

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

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. 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.
3	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 CDBRP is the multi-site, case-control study, BD-STEPS.”

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4	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.”
5	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.
6a	Section I.2.I. Funding Opportunity Description, Approach, Activities for both Components A and B	Does the phrase “Unless prohibited,” allow for the requirement to pre-consent by [an applicant] to release contact information for women of specific eligible cases (e.g. pregnancy losses) or for all cases and controls?	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.
6b		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, and applicants should document their ability per Section III.5. Eligibility Information, Responsiveness.
6c		If [an applicant] can release names and contact information for women of	Please refer to Section I.2. Funding Opportunity Description, Approach. I. Activities for both Components A and B, Project Management.

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		eligible cases and controls without pre-consenting, does the applicant need to budget for any gift card reimbursement?	"...participant mailings and standardized participant incentives as agreed upon by CDC and the other recipients are the responsibility of CDC."
6d		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."
7	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."
8	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." 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."
9	Section IV.5. Application and Submission	Does this requirement refer to submitting a DMP for Component A	One data management plan is required for each application. Please refer to Section IV.5. Application and Submission Information, PHS 398 Research

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	Information, PHS 398 Research Plan Component. "A DMP is required for each collection of public health data proposed."	and one for 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.)?	Plan Component. Please provide the minimum criteria as listed in the NOFO and refer to the information found at the links provided in the NOFO for more information: Chronic Disease Center Notice of Funding Opportunities CDC and http://usgs.gov//prodcuts/data-and-tools/data-anagement/data-management-plans .
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.