Supporting Statement B

for

Population-based surveillance of outcomes, needs, and well-being of children and adolescents with congenital heart defects

New

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B. Collections of Information Employing Statistical Methods

B.1. Respondent Universe and Sampling Methods

The target population for this project is individuals born between 2006 and 2021 with a congenital heart defect (CHD). Parents and caregivers of these individuals will serve as respondents for the CHSTRONG-KIDS survey. Statistical sampling methods will not be employed due to the low prevalence of CHD. Instead, all eligible children and adolescents in the participating population-based surveillance systems will be included. This census design for case ascertainment will allow for sufficient sample sizes and better representation of the CHD population to describe longer-term outcomes among children and adolescents with CHD and the needs and experiences of their caregivers. CDC estimates that a total of 7,667 respondents will be recruited over a 3-year period.

Survey Sites

The CHSTRONG-KIDS survey will be administered at 3 sites. One site will be Atlanta, Georgia, where CDC has managed and led the Metropolitan Atlanta Congenital Defects Program (MADCP) since 1967 and has a history of collaboration with local hospitals and the Georgia Department of Health. A competitive review process is underway to select the two additional sites (**Attachment 3**). These sites will be selected based on:

- Existence of an established, population-based local birth defects surveillance system
- Ability to document a minimum of 30,000 births per year in the catchment area
- Capacity to administer the CHSTRONG-KIDS survey to all qualifying respondents

CDC may adjust the total estimated burden after final selection of funded sites.

CHD Cases

- Confirmed diagnosis in an active, population-based birth defects surveillance system of a CHD with an ICD-9-CM/BPA codes between 745-747 and ICD-10-CM codes between Q20 and Q26. At minimum, sites must survey all children with the CHDs below. Sites may choose to expand the list of CHDs and survey children with other CHD types.
    - Aortic valve stenosis
    - Atrial septal defect (ASD)
    - Atrioventricular septal defect (AVSD) or Atrioventricular canal (AV canal)
    - Bicuspid aortic valve
    - Coarctation of aorta
    - Ebstein Anomaly
    - Hypoplastic left heart syndrome (HLHS)
    - Patent ductus arteriosus (PDA)
    - Pulmonary atresia
    - Pulmonary valve stenosis
    - Single ventricle (double inlet left ventricle)
    - Tetralogy of Fallot (TOF)
    - Transposition of the great arteries (TGA)
    - Tricuspid atresia
    - Truncus arteriosus
    - Ventricular septal defect (VSD)

Respondents for the CHSTRONG-KIDS survey

- Inclusion criteria
    - Child's birth date between 2006 and 2021
    - Child born within the catchment area of a selected site
    - Child has an eligible CHD documented within the site's active, birth defects surveillance system
    - Parent's ability to complete the CHSTRONG-KIDS survey in English or Spanish **(Attachments 4 and 5)**
- Exclusion criteria
    - Parent or caregiver currently incarcerated
    - Parent or caregiver younger than 18 years of age
    - Child with CHD is deceased

B.2. Procedures for the Collection of Information

Site-specific birth defects surveillance data will be used to identify children and adolescents with CHDs. Once children and adolescents with CHDs are identified for the project, sites will link their birth defects surveillance data to vital records death certificates to ensure that the children and adolescents were not issued a death certificate; parents or caregivers of children with CHD determined to be deceased will not be contacted for participation in the project. Following linkage to vital records, online tracing providers and other tools (social media, Division of Motor Vehicles database, state Medicaid database, etc.) will be used to find up-to-date contact information for the parents or caregivers of the children or adolescents with CHDs, including street address, phone number, and email address, when possible. In order to conduct tracing, each site must abstract the following information from their birth defects surveillance systems: infant's birth date, race, infant's first and last name, mother's first name, maiden name, and/or married name, mother's city, county, and zip code of residence at infant's birth. Subjects may currently live outside their state of residence at birth.

After eligible subjects are identified and located, the site will mail survey materials. The survey mailing will include: 1) a letter introducing the project in English **(Attachment 17)** or Spanish, if requested **(Attachment 18)**; 2) a participant information sheet explaining rights as a survey participant in English **(Attachment 15)** or Spanish if requested **(Attachment 16)**; an English or Spanish paper survey questionnaire **(Attachments 4 and 5**); 3) an addressed and postage-paid return envelope addressed to CDC; and 4) a $5 gift card to thank participants for their time.

B.3. Methods to Maximize Response Rates and Deal with Nonresponse

Two weeks before the recruitment mailing, an initial letter will be mailed to each address believed to be the primary residence of the parent or caregiver of the eligible child to confirm that the address is valid before sending the recruitment materials and to notify residents of the upcoming recruitment mailing **(Attachment 20)**. If this initial letter or any subsequent recruitment mailing is returned as undeliverable, project sites will use other potential street addresses, email addresses, or phone numbers identified in the tracking and tracing.

To maximize response rates, in addition to the $5 gift card provided in the introductory letter with the survey, eligible parents or caregivers will simultaneously be notified (**Attachments 17 and 18**) that they will receive a follow-up thank you letter, including a $20 gift card, upon return of the survey as a token of appreciation for their time and effort.

Within two weeks after the recruitment mailing, project sites will send a postcard to the individual thanking them for completing the survey and reminding them to complete the survey, if not already done (**Attachment 21**). The postcard will include a phone number and email address to contact if another survey is needed. Approximately two weeks after the reminder postcard is sent, recruitment materials will be sent once again, without a gift card, to any parents or caregivers who have not yet responded.

Sites will sample 100% of eligible CHD cases identified in their birth defects surveillance systems to generate sufficient sample size compensating for non-response. Furthermore, CDC will receive birth defects surveillance data from all sites for all individuals identified in their birth defects surveillance system, including those individuals who did not complete the survey. With this information, CDC will be able to evaluate the presence of any non-response bias. Age, race, location, and type of CHD are all factors that may be associated with non-response and will be considered in the evaluation. If characteristics of non-respondents are found to differ from respondents during analysis, statistical methods will be considered to address non-response bias as has been done in a similar survey project among adults with CHD [16-18].

B.4. Tests of Procedures or Methods to be Undertaken

The paper surveys have been evaluated by less than 10 CDC staff to ensure appropriate skip patterns and determine the time required for completion. These surveys represent new survey material for data collection.

B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The statistical aspects of the design of this project are the responsibility of the Principal Investigator and Co-Investigators:

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Analysis of CHSTRONG-KIDS data is the primary responsibility of Sherry Farr, Karrie Downing, and Shannon Moss.