

RFA-DD-23-001 BD-STEPS NOFO Potential Applicant Questions

Additional questions 13 – 26 added below, and published on December 12, 2022.

Q#	Category/Section	Question	Answer
1	Section I.2. Funding Opportunity, Approach	Are stillbirths with and without birth defects to be selected and included for Components A and B?	Please refer to Section I.2. II. Activities Specific for Each Component <u>Component A. Data Collection</u> “Applicants are expected to ... identify all cases (either live born, stillborn, or induced abortions) diagnosed with any of the proposed eligible birth defects (Table 1) within one year of delivery.” <u>Component B. Data Collection</u> “Applicants are expected to ... identify pregnancies that ended in a stillbirth not ascertained as part of component A ... -- either those with birth defects other than those ascertained in BD-STEPS or those without a birth defect.”
2	Section I.2.I. Funding Opportunity Description, Approach	Does the shared “tracking” database refer to the clinical database?	Yes. For details, please see Section I.2.I. Activities for both Components A and B, Data Reporting. “On at least a monthly basis, applicants will be expected to transfer identifiable, individual-level clinical and demographic data (without contact information) from potentially eligible cases and controls to CDC using SAMS. This clinical and demographic data should conform to the structure and format of the CDC clinical database.”
3	Section I.2. Funding Opportunity Description, Approach. “The applicants should also provide evidence of legal authority to share identifiable, individual-level contact information with the interviewing contractor ... to create a pooled analytic database.”	Does the requirement to provide evidence of legal authority for sharing identifiable, individual-level contact information preclude the use of pre-consenting of mothers of eligible cases and controls to obtain permission to share the contact information?	Please see the full paragraph in Section I.2.I. Project Management, as well as Section III.3. Eligibility Information, Additional Information on Eligibility. The NOFO does not exclude pre-consent as evidence of legal authority.
4a.	Section I.2.I. Funding Opportunity Description, Approach.	Does the phrase “Unless prohibited,” allow for the requirement to pre-consent by [an applicant] to release contact	Per Section I.2. Funding Opportunity Description, Approach, the NOFO does not exclude a pre-consent process as part of the applicant’s research plan.

Q#	Category/Section	Question	Answer
	Activities for both Components A and B.	information for women of specific eligible cases (e.g., pregnancy losses) or for all cases and controls?	
4b.		If pre-consenting is required for [an applicant], is the application still responsive to the NOFO?	Please refer to Section III.3. Eligibility Information, Additional Information on Eligibility; applicants should document their ability per Section III.5. Eligibility Information, Responsiveness.
4c.		If [an applicant] can release names and contact information for women of eligible cases and controls without pre-consenting, does the applicant need to budget for any gift card reimbursement?	Please refer to Section I.2. Funding Opportunity Description, Approach. I. Activities for both Components A and B, Project Management. "...participant mailings and standardized participant incentives as agreed upon by CDC and the other recipients are the responsibility of CDC."
4d.		If [an applicant] needs to pre-consent to release names and contact information for mothers of specific eligible cases (e.g., pregnancy losses) or for all cases and controls, does the applicant need to budget for the needed gift cards to conduct the pre-consenting or will those be provided by CDC?	Please refer to Section I.2. Funding Opportunity Description, Approach. The NOFO does not discuss a pre-consenting activity. Regarding incentives: "...participant mailings and standardized participant incentives as agreed upon by CDC and the other recipients are the responsibility of CDC."
5	Section I.2. Funding Opportunity Description, Approach, Evaluation/ Performance Measurement. "Award recipients are expected to create an evaluation plan within six months after award start date that assesses".	Is the draft of this plan a required component of the Research Plan for the application?	Please refer to the instructions for providing a Research Plan under Section IV.5. Application and Submission Information, Research Plan Narrative, "The applicant's research plan should address activities that will be conducted over the entire period of performance...". The NOFO does not specify anything further regarding the evaluation plan.
6	Section IV.5. Application and Submission Information, PHS 398	Does this requirement refer to submitting a DMP for Component A and one for	One data management plan is required for each application. Please refer to Section IV.5. Application and Submission Information, PHS 398 Research Plan Component. Please provide the minimum criteria as listed

Q#	Category/Section	Question	Answer
	Research Plan Component. "A DMP is required for each collection of public health data proposed."	Component B and/or refer to submitting a DMP for each collection of public health data within a component (e.g., interview, bloodspot collection, etc.)?	in the NOFO and refer to the information found at the links provided in the NOFO for more information: https://www.cdc.gov/chronicdisease/pdf/nofo/DMP-Temaplate-508.docx and http://usgs.gov/prodcuts/data-and-tools/data-anagement/data-management-plans .
7	Section I.1. Funding Opportunity Description	Does this funding opportunity only refer to NBDPS centers in the US?	This is a new opportunity for the Birth Defects Study To Evaluate Pregnancy exposureS (BD-STEPS), not the National Birth Defects Prevention Study (NBDPS). Per Section I.1. Funding Opportunity Description, Background and Purpose: "In 1996 Congress appropriated funds to initiate some of the activities described in the Birth Defects Prevention Act of 1998, including funding the Centers for Birth Defects Research and Prevention (regional, in the US). One of the two major collaborative activities of the CBDPRP is the multi-site, case-control study, BD-STEPS.
10	Section IV, Application and Submission	In the forms it indicates that PHS Indirect Cost Forms should only be used for multi-project applications. If we are applying for both component A and B, would this be considered a multi-project application?	No, the award for this NOFO is not considered a multi-component project since a separate application is required for Component A and Component B. Please refer to Section IV.5 - The SF424 (R&R) Application Guide includes instructions for applicants to complete a PHS 398 Research Plan.
11	Section III, Eligibility	I am the PI on a [foreign] pregnancy, mother, child cohort (4 million pregnancies and children with over 22 years of follow-up), and a similar cohort in the US. I am wondering if my team and I are eligible.	Please refer to Section III.2 Eligibility Information, Foreign Organizations. "Foreign organizations are not eligible to apply... For this announcement, applicants may include collaborators or consultants from foreign institutions."
12	Section IV, Application and Submission	We are planning to apply for both Component A and Component B. Are we supposed to open a second application package under this opportunity for component B (thus one package for A and a separate for B), or do we submit only one package for both components?	Please refer to Section III.10. Eligibility Information, Number of Applications: "Only one application per institution (normally identified by having a unique UEI number) is allowed for each component for a potential of two applications per applicant. One application for Component A: BD-STEPS Core; and one optional additional application for Component B: BD-STEPS Stillbirths."

Q#	Category/Section	Question	Answer
			Also refer to Section IV.5. PHS 398 Research Plan Component. <u>Research Plan Narrative</u> : “A separate application must be submitted for each Component.”
13	Overall	Is there a way for applicants to sign up to be notified when questions and answers/updates to the RFA are posted on Grant.gov?	Yes, on Grants.gov, navigate to Manage Subscriptions GRANTS.GOV and select <i>Subscribe to opportunities</i> .
14	Executive Summary, Funds Available and Anticipated Number of Awards	Is it possible that additional funding will be made available to allow an average of \$300,000 per site for more than two sites for Component B?	Yes, CDC allows for the possibility to make up to nine awards as funds become available.
15	Executive Summary, Mechanism of Support, Budget and Project Period	Is there an inconsistency? The estimated total Component A funding of \$5.3M a year, divided by nine expected awards = \$588,888/year. This seems a lot lower than the stated \$700k average Component A award estimate, and would only cover 7.6 awarded sites @\$700k each [not 9].	No, CDC allows for the possibility to make up to nine awards as funds become available. Please refer to the Executive Summary. Mechanism of Support, Funds Available and Anticipated Number of Awards: “Because the nature and scope of the proposed research will vary from application to application, it is also anticipated that the size and duration of each award may also vary. The total amount awarded, and the number of awards will depend upon the number, quality, duration, and cost of the applications received.”
16	Executive Summary, Mechanism of Support, Budget and Project Period	Although the NOFO states that CDC anticipates up to nine awards for Component B, the entire budget amount (\$2,100,000) only accommodates two sites being awarded \$300,000 annually. Please explain. What is meant by support?	• Support in this context means funding. • CDC allows for the possibility to make up to nine awards as funds become available. • The NOFO is amended to increase Component B funding and reduce Component A funding. Please refer to Amendment 2. The update is as follows: Component A: The estimated total funding (direct and indirect) for the first budget period, 9/1/2023 - 8/31/2024, is reduced from \$5,300,000 to \$4,900,000. The estimated total funding (direct and indirect) to support up to nine awards for the entire project period of 3.5 years, 9/1/2023 - 2/28/2027, is reduced from \$18,550,000 to \$17,150,000.

Q#	Category/Section	Question	Answer
			Component B: The estimated total funding (direct and indirect) for the first budget period, 9/1/2023 - 8/31/2024, is increased from \$600,000 to \$900,000. The estimated total funding (direct and indirect) to support up to nine awards for the entire project period of 3.5 years, 9/1/2023 - 2/28/2027, is increased from \$2,100,000 to \$3,150,000.
17	Section I.2.I. Funding Opportunity Description, Approach, Activities for both Components A and B	Does the following sentence mean that CDC will be doing all the mailings (including: pre-letters, intro letters, thank you letters, and consents), as well as purchasing and sending incentives? “Unless prohibited, any participant mailings and standardized participant incentives as agreed upon by CDC and the other recipients are the responsibility of CDC.”	The NOFO is amended to clarify CDC’s role. Please refer to Amendment 2. - The stated paragraph is replaced with the following: All participant incentives are the responsibility of CDC. All participant mailings and e-consents are the responsibility of CDC except for those required by the recipient’s regulations. Any mailings and consents that are specific to the recipient, and required by the recipient’s regulations, such as pre-consents, may be included in the proposed research plan. This NOFO is being amended to clarify activity information. Consent expectations are updated: - Recipients are expected to receive and store completed hard-copy consents and, if permitted by state regulations, e-consents for the infectious disease linkage. It replaces the sentence “Applicants will be expected to obtain hard copy consents or e-consents, if it is allowed, for the infectious disease linkage.” - Recipients are expected to receive and store completed hard-copy consents and, if permitted by state regulations, e-consents for newborn blood spots. It replaces the sentence “Applicants will be expected to implement hard copy consents or e-consents, if it is allowed, for the newborn bloodspots.”
18	Section I. Funding Opportunity Description, 2.I Approach, Activities for Component A, Case Ascertainment	What is the CDC actual definition of an “active” birth defects surveillance system for this cooperative agreement? Per the statement “Applicants are	An “active” birth defects surveillance system refers to a surveillance system with active case ascertainment.

Q#	Category/Section	Question	Answer
		expected to describe the existing active birth defects surveillance system” and Section III.3 Eligibility Information.	
19	Section I. Funding Opportunity Description, 2.I Approach, Activities for Components A, Case Ascertainment	Are applicants which use hybrid case ascertainment, not active, eligible to apply? Hybrid per the NOFO: “defined at https://www.cdc.gov/ncbddd/birthdefects/surveillancemanual/facilitators-guide/module-3/mod3-3.html#Active .”	Yes. Per the definition, “Hybrid case ascertainment uses a combination of passive and active reporting systems,” which includes active case ascertainment. Please refer to Section I.2. II. Activities Specific to Each Component. <u>“Case ascertainment:</u> Applicants are expected to use data from existing, funded, population-based, birth defects surveillance systems with active case ascertainment ...” Please note the criteria in Section III.5, Eligibility Information/Responsiveness. “Evidence must be presented that the applicant has access to ... surveillance system with active case ascertainment...”
20	Section I.2. Funding Opportunity Description, Approach	Which entity obtains parental consent to participate? Is the expectation that the funded jurisdiction contact the parent for consent and then pass case information and contact information to CDC for completion of the survey? Or is the expectation that the jurisdiction will sample cases and provide contact information to CDC and then CDC reaches out for consent?	This NOFO is being amended to clarify activity information. Please refer to Amendment 2. Consent expectations are updated: <u>I. Activities for both Components A and B/Data collection</u> <u>Core interviews:</u> CDC, via a central interviewing contractor, is responsible for contacting women about their interest in participating, obtaining their consent, and for conducting the interviews. This replaces the statement: CDC, via a central interviewing contractor, is responsible for contacting women about their interest in participating and for conducting the interviews.
21	Section I.2. Funding Opportunity Description, Approach, Activities Specific to Each Component	In Component B activities, the NOFO says that “Women who experienced a stillbirth and mothers of controls will be invited to answer additional questions in a supplemental interview related to risk factors for stillbirth, such as sleeping position, and maternal disease	Yes. The NOFO is amended to clarify the stillbirth populations and expected activities. Please refer to Amendment 2. Section I.2 Approach <u>Component A focuses on birth defects and Component B focuses on stillbirth.</u> Component B activities are to include stillbirths ascertained as part of Component B and stillbirths ascertained in Component A. Section IV. Research Plan Narrative

Q#	Category/Section	Question	Answer
		and medication use throughout pregnancy.” What about the women who experienced stillbirths ascertained in Component A? Do they receive the supplemental interview?	Component B activities should include stillbirth cases ascertained in Component A and Component B.
22	Section I.2. Funding Opportunity Description, Approach, Activities for both Components A and B	Would all stillbirths included in the study and interviewed be eligible for the infectious disease consent?	Yes. Please see Section I.2. Approach, I. Activities for both Components A and B, Core Interview and Linkage to National Electronic Disease Surveillance System "Women who experienced a pregnancy affected by a birth defect and/or stillbirth and mothers of controls will be asked for consent to allow applicants to request their reportable disease records from their state health departments."
23	Section I.2. Approach, I. Activities for both Components A and B	Would all stillbirths included in the study and interviewed be eligible for the online occupational survey based on occupation?	Yes. Please see Section I.2. Approach, I. Activities for both Components A and B, Online survey "Women who experienced a pregnancy affected by a birth defect and/or stillbirth and mothers of controls will be queried about occupational exposures before and during pregnancy via online surveys." The NOFO is amended to clarify the stillbirth populations and expected activities. Please refer to Amendment 2. Section I.2 Approach <u>Component A focuses on birth defects and Component B focuses on stillbirth.</u> Component B activities are to include stillbirths ascertained as part of Component B and stillbirths ascertained in Component A. Section IV. <u>Research Plan Narrative</u> Component B activities should include stillbirth cases ascertained in Component A and Component B.

Q#	Category/Section	Question	Answer
23	Section I.2. Funding Opportunity Description, Approach	Would all stillbirths ascertained in the catchment area be eligible to participate in the study, including stillbirths with any structural birth defect (e.g., anencephaly), with the presence of a chromosomal abnormality (e.g., Copy Number Variant, Trisomy 21) or a tumor (e.g., teratoma)?	Yes. For Component A, only stillbirths in the catchment area with the proposed eligible birth defects are eligible. For Component B, all stillbirths in the catchment area are eligible. Please refer to Section I.2. Funding Opportunity Description, Approach <u>Component A/Data Collection/Case ascertainment:</u> Applicants are expected to ... timely identify all cases (either live born, stillborn, or induced abortions) diagnosed with any of the proposed eligible birth defects (Table 1) within one year of delivery. <u>Component B/Data Collection/Case ascertainment:</u> Applicants are expected to ... timely identify pregnancies that ended in a stillbirth not ascertained as part of component A in their BD-STEPS catchment area – either those with birth defects other than those ascertained in BD-STEPS or those without a birth defect.
24	Section II. Award Information Estimated Total Funding	Should the year 4 budget be no more than \$400k instead of \$800K since it is only for a 6-month period?	\$800,000 is the maximum permitted (ceiling) each budget period for component A. The budget is based on the applicant's activities described in its research plan for the budget year (6 months for year 4). The NOFO is updated to accommodate a smaller annual amount by amending the award floor for Component A is \$200,000 and Component B to \$100,000.
25	Section III.3. Eligibility Information	Per our privacy officer, we do not have authority to release PII to CDC prior to consent being obtained. Are we eligible to apply?	Yes. Please refer to Section III.3. Eligibility Information, Additional Information on Eligibility. Applicants should document their ability per Section III.5. Eligibility Information, Responsiveness. More information about HHS' privacy protections and Privacy and Confidentiality Unit contact information is found at Section VI.3 Award Administration Information, Data Management Plan https://www.cdc.gov/grants/additionalrequirements/ar-36.html.
26	Section IV Application and Submission Information/Research Plan Narrative/Component A	<u>Project Management</u> Provide a staffing and management plan that includes at least the following: Principal Investigator, Project Manager, Data Manager (15% FTE minimum), Epidemiologist(s),	A. Does "each 5% FTE minimum" refer to the Epis and Clinical Geneticist/Pediatric Cardiologist? Answer: No. "Each" only modifies the geneticist and cardiologist. B. Can the 5% FTE minimum for the two clinicians be covered by budgeting for their services the equivalent amount of hourly time under a fee-for-service contract? Answer: Yes, FTE abbreviates full-time equivalent.

Q#	Category/Section	Question	Answer
		Clinical Geneticist and Pediatric Cardiologist (each 5% FTE minimum).	C. If using a three M-PI model, are there FTE minimums for each M-PI and the project manager? Answer: No. The NOFO does not specify percentage effort for the PI(s) or project manager.
			D. Must job titles exactly match the required personnel (e.g., Medical Research Specialist that covers the “Data Manager” role)? Answer: Yes. These are roles, not titles. Clearly indicate the role in the budget justification and as relevant, the research plan.