

Frequently Asked Questions (FAQs) for [NOT-OD-21-087](#)

[NOT-OD-21-087](#): Notice of Special Interest (NOSI): Developing and Testing Multilevel Physical Activity Interventions to Improve Health and Well-Being

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INTRODUCTION

The Notice of Special Interest (NOSI) [NOT-OD-21-087](#) encourages highly innovative and promising translational research to improve our understanding on increasing and maintaining health-enhancing physical activity using multi-level interventions in a wide range of population groups across the lifespan. This includes efficacy, effectiveness and dissemination and implementation studies. It also includes support for pilot, exploratory, or developmental work in preparation for full-scale, fully powered efficacy studies, preliminary feasibility studies, as well as expanded feasibility work for a discrete, specified, circumscribed project that is based on well-established theory, existing data and evidence-based interventions.

To date, there are 13 NIH Institutes and Centers, and Offices participating in this NOSI. This NOSI replaces two expired NIH funding announcements. [PAR-18-307](#): Developing Interventions for Health-Enhancing Physical Activity (R21/R33 - Clinical Trial Optional) and [PAR-18-324](#): Testing Interventions for Health-Enhancing Physical Activity (R01 - Clinical Trial Optional). In addition, the following notices were published to inform prospective applicants and research community that two Physical Activity PARs were reissued with new and revised research priorities - [NOT-OD-21-085](#) and [NOT-OD-21-086](#).

It is important to note that most NIH Offices (ODP, OBSSR, ORWH, etc.) **do not** hold or manage grants. However, these Offices may consider providing co-funding support for grants that the participating Institutes and Centers decide to fund. **All investigators planning to submit an application in response to this NOSI are strongly encouraged to contact and discuss their proposed research/aims with program staff/scientific contacts listed on this NOSI well in advance of the application receipt date to better determine appropriateness and interest of the relevant Institute.** Applicants must select the IC and associated FOA to use for submission. The selection must align with the IC requirements listed to be considered responsive to that FOA. The Scientific/Research Contacts are named under *Section VII, Scientific Research Contacts* section.

The frequently asked questions listed below address general questions from prospective investigators in the field. In addition, this document also includes questions that were submitted prior to or during the technical assistance webinar in response to this NOSI. A recording of this webinar and the presentation slides can be found on the ODP website

APPLICATION SUBMISSION

Q1. How should I submit my application?

A1. Applicants must select the IC and associated FOA to use for submission of an application in response to this NOSI. The selection must align with the IC requirements listed to be considered responsive to that FOA. Applications must be submitted electronically and follow the instructions in the SF424 (R&R) Application Guide, except where instructed to do otherwise (in the FOA or in a Notice from NIH Guide for Grants and Contracts).

Q2. Where in the application do we reference this NOSI?

A2. Applicants must include “NOT-OD-21-087” (without quotation marks) in the Agency Routing Identifier field (box 4B) of the SF424 R&R form. Applications without this information in box 4B will not be considered for this initiative.

Q3. When are NOSI-related applications due?

A3. This notice applies to due dates on or after June 5, 2021 and subsequent receipt dates through February 16, 2024. Applicants must select the IC and associated FOA to use for submission of an application in response to this NOSI. First available application due dates are also listed for each FOA in respective IC section.

Q4. Can an organization submit more than one NOSI-related application?

A4. Yes. Applicant organizations may submit more than one application, provided that each application is scientifically distinct. The NIH will not accept duplicate or highly overlapping applications under review at the same time.

Q5. When and how do I apply for co-funding from participating NIH Offices (e.g., ODP, OBSSR, ORWH, etc.)?

A5. Applicants do not directly apply for co-funding to the participating NIH Offices. IC program staff may request co-funding for meritorious applications that ICs are interested in funding.

Q6. Can potential applicants request a completed application for a successfully funded grant from prior PARs (PAR -18-307 and PAR-18-324)?

A6. NIH only releases grant applications from successful grants through the Freedom of Information Act request process. However, the [NIH RePORTER](#) website does provide some details of funded applications that might be of interest to potential applicants. [NIH RePORTER](#) is an electronic tool that allows users to search a database of NIH-funded research projects and access publications and patents resulting from NIH funding.

RESEARCH OBJECTIVES AND SCOPE

Q7. How can I determine whether my research topic is a better fit for NOT-OD-21-087?

A7: Investigators must carefully review the specific research interests of NIH Institutes and Centers that are participating in this NOSI. In addition, they are strongly encouraged to contact and discuss their proposed research/aims with Program staff/Scientific Contacts listed on this NOSI

well in advance of the application receipt date to better determine appropriateness and interest of the relevant Institute.

Q8. If my research project is relevant to more than one IC, what information should I use to determine which IC is the best to receive my application?

A8. Applicants whose research may be relevant to more than one NIH IC are highly encouraged to discuss potential research aims with the Scientific/Research Contacts at participating ICs well in advance of the application deadline to ensure overall fit of the proposed research with programmatic priorities, as stated in the NOSI (see [Scientific Research Contacts section](#)). The Contacts are the most appropriate individuals to help applicants identify alternative FOAs if it is determined that the applicant's research goals are not well-aligned with any of the participating IC's research priorities. The research interests and priority research areas of each participating IC are outlined in each FOA.

Q9. FOAs listed in NOSI under various ICs state that clinical trials are required or clinical trial optional. How do I determine my proposed study meets NIH definition of clinical trial?

A9. Both applications that either propose and those that do not propose clinical trial(s) will be accepted for these funding opportunities. Applicants proposing to conduct a clinical trial should review the [NIH Definition of a Clinical Trial](#) to determine whether or not you are conducting a clinical trial. It states a clinical trial is "a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include a placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavior outcomes." A [decision tool](#) is available to assist with the determination.

Q10. May I request IC contacts to review my project summary to see if my proposal would be a good fit for this funding mechanism.

A10. Yes, prospective applicants are highly encouraged to share their specific aims page with scientific/research contacts listed in the NOSI. Their names and contact information are found in the NOT-OD-21-087 under Section VII. Agency Contact.

Q11. How do you define multi-level physical activity interventions and what is the significance of them?

A11. For the purposes of this NOSI multi-level is defined as influencing at least two levels of influence (e.g., incorporate intervention targets at the intrapersonal, interpersonal, organizational, community, and/or public policy levels). Interventions provided simultaneously at several levels across the Socio-Ecological Model are most likely to be successful in achieving increases in physical activity. Applicants are encouraged to use the Socio-Ecological Model for conceptualizing multi-level interventions. For example, an intervention might focus on incorporating components of a

healthy diet in combination with increasing physical activity at a school or workplace. Likewise, an intervention might include technology-based challenges at the interpersonal level, as well as the initiation/strengthening of joint-use agreements for community members to use recreation facilities at the public policy level. Intervention settings can include, but are not limited to, healthcare settings, worksites, households, schools, green space, parks and recreation centers, other community organizations and settings, or entire communities.

Q12. Does the project need to cover specific objectives?

A12. At minimum, the proposed study must: 1) include physical activity as one of the primary outcomes 2) inform development of or test an intervention or program that acts on at least two socioecological domains or levels; and 3) demonstrate high potential for scalability and sustainability.

Q13. What are the study populations of interest for this NOSI?

A13. A wide range of Studies that responsiveness to this NOSI should include wide range of population across the lifespan, and in diverse populations, particularly those at high risk for sedentary behavior, those at high risk for disease conditions associated with inactivity, and those at risk for food insecurity. Populations of interest include, but are not limited to:

- Sedentary or inactive individuals or groups of all ages
- Persons or groups at high risk for conditions associated with inactivity (e.g., overweight, obesity, etc.)
- Person with a disease (e.g., malnutrition, cancer, age-related diseases, etc.) or condition (e.g., serious mental illness, nicotine dependence, etc.) that might be improved by physical activity
- NIH-designated populations who experience health disparities in the United States (which include racial and ethnic minority groups (Blacks or African Americans, Hispanics or Latinos, American Indians and Alaska Natives, Asian Americans, Native Hawaiians and other Pacific Islanders), less privileged socioeconomic status, sexual and gender minorities, and underserved rural populations
- Eligible participants of major food and nutrition assistance programs (e.g., Supplemental Nutrition Assistance Program, Child Nutrition Programs and Women Infants and Children Program, etc.) and other food distribution programs
- Eligible participants of social service or community programs, such as child welfare and justice programs
- Persons with physical, developmental, or intellectual disabilities
- Underserved populations at higher risk for conditions associated with inactivity

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- Populations in communities with a high burden of health disparities (e.g., geographic regions like the Mississippi Delta or Appalachia, rural and urban neighborhoods, etc.) with low physical activity levels

Q14. Is there any guidance on type of projects that would be considered nonresponsive?

A14. Yes, projects that fall into these two categories would be considered non-responsive – 1) Projects that do not include physical activity as one of the primary outcomes 2) Projects that do not consider more than one level of analysis (individual, interpersonal, institutional, community, and policy)

Q15. What types of pre-existing data do I need to have for my R01 application?

A15. Generally, feasibility and pilot data are expected for R01 applications. Special considerations might be given for [Early Stage Investigators](#) (ESIs). Applicants are strongly encouraged to reach out to one or more of the Scientific/Research Contacts from the participating ICs listed in the NOSI to discuss potential research aims, to determine project fit with programmatic research priorities, and to gain an understanding about what data might be expected for a given study

Q16. What is PhenX Toolkit?

A16. The PhenX Toolkit (consensus measures for Phenotypes and eXposures) provides recommended standard data collection protocols for conducting biomedical research. The protocols are selected by Working Groups of domain experts using a consensus process, which includes the scientific community. The Toolkit provides detailed protocols for collecting data and tools to help investigators incorporate these protocols into their studies. Using protocols from the PhenX Toolkit facilitates cross-study analysis, potentially increasing the scientific impact of individual studies. In particular, human-subject studies should incorporate SDOH measures from the Core and Specialty collections that are available in the Social Determinants of Health Collection of the [PhenX Toolkit](#).

APPLICATION REVIEW

Q17. Where will my application be reviewed?

A17. Applications will be evaluated for scientific and technical merit by an appropriate Scientific Review Groups convened by the Center for Scientific Review (CSR), in accordance with [NIH peer review policy and procedures](#). Assignment to a Scientific Review Group will be shown in the eRA Commons.

Q18. What if I apply to one IC and then after the first scientific review opt to submit to another IC? Would that be considered a new application or a resubmission?

A18. Several factors are used to determine whether an application is considered a new application or a resubmission, and the Scientific/Research Contacts listed in each FOA are the most appropriate individuals to contact regarding this ([see Scientific/Research Contacts statement above](#)). In this case, it is very important to have a discussion with Scientific/Research Contact from the “new” IC. Refer to the [OER Glossary](#) and the SF424 (R&R) Application Guide for details about application types.

Q19. What factors determine what study panel will review my application?

A19. All grant applications submitted to the NIH go to the Division of Receipt and Referral (DRR) within the CSR. For more information on the Receipt and Referral process, see [CSR: Submission and Assignment Process](#). Prior to submitting your application, questions regarding the scientific review process can be discussed with the Scientific/Research Contact(s) from the participating IC(s) ([see Scientific/Research Contacts statement above](#)) or with a Scientific Review Officer from CSR.

Q20. Is it best to request a particular study section? How do I ensure that my application is reviewed by a panel with appropriate expertise?

A20. Applications are assigned for review based on relevance of that application to the guidelines of an individual study section as well as administrative requirements such as pre-determined review clustering agreements. NIH will consider all assignment requests. However, it is not always possible to assign an application to the requested study section. The [Assisted Referral Tool \(ART\)](#) was developed by the CSR to recommend potentially appropriate study sections. The information you provide ART is only used to recommend study sections; recommendations made by ART are solely for the benefit of the user and there is no guarantee that your application will be assigned to one of the study sections identified by ART.

AWARD SELECTION

Q21. On what basis are applications selected for funding?

A21. Applications will be selected for funding based on scientific merit, current NIH program research priorities, and availability of funds. Applicants are highly encouraged to discuss potential research aims with the Scientific/Research Contacts from the participating ICs to determine fit with programmatic research priorities ([see Scientific/Research Contacts statement above](#)).

Q22. Are early stage investigators less likely to receive funding as a PI for a non-profit institution?

A22. Applicants from non-profit institutions are not less likely to receive funding. Specific policies that support early stage investigators are highlighted [here](https://grants.nih.gov/policy/early-investigators/index.htm) (<https://grants.nih.gov/policy/early-investigators/index.htm>).

QUESTIONS RECEIVED DURING PHYSICAL ACTIVITY TA WEBINAR

Q23. Could you clarify the multilevel physical activity intervention definition for this NOSI?

A23: For the purposes of this NOSI multi-level is defined as influencing at least two levels of influence (e.g., incorporate intervention targets at the intrapersonal, interpersonal, organizational, community, and/or public policy levels). Interventions provided simultaneously at several levels across the Socio-Ecological Model are most likely to be successful in achieving increases in physical activity. Applicants are encouraged to use the Socio-Ecological Model for conceptualizing multi-level interventions.

Q24. Does NICHD have an R15 and R21 program that is part of this NOSI?

A24: Yes, the NICHD has a R21 that requires a clinical trial and a basic. The NOSI highlights specific areas of interests by participating ICs. Each participating IC has listed the FOAs that are relevant in their respective sections of the NOSI. For example, NICHD will accept R01, R21, R03 and R15 applications.

Q25: In this NOSI, I do not see the NICHD FOA for R21. Do we apply to the parent R21 FOA, PA-20-194?

A25: Yes, if you do not see a particular FOA of interest listed in the IC-specific table, you may apply to one of the NIH Parent Announcements listed in this NOSI. In this case, PA-20-194 is the correct one. Please make sure you include the NOSI number (NOT-OD-21-087) in the Agency Routing Identifier field (box 4B) of the SF424 R&R form.

Q26. Does NICHD have R34 (planning grant for clinical trials/research project) under this mechanism?

A26: No, NICHD does not have R34 listed in the NOSI, but you can locate relevant parent announcement.

Q27: where can I find the link for the NOSI?

A27: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-087.html>

Q28. How many applications are expected to be funded under this NOSI?

A28: There are no set number of applications connected to this NOSI. All applications should be targeted to FOAs specific to ICs, interested applicants are encouraged to reach out to the Scientific Contacts listed in the NOSI.

Q29: Given the strong emphasis on physical activity (PA) as an outcome, is there a preference for how PA is measured?

A29: Validated objective and self-report measurements of PA are encouraged across multiple levels. Since the measurement should match the innovative research question, and it's recommended that applicants contact program officers to discuss their aims and associated measurements.

Q30: Would you mind clarifying how this NOSI applications will be reviewed? Will they be assigned to current councils from each institute, or there are plans to have a dedicated panel for this NOSI?

A30: Applications will be evaluated for scientific and technical merit by an appropriate Scientific Review Groups convened by the Center for Scientific Review (CSR), in accordance with [NIH peer review policy and procedures](#). The application will be referred and reviewed based on the guidelines outlined in the FOA to which your application was submitted. Specific questions about the ideal FOA and/or review procedures should be directed to the Scientific/Research Contact listed in the FOA or those individuals listed in this NOSI (under the "Inquiries" section).

Q31. What is meant by "co-funds" for ORWH? Would we apply to a different IC and ORWH may contribute to funding the proposal? If that's the case, how would we bring the proposal to the attention of ORWH?

A31: ORWH doesn't have grant making authority, and they fund research in collaboration with other ICs. Both ORWH and other ICs whose work is aligned with the proposal, could be named on the application. Also, the program director from the IC could be consulted prior to application and he/she could submit the application for cofunding consideration with ORWH.

Q32: It was mentioned earlier that this NOSI is replacing prior announcements for R21 and RO1s. R15s are included in the current NOSI, correct?

A32: The NOSI highlights specific areas of interests by participating ICs. Each participating IC has listed the FOAs that are relevant in their respective sections of the NOSI. For example, NICHD will accept R01, R21, R03 and R15 applications. Look at the NOSI in each section and the IC's have listed the mechanisms that are relevant to each IC.

Q33: Is the PhenX toolkit relevant to individual and interpersonal levels of this NOSI?

A33: Yes, please check the toolkit physical activity and physical fitness research domains to explore any recommended protocols - <https://www.phenxtoolkit.org/>.

Q34: How would the NIH Stage Model be used to address multiple levels? To clarify perhaps, can the NIH stage model be used instead of the socio-ecological model system?

A34: The [Stage Model](#) is a model of behavioral intervention development composed of multiple stages. It is a framework to help investigators think about stage of their research intervention, refinement, pilot, efficacy testing etc. The [socioecological models](#) offer a systematic approach by which population specific determinants for overall physical health and wellbeing can be identified, measured and analyzed. Both are different models.

Q35: In discussing a physical activity outcome, do you mean outcomes such as steps/day, minutes of walking/week, six-minute walk test, or other specific outcomes?

A35: It is up to the Principal Investigator (PI) to justify the relevance and selection of physical activity measure. It can be any of those outcomes, but PIs must justify the measure and relevance as a measure of physical activity.

Q36: If the PI is an early investigator not currently funded by NIH but has a strong C01 or team that have had funding from NIH would these applications be considered?

A36: Yes, early stage investigators are encouraged to apply.

Q37: What if you have a grant pending review in an upcoming study section that fits this NOSI but was submitted before it was published? Is there a way to associate the application with this NOSI before it goes to Council?

A37: Duplicate applications cannot be in review at the same time, per NIH guidelines. If you currently have an application in the review process, you need to wait for receive feedback from

NIH before submitting again. During the review process, reviewers certainly try to connect the application with relevant NOSIs.

Q38: NIMH talked about addressing “serious mental illness” but did not talk about prevention. Will the Institute consider prevention of symptoms of mental illness with a physical activity primary outcome?

A38: Yes, NIMH support prevention intervention research. Please note that it should be consistent with experimental therapeutic approach, which can be located on the [NIMH homepage](#). For any specific questions, please reach out to the program-specific contacts on the NOSI.

Q39: Is there general enthusiasm for multilevel interventions where the interpersonal community is online, and the place of intervention is virtual?

A39: It is entirely up to the Principle Investigator on how they design the studies and per requirements of the FOAs from specific IC. For more targeted questions, please connect with the IC-specific contacts listed in the NOSI.

Q40: When I go through the NOSI, I saw some information like “NICHD’s FOAs for this NOSI include the following or their subsequent reissued equivalents.” Does it mean we can apply those R01/03/15 topics using this NOSI “multilevel physical activity intervention”? Or how these related to each other?

A40: FOAs listed under NICHD make a distinction between the need for clinical trial required or optional and specific mechanisms, as an example. All FOAs listed can be used to send applications based on the type of study. For any specific questions, please connect with the program-specific contacts listed in the NOSI.

Q41: Would observational studies fit in the scope of the NOSI if they are observing how community level systems changes can impact PA? For instance, thinking of active transportation improvements?

A41: ICs are primarily interested in interventions that are effective for improving physical activity. Rigorous research study designs like experimental, quasi-experimental, observational, modeling, cluster randomization, stepped-wedge, Type III hybrid effectiveness, etc., offer tremendous benefit in multilevel intervention studies and are allowed. It is also important to connect with the underlying parent FOA requirements associated with this NOSI. Please connect with the IC-specific contacts to discuss research designs.

Q42: How are pragmatic trials viewed in relation to this NOSI?

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A42: Pragmatic trials are conducted in real-world practice settings and they are somewhat close to natural experiments. The NOSI encourages studies proposing to address multilevel interventions and they can include experimental designs or natural experiments created by changes in policy.

KEY OF ABBREVIATED TERMS

ART – Assisted Referral Tool

CSR – Center for Scientific Review

DRR – CSR Division of Receipt and Referral

ESIs – Early Stage Investigators

FOA – Funding Opportunity Announcement

ICs – NIH Institutes, Centers, and Offices

NICHD – *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

NIH – National Institutes of Health

OBSSR – Office of Behavioral and Social Sciences Research

ODP – Office of Disease Prevention

ORWH – Office of Research on Women's Health

PA – Physical activity

PAR – Program Announcement with special receipt, referral, and/or review considerations, as described in the PAR announcement

PDs/PIs – Program Directors/Principal Investigators