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INTRODUCTION

This Funding Opportunity Announcement (FOA) <u>PA-18-932</u> invites applications that seek to develop and understand strategies to reduce disparities in the uptake of evidence-based screening. Research supported by this initiative should enhance the screening process: (1) <u>in diverse populations</u>, (2) in diverse clinical and community settings, and/or (3) with traditional, non-traditional and/or allied health care providers.

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APPLICATION SUBMISSION

When are applications due?

This program announcement only supports the R01 grant mechanism. The due date follows the <u>standard dates</u> for R01 new, resubmission, renewal, and revision submissions.

How should I submit my application?

Applications must be submitted electronically. Applicants should follow the instructions in the <u>SF424</u> (R&R) Application Guide, including Supplemental Grant Application Instructions.

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. Applicants are encouraged to communicate with the NIH scientific contact persons listed at the bottom of the FOA 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 <u>SF424 Application Guide</u> and the <u>Table of Page Limits</u> must be followed.

RESEARCH OBJECTIVES AND SCOPE

How is evidence-based screening defined for the purposes of this FOA?

Evidence-based screening is defined as a preventive service (1) focused on detection of an undiagnosed disease in asymptomatic populations, and (2) screening recommended and proven to be effective based on rigorous systematic reviews conducted by authoritative committees (e.g., US Preventive Services Task Force, Community Preventive Services Task Force, or other authoritative bodies such as Cochran or NICE that undertake systematic evidence-based reviews).

What types of evidence-based screening are the focus of this FOA?

The type of evidence-based screening depends upon the gaps in uptake for a specific evidence-based screening. While there is no specific list of evidence-based adult screenings that are the focus of this FOA, applicants are referred to the <u>US Preventive Services Task Force list of recommended screening tests</u>. Applicants are encouraged to contact the scientific contact person from the relevant IC(s) to discuss the selection of evidence-based adult screening and the match with IC priorities.

How is the screening process defined?

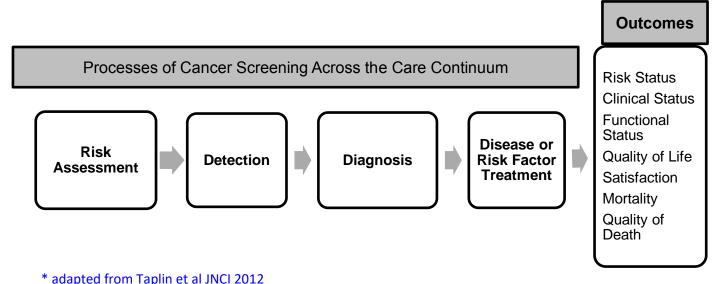
For the purposes of this FOA, the process of screening encompasses any of the five phases of screening. Figure 1 displays an abbreviated adaptation of the screening continuum that has been applied in cancer and serves as a good general framework for the screening process in other health areas. The first phase is risk assessment during which risk factors and prior screening history may be considered. The second phase is detection during which asymptomatic populations receive appropriate evidence-based screening. Phase three involves diagnostic evaluation when a patient is often referred for more in-

Last updated: October 26, 2018

depth imaging, biopsy, laboratory tests or other appropriate procedures. Phase four involves disease or risk factor treatment and may also require referral for those appropriate treatments. The final phase is considered an assessment for the final outcomes of screening and generally involves longer term assessment of morbidity, mortality or any assessment of potential side effects. This may involve assessment of risk status, functional status, clinical status, adverse events or quality of life/death. On a population level, it may involve estimating mortality, morbidity and cost-effectiveness. The phases on this continuum may or may not be discrete depending on the health outcome. For example, there is often overlap with risk detection and diagnosis in addictions. As a result, we highly recommend that potential applicants contact the scientific contact person from the relevant IC(s), listed on the funding opportunity announcement, prior to submitting a grant application.

While people may receive initial screening, one of the challenges of the screening process is the transition from one phase to another for patients with abnormal findings on screening. These transitions often require referral to other health care providers and may result in patients not completing the entire diagnostic, risk management and treatment process that is necessary to achieve the benefit of screening.

Figure 1. Steps and Interfaces in the Screening Process*



How do I know if my application is within scope for this program announcement? The application must meet the following criteria to be considered within scope:

The proposed investigation must have strong scientific rationale.

- Investigators who propose to study a preventive intervention focused on evidence-based screening should demonstrate the potential for the intervention to be scalable and sustainable in real world settings.
- Investigators may develop or test interventions designed to modify determinants such that they promote use of evidence-based screenings in diverse populations, and for any period across the life course that these screenings are recommended to occur.
- Investigators may propose research designed to examine mechanisms for inequities in uptake of evidence-based screening based on sex, race, ethnicity, age, geography or socioeconomic status, or any other factors that may be relevant to examine.
- Investigators may propose research that evaluates the impact of the uptake of evidence-based screening on other health care outcomes (utilization, expenditures, or other relevant factors) within diverse populations.
- Investigators may propose research designed to examine and understand context (e.g. arealevel SES or setting/type of organization providing screening services) as a mechanism influencing disparities in evidence-based screening services in diverse populations.
- Additionally, investigators may propose research that explores the use of allied or non-traditional healthcare providers for provision of evidence-based screening services within diverse populations.
- Investigators may propose observational research designs that involve primary data collection
 or secondary analysis of existing datasets. Please contact a program official from the
 participating Institutes for further information about availability of relevant existing data
 resources and the process for accessing such data.

Applicants are encouraged to contact the scientific contact person from the relevant IC(s) to regarding whether the topic is within scope and of IC scientific priorities before submitting an application. Investigators should also review the IC priority statements in the <u>program announcement</u>. Applications will be evaluated for scientific and technical merit by appropriate Scientific Review Group(s) convened by the Center for Scientific Review, in accordance with NIH peer review policy and procedures, using the stated review criteria. Final assignment to a Scientific Review Group will appear in the eRA Commons.

What are examples of research designs that are appropriate for these program announcements?

Several research designs may be appropriate for this program announcement. The choice will depend on the research question. For intervention research it will also depend on whether randomization is possible. Randomized controlled trials are not required components of applications submitted in response to this announcement but they are allowed. In some cases, a randomized design may not be possible or feasible, or would raise ethical concerns that are difficult to address. In such instances, investigators could propose and justify alternative, high-quality study designs. Such designs include, but are not limited to, quasi-experimental designs such as multiple baseline or interrupted time series, regression discontinuity, pre-to-post intervention with external comparison, natural experiments, or others. For proposals involving interventions, applicants should describe the strongest study design that can evaluate the effects of an intervention program with high internal validity, taking into account

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external validity and generalizability. In the case of secondary data analyses, the data must be well described and appropriate for this funding initiative. For more guidance, please visit these resources developed by NIH on <u>Training in Prevention Methods Research</u>, <u>Resources for Researchers</u> and <u>Pragmatic and Group-Randomized Trials</u>.

Is a research proposal that includes cost-effectiveness aims considered within scope?

Although cost-effectiveness research is high priority research for NIH (see https://grants.nih.gov/grants/guide/notice-files/not-od-16-025.html), applicants are encouraged to speak with the scientific contact person from the relevant IC for additional information related to IC priorities.

What if specific elements of my proposal, such as the population, intervention components, and/or focus of a secondary analysis (if one is proposed) do not match well with any of the participating Institutes/Centers (ICs) research priorities?

Applications are assigned to an individual IC based on the scientific topic and fit with IC priorities. Applicants are encouraged to contact the scientific contact/program official from the relevant IC(s) to discuss potential research well in advance of the application deadline. The scientific points of contact, listed at the end of the funding opportunity announcement, can help applicants identify alternative FOAs if it is determined that the applicant's research goals are not well-aligned with the purpose of this FOA and/or refer them to other ICs whose priorities better fit the proposed research. For additional information about how grants are assigned after submission, please refer to the <u>Assignment Process</u> through the NIH Center for Scientific Review.

The NIH Office of Disease Prevention does not manage grants but will consider co-funding applications that have been identified as meritorious in review and that ICs consider for funding. Co-funding requests are initiated by ICs—not individual applicants.

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. Applicants are highly encouraged to discuss potential research aims with program officials at participating NIH Institutes/Centers (ICs) to determine fit with programmatic research priorities. Applications which do not align with research priorities at any of the participating ICs may be rejected without review.

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 specific Institute in their cover letter, but NIH will make the final determination regarding Institute management and oversight. The NIH Office of Disease Prevention does not have

grant making authority; as a result, this office does not manage grants. The primary awarders of grants in response to this announcement will be one of the Institutes or Centers that are participating on this FOA.

Last updated: October 26, 2018