Formative Assessment of Barriers to Transition from Adolescent to Adult for Individuals with Congenital Heart Defects

Supporting Statement – Section A

OMB No. 0920-1154

Submitted: April 12, 2017

Program Official/Project Officer

Jill Glidewell Health Scientist National Center on Birth Defects and Developmental Disabilities 4770 Buford Highway, Chamblee, GA 30341 404-498-3538 770-488-3266 <u>LypO@cdc.gov</u>

Table of Contents

Section A. Justification

- 1. Circumstances Making the Collection of Information Necessary
- 2. Purpose and Use of the Information Collection
- 3. Use of Improved Information Technology and Burden Reduction
- 4. Efforts to Identify Duplication and Use of Similar Information
- 5. Impact on Small Businesses or Other Small Entities
- 6. Consequences of Collecting the Information Less frequently
- 7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
- 8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency
- 9. Explanation of Any Payment or Gift to Respondents
- 10. Assurance of Confidentiality Provided to Respondents
- 11. Justification for Sensitive Questions
- 12. Estimates of Annualized Burden Hours and Costs
- 13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers
- 14. Annualized Cost to the Government
- 15. Explanation for Program Changes or Adjustments
- 16. Plans for Tabulation and Publication and Project Time Schedule
- 17. Reason(s) Display of OMB Expiration Date is Inappropriate
- 18. Exceptions to Certification for Paperwork Reduction Act Submissions

19.

20. Exhibits

- 21. Exhibit A.12.A Estimated Annualized Burden Hours
- 22. Exhibit A.12.B Estimated Annualized Burden Costs
- 23. Exhibit A.14 Estimated Cost to the Government
- 24. Exhibit A.16 Project Time Schedule
- 25.
- 26.
- 27.
- ---

28.

29. List of Attachments

30.

- 1) Survey instrument
- 2) Emory University: Telephone recruitment script
- 3) New York State Department of Health: Pre-notification Letter
- 4) New York State Department of Health: Introduction Letter
- 5) New York State Department of Health: Reminder Letter
- 6) New York State Department of Health: Reminder Postcard
- 7) New York State Department of Health: Thank you letter
- 8) IRB Letter
- 31.
- 32.
- 33.
- 34.
- 35.
- 36.
- 37.
- 38.
- 39.
- 40.
- 41.
- 42.
- 43.
- 44.
- 45. 46.
- <u>4</u>7.
- 48.
- 49.
- 50.
- 51.
- 52.
- 53.

54.

- 55.
- 56.
- 57.
- 58.

59. Section A – Justification

60.

1. Circumstances Making the Collection of Information Necessary

61.

62. Background

63. Congenital heart defects (CHD) are one of the most common birth defects in the United States, occurring in approximately 9 newborns per 1,000 live births or about 40,000 affected newborns per year in the US. There has been a tremendous improvement in survival over the last 5 decades for persons born with CHD. This is due to improved surgical outcomes and medical care advancements. This improved survival has increased the number of persons living with CHD who would have otherwise died in childhood (1-12). In the current era, about 85% of children born with CHD survive to adulthood (13). However, CHD is rarely, if ever, cured. Late sequelae are thought to be common, including the need for additional surgeries, development of arrhythmias, heart failure and non-cardiac complications including neurocognitive impairments. Thus, CHD should be thought of as a chronic condition with the need for frequent care and follow-up. 64.

However, it is increasingly becoming recognized that a majority of 65. adolescent/young adult CHD patients do not successfully transition from pediatric to adult CHD specialty care, despite clinical recommendations to do so. There is limited insight into patterns of healthcare use, care access and best practices for transitioning from pediatric to adult care. More than half of adolescents are lost to follow-up starting in childhood (14), re-entering care through emergency rooms at twice the national rate (15,16). Many patients fall out of care during their adolescent years or may only receive occasional care from primary care providers (rather than the recommended schedule of care from cardiac specialists). Some persons with CHD do not reemerge in healthcare settings until they develop a problem like heart failure or arrhythmias, complications which might have been prevented had they remained in cardiac specialty care. These events cause significant costs in terms of morbidity/mortality to the patient, as well as unnecessary economic costs for the healthcare system. A recent review in Canada, suggests improved survival for those who stay in adult CHD specialty care (17). In order to develop effective interventions to increase the number of persons remaining in CHD specialty care, it is important to understand why these young patients drop out of care, stay in care, or receive only intermittent care.

66. This data collection is being conducted using the Generic Information Collection
OMB No. 0920-1154. Data will be collected from Emory University and New York State
Department of Health acting in their official capacities.
67.

2. Purpose and Use of the Information Collection

69. The purpose of this formative survey (Attachment 1) is to understand current processes for transition from adolescent to adult CHD care, in order to develop educational materials aimed at improving these transition processes. Through this survey, the two funded sites will assess barriers to appropriate transition of care and parental understanding of the healthcare needs of their adolescent. The target population for this study includes parents/guardians of adolescents with CHD. The survey instrument is the same for both Emory and NYS DOH. However, their administrative methods differ. Parents of adolescents will be surveyed through the following methods: 1) Emory: a clinic-based survey completed either remotely via the internet or in patient waiting rooms on an electronic tablet, and 2) NYS DOH: a mailed survey to parents of adolescents with CHD that have been identified by the New York Congenital Malformations Registry. The results from this formative survey will be used to inform the development of educational modules/tools targeted to healthcare providers that will address key knowledge and healthcare use gaps. We plan for the survey project to be completed by December 2017 and the educational modules/tools developed and disseminated in Years 3-4. The ultimate audience for the results of this survey are clinicians, public health professionals, and stakeholders involved in CHD clinical care and the public health impact of CHD.

70. Under FOA #CDC-RFA-DD15-1506, the proposed survey will be completed by two of the funded sites, Emory University and the New York State Department of Health (NYS DOH). The purpose of the survey (Attachment is to understand current processes for transition from adolescent to adult CHD care, in order to develop educational materials aimed at improving these transition processes. Through this survey, the two funded sites will assess barriers to appropriate transition of care and parental understanding of the healthcare needs of their adolescent. The target population for this study includes parents/guardians of adolescents with CHD. The results from this survey will be used to develop educational modules targeted to healthcare providers that will address key knowledge and healthcare use gaps identified by the survey. We plan for the survey project to be completed by December 2017 and the educational modules developed and disseminated in Years 3-4. The ultimate audience for the results of this survey are clinicians, public health professionals, and stakeholders involved in CHD clinical care and the public health impact of CHD.

71. The following components are included in the survey (also see survey attachment):

A. Recent healthcare experiences: This section asks parents to discuss their recent experiences with getting or attempting to get medical care for their adolescent children with CHD.

B. Barriers to Care Questionnaire (BCQ): The BCQ is a 40-item scale designed to measure parental reports of barriers to accessing care or adhering to medical advice. The BCQ is a validated tool that has been shown to be feasible, reliable and valid for children with special healthcare needs (18). The BCQ yields a 0 to 100 score (higher scores are better, denoting fewer barriers) for the total scale and for the subscales. The BCQ subscales include the following:

• Pragmatics: logistical and cost issues that might prevent or delay appropriate utilizations

• Skills: acquired or learned strategies to navigate, manipulate, or function competently within the health care system (19)

• Expectations: parent expectations of receiving poor quality care (20, 21)

• Marginalization: the internalization and personalization of negative experiences within the health care systems (22)

• Knowledge & Beliefs: lay or popular ideas about the nature and treatment of illness, which may differ from those of mainstream allopathic medicine (19). 73.

C. Pediatric Quality of Life Inventory TM (PedsQLTM): The PedsQL TM inventory is intended to assess health-related quality of life for children with various disease diagnoses. The tool has been validated in healthy and chronically-ill populations and also for adolescent populations with CHD diagnoses (23). There is a short-form of the questionnaire (15 questions), a general module (15 questions) and a variety of disease-specific modules, of which we would focus on the cardiac module (27 questions). 74.

D. Transition from pediatric to adult cardiac care: In this section, we will include questions specific to the concerns that parents have about the transition for their children from pediatric to adult cardiac care.

75.

E. Education and resource preferences for parents of adolescents with CHD.

76. In this section, we will include questions about how parents prefer to receive educational materials and resources, as well as what technology they have access to in their homes that may facilitate access to educational materials.

77.

F. Demographic characteristics of adolescent patients and their patients: In this section, we include questions about the demographic of the adolescent patients and the parent/caregiver completing the survey.

78.

79. The data collection system consists of a 1) Emory: a clinic-based, electronic survey completed by the parent/guardian of an adolescent, either remotely via the internet or in-person in patient waiting rooms using an electronic tablet; 2) NYS DOH: a mailed,

paper survey to parents/guardians of adolescents with CHD that have been ascertained from the New York Congenital Malformations Registry. The content of the survey is the same for both Emory University and NYS DOH and has been designed to assess barriers to transition from adolescent to adult care. See site-specific data collection methodologies below.

80.

81. <u>Emory University</u>

82. This formative survey will be conducted at multiple clinic locations of the Congenital Heart Center of Georgia, a combined effort of the Sibley Heart Center, Children's Healthcare of Atlanta and Emory Adult Congenital Heart Center. This collaboration currently serves greater than 90% of children and adults with CHD in the 5-county metro-Atlanta area. This survey will be conducted at all of the 22 Sibley Heart Center clinics in Georgia. Each of these locations is a standard medical/clinical setting, consisting of a waiting room/area and patient exam rooms. At the metro-Atlanta based clinics, the survey may be conducted either remotely via internet by the participant or in the waiting room of the Sibley Heart Center clinic. For those clinics located outside of the metro-Atlanta region, participants will be asked to participate remotely from wherever they may have internet access.

83. <u>Recruitment:</u> Data will be collected from parents/guardians of adolescent CHD patients attending any of the 22 Sibley Heart Center clinics in Georgia. Parents/Guardians will be recruited based on the appointment logs of the Sibley clinic locations. Each week, a member of the project team will review the patient appointment logs for the participating clinics. Adolescent patients on the log (ages 11-17) with a diagnosis of congenital heart defect will be identified and contact information for the patient's parent/guardian(s) will be collected from the medical records database. A member of the project team will contact the parent/guardian via telephone (Attachment 2) to inquire whether he/she would be willing to participate in the survey. Each parent/guardian will be contacted three times. If a parent/guardian cannot be reached after 3 tries, he/she will be removed from the initial contact list (he/she may still be approached in-person in the clinical setting).

84. Upon reaching the parent/guardian via telephone, a member of the project team will explain the purpose of the survey and ask the parent/guardian if he/she would be willing to participate in the survey. If the parent/guardian responds affirmatively, the project team member will ask for a valid email address and will email the parent/guardian a participation link for the study and a token/password that may be

only used once to access the secure link. Parents/guardians attending clinics outside of the metro-Atlanta region will only be provided the option of completing the survey remotely via internet. Parents/guardians attending the metro-Atlanta clinics will be will be given the option to complete the survey prior to the scheduled appointment or may complete the survey while waiting in the waiting room for the appointment scheduled that week.

85. Prior to each study day in the metro-Atlanta clinics, a member of the project team will review the eligible patients scheduled for the day and will check the project database to determine whether the parent/guardian has completed the survey yet. Once parents/guardians arrive in the waiting room, a project team member will approach any parents/guardians that have not completed the survey and ask them if they would like to do so at that time. If the parent/guardian agrees to participate in the survey, the team member will provide a brief overview of the survey and consent process and will give the parent/guardian a paper consent form and an electronic tablet to complete the survey.

86. <u>Data Collection Procedures:</u> Data for the survey will be collected via REDCap online (either remotely via web link or on an electronic tablet). REDCap is a secure web application for building and managing online surveys and databases. For remote completion, the front page of the survey will provide a brief description of the survey (mirroring what the team member will have told the participant on the telephone) and a consent form which will be completed electronically. Due to Emory University rules, participants completing the survey in-person in the clinic setting will be asked to complete a paper consent form. Upon signing the informed consent, the parent will complete the survey on the tablet. It is estimated that completion of the consent form and the survey will take approximately 15-20 minutes.

87. New York State Department of Health

88. The NYS DOH will be using the New York State Congenital Malformations Registry (CMR) to identify a cohort of 11-17 years olds (as of July 1st, 2017) with congenital heart defects (CHD) whose residence at birth was in one of the eleven CHD surveillance counties (Alleghany, Bronx, Cattaraugus, Chautauqua, Erie, Genesee, Monroe, Niagara, Orleans Westchester, Wyoming) for the previously mentioned project (FOA DD1501506). Data from the New York State Statewide Planning and Research Cooperative System (SPARCS) will be merged with data from the CMR to exclude individuals who do not meet the CHD case definition. Specifically, individuals with isolated atrial septal defects, ventricular septal defects, and patent/persistent ductus arteriosus who did not have corrective surgery within their first five years of life will be excluded. Adolescents who

are not living at the time the cohort is identified will also be excluded. Please refer to the accompanying adolescent transition survey flowchart to better visualize the cohort selection process.

89. The target population for this study includes parents/guardians of adolescents with CHD in the cohort. For budgetary reasons, 1000 adolescents with CHD will be randomly selected from the original cohort. The parents of those adolescents will be surveyed. NYS DOH aims to survey one parent/guardian for each of the adolescents. Current mailing addresses will be obtained using records provided by the New York State Immunization Information Service (NYSIIS), a registry containing immunization history and accompanying contact information for individuals under the age of 19 in New York. In cases where an updated address for the adolescent cannot be found using NYSIIS, we will use the LexisNexis® Accurint® tracing tool. We will trace adolescents directly if they are between the ages of 13 and 17 and we will trace the mothers of the adolescents if the adolescents are between the ages of 11 and 12 because Accurint does not store any information for individuals under the age of 13 or older. If the mother is determined to be deceased, we will trace the father. Parent information to be used for tracing will be obtained using the Congenital Malformations Registry.

90. A pre-notification letter (Attachment 3) will be mailed to one parent for each adolescent one week prior to the survey instrument (Attachment 1) mailing, informing them of the nature of the survey and requesting their participation (Attachment 4). The initial survey mailing will include a cover letter (Attachment 4), the survey instrument, and a pre-addressed, postage-paid envelope for returning the survey to the New York State Department of Health. One week after the initial survey mailing each parent will receive a reminder postcard thanking (Attachments 6, 7) those who have responded and reminding those who have not to do so. One month after the initial survey mailing, we will send a second survey mailing to non-responders with a cover letter, survey instrument, and pre-addressed, postage-paid envelope for returning the completed survey instrument. At the conclusion of the survey administration period, a thank you letter and a \$10 gift card will be sent to all survey respondents. All contact with survey participants will be made through mail. All surveys will be self-administered.

3. Use of Improved Information Technology and Burden Reduction 91.

92. **Emory University:** Data for the survey will be collected via REDCap online (either remotely via web link or on a tablet). REDCap is a mature, secure web application for building and managing online surveys and databases. REDCap provides an encrypted, backed-up place to store the data and facilitates compliancy with HIPAA policies and

procedures. Data collected in the survey will automatically populate a REDCap database for the purposes of analysis. Only de-identified data will be downloaded from the REDCap data base. All data captured for this study will be automatically uploaded to the secure Emory University REDCap system.

93. **NYS DOH:** The NYS DOH site will employ a paper-only survey process. As surveys are returned to the NYS DOH, members of the project team will manually enter survey responses into a Microsoft Access database (de-identified data only).

94.

4. Efforts to Identify Duplication and Use of Similar Information

95.

96. Information addressing transition perceptions and preparedness among adolescents with CHDs in the United States is lacking. A limited number of studies have examined adolescent thoughts about transition for the CHD population. Even fewer studies have examined perceptions of transition in a racial/ethnically and socioeconomically diverse CHD patient population. (24, 25).
97.

5. Impact on Small Businesses or Other Small Entities

98. No small businesses will be involved in this data collection.99.

6. Consequences of Collecting the Information Less Frequently

100.

101. This request is for a one time data collection. There are no legal obstacles to reduce the burden. This survey will aid in understanding current processes in transitioning from adolescent to adult care. Data will be used to assess barriers to appropriate transition of care and parental understanding of the healthcare needs of their adolescent. Without this survey data, knowledge gaps will not be identified. Furthermore, the sites will not have adequate current information to develop effective educational materials for healthcare providers aimed at improving these transition processes. 102.

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

103. There are no special circumstances with this information collection package. This request fully complies with the regulation 5 CFR 1320.5 and will be voluntary.104.

- 8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency
- A. The Federal Registry Notice was published for this collection on July 18, 2016, Vol. 81, No. 137, pp. 46680. (See Attachment 2) No public comments were received. 105.
- B. Partners & Collaborators:

- a.Centers for Disease Control & Prevention, National Center on Birth Defects and Developmental Disabilities, Division of Congenital and Developmental Disorders, Birth Defects Branch, Surveillance Team
- b. Emory University School of Medicine, Emory School of Public Health, Emory School of Nursing, Emory University, Sibley Heart Center
- c.New York State Department of Health, Stanford University (Consulting Cardiologist), Montefiore Medical Center

107.

9. Explanation of Any Payment or Gift to Respondents

108. As a token of appreciation, an incentive will be provided to participants of the survey. Emory University will provide a \$10 e-gift card upon completion of the survey. Upon completion/submission of the survey, participants will be asked to confirm an email address that they would like the incentive e-gift card to be emailed to and told that they will receive the gift card within 5 days. Surveys will not be considered complete if greater than 10 questions have been left blank/skipped. At the end of each work week, our study coordinator will batch email e-gift cards to the participants. All incentive e-gift cards will be provided electronically.

109. As a token of appreciation and a method to increase NYS DOH response rates, a \$10 gift card will be provided to participants upon completion of the survey.110.

10. Assurance of Confidentiality Provided to Respondents

111. This submission has been reviewed by the NCBDDD Privacy Officer, who has determined that the Privacy Act does not apply because no personal identifiable information will be collect. Data that is collected will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law. This data collection is surveillance and is not research involving human subjects. 112.

113. <u>Emory University</u>: To protect participant information, Emory will use a secure REDCap system and server, such that information entered in the survey automatically populates the REDCap database via a secure connection. Survey questions/data will not be kept on the physical tablets used for data collection. The project protocol (as approved by Emory IRB) also includes physical and procedural arrangements for the security of the data and protection of the identities of the respondents. All weekly screening logs, in which potential participants will be identified, will be shredded after the completion of the week's appointments. Only de-identified data will be downloaded from the REDCap database for the purposes of analysis. While some demographic factors (age, race, insurance) will be included in the data for analysis, any name and address information will be excluded. Once data is exported from the REDCap system for analysis, all electronic text or data files will be maintained on password-protected project computers at Emory University and will be available only to project staff. For the purposes of analysis, only de-identified data will be downloaded out of the REDCap database for use with statistical packages (SAS, STATA, SPSS).

114. The information provided by participants will be treated in a secure manner, and will not be disclosed to anyone except for the members of the project team conducting the study. Respondents will be assured that every effort will be made to keep their responses secure. Paper copies of consent forms will be retained by the project coordinator and transferred to a locked file cabinet in a locked study office at the end of each day of data collection.

115. <u>NYS DOH</u>: The NY Bureau of Environmental and Occupational Epidemiology routinely handles personal data and strictly adheres to the secure data security practices of the NYS DOH. All data will be maintained on password-protected computers and on servers with section-specific and project-specific password-protected folders. Returned hard copy surveys will be stored in locked filing cabinets and will only be accessible to the members of the project team at NYS DOH. The team will use identifiable data to contact survey participants, but will not collect any personally-identifying information on the survey instrument itself. Instead, NYS DOH will assign each potential participant an ID number that will be used on the survey and with which all responses will be associated. The crosswalk between identifiable information and the assigned ID number will be stored in a password protected Microsoft Access database. Identifiable information will be retained to distribute survey mailings and link survey responses to information about the severity of the child's CHD. Any reports developed using this survey will present aggregated data to protect personal information of both parent and child. When the project is complete, all individual-level identifiable information will be destroyed.

116.

117. Privacy Impact Assessment

118. *Informed Consent:* If parents/guardians indicate interest in participating in the survey when contacted via telephone, the project team member will explain the general scope of the survey and the time required.

119. For those participants completing the survey remotely, the first webpage that the parent will access remotely will include an informed consent coversheet that describes the purpose of the survey, the administration of the survey and any risks/benefits associated with completing the survey. Participants will be asked to digitally sign the consent cover sheet indicating that they are willingly participating

in the survey. Participants will also be provided with a contact number for a study staff member in case of any questions/concerns regarding the informed consent document or the administration of the survey itself.

- 120. For those participants completing the survey in the waiting room, the project team member will approach interested parents and ask them to sign a paper consent form. Upon completing the consent form, the project team member will present an electronic tablet) to the parent so that they can complete the survey. The team member will remain available (in the waiting room) to participants to answer any questions related to the consent process or any issues with administration of the survey.
- 121. As surveys are returned, members of the Congenital Heart Defects Surveillance Team will manually enter survey responses into a Microsoft Access database. The hardcopy surveys will be stored in a locked filing cabinet. Data collected will not be accessible to anyone outside of the Congenital Heart Defects Team.

122. **11.** Institutional Review Board (IRB) and Justification for Sensitive Questions

123. IRB Approval

124. This data collection is surveillance and is not research involving human subjects (Attachment 7).

125.

126. Sensitive Questions

127. No information will be collected that are of personal or sensitive nature.

128.

129. **12.** Estimates of Annualized Burden Hours and Costs

130. It is estimated that Emory University will have 300 respondents with one response per respondent. The survey is estimated to take 20 minutes to complete. Therefore, at 20 minutes per survey for 300 respondents, the total burden hours is estimated to be 100 hours. The median hourly wage rate is estimated to be \$17.40 based on the most recent (May 2015) National Occupational Employment and Wage Estimates for all occupations, published on the Bureau of Labor Statistics website

(http://www.bls.gov/oes/current/oes_nat.htm).

131. It is estimated that New York site will have 800 respondents with one response per respondent. The survey is estimated to take 20 minutes to complete. Therefore, at 20 minutes per survey for 800 respondents, the total burden hours is estimated to be 267 hours. The median hourly wage rate is estimated to be \$17.40 based on the most recent

(May 2015) National Occupational Employment and Wage Estimates for all occupations, published on the Bureau of Labor Statistics website

(<u>http://www.bls.gov/oes/current/oes_nat.htm</u>). The total burden hours is 367.

132.

133.

134. <u>Table A.12.A</u>:

135. Estimated Annualized Burden Hours and Costs to Respondents – PSR Survey

136. Type of Respo ndent	137. No. of Res pon dent s	138. N o. of Respon ses per Respon dent	139. Avera ge Bu rd en pe r Re sp on se (in ho ur s)	140. Tot a l B u r d e n H o u r s	141. Ho r l y W a g e R a t e	142. Total Res pon den t Cos ts
143. Parent of adoles cent with conge nital heart defect (Emor y site)	144. 300	145. 1	146. 20/60	147. 100	148. \$1 7 4 0	149. \$1,740
150. Parent of	151. 800	152. 1	153. 20/60	154. 267	155. \$1	156. \$4,645.

adoles						
cent						
with						
conge					7	
nital						80
heart					4	80
defect					0	
(New						
York						
site)						
157.	158.	159.	160.	161.	162.	163.
тотис	1100			0/8		A (00E

165. The annualized cost burden is shown in Table A.12.A. The median hourly wage rate is based on the most recent (May 2015) National Occupational Employment and Wage Estimates for all occupations, published on the Bureau of Labor Statistics website which is \$17.40. See http://www.bls.gov/oes/current/oes_nat.htm.

166.

167. **13.** Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

168. There are no other costs to respondents or record keepers.

169. There will be no direct costs to the respondents other than their time to participate in each survey.

170.

171.

172.14. Annualized Cost to the Government

173. The average annualized cost to the Federal Government to collect this information is \$8,975. The federal government personnel estimate is based on the cost of the lead Health Scientist and Medical Officer who are responsible for the management and oversight of the project (See Table A.14).

174.

175. **Table A.14:** Estimated Annualized Cost to the Federal Government

		177. T
		otal (\$)
F 180	Hoalth	181
	ientist (GS-	101.
	F 180. Sci	F 180. Health Scientist (GS-

Govern	13a	t 0.05	182	\$
oovern				
ment	FIE	2)	5,775	
179. P ersonn	184. al C	Medic Officer (GP-	185. 186.	\$
ercosts	FTE	at 0.02 E)	3	,200
	188.		189.	
190.	191.		192.	
193.	194.		195.	
196. T	197.		198.	
Annual ized Cost to Govern ment			199. 8	\$,975

201.

202. 15. Explanation for Program Changes or Adjustments

203. This is a new information collection request, therefore program changes and adjustments do not apply.

204.

205.

206. 16. Plans for Tabulation and Publication and Project Time Schedule207.

	214. Date		215.	Task	216.	St
213.	Emory Site:					
212.						
211.						
210.						
208.	<u>Project Time</u> 209	<u>e Schedule</u>				

		atus
217. Septe mber 2016	 Submit IRB application Initial IRB application approved 	218. C omplete 219. C omplete
220. Octob er 2016	• Contact clinic administrators to discuss implementation of survey in clinical sites	221. C omplete
222. Nove mber 2016	 Submit IRB amendment to include survey incentive IRB amendment approved Develop RedCap survey instrument for data capture Develop RedCap database 	223. C omplete 224. C omplete 225. C omplete 226. C omplete 227. C omplete
228. Febru ary 2017	• Compile list and contact information for eligible patients from clinics	229.
230. March 2017	 Build Access database to store survey mailing addresses, survey tracking, incentive tracking information Populate Access database 	231.
232. May 2017	Receive OMB approval	233.
234. June 2017	 Finalize RedCap database build Purchase/prepare incentives 	235.
236. July - December 2017	 Recruitment (reviewing weekly clinic logs, telephone contacts) Data collection (completing of online survey) Provision of incentives 	237.
238. Januar y 2018	• Data cleaning	239.
240. Febru	Survey analysis	241.

ary- March	•	Development of educational modules/tools	
2018			

242. New York site:

243. Date	244. Task	245. St
		atus
246. Septe	 Enumerate initial adolescent cohort using 	247. C
mber 2016	CMR and SPARCS data	omplete
248. Octobe	 Submit IRB application 	249. C
r 2016		omplete
250. Novem	 Apply for access to New York State 	251. C
ber 2016	Immunization System (NYSIIS) data	omplete
252. Decem	 Receive IRB approval 	253. C
ber 2016	 Merge updated address information from 	omplete
	NYSIIS to determine mailing addresses for	
	the adolescents with CHDs	
254. Januar	 Using LexisNexis® Accurint®, trace the 	255.
y 2017	adolescents with CHDs in our cohort who	
	were not found in NYSIIS. Obtain up to date	
	mailing information.	
256. Februa	• Take a random sample of 1000 adolescents	257.
ry 2017	with CHDs	
258. March	Build Access database to store survey	259.
2017	mailing addresses, survey tracking	
	information, and survey responses	
260. April 2017	Continue building Access database	261.
262. May	Receive OMB approval	263.
2017	Update Access database with mailing	
	address information for the sample	
264. June	Prepare mailings	266.
2017	 Mail pre-notification letters 	
	(June 24, 2017)	
	 Mail initial survey packets 	
	265. (June 30, 2017)	
267. July	 Mail reminder postcards 	268.
2017	(July 7, 2017)	
	 Mail second survey packets to non- 	
	respondents (July 31, 2017)	
	Manually enter survey responses in Access	
	database as they are received	
269. August	 Mail thank you letters and gift cards to 	270.
2017	respondents	

	 (August 30, 2017) Manually enter survey responses in Access database as they are received 	
271. Septe	Data cleaning	272.
mber 2017		
273. Octobe	Data cleaning	274.
r 2017		
275. Novem	Survey analysis	276.
ber 2017		
277. Decem	Survey analysis	278.
ber 2017		
279. Februa	Survey analysis	280.
ry- March	• Development of educational modules/tools	
2018		

282.

283. 17. Reason(s) Display of OMB Expiration Date is Inappropriate

284. The OMB Expiration Date will be displayed.

285.

286.

287. 18. Exceptions to Certification for Paperwork Reduction Act Submissions

288. There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

289.

- 290.
- 291.
- 292.
- 293.
- 294.
- 295.
- 296. 297.
- 298.
- 299.
- 300.
- 301.
- 302.
- 303.
- 304.
- 305.

- 307.
- 308.
- 309.
- 310.
- 311.
- 312.

313. **References**

- 314.
 - 1. Knott-Craig CJ, Elkins RC, Lane MM, et al. A 26-year experience with surgical management of tetralogy of Fallot: risk analysis for mortality or late reintervention. Ann ThoracSurg 1998;66:506-11.
 - 2. Alexiou C, Mahmoud H, Al-Khaddour A, et al. Outcome after repair of tetralogy of Fallot in the first year of life. Ann ThoracSurg 2001;71: 494-500.
 - 3. Bacha EA, Scheule AM, Zurakowski D, et al. Long-term results after early primary repair of tetralogy of Fallot. J ThoracCardiovascSurg 2001;122:154-61.
 - 4. BolRaap G, Meijboom FJ, Kappetein AP, et al. Long-term follow-up and quality of life after closure of ventricular septal defect in adults. Eur J CardiothoracSurg 2007;32:215-9.
 - 5. Bouchart F, Dubar A, Tabley A, et al. Coarctation of the aorta in adults: surgical results and long-term follow-up. Ann ThoracSurg 2000;70:1483-8 [discussion 1488-9].
 - 6. Pillutla P, Shetty KD, Foster E. Mortality associated with adult congenital heart disease: trends in the US population from 1979 to 2005. American Heart Journal. 158 (5): 874-879.
 - 7. Cohen M, Fuster V, Steele PM, et al. Coarctation of the aorta. Long-term follow-up and prediction of outcome after surgical correction. Circulation 1989;80:840-5.
 - 8. GuntherothWG.Coarctation of the aorta:long-termfollow-upand prediction of outcome after surgical correction. Circulation 1990;81: 1441.
 - 9. HaasF,WottkeM,PoppertH,etal.Long-termsurvivalandfunctional follow-up in patients after the arterial switch operation. Ann ThoracSurg 1999;68:1692-7.
 - 10. Hager A, Kanz S, Kaemmerer H, et al. Coarctation Long-term Assessment (COALA): significance of arterial hypertension in a cohort of 404 patients up to 27 years after surgical repair of isolated coarctation of the aorta, even in the absence of restenosis and prosthetic material. J ThoracCardiovascSurg 2007;134:738-45.
 - 11. MeijboomF,SzatmariA,UtensE,etal.Long-termfollow-upafter surgical closure of ventricular septal defect in infancy and childhood. J Am CollCardiol 1994;24:1358-64.
 - 12. NollertG,FischleinT,BouterwekS,etal.Long-termsurvivalin patients with repair of tetralogy of Fallot: 36-year follow-up of 490 survivors of the first year after surgical repair. J Am CollCardiol 1997;30:1374-83.
 - 13. Inglessis I, Landzberg MJ. Interventional catheterization in adult congenital heart disease. Circulation 2007;115:1622-33.

- 14. Mackie AS, Ionescu-Ittu R, Therrien J, Pilote L, Abrahamowicz M, Marelli AJ. Children and adults with congenital heart disease lost to follow-up: who and when? *Circulation* 2009;120:302-9.
- 15. Knauth A, Verstappen A, Reiss J, Webb GD. Transition and transfer from pediatric to adult care of the young adult with complex congenital heart disease. *Cardiol Clin* 2006;24:619-29, vi.
- 16. Williams RG. Transitioning youth with congenital heart disease from pediatric to adult health care. *J Pediatr* 2015;166:15-9.
- 17. Marelli AJ, Mackie AS, Ionescu-Ittu R, Rahme E, Pilote L. Congenital heart disease in the general population: changing prevalence and age distribution. *Circulation* 2007;115:163-72.
- 18. Seid, M. Barriers to Care and Primary Care for Vulnerable Children With Asthma. Pediatrics. 2008. 122: 994-1002
- 19. Soho E, Seid M. Cultural Issues in Health Services Delivery: What Kind of "Competence" is Needed and from Whom? Annals of Behavioral Science and Medical Education. 2003. 9: 97-100
- Doescher MP, Saver BG, Franks P, Fiscella K. Racial and Ethnic Disparities in Perceptions of Physician Style and Trust. Archives of Family Medicine. 2009. 9: 1156-1163,
- 21. Crain EF, Kercsmar C, Weiss KB et al. Reported Difficulties in Access to Quality Care for Children with Asthma in the Inner City. Archives of Pediatric and Adolescent Medicine. 1998. 152:333-339.
- 22. Kreps GL. Communicating to Promote Justice in the Modern Health Care System. Journal of Health Communication. 1996. 1:99-109.
- 23. Uzark K, et al. Quality of life in children with heart disease as perceived by children and parents. Pediatrics. 2008. 121(5):e1060-7
- 24. Lopez KN, Karlsten M, Bonaduce De Nigris F, King J, Salcicciolo K, Jiang A, et al. Understanding age-based transition needs: perspectives from adolescents and adults with congenital heart disease. Congenit Heart Dis. 2015;10(6):561-71.
- 25. Norris MD, Webb G, Drotar D, Lisec A, Pratt J, King E, et al. Prevalence and patterns of retention in cardiac care in young adults with congenital heart disease. J Pediatr. 2013;163(3):902-4 e1. 315.
- 316.
- 317.
- 318.
- 319.
- 320.
- 321.