RFA-DP-24-081: Effectiveness of Telehealth-Based Programs to Detect Glaucoma Among High-Risk Populations in Community Health Settings

Please note:

A. The NOFO modification published January 23rd replaces the heading Target Population, with Population of Focus. Please note that the description remains the same as in the original NOFO, although it is omitted. It is stated as follows:

> The study population is people in the US at high-risk for and disproportionally affected by glaucoma, including people 65 and older, those with a family history of glaucoma, those with diabetes, non-Hispanic Black and Hispanic adults aged 50 and older, and/or those living in poverty and lacking access, resources, and/or education regarding vision and eye health. Included among this population are those affected by disparities such as, but not limited to, race, ethnicity, gender, geography, and socioeconomic status.

B. If requesting indirect costs in the budget based on a federally negotiated rate, a copy of the indirect cost rate agreement is required as part of the application. Include a copy of the current negotiated federal indirect cost rate agreement or cost allocation plan approval letter in the R&R Budget Form as part of the budget justification attachment.

C. CDC has retired the Risk Assessment Questionnaire Requirement and applicants are no longer required to submit it as part of their NOFO application. This instruction supersedes instructions under *Section IV, 11: Other submission requirements and information*. Risk questionnaires that are submitted will not be reviewed. CDC continues to conduct the review of risk posed by applicants and we may ask for additional information prior to the award based on the results of the review.

D. The following information from the amendment to the NOFO published January 23, 2024:

For the purposes of this NOFO, please use the following definitions:

- Management is defined as referral, monitoring, and coordinating adherence to care.
- Usual care is defined as care outside of the intervention arm of the study; care that is the norm for that particular care setting.

Updated Questions and Answers as of January 23, 2024, # 25 - 46

#	Question	Answer

25	Can we budget for equipment?	The NOFO does not prohibit equipment as a direct or indirect cost. Please refer to the CDC budget preparation guidance for the definition of equipment.
26	Since the insurance reimbursement for disadvantaged participants is uncertain, is there a specific protocol for estimating an annual budget for uninsured or underinsured expenses? Such as in the NIH policy manual, Research Patient Care Costs Supported by NIH Sponsored Agreements Research Patient Care Costs Supported by NIH Sponsored Agreements? Additionally, would any recovery of expenses (lack of insurance or under insured) be considered as a budget category for the estimated amount of uninsured/unrecovered participant screening fees and follow-up examinations?	The NOFO does not identify a specific protocol that recipients should use to estimate insurance reimbursements in this population; however, the NIH Policy Manual is an appropriate guide. 6352-2 - Research Patient Care Costs Supported by NIH Sponsored Agreements Please follow CDC budget guidance under **Other** for budget category information regarding itemizing expenses that align with your proposed plan.
27	In the application on the cover page, do we put the amount of what we would request for the full 5 years since we will only be putting the first-year detailed budget into the application?	Yes. Please refer to instructions on https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.100-how-to-use-the-application-instructions.htm
28	Is there a tangible scope to the geographic location requirement, such as a zip code or city, whereas a county would be too large?	The NOFO does not specify a tangible scope expected by the geographic location. Please refer to **Section V.4 Application Review Information, Programmatic Priorities** for information about the selection process.
29	Should A applications be in partnership with B applications?	The NOFO does not indicate specific partners. Please see the Executive Summary**, Collaboration/Partnerships**. In addition, applications for Component A will be evaluated separately, including with a distinct merit review panel than applications for Component B.
3**0**	What is the expected time for review and funding decisions?	Please see the **Key Dates** section of the NOFO. Applications that meet the eligibility and responsiveness criteria will enter into the scientific merit review in mid-March. All applicants will be notified about final funding decisions in late July.

31	Do we need a non-telehealth control arm?	Please refer to the NOFO Section I.2, “Strategies and Activities, Component A: Comparative effectiveness trials in high-risk populations. • Test the real-world efficacy of the intervention compared to usual care that is well-described and justified. The proposed study should have an intervention and a control arm, and should be conducted in a real-world setting(s).” The control arm should be whatever is usual care for your setting.
32	How do we define "conventional care" for comparative effectiveness in a screening study design?	Conventional care is not in the NOFO. Please refer to **Amendment II on www.Grants.Gov**, which states: Usual care is defined as care outside of the intervention arm of the study; care that is the norm for that particular care setting.
33	We are not yet FDA approved. Would this affect our eligibility or application scoring?	We cannot address specific questions about the merit of proposed research plan. The NOFO does not specify FDA approval; however, CDC expects that recipients use evidence-based medicine. Please note the criteria in Section V. Application Review Information for information about how applications will be assessed.
34	Given this quote on page 9, "Demonstrate how the methods to perform glaucoma detection in a real-world setting can generate evidence for detecting other eye diseases, functional vision loss, and vision impairment," --would you please clarify what is intended? Does 'method' here mean tonometry, or the intervention as a whole?	This method refers to the intervention as a whole.
35	Any screening program will have people who are not the proposed targeted population. How should these be handled in the grant?	Applicants should be able to clearly describe their study population based on the characteristics noted in the NOFO in **Section I. Funding Opportunity Description, Strategies and Activities, Component A**: “Study settings should be in geographic locations in the United States with high proportions of people living at or below the federal poverty level, in communities that are predominantly comprised of minority groups, and among communities that are less likely to access eye care services.”

36	Please clarify the telehealth aspect for glaucoma screening for high-risk patients.	We cannot provide specific guidance for the development of a research proposal, however we can call your attention to some portions of the NOFO that might be able to help you determine whether/how your research interests relate to the intent of this NOFO. Please review **Section I. Funding Opportunity Description**, 1. Background and Purpose and 2. Approach, Outcomes, as well as Section IV.5.
37	Across the NOFO, both a comprehensive eye examination and screening for other diseases are mentioned. Will there be concrete expectations defined by the CDC/Vision Health Initiative, or is this more open-ended for us to pitch our program? What are the expectations for the research beyond glaucoma screening, monitoring and treatment.	This is a new, competitive NOFO with requirements stated in the NOFO, and not the Vision Health Initiative. Please refer to **Objectives/Outcomes** in Section I.2 of this NOFO for expectations, and to Section IV. Research Plan.
38	Are we responsible in determining how to conduct telehealth glaucoma screenings? Or will CDC guide us with the appropriate instruments to use and the protocol to perform glaucoma screening [via] telehealth?	CDC will not direct recipients' intervention, however, it does expect that recipients use evidence-based medicine; additionally, the NOFO provides several sources for standards indicated in **Section I. Funding Opportunity Description, Background**, including the references. The NOFO further indicates in I.2 Approach, Strategies and Activities, that the Component B recipient is expected to coordinate study protocols among Component A recipients.
39	Notwithstanding our eligibility as a small business, should we expect to be scored lower than entities that are already established in telemedicine for communities at or below the poverty level? In other words, are we perhaps not the intended type of entity for this grant? If so, would teaming with a university allay any disadvantage here? We anticipate access to at least one inner city location.	There are no eligibility requirements for this research NOFO related to an entity's established service in any community. Please see Section III. Eligibility Information. We cannot comment on the merit of a specific entity or its proposed research plan, however, we can call your attention to some portions of the NOFO that might be able to help you determine whether/how your research interests relate to the intent of this NOFO: **Executive Summary, Collaboration/Partnerships** and also **Section V Application Review Information**, **Scored Review Criteria,** Investigator(s), Approach and Environment.

40	What depth/character of science is desired for comparative effectiveness for screening in the study design?	CDC cannot provide specific study design guidance for the development of a research proposal. Please refer to **Section V.1 Criteria** for how proposals will be evaluated for scientific and technical merit. Additionally, the NOFO provides several sources for standards indicated in **Section I. Funding Opportunity Description, Background**, including the references.
41	Can you clarify the scope of management and its relative importance compared to screening?	Please refer to Amendment II on www.Grants.Gov for the scope, which states: Management is defined as referral, monitoring, and coordinating adherence to care. Relative importance is not specified in the NOFO.
42	What if the partners agree to participate based on the planned/proposed intervention. Do they have to be willing to change if the coordinating center wants a different protocol across all settings?	No, recipients are not expected to substantively change their intervention plan with partners. Please refer to the NOFO Section IV.5. PHS 398 Research Plan, Component B, which states: "Promoting and facilitating a multi-study, collaborative environment among Component A recipients who will independently implement the community-based interventions." Regarding protocols, please refer to the NOFO Section I.2 Activities, Component B, which states: Collaborate with Component A recipients.
43	If there are going to be common protocols across all the projects, how much space is there actually for innovation? And how specific should the protocol be?	"Common study protocols" is not described in the NOFO as prescribing recipient interventions. Proposed research plans should be able to address Section IV.5 PHS 398 Research Plan Component of the NOFO, and respond to the criteria in Section V.
44	Is providing clinical support software to health care providers by optimizing process, procedures, and data for standardizing health care services consistent with Component B?	All of the strategies and activities in Component B is expected. We cannot provide specific guidance for the development of a research proposal, but we can call your attention to some portions of the NOFO that might be able to help you determine whether/how your expertise relates to the intent of this NOFO. Please refer to the Section IV.5. PHS 398 Research Plan Component and to the Executive Summary, **Collaboration/ Partnerships.**

45	a) The NOFO requires screening and management. Does management include monitoring of glaucoma? b) When the NOFO describes screening and management, what is meant by management of glaucoma given that management of glaucoma introduces a much different study design than screening?	An amendment was published on Grants.Gov on January 23, 2004. Please refer to the added definition, for the purposes of this NOFO, which states: *Management is defined as referral, monitoring, and coordinating adherence to care.*
46	a) To reduce the burden of glaucoma would require not just diagnosis but also treatment. Should this be addressed in Component A, or can we focus just on diagnosis? Or diagnosis and referral? b) Does management and monitoring of glaucoma mean that after a patient is screened and diagnosed with glaucoma, the research project should also include treating the disease and monitoring for changes?	An amendment was published on Grants.Gov on January 23, 2004. Please refer to the added definition, for the purposes of this NOFO, which states: Management is defined as referral, monitoring, and coordinating adherence to care. Please see the NOFO Section 1.2 Approach, Strategies and Activities and Section IV.5 for a description of expectations. Management does not include providing treatment as an activity.

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#	Category/ NOFO Section	Question	Answer
1		Can the informational Webinar recording or transcript be shared?	The webinar will not be shared, but questions and answers from the webinar are being published. Only content from the NOFO was discussed. Please email any questions to ResearchNOFO@cdc.gov and place RFA-DP-24-081 in the subject line.
2		If the direct costs are $500,000 and over, is a letter needed to request permission for that amount?	Prior approval requirements do not apply to this NOFO.
3		Will this NOFO be available for resubmissions if the first proposal is reviewed but not funded? If so, will it be annual?	This is a one-time opportunity and resubmissions will not be accepted under this NOFO.

#	Category/ NOFO Section	Question	Answer
3		In previous years, how many applications were received?	This is a NEW NOFO, therefore there is no historical data. However, CDC is not able to share information about previous RFAs.
4		Is there an appropriate process to notify prospective applicants of organizations that are interested with partnering and/or contributing to the project?	CDC does not have a process to link prospective applicants with potential partners.
5	Overview	Is this initiative we propose broadly consistent with the goals of the RFA?	We cannot provide specific guidance for the development of a research proposal, but we can call your attention to some portions of the NOFO that might be able to help you determine whether/how your research interests relate to the intent of this NOFO. Please review **Section I. Funding Opportunity Description**, 1. Background and Purpose and 2. Approach while considering your research goals. Please review **Section III. Eligibility Information**, 5 Responsiveness and **Section V. Application Review Information** for information on how the applications will be reviewed.
6	Purpose	Clarify real-world clinical sites. FQHCs are not the only sites we can partner with. Example most tribal sites are not FQHCs.	The NOFO does not require a specific type of site; FQHCs are mentioned only as an example. Please refer to the stated purpose for more information: This NOFO aims to support the study of replicable and scalable interventions that use real-world, payer-provider reimbursement structures within community-based, health care delivery settings.
7	Overview, Executive Summary	Would two or more principal investigators be permitted?	Please refer to the Executive Summary, which states: “Eligible Project Directors/Principal Investigators. Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. Number of PDs/PIs. Applications may include more than one PI; however, the first PI listed on the application will be the contact PI for all correspondence.” Additional PIs should be referred to as Co-PIs.

#	Category/ NOFO Section	Question	Answer
8	Overview, Executive Summary: Objectives/Outcomes	Significant discussion in the NOFO addresses scalability of the program design. What features or outcomes are of priority importance on this questions?	Please refer to the **Objectives/Outcomes** as stated in the NOFO: A blueprint for future scaling and replication of the intervention to decrease disparities in glaucoma care and minimize glaucoma-related vision impairment beyond the study setting.
9	Section I	We are particularly interested in retention in care/continuation of care at [certain points in the five years]. Is this outcome consistent with the RFA goals?	Please refer to Objectives/Outcomes in Section I of this NOFO, "…include the following outcomes for Component A: Patient-centered outcome measures such as vision-related quality of life, patient satisfaction, functional status, **adherence to follow-up**, and if possible, improved vision."
10	Section I, Approach, Target Population	Within the goals of the RFA, is including a rural area an important consideration for our grant submission?	Please refer to the Target Population as stated in the NOFO for information about determining the target population. It states: The study population is people in the US at high-risk for and disproportionally affected by glaucoma, including people 65 and older, those with a family history of glaucoma, those with diabetes, non-Hispanic Black and Hispanic adults aged 50 and older, and/or those living in poverty and lacking access, resources, and/or education regarding vision and eye health. Included among this population are those affected by disparities such as, but not limited to, race, ethnicity, gender, geography, and socioeconomic status.
11	Section I, Approach, Collaboration/Partnerships	When considering provider-payer settings as defined in the NOFO, should we include reimbursement from federal sources as part of our study design	The NOFO does not specify expected types of payers, however, it provides an example such as Federally Qualified Health Centers, which uses federal sources. [See Section IV.5. PHS 398 Research Plan Component, Component A.]
12	Section I, Approach, Collaboration/Partnerships	Is there a priority for a site to be a federally funded agency like FQHC?	No, the NOFO does not indicate a priority site(s).
13	Section I, Approach, Strategies and Activities	Is a 2-day trip to Atlanta per year required to review work in progress with the CDC team.	The NOFO does not require a trip to Atlanta.

#	Category/ NOFO Section	Question	Answer
14	Section II. Award Information, Award Ceiling	Is the funding cap for component A $950,000 the total costs per year?	Please refer to the related sections of the NOFO: Executive Summary, Budget and Period of Performance: "The estimated total funding (direct and indirect) for the first budget period, September 30, 2024 - September 29, 2025, is $3,000,000," and Section II. Award Information, the "Award Ceiling is $950,000 Per Budget Period," inclusive of direct and indirect costs.
15	Section II. Award Information, Award Floor	Should the proposed budget be broken out as $687,500 per year for five years for Component A, and $250,000 for five years for component B? However, the RFA mentions a floor of $950,000?	As stated in the NOFO, Section II. Award Information, "Awards issued under this NOFO are contingent on the availability of funds and submission of a sufficient number of meritorious applications. The award ceiling is $950,000 per budget period. The Award Floor is $0 per budget period. CDC cannot recommend budgets for applicants.
16	Section II. Award Information, Anticipated Number of Awards	The estimated funding for the first budget period for Component A is $2,750,000 (direct and indirect) and the number of awards is 4. Is it your recommendation that we budget for year one as 25% of $2,750,000 (or $687,500)?	Please refer to NOFO, Section II. Award Information. As stated, the number of awards is anticipated. CDC cannot recommend budgets for applicants. The award ceiling for the budget is $950,000 per budget period, inclusive of direct and indirect costs.
17	Section III and Section IV, Appendix	What is allowed in the Appendix and what is required to be in the Appendix. Do you have guidance that you can share with me? Is the Appendix where I upload the current F&A Rate Agreement?	Please see the NOFO section IV.5. PHS 398 Research Plan Component under Appendix, which directs applicants to *Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide*. Also see **Section III. Eligibility Information, 5. Responsiveness** for required evidence. It states: Applications for Component A must place evidence in Appendix 1. The F&A rate agreement may be included with the budget justification.

#	Category/ NOFO Section	Question	Answer
18	Section IV. Application and Submission Information, 5. PHS 398 Research Plan Section	Is it acceptable that usual care includes no care if that is actually what is happening?	Possibly; however, data on participants in the control arm are required in order to compare with the intervention arm. Participants in the control should be clearly described.
19	Section IV. Application and Submission Information, 5. PHS 398 Research Plan Section Consortium/Contractual Arrangements	Can an organization applying for Component A (Comparative effectiveness trials among high-risk populations within community-based settings) be a subcontractor to Component B (coordinating center)?	As stated in the NOFO: "It is expected that the applicant organization will directly conduct the majority of the activities outlined in this NOFO throughout the entire period of performance. It is expected that the work plan described in the Research Strategy section of the application and the SF-424 Research and Related Budget will demonstrate the applicant organization's involvement throughout the entirety of the period of performance. The applicant organization cannot serve as a pass-through to fund another entity to conduct the majority of the activities." The NOFO does not specify anything further.
20	Section IV, 5. PHS 398 Research Plan, Consortium/Contractual Arrangements	One of our consultants/ collaborators is also a collaborator on another group's application for this RFA. Is this allowed/ acceptable?	The NOFO does not specify. Upon award, the budget will be reviewed to ensure all funds are specific, allocable, and do not represent any duplication in funding.
21	Section IV, 5. Consortium/Contractual Arrangements	We would like to partner with a co-investigator for their expertise and that would require a nominal subaward of approximately 10-20% of the yearly direct costs. Would this be acceptable?	Please refer to Section IV, 5 to determine if the arrangement corresponds with the NOFO's requirements in the research plan. As stated: "It is expected that the applicant organization will directly conduct **the majority of** the activities outlined in this NOFO throughout the entire period of performance."
22	Section IV. Application and Submission Information; 5. PHS 398 Research Plan Component A.	The FOA mentions the intervention vs control arms. Does intervention apply to screening or management, or should it involve both? If it should include both, does it need to have a control arm for each (screening & management)?	As stated in the NOFO**:** "The research plan should describe an innovative telemedicine intervention to detect and manage glaucoma in the target population." Applicants are encouraged to describe a plan as instructed in this section and meet the review criteria in Section V.

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23	Section IV. Application and Submission Information; 5. PHS 398 Research Plan Component A.	What types of controls are acceptable? Does it have to be parallel controls or can it be a pre-/post-intervention?	The NOFO does not specify which types are acceptable. Applicants are instructed to describe the research plan in the application. Refer to Section IV.5.
24	Section V. Application Review Information; 4. Review and Selection Process; *Programmatic Priorities*	Is CDC intending to obtain geographic coverage for the entire United States? If so, which regions are priorities for funding this year?	As stated in the NOFO, a programmatic priority is: "Distribution of the locations of proposed study sites that reflect the regions of the United States." The NOFO does not specify regional priorities.