

# FULL APPLICATION INSTRUCTIONS FOR ORCASTRAIT PILOT STUDY FUNDING

All applications should be done and submitted in NIH-style proposal formatting. Pilot research must involve a clinical trial (control conditions not necessary) and be feasible within a one-year time period. These projects also should reflect familiarity with the NIH Stage Model for Behavioral Intervention Development (<u>https://www.nia.nih.gov/research/dbsr/stage-model-behavioral-intervention-development</u>).

The Pilot Core will support two or more innovative projects at \$95,000 for direct costs for 1 year for each project selected.

Here is a comprehensive list of what is needed in your project application:

# **Project Proposal**

- 1. Cover page with project title, investigators' names and affiliations
- 2. Abstract up to 350 words
- 3. 4-5 page proposals (in Arial 11-point font). It must include:
  - a. Specific Aims. The research hypothesis or scientific question to be investigated must be clearly stated. (1 page max)
  - b. Explanation of project's relevance in one of the top three selection priorities:
    - i. Work leading to innovative care provider intervention research advantaged or enhanced by technology
    - ii. How it tangibly moves an intervention closer toward later Stage Model destinations
    - iii. How the project engages early career, women, and minority researchers or established investigators applying their old knowledge into a new area of research important to the goals of ORCASTRAIT
  - c. Anticipated scientific significance and innovation
  - d. Preliminary data (if applicable)
  - e. Research design, methods (include description of the intervention, study methods, sample size and justification, analytic plan)
  - f. Literature cited (not counted in page limit)
  - g. Human subject protections research plan (human subject protection plan guidelines)
  - h. NIH biosketch for all investigators (biosketch form)
  - i. Budget to include:
    - i. A 1-year budget on the NIH Budget Form\_4 (<u>budget form link</u>). Budget not to exceed \$95,000 (direct costs)
    - ii. Total budget and budget justification on NIH Budget Form 5 (budget form link)
      - Budget may not exceed \$95,000 in direct costs. The maximum budgeted project period is one year. Facilities and Administrative (F&A) Costs – indirect costs – are allowed at the applicant institution's approved negotiated rate but must be calculated as part of the total costs. Direct costs should reflect the actual needs of the proposed project.
  - j. A NIH planned enrollment form (phs inclusion form link)



Submit All Materials To ORCASTRAIT Project Proposal Team

## **Selected Applicant Additional Requirements**

If your proposal is selected by committee, please complete the NIH Human Subjects Study Form F and include the Data Safety and Monitoring Plan and other required attachments outlined in the form (<u>Subject Study Form</u>).

#### Proposals Will Be Peer Reviewed and Scored Using an NIH Scoring System

Scoring will address weakness/strengths in each of the following five dimensions:

- 1) Meaningful Caregiving Context or Situation
- 2) Relevance to one or all of the three selection priorities
- 3) Robustness of Proposed Trial
- 4) Feasibility of Completion in One-Year
- 5) Likelihood of Competitiveness of Next Submission

Investigators whose applications are to be recommended for support will be notified by March 1st, 2021. At that point, investigators will be asked to collaborate with the Roybal Center Pilot Core in the preparation of additional documents that will be submitted to NIA for project approval.

## **Project Reporting and Return on Investment**

A substantive written report describing the research findings and a detailed expenditure report will be due to ORCASTRAIT study team within 60 days of the grant's end date. A manuscript prepared for submission that describes the funded project methods and results may be used as the final narrative report. ORCASTRAIT may also seek information about research progress for purposes of research dissemination and fundraising.

All publications, reports or presentations of research supported by these funds, shall acknowledge such support, using the following wording:

*The research described here was supported by a grant from the National Institutes of Health, National Institute on Aging (P30 AG024978).* 

# ORCASTRAIT welcomes applications from all qualified individuals. We do not discriminate based on race, color, religion, sex, national origin, disability, age, genetic make-up, gender identity, or sexual orientation.