Supporting Statement B

Congenital Heart Survey To Recognize Outcomes, Needs, and well-beinG (CH STRONG)

OMB number 0920-1122

Reinstatement with Change

Sherry L. Farr, PhD
Epidemiologist
Centers for Disease Control and Prevention
Email: SFarr@cdc.gov
Phone: 404.498.3877
Fax: 404.498.3040

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Supporting Statement Part B.

B. Collections of Information Employing Statistical Methods

B.1. Respondent Universe and Sampling Methods

Respondents will be recruited from three sites. Respondents in Atlanta will be selected from the Metropolitan Atlanta Congenital Defects Program (MACDP) surveillance system. The additional two sites, Arkansas Center for Birth Defects Research and Prevention and the University of Arizona College of Medicine, Tucson, will also select respondents from their birth defects surveillance systems. The collection of information for individuals with congenital heart defects (CHDs) does not employ statistical sampling methods because all identified individuals with a CHD born between 1970 and 1997 will be recruited to participate.

Exclusion criteria: Subjects with a CHD will not be eligible to participate in CH STRONG if 1) they were not born in the site's catchment area as defined at the time of their birth; 2) they are currently incarcerated; 3) they are younger than 18 years of age; 4) they cannot complete an English or Spanish survey **(Attachments 3, 13)**; or 5) they are deceased.

CHDs will be identified using appropriate ICD-9-CM codes or ICD-CDC/BPA modified codes within the range of 745.0-749.0 found in the birth defects surveillance systems. Individual CHDs are rare occurrences, so it is necessary to ascertain all potential cases in order to track and trace, disseminate the survey, and collect and analyze data.

B.2. Procedures for the Collection of Information

Once adults born with CHDs are identified for recruitment from the three selected sites, the site will link the subjects' birth defects surveillance data to state and/or national vital records death certificates, depending on availability of vital records at the site, to ensure that subjects were not issued a death certificate; following this linkage, 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 individuals 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: birth date, race, mother's maiden name and/or married name, infant's

last name, city, county, and zip code of residence. Subjects may currently live outside their state of residence at birth.

After eligible participants are identified and contact information is found through tracking and tracing, the site will mail survey materials. The survey mailing will include: 1) a letter introducing the project in English **(Attachment 4)**; 2) a consent document explaining rights as a survey participant in English **(Attachment 5)**; a paper survey questionnaire and information on how to complete the online survey, if so desired **(Attachments 3, 6, 13**); 3) an addressed and postage-paid return envelope addressed to CDC. A pre-paid incentive of $5 (in the form of a gift card) will be mailed in the initial mailing and an additional $10 gift card will be sent to individuals after they return their surveys. The introductory letter includes a sentence written in Spanish informing the participant to call a 1-800 number to request Spanish language documents, if needed **(Attachment 13, 14, 15).**

If no current address is available for the individuals with CHD, sites will trace the individuals' mothers. Mothers will be sent an introductory letter in English **(Attachment 16)** or Spanish if requested **(Attachment 17)** and a contact information form for their child in English **(Attachment 18)** or Spanish if requested **(Attachment 19)**.

During the first round of data collection, the three CH STRONG sites sent recruitment materials to approximately 600 total individuals (200 from each site). During that period, we realized that the tracking and tracing process to identify current contact information for eligible individuals did not work well and approximately 15% to 20% of recruitment materials were being returned as undeliverable due to incorrect or out of date addresses. Therefore, the three sites decided to conduct more intensive and time-consuming tracking and tracing to identify better contact information for eligible individuals. Sites also decided to conduct further tracking and tracing on those individuals whose materials were returned as undeliverable.

The CDC contracted with a survey organization to conduct tracking and tracing for the MACDP sample. At the CDC site, intensive tracking and tracing began in April 2017 and will conclude in the winter of 2018. At the other sites, intensive tracking and tracing will end in spring 2018. In addition to more intensive

tracking and tracing, the sites decided to send recruitment materials in batches rather than all at once (i.e. sending materials to approximately 200 individuals per site every two to four weeks). This ensured that problems with the recruitment process were caught immediately and could be modified in subsequent rounds of recruitment.

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

Fifteen dollars in the form of gift cards will be used as an incentive to maximize response rates. This amount will be split between the initial recruitment mailing and in a letter thanking the individual for participating. Participants also have the option of completing the survey on paper or online **(Attachments 3, 6, 13)**.

If the 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, including tracking and tracing the mother named on the birth certificate **(Attachments 16, 17, 18, 19)**. Due to the anticipated mobility of this population, an anticipated 20% of subjects' mothers will be tracked and traced, with follow up via mail **(Attachments 16, 17)** and/or phone. Mothers will be asked to provide best contact information for the eligible individuals **(Attachment 18, 19)**.

Within two weeks of the initial 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 9)**. The postcard will include a phone number and email address to contact if another survey is needed. If a completed survey is not returned within one month of the initial mailing, the site will send another survey without incentive. One additional postcard will be sent to remind the individual to complete the survey.

Based on previous work done in the National Birth Defects Prevention Study (OMB 0920-0010) in the Division of Birth Defects and Developmental Disabilities, a 70% response rate is anticipated.

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 non-response and will be considered in the evaluation.

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

The paper surveys have been evaluated by fewer than 10 CDC staff to ensure appropriate skip patterns and determine the time required for completion. The online survey will be similarly evaluated by individuals within the Division of Birth Defects and Developmental Disabilities. These surveys represent new survey material for data collection.

When analyzing the data, prevalence estimates with 95% confidence intervals (CI) will be calculated for demographic characteristics, type of CHD, and important outcomes of interest, such as quality of life, disability, and educational outcomes. Prevalence estimates will be calculated overall, and stratified by site, type of CHD, and important demographic characteristics, such as age and sex. For certain questions, prevalence estimates and associated 95% CIs will be compared to those from national, state, or local publicly available population-based surveys, such as the Behavioral Risk Factor Surveillance System **(Attachment 11)**. Amongst adults born with CHD, univariate and multivariable log-binomial regression may be used to determine risk factors for given outcomes, such as poor quality of life. Risk factors may include type of CHD, number of surgeries, demographic characteristics, and healthcare use and access.

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

The statistical aspects of the design of CH STRONG are the responsibility of the Principal investigator:

Sherry L. Farr, PhD
Epidemiologist
Division of Birth Defects & Developmental Disabilities

National Center on Birth Defects and Developmental Disabilities
Centers for Disease Control & Prevention
4770 Buford Hwy, MS: E86
Atlanta, GA 30341
404.498.3877

RTI International is currently contracted by CDC to manage all CH STRONG tracking and tracing activities; the RTI International primary contact is the following:

Nedra Whitehead, PhD, MS, CGC
Environmental Health Sciences RTI International
2951 Flowers Road, Suite 119
Atlanta, Georgia 30341
770-986-5051

Analysis of CH STRONG data is the primary responsibility of Dr. Farr.