

Supporting Statement Part A

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

New

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Supporting Statement Part A. Justification

A. Justification

Goal of the project: The purpose of this project is to evaluate cardiac and other healthcare utilization, barriers to health care, quality of life, social and educational outcomes, transition of care planning from childhood to adulthood, and mortality of children and adolescents with congenital heart defects (CHD) as well as needs and experiences of their caregivers.

Intended use of the resulting data: Data from this project will enable federal, state, and local governments and organizations to understand the needs of children and adolescents with CHD and their caregivers, allocate resources, and establish programs accordingly.

Methods to be used to collect: This is a cross-sectional surveillance project. Data will be collected once from a participant (i.e. caregiver of child or adolescent with CHD), via paper survey.

The subpopulation to be studied: This project will survey adult caregivers of children 2 to 17 years of age who were born with a CHD as identified through population-based birth defects surveillance systems in three participating sites in the United States; one of which will be metropolitan Atlanta, GA (administered by the Centers for Disease Control and Prevention). The other two sites will be determined through an objective and competitive funding process.

How the data will be analyzed: Prevalence estimates with 95% confidence intervals will be calculated overall, by type of CHD, and by important demographic characteristics, such as age and sex. Using chi square tests, prevalence estimates will be compared to those among the general population of U.S. children from national, state, or local publicly available population-based surveys, such as the National Survey of Children's Health, (OMB No. 0607-0990, exp. 04/30/2024). Amongst children and adolescents born with CHD, univariate and multivariable log-binomial regression may be used to determine risk factors for given outcomes, such as loss to cardiology follow-up.

Section A.1. Circumstances Making the Collection of Information Necessary

This Information Collection Request is submitted under the classification “New” request. The length of data collection requested for OMB-PRA approval is 3 years. The National Center on Birth Defects and Developmental Disabilities (NCBDDD) at the Centers for Disease Control and Prevention (CDC) is making this request as authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241) **(Attachment 1)**.

Background

Congenital heart defects (CHD) are the most common type of structural birth defects in the United States, affecting approximately 1 in 110 live-born children [1], and are a leading cause of birth defect-associated infant mortality, morbidity, and healthcare costs [2, 3]. CHD includes at least 18 different types of CHD diagnoses of varying phenotype and severity, each with a specific set of guidelines for care, management, and cardiology follow-up. Based on advances in survival, there are approximately 1 million children and adolescents with CHD in the United States [4].

Existing birth defects surveillance systems provide information on prevalence of all types of CHD at birth. Since 1967, the CDC has administered and managed a birth defects surveillance program to understand birth prevalence of congenital defects in Atlanta, GA, the Metropolitan Atlanta Congenital Defect Program (MACDP; <https://www.cdc.gov/ncbddd/birthdefects/macdp.html>). In addition to providing birth defect prevalence, MACDP and similar birth defects surveillance systems across the United States have been used to identify individuals born with birth defects for participation in research and surveillance projects. For example, the Birth Defects Study to Evaluate Pregnancy exposureS (BDSTEPS; bdsteps.org; OMB# 0920-0010), a multi-site research study funded by the CDC, uses information from MACDP and other U.S. birth defects surveillance systems to identify pregnancies affected by certain birth defects and interview mothers on possible exposures that may increase the risk for birth defects in their children.

With vast declines in mortality from pediatric heart disease over the past 30 years [5], it is vital to evaluate health, social, educational, and quality of life outcomes of those with CHD beyond infancy and by CHD type. Through the Congenital Heart Survey To Recognize Outcomes, Needs, and well-beinG (chstrong.org; OMB# 0920-1122), a CDC-funded surveillance project among young adults with CHD, MACDP and two additional sites in Arkansas and Arizona identified individuals born with CHD between 1980 and 1997 and surveyed these adults on their health, healthcare access, and quality of life [6]. Thus far, CH STRONG has provided stakeholders information on comorbidities [7], disability [8], and healthcare planning [9] among adults with CHD. However, U.S. population-based data are still lacking on longer-term outcomes among children and adolescents with CHD.

Current population-based research among children and adolescents with CHDs relies on cross-sectional data from national surveys (e.g., National Survey of Children's Health [NSCH], OMB No. 0607-0990, exp. 04/30/2024; National Health Interview Survey [NHIS], OMB No. 0920-0214, exp. 12/31/2023) or administrative healthcare data. All of these lack detailed information on type of heart problem (congenital or acquired), specific type of CHD, presence of other birth defects, and details at birth (e.g., preterm birth). Beyond survival and some medical outcomes, only limited data are available to address other social and quality of life issues of children with CHD, such as developmental delays and educational outcomes. The scant data on outcomes among children with CHD and absence of information on outcomes by CHD type is insufficient to provide stakeholders insight into the public health questions that remain for children with CHD or to develop services and allocate resources designed to improve long-term health and wellbeing.

Section A.2. Purpose and Use of Information Collection

The target population for this project is children and adolescents born between 2006 and 2021 with a congenital heart defect (CHD). Parents and caregivers of these individuals will serve as respondents for the Congenital Heart Survey to Recognized Outcomes, Needs and well-beinG among Kids (CHSTRONG-KIDS survey). The project will survey parents or caregivers of identified children with CHD to evaluate cardiac and other healthcare utilization, barriers to health care, quality of life, social and educational outcomes, transition of care planning from childhood to adulthood, and mortality of children and adolescents with CHD as well as needs and experiences of their caregivers. One site will be Atlanta, Georgia, where CDC has managed and led the Metropolitan Atlanta Congenital Defects Program (MADCP; <https://www.cdc.gov/ncbddd/birthdefects/macdp.html>) 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**). All three sites will use their respective population-based birth defects surveillance systems to identify all eligible children and adolescents born with CHD between 2006 and 2021 within their catchment area and recruit their parents or caregivers to complete CHSTRONG-KIDS (**Attachments 4 and 5**).

Currently, Congress has appropriated approximately \$7 million per year to CDC to conduct surveillance among individuals with CHD. Project information and results will be disseminated to healthcare providers, patients, families, national patient and clinical organizations, the public, and other stakeholders via emails, newsletters, websites, social media, publications, presentations, and other methods. Findings from this project will enable federal, state, and local governments and organizations to understand the needs of children and adolescents with CHD and their caregivers, allocate resources, and establish programs accordingly.

Section A.3. Use of Improved Information Technology and Burden Reduction

All data will be collected via paper survey; in CH STRONG (chstrong.org; OMB# 0920-1122), a similar survey project on adults with CHD that offered an online survey option in addition to paper, more than 80% of participants opted to complete and return the paper survey [6]. To eliminate the need to ask additional questions already captured in electronic surveillance databases, information from the birth defects surveillance system (e.g. birth defect diagnoses, age at CHD diagnosis, birth year, birth weight, birth length, gestational age, mother’s age at delivery, father’s age at delivery, plurality, sex, and maternal race/ethnicity, census tract-level socioeconomic indicators and rurality for birth residence) will be electronically linked by use of a unique identification number to the respondents’ survey information. Additionally, the survey includes skip patterns so that parents or caregivers are only asked age-relevant questions about their child (**Attachments 4 and 5**).

Section A.4. Efforts to Identify Duplication and Use of Similar Information

Most existing population-based national surveys collecting data on children do not inquire about childhood heart conditions (e.g., National Health and Nutrition Examination Survey (NHANES), OMB No. 0920-0950, exp. 04/30/2023). Of surveys that do, some inquire about childhood “heart conditions” (congenital and acquired), but not CHD specifically (e.g., National Survey of Children’s Health (NSCH), OMB No. 0607-0990, exp. 04/30/2024), and another includes one question on whether the child has CHD, but does not provide further detail on the specific CHD type (National Health Interview Survey (NHIS), OMB No. 0920-0214, exp. 12/31/2023). Additionally, none of these surveys validate parent or caregiver responses. Thus far, these surveys have been used to broadly describe a limited selection of long-term non-cardiac outcomes including preventive care utilization [10], functional limitations [11], educational needs [11], and transition from child to adult care [12] among children with any heart conditions and financial burdens and mental health of their caregivers [13] or, among children with CHD, their general healthcare utilization, health outcomes and academic outcomes [14]. However, children with heart conditions are a heterogeneous group, comprised of children with congenital and acquired heart problems and syndromes. Furthermore, CHD itself includes at least 18 different types of CHD diagnoses of varying phenotype and severity, each with a specific set of guidelines for care, management, and cardiology follow-up.

CHD is a rare condition, affecting less than 1% of infants; therefore, adding a question that would provide enough detail on CHD type to these population-based surveys would not provide sufficient sample size to generate precise prevalence estimates for healthcare access, quality of life, and other issues among children with CHD. For example, a previous publication using National Health Interview Survey (NHIS, OMB No. 0920-0214, exp. 12/31/2023) data from 1997 to 2011 identified 462 children with CHD [14]. Stratifying this sample further by CHD type would result in numbers too low to generate prevalence estimates and findings generalizable to the larger U.S. population of children with CHD. Furthermore,

data on outcomes of interest specific to those with CHD, such as cardiac healthcare access and utilization, are not collected on existing surveys.

Section A.5. Impact on Small Businesses or Other Small Entities

This data collection will not involve small businesses.

Section A.6. Consequences of Collecting the Information Less Frequently

The consequence of not collecting the information would be to have no information from U.S. population-based data sources to inform the public health needs of and resource allocation for services targeting U.S. children with CHD, a group that is increasing in size and currently totals over 1 million.

Each respondent will be asked to respond once.

There are no legal obstacles to reduce the burden.

Section A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with regulation 5 CFR 1320.5.

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Section A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

- A. A copy of the agency's 60-day Federal Register Notice is attached (*60-day Federal Register Notice Attachment 2*). The notice, as required by 5 CFR 1320.8 (d), was published on February 14, 2022 (Vol. 87, No. 30, pages 8252-8253). CDC received 5 public comments in response to this notice (**Attachments 6-10**).

Comment 1 (Attachment 6): I believe having population based surveillance of outcomes, needs and well being of children and adolescents with congenital heart defects will allow us to see patterns of this illness due to their environment. Having more money may allow the parents to provide more treatments for this defect than those on a lower income. Also we always need to take in account the overall wellbeing of the children no matter what their parents income is. Everyone deserves a fair chance at health care.

Response to Comment 1: Thank you for your support of this project.

Comment 2 (Attachment 7): Congenital Heart Defects are often needing early intervention support from multiple professions, such as physical therapy, occupational therapy, developmental therapy, and more. Population-based surveillance of the outcomes, needs, and well-being of children with CHD can inform these professions and beyond to be better prepared and knowledgeable of the current therapy practices and future intervention strategies. Occupational therapy is especially interested in developmental milestones being met, social outcomes, mental and physical well-being, and medical fragility for children

in this population. Especially considering critical congenital heart defects can inform future policies and standards of care in NICUs and state-funded early intervention programs. A small study involving 18 infants between the ages of one and 18 months old found that there was a positive correlation between CHD and gross motor delays (Paula et al., 2020). With a new method of collecting data on CHD populations, more information like this can be obtained to improve intervention strategies for occupational therapy practitioners in inpatient, early intervention, school-based and outpatient settings that can produce life-long impacts in participation and well-being.

Paula, Í. R., Oliveira, J. C., Batista, A. C., Nascimento, L. C., Araújo, L. B., Ferreira, M. B., Gomes, M.B., & Azevedo, V. M. (2020). Influência da Cardiopatia Congênita no Desenvolvimento Neuropsicomotor De Lactentes. *Fisioterapia e Pesquisa*, 27(1), 41–47. <https://doi.org/10.1590/1809-2950/18039627012020>

Response to Comment 2: Thank you for this reference and for your comments on therapies and other needs of children with CHD.

Comment 3 (Attachment 8): In the event that having populace based secret(ly) recording or watching occurs, needs and prosperity of kids and adolescents with conceived with heart flees will allow us to see plans of this ailment because of their incorporating conditions. Having more cash might permit the watchmen to give a larger number of drugs to this flaw than those on a lower pay. The lower pay gets everything free of charge however the center individuals get nothing since they make excessively,, yet in actuality they simply make to the point of getting by throughout everyday life. Likewise we generally should consider the all around success of the youngsters regardless their watchmen pay is on the grounds that a many individuals simply have to the point of covering their bills. Everyone has a sensible chance at prosperity care. Everybody can not bear the cost of medical services and it sucks. People on the planet are extremely debilitated and can not bear the cost of the medication that helps treat their circumstances. Individuals fit the bill with the expectation of complimentary food stamps however nobody appears to meet all requirements with the expectation of complimentary wellbeing.

Response to Comment 3: Thank you for your comment.

Comment 4 (Attachment 9): Children who have congenital heart diseases are always spending there time at the hospital. They have to get regular check up to make sure they are doing well. But people don't realize is that it takes a mental toll on them. It can cause them to isolate and feel alone while growing up because they never have time to go anywhere. Having studies that assist doctors in figuring out patterns of the illness and how to help them is a good thing. It lets children not have to be in the hospital all the time and have a normal childhood. They know what needs and services are most useful to the disease. Helping parents with healthcare is going to take a burden off of them. Even if they are not the ones sick it also affects the mentally and physically. Parents shouldn't have to worry if there kid can be treated because they don't have enough money. They should be able to spend with there child.

Response to Comment 4: Thank you for your comment and for your support of this project.

Comment 5 (Attachment 10):

To whom it may concern,

Thank you for the opportunity to comment on “Population-based Surveillance of Outcomes, Needs, and Well-being of Children and Adolescents with Congenital Heart Defects.” I am Anisha Chopra a current junior in high school and College Credit Plus student majoring in Psychology.

I would like to provide supporting statements and suggestions regarding this notice. I believe the proposed collection of information is necessary for the proper performance of the agency. The CDC's mission is to protect the American people from health, safety, and security threats. The leading cause of birth defect associated illness and death are congenital heart diseases. It is the CDC's duty to intervene where they can and try to make changes to improve the health of those children. "In addition to the medical costs of care for CHDs, families of children with CHDs can face other costs, such as high out-of-pocket expenses, financial problems, greater care-giving hours, quitting or reducing hours at work in order to care for their child, and decreased mental health." (Centers for Disease Control and Prevention, 2022) This being the case, the proposed project will be able to gather data pertaining to the specifics of the hardship's children with CHD and their families go through. The thoroughness of the questionnaire really allows for officials to see what the most resources need to be allocated towards. The information is very practical and accounts for many demographics of people given the large sample size and sampling method.

In order to minimize the amount of burden time in this collection of information, I believe the survey should be administered electronically if phone numbers or emails can be acquired through the birth defect surveillance system. Mailing surveys may require even more time than what is predicted because participants have to take the time to fill it out and mail it back to the appropriate location. The nonresponse bias for either type of survey would be approximately the same so this would not be an issue when changing the administering format. "The response rates in this research are 50 percent for the mail version and 44 percent for the Internet version (Table 1). It is important to note that these two rates are not statistically different ($p=0.21$)." (Poole & Loomis, 2009) In summary, I believe this project will have pertinent information to the CDC in improving overall health and well-being of those with CHD. This information may be more quickly and effectively acquired through electronic means.

Bibliography

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Centers for Disease Control and Prevention. (2022, January 24). Data and statistics on congenital heart defects. Centers for Disease Control and Prevention. Retrieved April 14, 2022, from <https://www.cdc.gov/ncbddd/heartdefects/data.html>

Poole, B., & Loomis, D. (2009). A comparative analysis of mail and internet surveys. Retrieved April 15, 2022, from <https://www.nrs.fs.fed.us/pubs/gtr/gtr-nrs-p-66papers/32-poole-p-66.pdf>

Response to Comment 5: Thank you for your support and suggestions. In a previous project that implemented similar tracking and tracing and recruitment methodology to survey adults with congenital heart defects (Congenital Heart Survey to Recognize Outcomes, Needs and Well-being (CH STRONG), OMB No. 0920-1122, exp. 05/31/2021), tracking and tracing efforts did not yield valid emails and phone numbers for the vast majority, and more than 80% of survey respondents opted to complete and mail the paper survey though an online option was provided [6]. Therefore, to save time and resources, this project has opted to mail a survey packet including a paper survey and a postage-paid envelope with a pre-filled return address.

B. In February 2022, we discussed this project with the branch chief of the pediatric cardiology section within the National Heart, Lung, and Blood Institute, Dr. Kristin Burns, who confirmed the surveillance would be beneficial and not redundant. Additionally, in November 2022, we spoke with

two Chief Medical Officers in the Food and Drug Administration’s (FDA) Center for Devices and Radiological Health, Dr. Andrew Farb and Dr. Vasum Peiris; both confirmed no overlap with projects at the FDA and Dr. Vasum Peiris added that our project has “the potential to generate some extremely valuable and meaningful data that will assist with improvements in CHD care.”

On March 24 and 28, 2022, the following list of representatives from several organizations outside of CDC were consulted and asked to provide input on the content of the data collection instruments for this project.

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Section A.9. Explanation of Any Payment or Gift to Respondents

Respondents will receive a \$5 gift card when sent the survey materials and a thank you letter (**Attachments 11 and 12**) with a \$20 gift card upon completion and return of the survey as a token of appreciation. Research suggests that providing tokens of appreciation to eligible participants when they receive the survey materials will increase response rates and prevent bias, making findings generalizable to U.S. children and adolescents with CHD. Literature examining the benefit of tokens of appreciation for participation was summarized by Yu J, et al. in their paper “A quantitative review of research design effects on response rates to questionnaires” [15]. It reviewed 497 response rates found in 93 journal articles and found that response rates increased with monetary and non-monetary gifts to participants.

Section A.10. Assurance of Confidentiality Provided to Respondents

The proposed data collection will have no anticipated effect on the respondent’s privacy.

The research determination for this project has declared it “Not Research – Public Health Surveillance” and therefore exempt from IRB review (**Attachment 13**). However, this data collection effort is subject to the Privacy Act and will be managed in accordance with CDC’s System of Records Notice (SORN) #09-20-0136, Epidemiologic Studies and Surveillance of Disease Problems, Department of Health and Human Services/CDC/National Center for Infectious Diseases. A privacy impact assessment for this project was reviewed and approved by a CDC Senior Official for Privacy (**See Privacy Act Attachment 14**).

Paper surveys will be mailed to parents or caregivers of children eligible to participate at their current residence (**Attachments 4 and 5**). Data collected by paper survey will be returned by mail from the participant to CDC. All survey data will be stored at the CDC. Information in Identifiable Form will be stored separately from other survey data. All project materials will be properly filed, maintained, and secured in a locked file cabinet in a locked office. Electronic data will be kept on password protected systems only accessible by CDC project staff. The CDC data manager will clean and remove Information in Identifiable Form from the survey data, link deidentified survey data to de-identified birth defects surveillance systems data via a participant identification number, and create a dataset for use by project staff. The linked dataset will not include Information in Identifiable Form. Project staff at funded sites may be given access to project data stored at CDC through secure data-transfer systems. Before obtaining the data, project staff must sign a Confidentiality and Data Use Acknowledgement form assuring they will not use these data in any way except for statistical reporting and analysis; they will not share the individual-level data with anyone not named on the data sharing and confidentiality form; they will not attempt to use the dataset to learn the identity of any person or establishment, and they will use reasonable measures to protect all individual-level data from eye observation, theft, or accidental loss or misplacement.

A participant information sheet will be provided to all individuals eligible to participate in the surveillance project (see **Attachments 15 and 16**). Completion of the survey will be taken as consent to participate. Because this work presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context, we will not request written documentation of informed consent. The participant information sheet informs the participant about the purpose and procedures of the project. Additionally, the participant information sheet states that there are no known risks to the participant and all personal information will be kept private to the extent allowed under federal laws. The participant information sheet also states there is no benefit to completing the survey, but answers may help identify unmet needs of children with CHD and their caregivers. Further, the participants will be reminded that their participation is voluntary and that they may choose not to answer a question at any time or may withdraw their survey from the project.

Section A.11. Justification for Sensitive Questions

The survey asks questions about topics that may be considered sensitive: medical diagnoses, disabilities, special healthcare needs, use of special education services, bullying, and adverse childhood experiences. These topics are included in the survey because several reports indicate they are important issues for children or adolescents with CHD. As mentioned, the participant information sheet (**Attachment 15 and 16**) states three times that participation is voluntary, nothing will happen if the person decides not to participate, that the participant may skip any question he/she does not wish to answer, and that all information collected will be kept confidential. Additionally, the survey instrument also states that the participant may skip any question he/she does not wish to answer (**Attachment 4 and 5**), and the section asking about adverse childhood experiences is prefaced with the following text: “The next questions are about events that may have happened during this child’s life. These things can happen in any family, but some people may feel uncomfortable with these questions. As a reminder, you may skip any questions you do not want to answer.” There is also a statement in the introductory letter that reads: “None of your answers will be linked to your name or your child’s name, nor will your name or your child’s name ever be released as having a heart condition, having completed the survey, or having been asked to participate.” (**Attachment 17 and 18**). Additionally, most questions on this survey are derived from the National Survey of Children’s Health (OMB No. 0607-0990, exp. 04/30/2024) which has been found acceptable by parents of 2-17 year-olds across the United States.

Section A.12. Estimates of Annualized Burden Hours and Costs

It is estimated that 7,667 respondents in total across all 3 years will complete the survey. The survey will be conducted 1 time only and survey completion will take 20 minutes, for a total burden of 2,556 hours. Given a 3-year length of approval, corresponding annual estimates are 2,556 respondents per year and 852 burden hours per year.

There are no costs to respondents other than their time.

EXAMPLE OF BURDEN TABLE:

A.12.A. Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Caregivers of individuals aged 2-17 years with a congenital heart defect	Congenital Heart Survey To Recognize Outcomes, Needs, and wellbeinG of KIDS	2,556	1	20/60	852
TOTAL		2,556	—	—	852

The annualized cost burden is shown in Table A.12.B. The median hourly wage rate is based on the most recent (May 2020) National Occupational Employment and Wage Estimates for all occupations,

published on the Bureau of Labor Statistics website which is \$20.17. See http://www.bls.gov/oes/current/oes_nat.htm.

A.12.B. Estimated Annualized Burden Costs

Type of Respondents	Form Name	Total Burden Hours	Average Hourly Wage Rate (\$)	Total Respondent Burden Costs (\$)
Caregivers of individuals aged 2-17 years with a congenital heart defect	Congenital Heart Survey To Recognize Outcomes, Needs, and wellbeinG of KIDS	852	20.17	\$ 17,184.84
TOTAL		852	—	\$ 17,184.84

Section A.13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no costs to respondents associated with either capital and startup efforts or operation and maintenance of services for this project.

Section A.14. Annualized Cost to the Government

The average annualized cost to the Government to collect this information is \$773,031 for this 3-year OMB approval period that is requested.

		Total (\$)
Federal Government Personnel costs	CDC Project Officer/Project Lead	11,769
	CDC Project Manager	16,751
	CDC Project Coordinator	9,960
	CDC MACDP Site Lead	11,551
	CDC Collaborator	5,500
	CDC Collaborator	5,500
Contractor	Tracking and tracing to determine current contact information for participants	12,000
Other State Birth Defect Surveillance Programs	Awardee #1 (TBD)	350,000
	Awardee #2 (TBD)	350,000
Total		\$773,031

Section A.15. Explanation for Program Changes or Adjustments

This is a new data collection.

Section A.16. Plans for Tabulation and Publication and Project Time Schedule

The recruitment materials will be prepared and printed for mailing in the first through third month after OMB approval. Throughout the four to 36 months after OMB approval, recruitment materials, which include the initial letter, introductory letter, survey questionnaire, participant information sheet, \$5 gift card, and pre-addressed, stamped envelope, and reminder postcards will be mailed by the selected birth defects surveillance sites to eligible individuals. Mailings will be completed in batches, for a total of 2,556 per year. Thank you letters and subsequent \$20 gift cards will be sent to all respondents upon receipt of completed questionnaires. Data will be collected, entered, cleaned, and linked throughout the following months after surveys are sent. Finally, data analysis and dissemination of findings is expected to occur between 36 and 48 months after OMB approval.

A.16.—Project Time Schedule		
Activity	Timeframe	
Recruit Participants	Prepare and print recruitment materials for distribution	1-3 months after OMB approval
	Send survey materials (initial letter, intro letter, questionnaire, participant information sheet, gift card, pre-addressed, stamped envelope, reminder postcards) to eligible participants	4–36 months after OMB approval
	Send thank you letters and gift cards to respondents	6-36 months after OMB approval
Analyze and Report Data from Surveillance Project	Enter data from paper surveys into database	7-36months after OMB approval
	Link questionnaire data to birth defects surveillance system data	37-38 months after OMB approval
	Clean data	39-40 months after OMB approval
	Analyze data, draft reports, and present findings	40-48 months after OMB approval

Section A.17. Reason(s) Display of OMB Expiration Date Is Inappropriate

NA

Section A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.