomed, as are later-stage studies that assess efficacy or effectiveness. (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: One year.

Award amount:
Up to $35,000 (direct + indirect costs). Investigators will also gain **access to research infrastructure** at the Center for Behavioral Cardiovascular Health that can facilitate enrollment, intervention delivery, follow-up, data analyses, data and safety monitoring, and mHealth devices for monitoring physical activity/sleep (e.g., Fitbit) and medication adherence (e.g., eCAPs). Investigators will also gain peer mentorship from investigators and advisors involved in the Roybal Center as well as opportunities for dissemination of their work through the Roybal Center' administrative core.

Note: *Projects that address* **fear of pain** *have the opportunity to apply for co-funding from the Translational Institute on Pain in Later Life (https://tripll.org/research/), another Roybal Center based at Weill Cornell Medical College and Cornell University.*

Number of awards:
Up to 3 awards per year.

Eligibility:
Applicants can be post-doctoral research fellows or faculty at any rank but must show evidence of being capable of completing the pilot study within one year. Applicants are not required to be affiliated with Columbia University. Preference will be given to applications from junior investigators and those likely to lead to future extramural funding.

Deadlines:
Applications are now being accepted. Applications must be submitted by **Wednesday, December 1st, 2021**.

Pilot Selection:
Pilot projects will be notified of the outcome of their application by **Tuesday, January 4th, 2022**. Pilot projects that are not selected will be given feedback and may resubmit their application the following year. Selected projects are expected to receive a notice of award in **July 2022**, pending NIA and IRB approval.

Review Process:
Reviewers 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 scientific merit, innovation, significance, applicant and multidisciplinary team, feasibility of using the pilot study data to submit a grant for external funding or publication, and alignment with goals, priorities and directions of the Columbia Roybal Center for Fearless Behavior Change. Early-stage investigator status will be considered and viewed favorably in funding decisions.

Two independent reviews will be obtained for each proposal. A "study section" will be convened in December 2021 at which the top ranked proposals will be discussed. A minimum of 2 proposals will be selected for funding in the upcoming year.

For any questions about the scientific content, please contact: Dr. Ian Kronish, Director, Columbia Roybal Center, ik2293@columbia.edu (212) 342-1335.

For any questions about the application process and format, please contact: Darlene Straussman, ds3900@cumc.columbia.edu (212) 342-4493.

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. Pilot projects will receive up to $35,000 for a one-year duration, inclusive of direct and indirect costs. Affiliation with Columbia University is not required to apply. Prior successful applications are available upon request.

Pilot Application Template

Please provide us with the following information:

1. **Title Page** (1 page)
    a. Provide the pilot 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 and/or consultants
    c. State the Stage of Intervention Development (Stage 0 to Stage V) 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 (e.g., fear of recurrent heart attack)
    f. State the targeted health behavior(s) (e.g., 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)
    c. Description of the study design including eligibility, recruitment, consent, randomization (if applicable), description of intervention and control (if applicable), and key measures. 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 future publication and funding (.5 page)

3. **Statistical Design and Power** (2 pages)
    a. State the statistical hypotheses of the proposal. If the study is a feasibility pilot, then hypotheses should be relevant to feasibility outcomes (e.g., feasibility of recruitment and retention, fidelity to study protocol)
    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, pilot and feasibility studies are not expected to be powered to test the efficacy of behavioral interventions.

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

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

    Note: *The maximal award is in the sum of $35,000, inclusive of indirect costs. Your detailed budget should directly support your protocol. Each item must be justified in the budget justification section of the application form. This pilot 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.*

6. **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

7. **Other Requirements**
    a. A member of the research team must commit to attending the annual Columbia Roybal Center Retreat and the bi-weekly pilot study work-in-progress meetings.

Submit Your Application
To submit your application, please attach all documents as PDF files and email them to Darlene Straussman at ds3900@cumc.columbia.edu using the subject line: **Roybal Pilot 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 thirty (30) days of notification of potential pilot funding. Once IRB approval is received, documentation must be submitted to David Lopez Veneros at dl2698@cumc.columbia.edu immediately.