LOI Evaluation Criteria:

We will apply the following criteria when considering EMBRACE trial applications:

a) significance/innovation of idea
b) clearly identified and measurable mechanism of action (e.g., Science of Behavior Change mechanisms such as self-regulation; stress resilience; and/or interpersonal/social processes)
c) clearly-specified intervention target level (individual living with dementia; caregiver; living environment; and/or neighborhood community)
d) inclusion of a tailored intervention delivered within home and/or community settings
e) potential of the trial to yield high-quality data leading to future extramural funding at a subsequent stage of the NIH Stage Model
f) scientific merit and feasibility of design/analysis.

Full Application Evaluation Criteria:

Scored Review Criteria Reviewers will consider each of the review criteria below in the determination of scientific merit and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Factor 1: Significance

Evaluate the importance of the proposed research in the context of current scientific challenges and opportunities, either for advancing knowledge within the field, or more broadly. Assess whether the application addresses an important gap in knowledge in the field, would solve a critical problem, or create a valuable conceptual or technical advance.

Evaluate the rationale for undertaking the study, the rigor of the scientific background for the work (e.g., prior literature and/or preliminary data) and whether the scientific background justifies the proposed study.

Innovation: Evaluate the extent to which innovation influences the importance of undertaking the proposed research. Note that while technical or conceptual innovation can influence the importance of the proposed research, a project that is not applying novel concepts or approaches may be of critical importance for the field. Evaluate whether the proposed work applies novel concepts, methods or

technologies or uses existing concepts, methods, technologies in novel ways, to enhance the overall impact of the project.

From Parent RFA Special Criteria: Does the project address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed project rigorous? Does the proposed clinical trial test hypotheses regarding the MoBC of an intervention that can inform the development of a potent, scalable intervention?

Factor 2. Rigor and Feasibility

Approach: Evaluate the scientific quality of the proposed work. Evaluate the likelihood that compelling, reproducible findings will result (rigor) and assess whether the proposed studies can be done well and within the timeframes proposed (feasibility).

Rigor: Evaluate the potential to produce unbiased, reproducible, robust data. Evaluate the rigor of experimental design and whether appropriate controls are in place. Evaluate whether the sample size is sufficient and well-justified. Assess the quality of the plans for analysis, interpretation, and reporting of results. Evaluate whether the investigators presented adequate plans to address relevant biological variables, such as sex or age, in the design, analysis, and reporting.

For applications involving human subjects or vertebrate animals, also evaluate: the rigor of the intervention or study manipulation (if applicable to the study design), whether outcome variables are justified, whether the results will be generalizable or, in the case of a rare disease/special group, relevant to the particular subgroup, whether the sample is appropriate and sufficiently diverse to address the proposed question(s).

For applications involving human subjects, including clinical trials, assess the adequacy of inclusion plans as appropriate for the scientific goals of the research. Considerations of appropriateness may include disease/condition/behavior incidence, prevalence, or population burden, population representation, and/or current state of the science.

Feasibility: Evaluate whether the proposed approach is sound and achievable, including plans to address problems or new challenges that emerge in the work. For proposed studies in which feasibility may be less certain, evaluate whether the uncertainty is balanced by the potential for major advances. For applications involving human subjects, including clinical trials, evaluate the adequacy and feasibility of the plan to recruit and retain participants. Additionally, evaluate the likelihood of successfully achieving the proposed enrollment. For clinical trial applications, evaluate whether the study timeline and milestones are feasible.

From Parent RFA Special Criteria: Does the study have adequate statistical power to test mechanism of behavior change and/or efficacy of the intervention. Does the clinical trial proposed include individuals that share a common problem or behavior for which the behavioral intervention is being developed? Does the applicant describe how they will recruit a sample that is inclusive of the targeted populations who may benefit from the intervention.

Factor 3. Expertise and Resources

Investigator(s): Evaluate whether the investigator(s) have demonstrated background, training, and expertise, as appropriate for their career stage, to conduct the proposed work. Assess the quality of the leadership team to facilitate coordination and collaboration.

Environment: Evaluate whether the institutional resources are appropriate to ensure the successful execution of the proposed work