

Supporting Statement B

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

OMB number 0920-xxxxx

New

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Supporting Statement Part B.

B. Collections of Information Employing Statistical Methods

Section 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, 12**); or 5) they are deceased.

CHDs will be identified using appropriate ICD-9-CM codes (745.0-746.85, 746.87-746.9, 747.1-747.4, 747.9) or ICD-CDC/BPA modified codes (745.0 - 746.860, 746.880-746.9, 747.1-747.4, 747.9) 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.

Section 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.

Approximately 30 days after eligible participants are identified, the site will mail survey materials. The survey mailing will include: 1) a letter introducing the project in English (**Attachment 7**); 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, 12**); 3) an addressed and postage-paid return envelope addressed to CDC. If a higher than 70% rate of correct address tracking and tracing is found at a given site, a pre-paid incentive of \$5 (in the form of a gift card) will be mailed in the initial mailing and an additional 10\$ will be sent to individuals after they return their surveys. For a lower than 70% rate of correct address tracking and tracing, incentives will only be distributed in the form of \$15 gift cards after a completed survey is received.

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 12, 13, 14**).

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 15**) or Spanish if requested (**Attachment 16**) and a contact information form for their child in English (**Attachment 17**) or Spanish if requested (**Attachment 18**).

The CDC will contract with a survey organization to conduct tracking and tracing for the MACDP sample. As part of tracking and tracing for MACDP, the contract organization will conduct basic tracking and tracing for all individuals with CHD and follow up with a sub-sample of individuals to confirm a correct street address was obtained. The percentage of individuals for whom correct addresses were obtained through basic tracking and tracing will determine the way incentives for participation are distributed: if a lower than 70% rate of correct address tracking and tracing is found in the MACDP sub-sample, incentives will be distributed after subjects call or email the project coordinator in his or her state of birth, or after a completed survey is received.

Section 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. Depending on the sub-sample described in Section B.2, this amount will either be split between the initial recruitment mailing and later in exchange for a completed survey, or will be sent in total as one gift card after the participants complete the survey or call/email the project coordinator. Participants also have the option of completing the survey on paper or online (**Attachments 3, 12, 19**).

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 15, 16, 17, 18**). 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 15, 16**) and/or phone. Mothers will be asked to provide best contact information for the eligible individuals (**Attachment 17, 18**).

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 8**). 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 call the individual to remind them to complete the survey (**Attachment 9**). If there is no response after at least 15 attempted contacts through mail and phone, the individuals will be marked as 'unreachable' in the site's tracking database.

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.

Section 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 10**). 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.

Section 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:

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

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