RFA-DP-25-043: Comprehensive Analysis, Surveillance, and Statistics Initiative for Diabetes in the Young (CASSIDY)

Questions and Answers

December 9, 2024

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Application

1. **This program will have two components: Component A focuses on surveillance of diabetes and Component B serves as a Coordinating Center. Is that true that our proposal can focus on one of these two components only, instead of on both of them?**

   ANSWER: As stated in Section I. Funding Opportunity Description, 2. Approach, "Applicants can apply for Component A or Component B; however, applicants cannot apply for both Component A and Component B."

   NOFO SECTION: Section I. Funding Opportunity Description, 2. Approach

   NOFO PAGE NUMBER(S): 10

2. **The RFA limits 1 institution per application, and can only do Component A or the Coordinating Center (not both). Our institution has a relationship with another institution, but they technically have distinct UEIs. Would it be against the policy for one institution to apply for component A and the related institution to apply for the coordinating center? If this is permitted, would it prohibit me from including others as MPIs in the coordinating center proposal?**

   ANSWER: The NOFO's Executive Summary states that "Only one application per institution (normally identified by having a unique UEI number) is allowed. Applicants can apply for Component A or Component B; however, applicants cannot apply for both Component A and Component B." So, for example, institutions will need to have unique UEI numbers to apply for this grant program. In terms of MPIs, the Executive Summary also states that "Applications may include more than one PI; however, the first PI listed on the application will be the "contact PI" for all correspondence." The NOFO does not state further information or restrictions regarding MPIs.

NOFO SECTION: Executive Summary

NOFO PAGE NUMBER(S): 3

3. **My co-investigators and I were hoping to discuss the fit of our population with the CASSIDY grant. Would you be willing to set up a call sometime this week or early next week?**

   ANSWER: Please send any questions you may have to researchnofo@cdc.gov and we will be happy to provide a response.

   NOFO SECTION: N/A

   NOFO PAGE NUMBER(S): N/A

4. **I'm quite interested in the CASSIDY RFA-DP-25-043. I have a question about the Component A Environment criteria Does the applicant provide evidence that the health information data used at their respective center can be shared with the Component B awardee (i.e., Coordinating Center) to provide network-wide estimates?I want to confirm/clarify that the requirement is to share line-level/patient level data (rather than aggregate data) with the coordinating center. This requirement of course will direct our approach.**

   ANSWER: Yes, applicants should provide evidence that they can share line-level data that is de-identified, if needed.

   NOFO SECTION: Section V. Application Review Information, 1. Criteria

   NOFO PAGE NUMBER(S): 31-32

5. **For the evaluation/performance measurement (page 12) and the translation plan (page 12), do we only include this information in "other attachments?" In other words, should we also describe these as part of the 12-page research strategy?**

   ANSWER: As stated in the NOFO, "Components A and B: For all performance/evaluation measurements, please upload all documents in the "Other Attachments" section of the application." It also states, "Components A and B: For all translation plans, please upload all documents in the "Other Attachments" section of the application.". Please be sure to review the entire NOFO, particularly Section IV. Application and Submission Information, 5. PHS 398 Research Plan Component, to learn exactly what should be included in the 12-page research strategy.

   NOFO SECTION: Section I. Funding Opportunity Description, 2. Approach & Section IV. Application and Submission Information, 5. PHS 398 Research Plan Component

   NOFO PAGE NUMBER(S): 12-13

6. **Can you confirm that the minimum denominator is 500,000 for youth and 500,000 for young adults – for a total of 1 million?**

ANSWER: In Section I. Funding Opportunity Description, 2. Approach, has been amended to state that "It is desirable for Component A applicants to have access to a large population under surveillance (i.e., denominator greater than 500,000 people) per age group."

NOFO SECTION: Section I. Funding Opportunity Description, 2. Approach

NOFO PAGE NUMBER(S): 34

7. **I will apply for the grant for the CASSIDY study when the detailed advertisement comes out. I have the abstract description of the project objectives. There should be a detailed specific objective of the study. This will help us to write a research plan clearly and explicitly. Another question is whether the submission date is January 10, 2025.**

   ANSWER: The full announcement was published on November 5, 2024 with a due date of January 10, 2025. Please navigate to grants.gov and click on the Related Documents tab to find the full publication for this funding opportunity.

   NOFO SECTION: N/A

   NOFO PAGE NUMBER(S): N/A

8. **We are wondering whether we could fold the centers we already work with as surveillance centers as part of our proposed work as the Coordinating Center? Or would this be beyond the scope of work for the Coordinating Center as outlined?**

   ANSWER: The Component B awardee will be funded to work with Component A awardees. As stated in the Approach:

   - "Component B will serve as the Coordinating Center and will provide an infrastructure for standardized approaches, analytical methods, and measures to be used for surveillance across Component A centers…" (page 9)
   - "The Coordinating Center will conduct administrative functions to support the coordination of the Component A centers." (page 10)

   NOFO SECTION: Section I. Funding Opportunity Description, 2. Approach

   NOFO PAGE NUMBER(S): 9-13

Eligibility

9. **I have a collaborator who is a faculty member at the University of South Florida. But, he is not a US citizen yet. Can he be the PI or Co-I of our proposal?**

   ANSWER: Please note that Section III. Eligibility Information states "For this announcement, applicants may not include collaborators or consultants from foreign institutions. All applicable federal laws and policies apply.' This section also states "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. CDC does not make awards to individuals directly. Individuals from organizations that are uniquely prepared to examine research relevant to undeserved groups, including sexual orientation and gender identity minorities as well as individuals with disabilities are always encouraged to apply."

NOFO SECTION: Section III. Eligibility Information

NOFO PAGE NUMBER(S): 14-18

Requirements

10. **Our registry focuses on children, adolescents, and some young adults. We were hoping to understand if there is a requirement to have adult patients included.**

    ANSWER: Per Section I. Funding Opportunity Description, 2. Approach, the Population of Focus section explains "The target population is youth (< 18 years) and young adults (18–44 years) in the United States. Per the objectives of the NOFO, Component A applicants will need to identify a population for surveillance (i.e., denominator) from which incident and prevalent diabetes cases can be ascertained among youth and young adults. The population under surveillance at each Component A center should be demographically and geographically representative of the youth and young adults residing within the center's geographic catchment area."

    NOFO SECTION: Section I. Funding Opportunity Description, 2. Approach

    NOFO PAGE NUMBER(S): 11

Scientific

11. **While we are applying for Component A (participating site), I found a specific line from Component B (coordination center) that says, "This includes creating data validation protocols and mechanisms to secure transmission of data and relevant data management reports between Component Awardees". There is no specific writing about what type of data each Component A awardee is required to "transfer". I imagine it would be impossible to request the whole database to be transferred. I want to learn more about the details to make sure we are in alignment with what CDC wants.**

    ANSWER: In Section V. Application Review Information, 1. Criteria, one of the criteria that reviewers will use to score applications is "Does the applicant provide evidence that the health information data used at their respective center can be shared with the Component B awardee (i.e., Coordinating Center) to provide network-wide estimates?".

    NOFO SECTION: Section V. Application Review Information, 1. Criteria

    NOFO PAGE NUMBER(S): 31-32

12. **Would a national approach be suitable for this grant as opposed to a strict regional/local geography?**

ANSWER: Thanks so much for your interest in this funding opportunity! I'm sorry, but I am not able to provide specific guidance or information on the appropriateness of your proposal to the NOFO. to the following sections of the NOFO can assist in developing your application:

- To get a detailed description of the intent of this NOFO, please especially review the Section I. Funding Opportunity Description (particularly the Background and Purpose). In particular, please note the following: "It is expected that Component A applicants include detailed information of the population under surveillance and its representativeness to the population of youth and young adults residing within the center's geographic catchment area. This includes a complete description of the population under surveillance by age, sex, race and ethnicity, health insurance coverage, and geographic area. Component A applicants are expected to describe completeness (i.e., level of missingness) of the data across these key characteristics as well." (page 9)
- Please also review Section III. Eligibility Information (5. Responsiveness) for details on what constitutes a responsive application.
- It would also be beneficial to take a look at the review criteria, which include the following:
    - Does the applicant provide a detailed description of the population under surveillance (i.e., denominator)?
    - Is the applicant able to define a denominator within a geographic area using criteria such as utilization of a health system or enrollment in a health plan?
    - Does the applicant have denominators greater than 500,000 people for both youth (< 18 years) and young adults (18–44 years)?
    - Does the applicant adequately describe the population under surveillance, including age, sex, race and ethnicity, health insurance coverage, and geographic distribution? Is it representative of the population of youth and young adults residing within the geographic catchment area?

NOFO SECTION: Section I. Funding Opportunity Description, Section III. Eligibility Information, and Section V. Application Review Information

NOFO PAGE NUMBER(S): 4-17, 18-22, and 28-35

13. **We wanted to discuss with you our [application], to ensure that it is deemed responsive to the RFA.**

    ANSWER: We are prohibited from reviewing applicant materials and advising on whether they would or would not be appropriate for a particular NOFO. You are encouraged to carefully review the entirety of the NOFO to determine if it would align with your proposal. To know what constitutes a responsive application, please review Section III, 5. Responsiveness.

    NOFO SECTION: Section III. Eligibility Information, 5. Responsiveness

    NOFO PAGE NUMBER(S): 16

14. **In [our dataset], we are not able to determine overlap with data from other investigators. Will this probable (but not defined) overlap be acceptable?**

ANSWER: As stated in the Approach section: “The Coordinating Center will also provide innovative statistical and analytic support including the development of analytic methods to identify incident and prevalent diabetes cases, validate diabetes cases by type, correct for potential sources of bias, and aggregate and harmonize data across Component A centers. It will support the timely dissemination of network-wide results describing the incidence, prevalence, and clinical characteristics of diabetes among youth and young adults in the United States.”

NOFO SECTION: Section I. Funding Opportunity Description, 2. Approach

NOFO PAGE NUMBER(S): 9

15. **[We] do not own the data [and] cannot contribute to a larger data pool. We can, however, and will contribute details of our analytic approach and strategy. Will this be acceptable?**

    ANSWER: In order to be responsive to this NOFO: "Letter(s) of agreement from the institution(s) providing data for the project that permit the applicant to participate in a multi-center study that will require data sharing with other institutions. Evidence must be provided in an Appendix."

    NOFO SECTION: Section III. Eligibility Information, 5. Responsiveness

    NOFO PAGE NUMBER(S): 16

16. **I understand that an institution is allowed to make no more than one application. My questions are about participating as an individual investigator in multi-institution teams. All of my questions are regarding Component A only.**

    If institution X and institution Y are submitting separate applications for Component A:

    a) **Can an individual investigator at (subawardee) institution Z serve as a co-I on institution X's application and as a co-I on institution Y's application?**
    b) **Can an individual investigator at (subawardee) institution Z serve as an MPI on institution X's application and as a co-I on institution Y's application?**
    c) **Can a PI who works at institution X (a PI on institution X's application) also be listed as a (subawardee) co-I or MPI on institution Y's application?**

    ANSWER:

    a) Yes, however please note what is stated in Section IV. Application and Submission Information, 12. Other Submission Requirements and Information on page 27: Applicants are responsible for reporting if this application will result in programmatic, budgetary, or commitment overlap with another application or award (i.e., grant, cooperative agreement, or contract) submitted to another funding source in the same fiscal year. Programmatic overlap occurs when (1) substantially the same project is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific objective and the project design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of

the funding source. Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source. Commitment overlap occurs when an individual's time commitment exceeds 100 percent, whether or not salary support is requested in the application. Overlap, whether programmatic, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. Any overlap will be resolved by the CDC with the applicant and the PD/PI prior to award.

b) Please note what is stated in Section IV. Application and Submission Information, 12. Other Submission Requirements and Information on page 27 regarding duplication of effort.
c) Yes, but please note what is stated in Section IV. Application and Submission Information, 12. Other Submission Requirements and Information on page 27 regarding duplication of effort.

NOFO SECTION: Section IV. Application and Submission Information, 12. Other Submission Requirements and Information

NOFO PAGE NUMBER(S): 27

17. We are confident we accomplish the aims proposed in the RFA, assuming work in a nationwide database would be considered responsive. I would like to understand more about how data sharing was accomplished in DICAYA since it is not possible to share individual data.

ANSWER: In order for an application to be responsive, it must meet all of the responsiveness criteria for the respective Component as outlined in Section III. Eligibility Information, 5. Responsiveness (pg. 16). If any criteria are unmet, the application will not enter the review process.

It is also important to note that, in Section I. Funding Opportunity Description, 2. Approach, it states: "Component A applicants are expected to have access to a large population under surveillance (i.e., denominator greater than 500,000 people) for both age groups constructed using methods such as health system utilization or health plan membership enrollment. It is expected that Component A applicants include detailed information of the population under surveillance and its representativeness to the population of youth and young adults residing within the center's geographic catchment area. This includes a complete description of the population under surveillance by age, sex, race and ethnicity, health insurance coverage, and geographic area. Component A applicants are expected to describe completeness (i.e., level of missingness) of the data across these key characteristics as well". So, it will be incumbent upon applicants to ensure that their proposed projects will be able to meet these expectations.

In terms of sharing data, please note that one of the responsiveness criteria states, "Letter(s) of agreement from the institution(s) providing data for the project that permit the applicant to participate in a multi-center study that will require data sharing with other institutions. Evidence must be provided in an Appendix." Furthermore, one of the criteria that peer reviewers will use to evaluate applications is: "Does the applicant provide evidence that the health information data used at their respective center can be shared with the Component B awardee (i.e., Coordinating Center) to provide network-wide estimates?" [pg.32]. So, applicants should provide evidence that de-identified line-level

data can be shared if needed. To learn more about how DiCAYA shared data, it might be helpful to review the protocol paper that was released this year: Hirsch AG, Conderino S, Crume TL, Liese AD, Bellatorre A, Bendik S, et al. Using electronic health records to enhance surveillance of diabetes in children, adolescents and young adults: a study protocol for the DiCAYA Network. BMJ open. 2024;14(1):e073791

NOFO SECTION: Section III. Eligibility Information, 5. Responsiveness; Section I. Funding Opportunity Description, 2. Approach; and, Section V. Application Review Information, 1. Criteria

NOFO PAGE NUMBER(S): 9, 16, and 32