

Questions and Answers from Potential Applicants for RFA-DP-22-001 “Real-world effectiveness of structured lifestyle interventions in preventing type 2 diabetes”

Q1. Component A: Is there an exclusion for this participant number requirement for small states?

Response to Q1:

Per Section III. Eligibility Information/3. Additional Information on Eligibility and 5. Responsiveness, all applicants must provide evidence of being able to **access** electronic records for building a cohort of individuals meeting eligibility criteria for the NDPP/MDPP (both participated in the NDPP/MDPP and not participated but eligible for the NDPP/MDPP program), individual program participation information of the NDPP/MDPP participants, medical records and health services utilization and cost data of all study participants. Thus, there is no exclusion. A minimum number of 5,000 reco/MDPP program enrollees and equal or greater number of matched controls is required per applicant.

Q2. Component A: “A minimum number of 5,000 NDPP/MDPP program enrollees and equal or a greater number of matched controls is required per applicant.” Is this a number of NDPP/MDPP participants that should be achieved over the course of the project? OR is this the number of eligible individuals that should be demonstrated to exist already in the electronic records?

Response to Q2:

Yes. A minimum sample of 5,000 participant electronic records for the intervention group (participants in the NDPP/MDPP). The equal or a greater number of matched controls electronic records (5,000 or more) should be followed for at least 5 years for new-onset type 2 diabetes. See Section I. Funding Opportunity Description, 2. Approach; Section IV. Application and Submission Information, 5. Research Plan, Core components.

Q3. Component A: Applicants are required to submit a budget for a 5-year period of performance with a ceiling of \$900,000 for all five years and the first-year award ceiling is \$570,000. Those ceilings include both indirect and direct costs. Is my interpretation of the budget requirements correct?

Response to Q3: For Component A, an applicant’s first-year ceiling is \$570,000 (direct and indirect).

Q4. Component A and B: For funding opportunity, RFA-DP-22-001, could you please confirm if the indirect rate is limited to 8%?

Response to Q4: Under “Budget and Period of Support” on page 40 of the NOFO, it states the 8% only applies to foreign institutions.

“If requesting indirect costs in the budget based on a federally negotiated rate, a copy of the

indirect cost rate agreement is required. Include a copy of the current negotiated federal indirect cost rate agreement or cost allocation plan approval letter.”

Q5. Component A: I read your NOFO and was perplexed at the sample size of 10,000 per site (I-5000 vs C-5000). I have been involved in a Cooperative U mechanism, and I am familiar with Power Analysis of such trials. The 10,000 per site (x 5 sites) sounds exorbitant. In the announcement it read, “*information on study sample size will be described in the next section.*” But I could not find that section. Can you provide information of how CDC came up with such sample size?

Response to Q5:

This NOFO is intended to evaluate the long-term effectiveness and cost-effectiveness of the SLI as delivered in the NDPP/MDPP, compared with no intervention. It is an observational study, not a random clinical trial. Applicants are required to set up an *electronic* longitudinal follow-up cohort, as described in Section I. Funding Opportunity Description, 2. Approach, Objectives, Outcomes and Target population.

Q6. Component A: Do applications for Component A have to demonstrate 5,000 participants already enrolled in a structured lifestyle program, or must the demonstrate the capacity to reach 5,000 enrollees?

Response to Q6:

Applications for Component A need to demonstrate the capacity to collect and link electronic data for 5,000 or more individuals enrolled in NDPP/MDPP and 5,000 or more who are eligible but not enrolled in NDPP/MDPP, which serve as a control group. The 5,000 individuals enrolled include those who already completed the SLI program before this study or those who enroll in and complete the SLI in the first year of the NOFO period to meet the five-year follow-up requirement of the SLI participants. See Section I. Funding Opportunity Description, 2. Approach, Collaboration/Partnerships; and Section IV. Application and Submission Information, Research plan, II Core components.

Q7. Component A: When does the cohort need to be assembled? I see that the grant is for 5 years and that the follow up duration for the cohort is a minimum of 5 years. This would suggest that the cohort needs to already be assembled at the time of the grant start. Or is it possible for the 5 years of follow up to extend beyond the original grant period?

Response to Q7:

The follow up duration for the cohort is a minimum of 5 years which could include the electronic data from NDPP/MDPP participants who enrolled in and completed the SLI program in the first year of the grant. The data needed by the study can be collected prospectively or retrospectively (see Section IV. Application and Submission Information, Research plan, II Core components).

Q8. The guidelines for RFA-DP-22-001 note that an LOI is due 12/27/2021. However, there are no instructions on how the LOI should be submitted. Can you please provide the instructions for

LOI submission? What are the requirements? Should it be submitted via email and if so, what is the email address?

Response to Q8: The NOFO will be amended in “Section IV. Application and Submission Information, 3. Letter of Intent” to include the following LOI instructions that were in advertently omitted:

The LOI date will generate once the Synopsis is published if Days or a Date are entered.

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information it contains allows CDC staff to plan for the review. By December 20, 2021, prospective applicants are asked to submit a letter of intent that includes the following information:

Name of the Institution:

Descriptive title of proposed research, including Component

Name, address, and telephone number of the PD(s)/PI(s)

Names of other key personnel

Participating institutions (if applicable)

Number and title of this funding opportunity

The letter should be emailed to: Researchnofo@cdc.gov. Include NOFO number in the email subject line.

Q9. Component B: Can CDC clarify whether the DCC (Component B) will be doing cross-awardee analyses, for example, whether the NDPP/MDPP SLI programs reduced health care utilization and costs across awardees or whether the DCC is expected to provide more guidance to the awardees who will be doing the analyses themselves?

Response to Q9: The DCC is expected to provide cross-awardee data analysis based on a core study protocol and for those studies that use data collected from more than one awardee. Individual awardees are expected to analyze the data from their own sites. See Section I. Funding Opportunity Description, 2. Approach/Objectives, Section IV Application and Submission Information/ Research Plan/Analytic approach.

Q10. Component B: Will Component A awardees also be collecting qualitative data on the system and individual level barriers and facilitators of participating in and completing of the program? If so, would the DCC be expected to harmonize or analyze qualitative interviews or focus groups across awardees?

Response to Q10: Yes, that is correct. See also Section IV. Application and Submission Information, Research Plan section III Analytic approach.

Q11. Component B: Will CDC be providing DPRP data to the DCC or would all data be provided/collected via the Component A awardees?

Response to Q11: No, CDC will not provide DPRP data. The applicants are required to collect and link all the data for the electronic longitudinal cohort. See Section I. Funding Opportunity

Description/2. Approach/Objectives and Section V. Application Review Information/ Scored Review Criteria.

Q12. Component B: Is there a chance of less than 5 awardees are made for Component A? If so, will that change the funding for Component B?

Response to Q12: Section II Award Information states: “Component A: (up to 5 awards) \$570,000 per award. Component B: (1 award) \$350,000”

Q13. The NOFO mentions "establishing an electronic study cohort of persons who are eligible for NDPP/MDPP to identify barrier and facilitators," so is there is an expectation for sites to conduct prospective patient-level surveys and/or interviews, and would this be for the entire cohort or a subsample?

Response to Q13: Per Section I. Funding Opportunity Description/2. Approach/Objectives; Section IV. Application and Submission Information/Research Plan/Core components, additional surveys of the study participants and/or NDPP/MDPP providers is anticipated. Per Section IV. Application and Submission Information/Research Plan/Core components, overall and stratified analyses will be provided based on power calculations for primary and secondary outcomes if the minimum 5,000 of required number was not adequate.

Q14. Would it be acceptable for some constructs to rely on validated composite measures of social determinants of health (e.g., area deprivation index)?

Response to Q14: Yes.

Q15. The NOFO lists over 20 potential facilitators and barriers, so we are wondering if they all need to be assessed? Will applications still be competitive with only a subset of these included?

Response to Q15: Yes

Q16. Is the collection of HRQoL at baseline at follow-up a requirement for all 5000+ DPP participants and 5000+ non-participants?

Response to Q16: Per Section IV. Application and Submission Information/Research Plan/Core components, overall and stratified analyses will be provided based on power calculations for primary and secondary outcomes if the minimum 5,000 of required number was not adequate.

Q17. Budget breakdown of indirect/direct costs guidelines

Response to Q17:

Please follow the guidance in the NOFO. Section V. Application Review Information /Additional Review Considerations/ and Period of Support, under Resource Sharing Plans: “The applicants can obtain guidance for completing a detailed justified budget on the CDC

website, at the following Internet Address: <https://www.cdc.gov/grants/applying/application-resources.html>”

Q18. Enrollment time frame of participants

Response to Q18:

The data should be for individuals who already completed the SLI program before this study or those who enroll in and complete the SLI in the first year of the NOFO period to meet the five-year follow-up requirement of the SLI participants. See Section I. Funding Opportunity Description, 2. Approach, Collaboration/Partnerships; and Section IV. Application and Submission Information, Research plan, II Core components.

Q19. Date of CDC Pending Recognition Status

Response to Q19:

CDC Pending Recognition Status is not considered. We just consider: Pre-intervention period, intervention period, and post intervention period. See Section I. Funding Opportunity Description, 2. Approach and Objectives/Outcomes.

Q20. Are the two components separate?

Response to Q20:

As described under NOFO Purpose: This NOFO has two (2) components: Component A-Longitudinal cohort, for establishing an electronic study cohort to answer the research questions, and Component B-Coordinating Center, to provide the infrastructure and analytic support for Component A.

Additionally, Additionally, under Executive Summary/Number of Applications, the NOFO, it states: If an applicant organization intends to apply to more than one component in this NOFO, the applicant must submit separate applications for each component. To be funded for Component B, applicants are not required to apply for and be funded for Component A.

Q21: Who is eligible to apply? Is there a need for a great deal of infrastructure?

Response to Q21:

Institutions/organizations listed in Section III, 1.A. are eligible to apply (see Executive Summary).

Yes, a well-established infrastructure is expected. Applicants for Component A are expected to demonstrate ability to collect all data components and to establish partnerships with organizations that processed the data including, but not limited to, data collection companies, community organizations, SLI providers, health care providers, employers, and health care insurance companies. Capacity to include and follow-up individuals' records from socio-demographic disadvantaged groups is required and is expected to be described in detail (see Section I. Funding Opportunity Description, 2. Approach, Collaboration/Partnerships; Section III. Eligibility Information, 3. Additional Information on Eligibility).

Q 22: Is this a one year grant?

Response to Q22:

Per Executive Summary/Budget and Project Period: “.....5-year period of performance, September 1, 2022 to August 31, 2027”

Q23. Is a DUNS number to register as an organization required? What does the application process consist of?

Response to Q23:

See Bullets 6: Required Registrations and 7. Universal Identifier Requirements and System for Award Management (SAM) under Section III: Eligibility Information of the notice of funding opportunity for information on the registrations required to apply for this opportunity. Links within this section also provide additional information. Also refer to Bullets 1. Eligible Applicants, 3. Additional Information on Eligibility and 5. Responsiveness for additional information on eligibility.

Q24. Is the required enrollment 5,000 patients engaged over the 5 years? Or is it 5,000 patients eligible (meet eligibility requirements) but may not enroll?

Response to Q24.

Applicants for Component A are expected to establish a longitudinal electronic cohort of individuals who participate (intervention group) and who do not participate (control group) in the NDPP/MDPP. The intervention group consists of individuals who participated in the NDPP/MDPP (either completing or not completing the program); the control group consists of those who met the NDPP/MDPP enrollment criteria but did not enroll in the program (*Section I. Funding Opportunity Description, 2. Approach/Objectives*). The minimum sample size of 5,000 NDPP/MDPP program enrollees and equal or a greater number of matched controls is required per applicant. The enrollees' electronic records include those who already completed the SLI program before this study or those who enroll in and complete the SLI in the first year of the NOFO period to meet the five-year follow-up requirement of the SLI participants (*Section I. Funding Opportunity Description, 2. Approach/Objectives; Section III. Eligibility Information, 3. Additional Information on Eligibility; Section IV. Application and Submission Information, Research Plan/Core components*).

Q25. Does the organization that provides structured lifestyle intervention must have CDC NDPP recognition be considered NDPP?

Response to Q25. No, the organization providing SLI does not need to have CDC recognition/credentials.

Q26. Or the organization that provides structured lifestyle intervention that follows the NDPP curriculum be considered eligible applicants(i.e., DPP-like program)?

Response to Q26: Yes, the organization should provide SLI according to NDPP curriculum.

Q27. Please provide guidance on the following questions regarding grant RFA-DP-22-001 Real-world effectiveness of structured lifestyle interventions in preventing type 2 diabetes. The grant packet only outlines funding for the first year (FY2022). Please provide information regarding funding strategy, including ceilings and floors, for years two through five.

Response to Q27: This information is available under Executive Summary/ Funds Available and Anticipated Number of Awards, Budget and Project Period, and under Section II. Award Information. Ceilings are for the first 12-month budget period only.

Q28. Please confirm the awardee for Component B will be the sole Coordinating Center for all data collected by all Component A awardees.

Response to Q28: That is correct.

Q29. When referring to NDPP/MDPP programs that would be evaluated, does that refer to programs that have received Full CDC Recognition? Or would it be possible to propose evaluation of a program that has Pending recognition?

Response to Q29: The NOFO does not specify that the programs have to have full CDC recognition so it would not be required.

Q30: What are CDC expectations regarding obtaining IRB consent from intervention and/or control study participants? Or rather, is there an expectation exemptions would be granted for consent forms?

Response to Q30: Refer to the “Research Plan section 10. Funding Restrictions, Human Subjects” for IRB information.

The IRB must approve the entire project including the control population description. The applicants may likely obtain waiver of informed consent since this is an electronic data collection but may need consent if additional surveys (by phone or otherwise) are employed.

Q31: [What are the] Number of years of study/funding: Is there no “limit” or cap on the number of years of the study?

Response to Q31: See Executive Summary/Budget and Project Period: “.....5-year period of performance, September 1, 2022 to August 31, 2027”

Q32: The criteria that states we need to have a “minimum number of 5,000 NDPP/MDPP program enrollees and equal or a greater number of matched controls is required per applicant. Does the database of 5,000 need to be existing program enrollees? Prospective enrollees?

Response to Q32: The data for the electronic cohort can be retrospective or prospective. See Section I. Funding Opportunity Description, 2. Approach, Collaboration/Partnerships; Section IV. Application and Submission Information, Research plan, II Core components.

Q32a: All housed in the DPP Express data base?

Response to Q32a: The NOFO does not specify so the applicant can determine this.

Q32b: Do these patients need specific medical codes to qualify? If so, what are they?

Response to Q32b: The inclusion criteria are described in Section I. Funding Opportunity Description, 2. Approach, Objectives, Objectives/Outcomes; Section III. Eligibility Information, 3. Additional Information on Eligibility.

Q32c: Can we use all prediabetic patients as prospectives that are associated with our hospital?

Response to Q32c: The data for the electronic cohort can be retrospective or prospective. See Section I. Funding Opportunity Description, 2. Approach, Collaboration/Partnerships; Section IV. Application and Submission Information, Research plan, II Core components.

Q33: Is the control group expected to have the same data collection (questionnaires, labs) as the intervention group during the follow up period?

Response to Q33: Yes (Section I. Funding Opportunity Description, 2. Approach, Objectives/Outcomes; Section IV. Application and Submission Information, Research plan, II Core components).

Q33a: It is typical for us to charge participants for participation in the diabetes prevention program, and ideally we would bill Medicare once we receive Medicare recognition for the MDPP. In participating in this study, are we forgoing payment for services?

Response to Q33a: The data for the electronic cohort are collected from electronic medical records. See Section I. Funding Opportunity Description, 2. Approach, Objectives/Outcomes, Collaboration/Partnerships; Section IV. Application and Submission Information, Research plan, II Core components).

Q34: Are there rules around payment for services as a part of this grant?

Response to Q34: The NOFO does not specify rules around payment for services.

Q35: Regarding RFA-DP-22-001, page 10, third paragraph, third sentence: is there any flexibility to the timing of SLI participation or do all 5,000 SLI participants need to be enrolled prior to the end of year 1?

Response to Q35: Under Section I. Funding Opportunity Description, 2. Approach, Objectives, it states: “A minimum sample size of 5,000 NDPP/MDPP program enrollees and equal or a greater number of matched controls is required per applicant. The 5,000 individuals' electronic records include those who already completed the SLI program before this study or those who enroll in and complete the SLI in the first year of the NOFO period to meet the five-year follow-up requirement of the SLI participants.”

Q36. I think I'm reading correctly that the Project Narrative and Budget Narrative are included as part of the 20 page limit for the research plan appendices, but I want to be sure that this is true. I could not find the specification for these two items in either the NOFO or the SF-424 Application Guide.

Response to Q36: On the www.grants.gov website, in the application download, the project narrative is included as part of the “Research and Related Other Project Information.” The “Research and Related Budget” section of the application kit contains a section for the applicant’s budget justification. The project narrative is normally 1 page, and the budget narrative is typically two to five pages. The information related to the narrative should not be counted with the Appendix

Q37. What is allowed in the appendices?

Response to Q37: For appendices, please refer to the following sections of the funding opportunity:

1. As stated under Section III, Award Information, Responsiveness criteria, evidence of being able to access a cohort of eligible individuals should be placed in Appendix A. Applicants must provide evidence of being able to access a cohort of individuals meeting eligibility criteria for the NDPP/MDPP (both participated in the NDPP/MDPP and not participated but eligible for the NDPP/MDPP program), individual program participation information of the NDPP/MDPP participants, medical records and health care utilization and expenditure data for all study participants. Evidence can be in the form of a letter(s) of agreement with home institution, data use agreements (if data obtained from other sources). Evidence should be placed in Appendix A.
2. Additionally, as stated in Section IV on Application and Submission Information, follow instructions as described in the SF424 (R&R) Application Guide. Do not use the appendix to circumvent page limits. A maximum of 10 PDF documents are allowed in the appendix. Additionally, up to 3 publications may be included that are not publicly available. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 20 pages for all appendices.