# Pre-Application Webinar: Improving Care and Outcomes for Cancer Survivors from Sexual and Gender Minority (SGM) Populations (R01 – Clinical Trial Optional)

PAR-23-292

Frequently Asked Questions (FAQ)

Pre-Application Webinar held November 17, 2023
The recorded webinar is available at:
https://cancercontrol.cancer.gov/brp/events/pre-application-webinar-improving-care-outcomes-cancer-survivors-sexual-gender-minority-populations

## General Questions

**Q1: What scope of research is appropriate for the R01 mechanism? How do I know if my research question is appropriate for the R01 mechanism?**

A1: The R01 provides support for health-related research and development based on the mission of the NIH. Please review the full text of PAR-23-292 to better understand the purpose, key requirements, review criteria, as well as descriptions of non-responsive applications.

**Q2: What is a PAR?**

A2: A PAR is a **Program Announcement** with Special **Review** Criteria and/or Special **Receipt** Dates. This PAR uses standard receipt dates, and therefore the "R" refers to special review criteria. PARs briefly highlight a specific topic of research or programmatic interest. A PAR allows program staff to specify review criteria and contribute to the identification of appropriate reviewers. NIH can often fund more projects using a PAR than an RFA and can typically do so over a longer period of time, which can lead to more projects being funded in an important topic area.

**Q3: How many years can this R01 be funded for?**

A3: The scope of the proposed project should determine the project period. The maximum project period is 5 years.

**Q4: Why is it helpful to submit a Letter of Intent?**

A4: Although not required, letters of intent are appreciated as they provide an opportunity for NIH and the Center for Scientific Review (CSR) to identify appropriate expertise for reviews.

## Questions asked during the webinar

**Q5: Since applications to this PAR will be reviewed in standing sections, how will reviewers comment on NOFO-specific criteria?**

A5: The planning team for this PAR worked closely with CSR to develop these criteria and the wording. CSR then communicates this to the reviewers as part of the preparation for the review process. The planning team has continued engagement with the Scientific Review Officers (SROs) to ensure they are aware of the criteria. The

scientific contacts do not have purview over the review, so they aim to provide as much information as possible ahead of time and try to be clear on the intention of the PAR.

**Q6: Will health professionals with SGM research expertise be involved in the review process? Is it possible to assess the knowledge of the reviewers related to SGM cancer survivors?**

A6: We really need health professionals with SGM expertise to apply to be peer reviewers. That said, since applications will go to standing study sections, the quick answer is "not necessarily." It is important to look at the rosters of the study sections to examine the background/expertise of the participants. If there is a particular scientific area that you do not think is appropriately addressed by the reviewers that may lead to an unfair review of the application, you are welcome to identify what the subject matter expertise is or training expertise. It is never in your best interest to identify a person that could be a reviewer, but it can be in your best interest to identify a topic area or subject matter area that is not well-represented. It is then at the discretion of the SRO to determine if they agree, but the SRO would have the ability to add ad-hoc reviewers for either the entire review or particular applications.

Reviewers are not selected based on a knowledge assessment, nor is a knowledge assessment completed by chosen reviewers.

**Q7: What is the process of becoming a reviewer? Is there a link you can share?**

A7: https://grants.nih.gov/grants/peer/becoming_peer_reviewer.htm

**Q8: Are international sites and international co-investigators allowed?**

A8: Yes, foreign applications are permissible. Please see the PAR for additional information.

**Q9: Can researchers pay their community partners?**

A9: Community partners, if included as collaborators, consultants, or as subcontractors can be paid.

**Q10: Can you provide an example of what might be considered a non-responsive application because it relates to decreasing cancer risk?**

A10: A proposed lifestyle intervention to reduce substance use as a way to decrease the incidence of cancer would be an example of a non-responsive application. Please see Section I. of the PAR for additional criteria for non-responsive applications.

**Q11: With the requirement that sexual orientation and gender identity (SOGI) data needs to be collected in clinical care workflows, does that prohibit data collection via surveys or in collaboration with community partners for this project?**

A11: The PAR is very focused on clinical care and clinical outcomes, which is why we are interested in SOGI data being integrated into clinical care. If you are not doing this, we would recommend reaching out to one of the scientific contacts to ensure your application is responsive to the PAR. That is not to say there is not a way data could be collected outside of clinical environments, we would just want to be sure your methods are responsive. What matters in the end is the ability to capture data and utilize it to either interpret your results or to ensure you've highlighted representation and/or the population you're capturing.

**Q12: Is this NOFO interested in using retrospective data? For example, if we contacted cancer survivors to ascertain SGM status, would this be in scope?**

A12: Yes, this would be an example of how it might be appropriate to use SOGI data from other sources. That said, we would want to ensure there is a clinical outcome and that you are following the requirements of the PAR.

**Q13: Given that SGM individuals make up 7.1% of the US population, and the population of cancer survivors within this group is even smaller, what if our sample size is low? If we provide rationale for a small sample size study design, would that be considered?**

A13: There is not going to be a comparison that says your site percentage is not high enough. What will matter is whether the sample size you have is adequate and if you are able to convince the reviewers that the noted sample size is adequate with a strong rationale and justification. There is no requirement that these studies be nationally representative unless that is the purpose of your proposed study.

**Q14: How important are preliminary data given the existing sparse data in the SGM cancer survivor population?**

A14: To the extent possible, it is important to have preliminary data in an application, and having preliminary data is a requirement of an R01. Preliminary data are critical, but that does not mean there must be preliminary data that has fully tested the population that you're interested in or all components you're interest in. There are creative ways to talk about preliminary data. This could include showing you've done a specific sort of intervention before, or you have experience capturing this kind of information, or you have community partners and ways that you've shown experience in these areas to help show readiness in addition to having specific preliminary data.

A good example of this is if you've tested an intervention in another minoritized community and you are thinking of revising it in some capacity and testing it here. For an R01, given the size and scope, it is important that you're demonstrating there is something you are working from. For some applications, just demonstrating that your institution can collect these data in some clinical settings may count toward the preliminary data requirement.

**Q15: Can the applications include both phase one and phase two clinical trials?**

A15: Our immediate answer would be no. These are not intended to be developmental for safety or tolerability or experimental topics in that way. These are really designed for population-based, more in phase three and/or pragmatic trials, or anything related to care delivery models. Implementation science is welcome as an approach, for example. If you have additional questions, please reach out to the scientific contacts to discuss more.

**Q16: Can you provide the scientific contact information from each participating Division or Center?**

A16:

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