

Webinar to Address Six New Funding Opportunities
In Behavioral Research

Webinar Questions and Answers

Q. What is the difference between a new and early-stage investigator? Can a new investigator receive special accommodation in review?

- A.** A new investigator is a research grant applicant coming to NIH for the first time, but may, in fact, have been in the field for many years and received funding from entities other than NIH. An early-stage investigator (ESI) is a new investigator who received his/her seminal degree within ten years. It is a major priority for us to have as many new and early-stage investigators as possible in our portfolio. Depending on the fiscal year budget, there may be a wider funding range for early-stage investigators. Importantly, new and early stage investigators can use their new or ESI status only once, so you should use that advantage wisely. For example, you may strongly consider not serving as a multiple investigator with a senior investigator on your first grant. We typically encourage new investigators to use their new investigator or ESI status on a grant that they are heading up independently because it sets them onto a good trajectory for getting their research moving. I strongly encourage you to talk to a program director to help advise you if you are a new or early-stage investigator.

FAQs for NIH New and ESI Policies

https://grants.nih.gov/grants/new_investigators/investigator_policies_faqs.htm

Q. For early-stage investigators, is it discouraged to have senior investigators on your research team as co-investigators or consultants?

- A.** It's a great idea to have senior investigators as consultants or co-investigators. Often they have a tremendous amount of insight, and they can mentor and be an important part of the team. However, be aware that if you are a multiple PI (a multiple PI mechanism is one where you can have more than one principal investigator) with a senior investigator, you expend your early investigator status. If you are starting your career, it may be advisable to use this status on your own grant where you are the only PI. This is something to discuss with your department chair and your department. You can also consult with our program directors.

Q. How are percentiles calculated for Special Emphasis Panels?

- A.** This is a complicated question because Special Emphasis Panels sometimes have percentiles and sometimes do not. Percentiles simply tell you where you are relative to the other applications in a given study section. A score of 20 might mean something different in one study section than in another study section, which is why there are percentiles. Some study sections do not percentile. For example, grants in response to a Request for Applications (RFA) are not percentiled but rather evaluated on a case-by-case basis. Applications in response to traditional Program Announcements are almost always percentiled because they go to traditional study sections at the Center for Scientific Review (CSR). PARs involve

Special Emphasis Panels and applications are often percentiled, but that is not always guaranteed for a variety of reasons. For example, when we receive only a small number of applications for a given FOA, the CSR may not deem it efficient to convene an independent panel to review them. Instead, the applications may get reviewed in a separate study section. If that study section does not percentile their own applications, then our applications would not be percentiled either. Often it is an advantage to have your application percentiled because if it falls within the funding range, then the chances of it getting funded are very high without much further internal review by NCI staff.

Q. Could you address the rationale for moving from the omnibus R21 mechanism to specific program announcements?

A. Because we had so many different R21 mechanisms across NCI that were becoming unwieldy to manage, we experimented with collapsing all R21s together into one big omnibus. We thought it would welcome applications that did not fit into specific R21 FOAs, and that it would make it easier for people to get funded. Now, we are finding that we are getting a large bolus of R21 applications, driving up the denominator and making it more difficult for applications to fall within the funding range. Additionally, we are getting a lot of applications that do not align with the priorities of the institution, and many applications are not the kind that could lead to an RO1 after the R21 project is completed. So, now many NCI divisions and programs have opted for program announcements that are more narrowly focused and targeted.

Q. Why are some of these program announcements both R21s and RO1s, and why are others only R21s?

A. When we develop funding priorities, we consider the state of the science. For those priorities that are just emerging and for which we are trying to build up some momentum, we will typically start with an R21 mechanism. RO1s, on the other hand, align better with scientific areas that are a bit more developed. The reason we have the R21 for the population-level strategies funding announcement is that it is a hot new area that has emerged over the last year or so. The funding announcement on new innovations in behavioral intervention research is a picture-perfect R21 mechanism because it is entirely designed to develop something that is high-risk, but potentially could be high-reward and then be scaled up to something that is more traditional in an RO1. It's cases like these where we use both the R21 and RO1 mechanisms. Of course, we also have funding opportunities that are just RO1s because we think the science is advanced enough that researchers can develop a project at the RO1 level without starting with an R21.

Q. How does an applicant handle a program announcement that is co-funded by multiple institutes?

A. I strongly encourage all applicants to include cover letters with their applications that specify their preferences regarding where their application goes. You could specify a study section, an institute, and program directors with whom you have been in contact. While it is the prerogative of the Center for Scientific Review to send your application wherever they want, often they will honor your preferences. It is also important to include your preferred

institutes in your cover letter and/or summary statement to improve the chances of co-funding with another institute. Co-funding with another institute helps us fund more applications.

Q. If an application isn't funded the first time, can it be resubmitted as a new application?

A. Yes. Most applicants have the choice to submit an A1, which is a revision to an O1 (new) application. The advantage of submitting an A1 is that you can indicate what improvements you have made to your application, which will help reviewers when assessing your application. Or, you can just start an A0 (new) application. Some people prefer this approach if they don't think that their application scored well enough or that the study section understood what they were trying to do.

Q. What happens to new investigators when the KO7 and the omnibus R03 disappear? These are often great mechanisms to get new investigators into the portfolio.

A. Regarding the KO7, we are cognizant that the community is concerned about whether the K99/R00 mechanism will work for our community. Rest assured that we are aware of your concerns and want to make sure this mechanism will work. We have people in our program and in our division who are in contact with the Center for Cancer Training to make sure they understand our priorities, the types of investigators coming out of that community, how they write grants, and what kinds of things they focus on. Regarding the RO3, my staff and I are aware that this mechanism has been a great way for new investigators to come in with new ideas. While I can't promise anything, I can tell you that we are all very passionate about making sure our junior investigators have opportunities so there will be much discussion about what to do next with the RO3 mechanism after the omnibus runs out. Of note, it has recently been renewed.

Q. Where does quality of life fall into the list of cross-cutting funding opportunities?

A. Quality of life is relevant to many of these funding announcements, and some more than others. I can imagine quality of life being relevant to the population-level strategies FOA as it might be the case that certain kinds of population-level strategies are ineffective for certain populations because of a negative effect on quality of life. And so, if we could design an intervention to improve quality of life among those populations, then maybe the population strategies would be more effective. In other FOAs, quality of life would be relevant, but would be a secondary outcome. For example, the primary outcome of the tobacco FOA is smoking cessation, and quality of life may be a secondary outcome. Similarly, the primary outcome for the FOA on the cognitive effects of chemotherapy is to identify the best possible way to measure those cognitive deficits, but clearly quality of life is related to those cognitive deficits and may confound those cognitive deficits. Quality of life plays a role here but as a secondary outcome.

Q. Which mechanism(s) would best address alcohol awareness?

A. I can imagine the communication FOA addressing alcohol awareness because the American public is not aware of alcohol as a risk factor for cancer. Another possibility is the integrative data analysis FOA. There are data on awareness, attitudes, and beliefs about risk factors for cancer. One could imagine putting together datasets from different parts of the government or otherwise to see how awareness of alcohol as a risk factor has changed over time and what kinds of communication mechanisms are most effective at getting people to understand risk factors for cancer.

Q. For the announcement on predicting behavior response to population-level cancer control strategies, would the policy to be studied need to already be in place or can it be a prospective policy?

A. Yes, it could be a strategy or a policy that is already in place or one that is in development, perhaps a policy that is being used elsewhere. What would be outside the scope of this FOA would be developing a brand-new policy from scratch and then testing to see if it's effective. The policy or strategy should be either in the development phase, implementation phase or already be in effect.

Q. For the announcement on innovative approaches to studying cancer communication, are there particular research designs that will or will not be funded by this announcement?

A. For the RO1, we primarily would be looking for experimental designs, but for the R21, lots of different study designs would be appropriate – quasi-experimental, longitudinal, prospective. You can contact the program director, Kelly Blake (Kelly.Blake@nih.gov), to discuss your study design proposals.

Q. Which of these funding mechanisms would be best suited for studying a pediatric cancer population?

A. Pediatric populations are usually welcome in many different FOAs. If you are looking at adolescent populations and tobacco use, the FOA that focuses on smoking cessation and socioeconomically disadvantaged populations would be relevant. You can also consider a pediatric population when designing a new intervention that has anything to do with behavioral risk factors and cancer.

Q. Can you provide examples of databases that could be used for the FOA on integrating existing data? What would be considered an R21 versus an R01 proposal?

A. There are a multitude of data options you can use for this FOA. It could be yours or a colleague's data that had been collected for another study that can be reused or integrated. Government sources include healthdata.gov, [HINTS \(Health Information National Trends Survey\)](http://hints.gov), and the CDC's [National Center for Health Statistics](http://nchs.gov). The Inter-University Consortium for Political and Social Research out of the University of Michigan offers a data repository (<http://www.icpsr.umich.edu/icpsrweb/>).

Most applications likely will be for the R21 mechanism. The level of complexity of the data merge, in addition to the cost, would be the factors that would distinguish between the R01

and R21 mechanisms. For example, you may be trying to combine disparate datasets that have common measures, but they're measured in a different way and you're trying to figure out a way to put them on a common scale. There have been some new techniques that have been applied or developed to do this. The [PROMIS \(Patient-Reported Outcomes Measurement Information System\) initiative](#) is doing some interesting work there. Maybe there's a new analytic procedure or method from another discipline that you'd want to apply to multiple types of data across multiple levels – this might raise the level of complexity to an R01 rather than an R21.

Q. What would constitute a multilevel intervention?

A. We typically separate levels into the individual level, the family or social level, the health care level, the community level, and the policy or federal level. If you're working at more than one of these levels, you are conducting multilevel research.

Q. Why is the *Stimulating Innovations in Behavioral Intervention Research* FOA an R21?

A. The purpose of this FOA is to design new high-risk, high-reward interventions that potentially could be scalable into an R01 application at a later point.

Q. Is a comparison group needed for intervention studies?

A. Yes, a comparison group is necessary for intervention studies. You must determine what peer reviewers would consider a reasonable control group (i.e., standard of care; people who get nothing at all). The caveat is when you are doing special designs like fractional factorial designs or SMART (Sequential, Multiple Assignment, Randomized Trials), which clearly has an impact on how you define a control group. You may have multiple control groups.

Q. Will there be a special review panel or standing panel for the smoking cessation PAR?

A. This PAR will have a special review panel. Review falls under the purview of the Center for Scientific Review (CSR) at NIH. Their goal will be to convene a panel with all the relevant expertise necessary for the review panel. We will certainly advise them to consider reviewers with specialized expertise in working with socioeconomically disadvantaged populations, dissemination, and implementation. Investigators can help CSR, and us, by submitting letters of intent, and by writing cover letters that specify the expertise you think necessary to evaluate your proposal.

Q. You mentioned obesity and physical activity in the webinar but didn't mention diet.

A. Whenever we talk about obesity, energy balance, physical activity, diet, we are referring to a medley of behaviors and outcomes, and we do not intend to exclude any of them from the list. Anytime you see those kinds of terms in any of our FOAs, we are referring to all of them.