

**2025 Roybal National Call for Clinical Trials on Behavioral Interventions in Aging**

Clinical Trial Proposal Template

**INSTRUCTIONS for Applicants**

* Applicants should complete this template and be sure to answer all sections.
* Instructions and explanatory text shown in red, *italics* should be deleted and replaced with the study specific text.
* Please submit final document as a PDF through the application portal.

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

**PI Name: *Last Name, First Name***

**Study Goals – Primary Research Question** *(max 200 words)*

*Briefly describe the goals of the proposed clinical trial. What research question(s) is asked?*

**Study Rationale** *(max 50 words)*

*Succinctly describe the rationale for the proposed clincial trial.*

**Specific Aims** *(max 200 words)*

*List the study Specific Aims and whether each aim is fully-powered, qualitative, or exploratory.*

**Study Design/Arms** *(max 50 words)*

*Describe the study design (e.g., RCT, MOST design, single-case within-subjects design), and study arms or conditions (listed as bullets).*

**Study Protocol** *(max 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** *(max 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** *(max 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.*

**Masked or Blinded Design? (Y/N)** *(max 50 words)*

*If yes, list who is masked or blinded (e.g., considering participant, care provider, PI, statistician, other study team members).*

**Participant Enrollment Duration** *(max 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.*

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

1. *What Stage (*[*Stage 0, I, II, III, IV, or V*](https://www.nia.nih.gov/research/dbsr/nih-stage-model-behavioral-intervention-development) *of the NIH Stage Model) of research is being proposed?*
2. *Is more than one* [*Stage*](https://www.nia.nih.gov/research/dbsr/nih-stage-model-behavioral-intervention-development) *of research being proposed? If so, please indicate all of the proposed* [*Stages*](https://www.nia.nih.gov/research/dbsr/nih-stage-model-behavioral-intervention-development) *and proposed stopping rules before proceeding to a subsequent* [Stage](https://www.nia.nih.gov/research/dbsr/nih-stage-model-behavioral-intervention-development)*.*
3. *For each* [*Stage*](https://www.nia.nih.gov/research/dbsr/nih-stage-model-behavioral-intervention-development) *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, max, 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, max, 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** |  |

**Fidelity Considerations** (max 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 Power** (max 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.*

**References**

*Please include a list of relevant citations.*