



MIDWEST ROYBAL CENTER
FOR HEALTH PROMOTION
AND TRANSLATION

Behavioral Intervention Funding Application

Our NIA-funded Roybal Center P30 is soliciting randomized controlled trials (RCT) to be included in our renewal application. The Midwest Roybal Center for Health Promotion and Translation is applying for its 6th consecutive funding cycle. To learn more about the Midwest Center:

<https://midwestroybalcenter.uic.edu/>

Upon renewal, our Roybal Center will fund two RCTs beginning June, 2024. RCTs can be funded for 1-2 years and up to \$200,000/award.

We ask that persons who intend to submit an application submit a letter of intent by **May 1, 2023** to Roxanne Dakers, MPH, rdakers@uic.edu. In the letter, please include your contact information and a brief summary (2-3 sentences) of your proposed RCT.

Investigators who seek funding are required to submit a description (four-page maximum) of their proposed projects as part of a *full application* by **May 8, 2023**. The Roybal Executive Committee will review proposals and will select awarded RCTs for inclusion in our renewal application.

Applications must:

- Include interventions that prevent or delay cognitive decline and AD/ADRD that:
 - Target mechanisms of behavior change to promote behavioral and lifestyle change in individuals or groups at risk of cognitive decline and AD/ADRD **AND/OR**
 - Spur the initiation and maintenance of physical activity regimens to prevent or delay cognitive decline and/or AD/ADRD that are personalized to individual or groups who share specific characteristics and/or preferences **AND/OR**
 - Leverage technology to prevent or delay cognitive decline and/or AD/ADRD
- Have a primary focus on behavioral and/or social intervention development. "Behavioral" is defined broadly, including interventions that target behavioral, psychological, interpersonal, or social processes. Behavioral interventions may be designed for use at the individual, family, dyad, group, community, institutional, or health systems level.
- Focus on mid-life and older individuals.
- Have goals to improve the health and well-being of people living with dementia (PLWD), or with a focus on behavioral and/or social interventions to prevent or delay cognitive decline and/or AD/ADRD.
- Specify, within their Specific Aims, the Stage of research, as defined by the NIH Stage Model, for the clinical trial proposed (<https://www.nia.nih.gov/research/dbsr/nih-stage-model-behavioral-intervention-development>).
- State and propose to test, within their Specific Aims, hypotheses regarding the mechanism of behavior change of interventions for the clinical trial proposed.
- Have the goal of serving as inclusive a population as possible, and applicants are required to describe how they will recruit participants from minority health and health disparity populations.
- Address issues of statistical power for proposed clinical trials. **All clinical trials must have adequate statistical power to test mechanisms of behavior change and/or efficacy of the intervention.** This includes Stage I "pilot" testing studies that include a specific aim to test the efficacy of an intervention, or the mechanism of behavior change of an intervention.

Awardees are expected to participate in Roybal Center activities pertaining to research, education, and service and will be expected to make brief presentations to the Center Executive and Advisory Committees during the course of the RCT and upon its completion. Awardees must comply with NIH and NIA reporting requirements e.g., ClinicalTrials.gov and CROMS. Funded RCTs may also be required to participate in an NIH data sharing plan and in a Center Data Safety Monitoring Committee.

ELIGIBILITY:

Open to all full time clinical or research faculty.

FORMAT OF APPLICATION:

Each funding request must include:

1. **Application Check List** (Form: Application Check List, 1 page)
2. **Roybal Funding Request Form** (Form: Cover Page, 1 page)
3. **Summary of Proposed RCT**. This summary should address specific aims, significance (To field and relevance to Roybal mission), design and methods, and proposed follow up studies (1/2 page)
4. **Project Description and Research Plan** (Form: Proposed Project Description and Research Plan, 4 pages max)
5. **Statement of Significance of Proposed Project and future follow-up funding plans** (Form: Project Significance, 1/2 page)
6. **Budget** (Forms: PHS 398 Detailed Budget for initial period, and budget form for entire project period)
7. **Itemized Budget Justification** (Form: Itemized Budget Justification)
8. **Biosketch** (NIH Format) and list of relevant publications (if any) of principal investigator and project collaborators, if available (5 pages max)

Please do not exceed the allowable number of pages in each section.

BUDGET:

Itemize the budget request and clearly justify each item. As a general rule, requests in the range of \$150,000 to \$200,000 (total Direct Costs) for up to a two-year period will be considered responsive to this. Please use the PHS 398 Detailed budget for the initial budget period and provide a budget justification. Note: Personnel of the Roybal Center's Administrative Core and/or the Behavioral Intervention Development Core will be available for assistance and will be added in to the submitted budget.

Dissemination activities must be included in the proposal and reflected in the budget at \$500 to \$700 for such activity. These activities may involve presentations at conferences or production of materials to distribute to the community, so the expenses should be included under the appropriate categories (mailing, travel, etc.). These items should be **clearly identified** as **dissemination activities in the budget justification**.

ALLOWABLE EXPENSES:

Allowable expenses which will be supported (if justified) include consumable supplies, incentives for participant participation, required travel, and small equipment purchases. Technical (consulting) assistance, student salaries, and faculty time are also allowed.

APPENDICES:

Information critical to evaluation of the proposal such as copies of survey instruments, focus group moderator guides, or letters from collaborators and community sites should be submitted.

REVIEW PROCESS:

A Review Committee comprised of members of the Roybal Executive Committee will be responsible for the review of all proposals. All responsive proposals will be evaluated and ranked; the top one to two proposals will be included in the upcoming Roybal Renewal application for funding beginning June 2024. All applications will receive an evaluation of their proposal and a letter stating the final funding decision.

PROJECT REVIEW CRITERIA

To be rated highly, applications should have the potential to develop into a high-quality substantial proposal.

- 1. Relevance.** The extent to which the project will contribute to the Roybal Center mission of developing, testing, and disseminating evidence-based interventions that promote physical activity and mobility with an emphasis on improving cognition. Which NIH stage does this project fall under (0-V)? Is the plan for translating to conduct future phases research present and reasonable?
- 2. Overall Impact** will this line of research exert a powerful influence on the research field addressed?
- 3. Significance.** Does the project address an important problem or a critical barrier to progress in the field? Is there a strong scientific premise for the project? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?
- 4. Investigator(s).** Are the PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance, and organizational structure appropriate for the project?
- 5. Innovation.** Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?
- 6. Approach.** Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Is the proposed sample size adequate and justified? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility, and will particularly risky aspects be managed? If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (exclusion) of children, justified in terms of the scientific goals and research strategy proposed?
- 7. Environment.** Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment, and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Principal Investigator (Last, First, Middle):

APPLICATION CHECKLIST

(Please check that all items listed are submitted with this application)

_____ **Cover Page** (Form: Cover Page, 1 page)

_____ **Summary Statement of Proposed Research** (Form: Summary Proposed Research, ½ page)

_____ **Proposed Roybal RCT Description and Research Plan**, 4-page limit, exclusive of literature references (Forms: Project Description and Research Plan)

_____ **Statement of Significance of Proposed Project:** *all applicants must also include plans for external application/funding here* (Form: Project Significance/External Funding, ½ page)

_____ **Budget** (Forms: PHS 398 Detailed Budget for initial period, and budget form for entire project period)

_____ **Itemized Budget Justification** (Form: Itemized Budget Justification)

_____ **Biosketch (NIH Format) and list of relevant publications (if any) of principal investigator and project collaborators, if available** (OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024))

Principal Investigator (Last, First, Middle):

Midwest Roybal Center for Health Promotion and Translation

Name and email of responsible financial officer/grant manager of your Academic unit: _____

GRANT COMPETITION

PROJECT TITLE (limit to 60 spaces):

PRINCIPAL INVESTIGATOR: _____
Name

UIN #: _____ Phone #: _____

Affiliation (University/Agency): _____

Address (Room and Building)

City, State Zip

E-mail: _____ Title: _____

Location(s) of research: _____

Collaborators (Name/Department/Agency): _____

Principal Investigator (Last, First, Middle):

SUMMARY STATEMENT OF PROPOSED RESEARCH

In ½ page or less, summarize your proposed research for someone without knowledge of your specific specialty, but with knowledge of your general academic field. Include a rationale explaining why your work is important to basic behavioral and social science research among older adults living in the U.S and how it will advance their cognitive functioning. Describe your vision for where you want to go with this line of inquiry (this section should include potential funding sources that will be interested in the information generated by this research).

Principal Investigator (Last, First, Middle):

PROPOSED ROYBAL RCT DESCRIPTION AND RESEARCH PLAN

(4-page limit exclusive of literature references)

The project description should be organized into the following sections:

- **Aims and Hypotheses:** This should be in outline form with objectives stated for the period of this project only. (1/2 page or less)
- **Significance and Innovation:** This should be a **brief**, critical review of the context of this proposal with respect to current knowledge in the field. A multi-disciplinary committee including people outside of your field of expertise should be able to understand why this research is important. (1 paragraph to 1/2 page)
- **Approach:** This section should provide sufficient detail to evaluate your familiarity with specific procedures to be used, experimental design, sample size justification and methods of data reduction and analysis. Interventions must be principle driven and identify a hypothesized mechanism of action for sustained behavior change. (3 pages or fewer).

Use 12-point font, 1-inch margins around, and single space.

Equipment must be justified on the basis of a specific need defined by the research proposed in this section.

APPENDIX: Material should be very limited; unpublished results required to evaluate the application are acceptable, however concise proposals with clearly defined goals and a plan that is feasible within **the timeline of the award** will be reviewed most favorably. The bibliography should cite only most relevant references.

Please note: The length of the trials can be from 1 to max of 2 years and have to be accomplished within the budget of \$200,000 direct per award.

Please document commitments from others that are crucial to the proposal - document with letters the following: access to site(s) and/or population(s) and direct help from collaborators in the community without which the proposed research would be difficult to achieve.

Principal Investigator (Last, First, Middle):

PROPOSED ROYBAL RCT DESCRIPTION AND RESEARCH PLAN

Principal Investigator (Last, First, Middle):

PROPOSED PROJECT SIGNIFICANCE/PLANS FOR EXTERNAL FUNDING

In ½ page or less, please describe the significance of your proposed research project. How does your project relate to the Roybal Center proposed themes and **will the project lead to a significant practical outcome?** Focus on how the proposal will contribute to the translation of basic behavioral and social science research findings to benefit the health and well-being of older adults (50+) living in the U.S. In addition, all applicants should describe any plans for securing follow-up external funding in conjunction with this research.

For each RCT: include an anticipated plan for navigation through the Stages (NIH Stage Model), describing the intended pathway of “next steps” needed to produce a potent and implementable intervention.

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY						FROM	THROUGH	
List PERSONNEL (<i>Applicant organization only</i>) Use Cal, Acad, or Summer to Enter Months Devoted to Project Enter Dollar Amounts Requested (<i>omit cents</i>) for Salary Requested and Fringe Benefits								
NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Summer Mnths	INST.BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
	PD/PI							
SUBTOTALS								
CONSULTANT COSTS								
EQUIPMENT (<i>Itemize</i>)								
SUPPLIES (<i>Itemize by category</i>)								
TRAVEL								
INPATIENT CARE COSTS								
OUTPATIENT CARE COSTS								
ALTERATIONS AND RENOVATIONS (<i>Itemize by category</i>)								
OTHER EXPENSES (<i>Itemize by category</i>)								
CONSORTIUM/CONTRACTUAL COSTS						DIRECT COSTS		
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD (<i>Item 7a, Face Page</i>)								\$
CONSORTIUM/CONTRACTUAL COSTS						FACILITIES AND ADMINISTRATIVE COSTS		
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD								\$

**BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD
DIRECT COSTS ONLY**

BUDGET CATEGORY TOTALS	INITIAL BUDGET PERIOD <i>(from PHS 398)</i>	2nd ADDITIONAL YEAR OF SUPPORT REQUESTED	3rd ADDITIONAL YEAR OF SUPPORT REQUESTED	4th ADDITIONAL YEAR OF SUPPORT REQUESTED	5th ADDITIONAL YEAR OF SUPPORT REQUESTED
PERSONNEL: <i>Salary and fringe benefits. Applicant organization only.</i>					
CONSULTANT COSTS					
EQUIPMENT					
SUPPLIES					
TRAVEL					
INPATIENT CARE COSTS					
OUTPATIENT CARE COSTS					
ALTERATIONS AND RENOVATIONS					
OTHER EXPENSES					
DIRECT CONSORTIUM/ CONTRACTUAL COSTS					
SUBTOTAL DIRECT COSTS <i>(Sum = Item 8a, Face Page)</i>					
F&A CONSORTIUM/ CONTRACTUAL COSTS					
TOTAL DIRECT COSTS					

TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PROJECT PERIOD

\$

Justification included on following page

ITEMIZED BUDGET JUSTIFICATION

Individual items over \$300 must be justified. Brand names and specifications must be justified relative to less expensive alternatives and source of quotations should be detailed. Equipment requested must be justified as an integral part of the proposed research. **Remember to include \$500-\$700 for dissemination activities.** Please provide enough information for the reviewers to understand your proposal.

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME:

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE:

EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.*)

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY

A. Personal Statement

B. Positions, Scientific Appointments, and Honors

C. Contributions to Science