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## INTRODUCTION

The Funding Opportunity Announcements (FOAs) [PAR-14-315](#) and [PAR-14-321](#) invite applications related to the development (R21/R33) and testing (R01) of interventions for health-enhancing physical

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activity. The objective of these PARs is to encourage innovative research to improve our understanding of how to increase and maintain health-enhancing physical activity. These FOAs seek studies that will make meaningful and lasting change within a wide range of population groups across the lifespan, with an emphasis on multilevel interventions that have the potential to be scalable so they can be implemented and sustained in a variety of real-world settings. To date, several questions have been submitted from various investigators about permissible research plans under these Program Announcements with Special Review Criteria (PARs). This list of frequently asked questions (FAQ) was developed to address these inquiries.

## APPLICATION SUBMISSION

### When are applications due?

#### For R01 applications:

- **New applications:** February 5, 2016; October 5, 2016; June 5, 2017, by 5:00 p.m. local time of applicant organization. Please note that this FOA uses non-standard application dates.
- **Resubmission applications:** March 5, 2016; November 5, 2016; July 5, 2017, by 5:00 p.m. local time of applicant organization.
- **AIDS Applications:** May 7, 2016; January 7, 2017; September 7, 2017, by 5:00 p.m. local time of applicant organization. All types of AIDS and AIDS-related applications allowed for this funding opportunity announcement are due on these dates.

#### For R21/R33 applications:

- **New applications:** February 16, 2016; October 16, 2016; June 16, 2017, by 5:00 p.m. local time of applicant organization. Please note that this FOA uses non-standard application dates.
- **Resubmission applications:** March 16, 2016; November 16, 2016; July 16, 2017, by 5:00 p.m. local time of applicant organization.
- **AIDS applications:** May 7, 2016; January 7, 2017; September 7, 2017, by 5:00 p.m. local time of applicant organization. All types of AIDS and AIDS-related applications allowed for this funding opportunity announcement are due on these dates.

### How should I submit my application?

Applications must be submitted electronically. Applicants should follow the instructions in the [SF424 \(R&R\) Application Guide](#), including Supplemental Grant Application Instructions, except where instructed in this FOA to do otherwise.

### Am I required to submit a letter of intent?

A letter of intent is not required, and it does not enter into the review process. Investigators are encouraged to communicate with NIH scientific contacts listed at the bottom of the FOAs ([PAR-14-315](#) and [PAR-14-321](#)) to discuss their research ideas and specific aims prior to submitting applications.

## PAGE LIMITATIONS

### Does the application have a page limit?

Yes. All page limitations described in the [SF424 Application Guide](#) and the Table of Page Limits must be followed.

## RESEARCH OBJECTIVES, SCOPE, AND RESPONSIVENESS

### What is the Phased Innovation (R21/R33) grant mechanism?

The Phased Innovation (R21/R33) grant mechanism provides support for up to two years (R21 phase) for research planning activities, formative assessments, and feasibility studies, followed by a possible transition to expanded research support (R33 phase). Transition to the R33 depends on the completion of applicant-defined quantifiable milestones, as well as program priorities and the availability of funds. During review, both phases of the grant will be reviewed, but only one impact score will be given for the application.

The R21 grant mechanism is intended to encourage exploratory/developmental research by providing support for the early and conceptual stages of project development. The NIH has standardized the Exploratory/Developmental Grant (R21) application characteristics, requirements, preparation, and review procedures in order to accommodate investigator-initiated (unsolicited) grant applications. Visit the [OER webpage](#) to learn more about R21 grants. In addition, [PAR-14-321](#) includes example descriptions of acceptable activities in the R21 phase.

The R33 award provides a second phase of expanded support for innovative exploratory and development research activities initiated under the R21 mechanism. Although only R21 awardees are generally eligible to apply for R33 support, specific program initiatives may establish eligibility criteria under which applications could be accepted from applicants demonstrating progress equivalent to that expected under R33.

For the R21/R33 grant, the Specific Aims must fully describe both the R21 and R33 phases and should be combined on one page in the application. However, information detailed in a preceding section need not be replicated in the same detail if used elsewhere in the application.

### How are milestones for the R21 phase of the Phased Innovation R21/R33 grant mechanism determined?

Milestones should be quantifiable measures such as: What target(s) will the intervention use to demonstrate effectiveness? What target(s) will the intervention focus on to establish achievement toward specific outreach and recruitment efforts, updates, etc.?

### What are the funding levels for the R21 and R33 PARs?

The FOA provides support for up to two years of R21 phase for research planning activities and feasibility studies at \$325K direct cost, no more than \$225K in any single year. The R33 mechanism provides support for up to three years at \$525K direct cost, no more than \$250K in any single year.

### How do I know if my application is responsive to this funding opportunity announcement (FOA)?

The application must meet the following criteria to be considered responsive:

#### **For both R21/R33 and RO1 PARs:**

- The proposed intervention must encompass multiple levels and should not focus on only the individual or the environment (See FAQ on what qualifies as a multilevel intervention). However,

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for the R21/R33 mechanisms that are intended to support pilot interventions and development of interventions, studies that are powered to provide statistically significant differences in physical activity or health outcomes are not required. This is addressed in more detail below.

- The proposed intervention should be scalable in real world settings. Working partnerships beyond academic institutions and uptake are encouraged.
- The proposal must develop or test an intervention that is expected to be sustainable one to two years after the intervention has been delivered.
- For both mechanisms, the primary outcome sought is a measure of physical activity and/or change in physical activity over the duration of the one- to two-year intervention period in the direction of achieving the health-enhancing physical activity goals for the targeted population or patient subgroup.
- Secondary outcomes include social outcomes and possible co-benefits of physical activity participation (e.g., effects on behavioral, cognitive, or psychosocial outcomes; effects on substance abuse, tobacco use, or cardiovascular disease risk factors) or adverse outcomes (e.g., injury).

**For R21 and R33 PARs:**

- Applications to this mechanism should be focused on doing the pilot research necessary for developing multilevel interventions to increase physical activity.
- Applicants should propose to conduct formative assessments and pilot studies.
- The proposed pilot intervention must address physical activity change but is not required to have a sample size that is sufficient to measure statistically significant changes in physical activity or related health outcomes.
- Examples of metrics that a pilot intervention might assess in terms of the physical activity intervention include the feasibility and acceptability of the physical activity intervention by participants as well as the feasibility and acceptability of the measurement tool for physical activity and its administration, such as timing, frequency of measurement, response rate or other issues.
- In terms of associated health outcomes, a pilot intervention might assess the feasibility and acceptability of capturing data on health outcomes, including sources and accuracy of data related to health outcomes.
- The proposed intervention must target a specific population or age group to study the feasibility and acceptability of intervention and evaluation protocols and materials in that group.

**For R01 PARs:**

- The proposed intervention must include physical activity change as a primary outcome and be designed to test statistically significant differences in the outcome based on the intervention.
- The proposed intervention must target a specific population or age group to study how physical activity benefits them.

Applicants are strongly encouraged to contact the NIH scientific research contacts listed in the FOAs ([PAR-14-315](#) and [PAR-14-321](#)) for feedback about responsiveness prior to submitting an application. Upon receipt, applications will be evaluated for responsiveness by the components of participating

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organizations at the NIH. If your application is deemed responsive, it will undergo scientific peer review by experts convened specifically for this FOA (by the NIH Center for Scientific Review). If your application is deemed nonresponsive, it will be withdrawn prior to evaluation of its scientific merit, i.e., peer review.

### What are examples of research designs that are appropriate for these PARs?

As noted above, to be appropriate for these PARs, the proposed intervention must act at two or more levels in addition to individuals, such as families, organizations, and communities. For that reason, these interventions might appear different than the traditional 2 condition (intervention and control) RCT. Multiple research designs are appropriate for these PARs, and the choice will depend on the stage of development of the research, the research question, and whether randomization is possible. Interventions within applications for both of these PARs might utilize a broad range of research designs including but not limited to designs such as fractional factorial, quasi-experimental, time-series, or multiple baseline designs, group-randomized trial, additive, or regression discontinuity. Interventions for the R21/R33 PAR applications are anticipated to be pilot tests and prototype studies while interventions for R01 PAR applications are expected to be full tests of efficacy or effectiveness.

### What qualifies as a multilevel intervention?

The proposed intervention must act at two or more levels, such as individuals, families, social groups, institutional/organization environments, worksite, health care systems, or community environments. The intervention is intended to be designed to demonstrate impact on the environment and individuals at multiple levels (e.g., how the study may influence policies at the macro level as well as on decision-making at the individual level). Applicants are encouraged to use the Socio-Ecological Model as a framework for conceptualizing ways to develop a multilevel intervention (i.e. incorporating intervention targets at the intrapersonal, interpersonal, organizational, community, and/or public policy levels). For example, an intervention might include pedometer-based challenges at the interpersonal level, as well as the initiation/strengthening of joint-use agreements for community members to use school recreation facilities at the public policy level. A different intervention might focus on methods for enhancing motivation at the intrapersonal level and creating online social support groups for physical activity at the interpersonal level. There are many ways for an intervention to qualify as multilevel.

### Is a research proposal in which the outcomes do not include physical activity considered responsive?

No. Physical activity must be one of the outcome measures for an application to be responsive to these PARs. However, R21/R33 proposals must address physical activity change but are not required to have sample sizes sufficient to measure statistically significant changes in physical activity or related health outcomes. In these developmental or pilot interventions physical activity should be measured, but with the goal of assessing feasibility and acceptability of the physical activity measurement tool and its administration, such as timing, frequency of measurement, response rate or other issues.

For all proposals, the intervention and any comparison/control group should use appropriate and well-justified physical activity measures to enable proper comparisons that are also feasible in real-world settings. Measurement of intervention processes and impacts is also encouraged to enable assessment of intervention fidelity and whether hypothesized mediators were affected; in the case of R21/R33

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proposals, preliminary tests of the effects of intervention materials on behavioral mediators and intermediate outcomes of physical activity change can be used to enable the identification of components of the intervention that appear most promising to investigate in an efficacy study. Measurement of secondary outcomes such as social outcomes and possible co-benefits of physical activity participation (e.g., effects on behavioral, cognitive, or psychosocial outcomes; effects on substance abuse, tobacco use, mental health, or cardiovascular disease risk factors) or adverse outcomes (e.g., injuries) may also be included.

If your proposal includes cardiovascular or mental health/psychosocial outcomes as *primary* outcomes, it may be better suited to funding mechanisms supported by the National Heart, Lung, and Blood Institute (NHLBI) or the National Institute of Mental Health (NIMH). Please contact the following program officers at those Institutes for more information:

NHLBI: Josephine Boyington and Lawton Cooper – Clinical Applications and Prevention Branch

NIMH: Amy Goldstein

### Is a research proposal in which the outcomes are obesity or energy balance considered responsive?

No. The intent of this announcement is to address physical activity as it relates to conditions other than obesity or energy balance, such as cardiorespiratory fitness or reduced rates of cancer, bone health, mental health, or substance abuse.

### Is a research proposal that includes cost-effectiveness aims considered responsive?

Complete cost-effectiveness analyses are beyond the scope of this announcement. However, an assessment on resources spent on intervention development and maintenance, as well as data on costs of implementing and sustaining the intervention, are encouraged. Costs can include actual costs for intervention development, implementation and, to a lesser degree, maintenance.

## AWARD SELECTION

### On what basis are applications selected for funding?

Applications will be selected for funding based on scientific merit, current NIH program research priorities, and availability of funds.

## POST-AWARD MANAGEMENT & REPORTING

### Which NIH Institute/Center (IC) will manage my award?

IC assignment is dependent on the nature and scope of the research projects proposed. Applicants may request assignment to a particular Institute in their cover letter, but NIH will make the final determination regarding Institute management and oversight. The offices (Office of Disease Prevention, Office of Behavioral and Social Sciences Research, and the Office of Women's Health) participating in these FOAs do not manage grants. Therefore, the primary awardee of the grant will be one of the Institutes or Centers that are participating on these FOAs. The offices will provide co-funding on selected grants.