NORTHWELL ROYBAL
Coordinating Center

2026-2027 Roybal National Call for Clinical Trials on Behavioral Interventions in Aging

Trial Investigator Information and Clinical Trial Proposal Template

(delete this intro page)

Project Title: *Please enter the title of the proposed clinical trial.*

PI Name: *Last Name, First Name*

Roybal Center Name: *Please enter the name of the Roybal P30 Center.*

Study Goals – Primary Research Question *(suggested 200 words)*
Briefly describe the goals of the proposed clinical trial. What research question(s) is asked?

Study Rationale *(suggested 50 words)*
Succinctly describe the rationale for the proposed clincial trial.

Specific Aims *(suggested 200 words)*
List the study Specific Aims and whether each aim is fully-powered, qualitative, or exploratory.

Public Health Problem *(suggested 250 words)*
Describe the public health problem that the intervention will address.

Study Design/Arms *(suggested 50 words)*
Describe the study design (e.g., RCT, MOST design, single-case within-subjects design), and study arms or conditions (listed as bullets).

Target behavioral mechanism and the measure used to measure this mechanism (e.g., fear of recurrent heart attack) *(suggested 50 words)*
State the target behavioral mechanism and measure used to measure this mechanism.

Target outcome(s)
State the targeted outcome(s) (e.g., depression, PTSD, cardiac medication adherence)

Study Protocol *(suggested 250 words)*
Briefly describe the protocol (e.g., how participants are enrolled, key procedures, proposed timeline of study). This should only be a few sentences in length.

Study Population *(suggested 100 words)*
Specify who will be recruited, providing key characteristics like general health status and demographics (e.g., age range, gender, race/ethnicity).

Sample Size *(suggested 50 words)*
State target accrual and estimated dropout rate.
Example: *300 participants will be enrolled to meet a final sample of 240 participants, estimating a 20% drop-out rate.*

Preliminary Studies *(suggested ½ to ¾ page)*
Include who was involved from team; what was done; what was found & how does it relate to proposed project).The goal of this section is to demonstrate that you and your research team are capable and ready to conduct the proposed trial (e.g., prior studies have provided all needed information and necessary expertise).

Masked or Blinded Design? (Y/N) *(suggested 50 words)*
If yes, list who is masked or blinded (e.g., considering participant, care provider, PI, statistician, other study team members).

Recruitment Plan *(suggested word count: 500-750 words)*
Provide a detailed recruitment plan outlining strategies for identifying, screening, consenting, and enrolling the target participant population, addressing potential barriers and ensuring diverse representation.

Participant Enrollment Duration *(suggested 100 words)*

Indicate time (e.g., in months) it will take for each individual participant to complete all study-related tasks after enrollment. ***Example:*** *Each participant will complete a baseline screening, 8 weekly intervention sessions, and 2 follow-ups at 6 months and 12 months. Total anticipated time for a participant to complete the study is 15 months.*

Retention Plan *(suggested word count: 250-500 words)*
Provide a comprehensive retention plan detailing proactive strategies to maintain participant engagement, minimize attrition, and ensure complete data collection throughout the study, addressing potential barriers and follow-up procedures.

Stage of Behavioral Development *(suggested 100 words or less)*

a. *What Stage (Stage 0, I, II, III, IV, or V of the NIH Stage Model) of research is being proposed?*
b. *Is more than one Stage of research being proposed? If so, please indicate all of the proposed Stages and proposed stopping rules before proceeding to a subsequent Stage.*
c. *For each Stage proposed, please explain why the research activities proposed fall under the specific Stage suggested.*

Description of Behavioral Intervention(s) and Goals

For every behavioral intervention in the study, please provide a separate table (example below) that specifies:

- **Brief Description of Intervention**
  - *Briefly describe all interventions in the proposed CT (2-3 sentences, suggested, per intervention). Example: Intervention # 1(Replace with name) is intended to improve emotion regulation skills and ultimately to improve mood. It is a 12-session (four 3-week modules) intervention, delivered over a 12-week period by community-based social workers. The four 3-week modules are: 1), 2), 3), 4).*
- **Core or Essential Elements**
  - ***For interventions with multiple components:***
    - *Specify the hypothesized core elements/components/ingredients of the intervention.*
    - *Specify the proposed method to determine the essential elements/components/ingredients of the intervention.*
    - *Identify the hypothesized mechanism(s) of behavior change of each core element/component, and the proposed method to test the hypothesized mechanism(s)*
  - ***For single component interventions:***
    - *Identify the hypothesized mechanism(s) of behavior change of the intervention, and the proposed method to test the hypothesized mechanism(s)*
- **Adaptation:** *If proposing a Stage I study to adapt, modify, or refine an existing intervention:*
  - *List the existing intervention you are modifying and what specific changes you will make, including rationale for modification:*
  - *Are you proposing to adapt the core elements of an existing intervention, related to the hypothesized mechanism(s) of change of the intervention?*
    - *If so, what are the PROPOSED CHANGES TO THE INTERVENTION?*
    - *Based on hypothesized mechanisms of behavior change, what is the rationale for this modification?*
  - *Are you proposing to adapt aspects of an existing intervention, unrelated to the hypothesized mechanism(s) of change of the intervention?*
    - *If so, what are the PROPOSED CHANGES TO THE INTERVENTION?*
    - *Based on hypothesized mechanisms of behavior change, what is the rationale for the modification?*
- ***Number of Modules*** *(e.g., topics to cover in the intervention)*
- ***Number of Sessions*** *(e.g., meetings, visits)*
- ***Length of Sessions*** *(e.g., 60 minutes)*
- ***Method of Intervention Delivery*** *(e.g., web-based, face to face, virtual, phone call)*
- ***Intervention Provider*** *(e.g., M.A. level research staff, formal care providers in nursing homes, occupational therapists in community health-care settings, etc.)*

Behavioral Intervention Details (*Create a new table for each intervention)*

Intervention Name	"
Brief Description of Intervention *In a separate table for each intervention, briefly describe all interventions in the proposed CT (2-3 sentences, suggested, per intervention).*	***Example:*** *Intervention # 1(Replace with name) is intended to improve emotion regulation skills and ultimately to improve mood. It is a 12-session (four 3-week modules) intervention, delivered over a 12-week period by community-based social workers. The four 3-week modules are: 1), 2), 3), 4).*
Core Elements (Essential ingredients)	
Hypothesized Mechanism of Action for each Core Element	
Adaption/Modification/Refine-ment of Existing Intervention?	*If so, please address the questions above*
Number of Modules	
Number of Sessions	
Length of Sessions	
Method of Intervention Delivery	
Intervention Provider	

Public Health Impact Statement *(suggested 250 words)*
Describe plans to engage a multidisciplinary team of scientists and stakeholders with lived experience in the design, conduct, or dissemination of the trial. Articulate plans to recruit and retain a representative sample of individuals impacted by this health event.

Fidelity Considerations (suggested 250 words)
Briefly outline how your study will address intervention fidelity. Indicate the fidelity measure you will use and the methodology you will use to collect data for this measure. For interventions that require delivery by individuals in the community, outline how and when materials will be developed to train these individuals to administer the intervention correctly and how any issues of sustained administration fidelity will be addressed.

Statistical Analysis (suggested 500 words)
State the statistical hypotheses of the proposal. State the primary and secondary outcomes. 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. Describe the rationale for the targeted sample size.

Statistical Power (suggested 750 words)
Has a power analysis been completed? Describe whether there is sufficient statistical power to answer the primary research question(s). If different from the primary research question(s), describe whether there is sufficient statistical power to test for: a) efficacy outcomes, b) mechanistic target outcomes, and c) core or essential component outcomes.

Long-Term Goals (suggested 250 words)

Briefly describe 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.

Please describe how this trial is consistent with the theme of the Columbia Roybal Center for Fearless Behavior Change.

References

Please include a list of relevant citations.