

ICR Non-Substantive CHANGE REQUEST MEMO, May 25, 2023

Population-based Surveillance of Outcomes, Needs, and Well-being of Children and Adolescents
with Congenital Heart Defects

OMB NO. 0920-1382

Expiration Date 1/31/2026

Summary:

We aim to field recruitment materials and surveys with the modifications described below by June 23, 2023.

- Names of funded sites have been added to Att 3.
 - o Reason: Since OMB approval, sites funded by CDC to collaborate on this project have been selected. We have replaced the placeholder for sites names with the actual names of sites.
- The initial letters and intro letters (Atts 17-18, 20, 30, 33-34) are now addressed to "Parent or Guardian of [Child's name]" rather than to "[Parent's name]"
 - o Reason: Sites will know the child's name for whom the survey is intended but may not know which parent or guardian would prefer to take the survey. Addressing these letters to a specific parent or guardian name might accidentally cause feelings of exclusion among potential participants.
- Edits to survey instrument, including reordering questions, minor edits to phrases in existing questions, and adding two new questions regarding household language and expectations for the child's future.
 - o After consulting with sites and collecting feedback from 6 parents of children with heart defects, minor edits were made to the survey instrument to improve sensitivity and clarity of the survey instrument.
- Recruitment materials and surveys will be offered in Somali (Att 21, 23, 26, 29-30) in addition to English and Spanish.
 - o Reason: Some sites have substantial Somali-speaking populations in their catchment areas. Therefore, this project will offer recruitment materials and survey in Somali to improve accessibility and representativeness.
- Participants will have the option to take the survey online in addition to paper (Att 24, 25). Because the final survey question collects PII (email) and therefore cannot be completed online, the final survey question will be sent as a follow-up mailing (Att 27, 28) to online participants.
 - o Reason: This change will improve accessibility, ease of taking the survey, and representativeness. The online survey will reduce burden by incorporating automatic skip patterns to save the participant time and effort in taking the survey.
- Families will have the opportunity to opt-out of the project via a postage-paid postcard (Att 31).
 - o Reason: This will prevent families from receiving unwanted survey mailings and will also save sites time and resources to conduct those mailings.
- One site will recruit and administer the survey by phone for those who may have trouble taking a paper/online survey or otherwise prefer to participate over the phone (Att 32-35).
 - o Reason: Added upon this site's request, this change will improve survey accessibility and representativeness.

Attachments (Those in bold font have been added or edited since OMB approval):

Original Attachments:

Attachment 1: Authorizing Legislation
Attachment 2: 60-Day Federal Register Notice
Attachment 3: List of Sites
Attachment 4: Survey English (paper)
Attachment 5: Survey Spanish (paper)
Attachment 6: Public Comment 1
Attachment 7: Public Comment 2
Attachment 8: Public Comment 3
Attachment 9: Public Comment 4
Attachment 10: Public Comment 5
Attachment 11: Thank You Letter English
Attachment 12: Thank You Letter Spanish
Attachment 13: Research Determination
Attachment 14: Privacy Impact Assessment
Attachment 15: English Participant Info Sheet
Attachment 16: Spanish Participant Info Sheet
Attachment 17: English Intro Letter
Attachment 18: Spanish Intro Letter
Attachment 19: Survey Question Crosswalk
Attachment 20: Initial Letter
Attachment 21: Reminder Postcards
Attachment 22: References

New Attachments:

Attachment 23: Survey Somali (paper)
Attachment 24: Survey English (online)
Attachment 25: Survey Spanish (online)
Attachment 26: Thank You Letter Somali
Attachment 27: Follow Up Question English
Attachment 28: Follow Up Question Spanish
Attachment 29: Somali Participant Info Sheet
Attachment 30: Somali Intro Letter
Attachment 31: Opt-out postcard
Attachment 32: MA Phone Script
Attachment 33: MA Initial Letter
Attachment 34: MA Introductory Letter
Attachment 35: MA Participant Information Sheet

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Background & Justification:

Proposed changes to this project will result in improved sensitivity of survey recruitment materials, improved accessibility of survey materials, improved data quality, and better representativeness of project findings.

Effect of Proposed Changes on Current Approved Instruments:

- *Show a crosswalk of the changes in table below*

Form	Current/Question Item	Requested Change
Congenital Heart Survey To Recognize Outcomes, Needs, and wellbeinG of KIDS	Any mention of "heart problem"	Change "heart problem" to "heart condition" throughout instrument
	Any mention of "his or her" or "him or her"	Change to "they", "them" or "their"
	Has this child ever had surgery for the heart problem they were born with?	Has this child ever had surgery for the heart condition they were born with? Heart surgery will result in scars on the middle of the chest, side, or back.
	When this child was first diagnosed with a heart problem, do you feel like you were provided enough information about what this meant for this child?	When this child was first diagnosed with a heart condition, were you provided enough information on what this meant for their emotional, social and physical health?
	Has a doctor or other health care provider talked with you about when this child will need to see heart doctors who treat adults?	Has a doctor or other health care provider talked with you about when this child will need to see heart doctors who treat adults (adult congenital heart cardiologist or adult cardiologist)?
	Has a doctor or other health care provider EVER told you that this child has... Intellectual disability (formerly known as Mental Retardation)	Has a doctor or other health care provider EVER told you that this child has... Intellectual disability
	DURING THE PAST 12 MONTHS, about how many days did this child miss school because of illness or injury?	DURING THE PAST 12 MONTHS, about how many days did this child miss school because of their heart condition, illness, or injury?
	Has this child EVER had any of the following special education or early intervention plans? (Select all that apply) b. Individualized Education Plan or IEP (used for special education services in children 3 or older)	Has this child EVER had any of the following special education or early intervention plans? (Select all that apply) b. Individualized Education Program or IEP (used for special education services in children 3 or older)
	Is this child CURRENTLY covered by any of the following types of health insurance or health coverage plans? c. Medicaid, Medical Assistance, or any kind of government assistance	Is this child CURRENTLY covered by any of the following types of health insurance or health coverage plans? c. Medicaid (including MassHealth, MinnesotaCare, PeachCare, or

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	plan for those with low incomes or a disability [Yes/No]	Georgia Families), Medical Assistance, or any kind of government assistance plan for those with low incomes or a disability [Yes/No]
	Please select the statement that best describes this child regarding the COVID-19 vaccine: a. This child has received at least two doses of vaccine for COVID b. This child has received one dose but not all recommended doses of vaccine, and I intend for them to receive a second dose c. This child has received one dose of vaccine, and I do not intend for them to receive a second dose d. This child has not received any vaccine for COVID-19 e. Other	Please select the statement that best describes this child regarding the COVID-19 vaccine: a. This child has received all recommended doses of vaccine for COVID-19 b. This child has received some but not all recommended doses of vaccine, and I intend for them to receive all recommended doses c. This child has received some but not all recommended doses of vaccine, and I do not intend for them to receive all recommended doses d. This child has not received any vaccine for COVID-19 e. Other
	What are your reasons for choosing not to get this child fully vaccinated?	What are your reasons for choosing not to get this child fully vaccinated for COVID-19?
	[None]	What is the primary language spoken in the household? a. English b. Spanish c. Somali d. Other, specify _____
	[None]	What expectations do you have for this child in the future?
	What is the biggest concern you have about this child's future?	What concerns do you have for this child in the future?

Effect on Burden Estimate:

- No change to burden estimate

Form	Approved Burden	Requested Burden
Congenital Heart Survey To Recognize Outcomes, Needs, and wellbeinG of KIDS	Respondents: 2556 Hours: 852 Costs: \$ 17,184.84	Respondents: 2556 Hours: 852 Costs: \$ 17,184.84
Total		
	Respondents: 2556 Hours: 852 Costs: \$ 17,184.84	Respondents: 2556 Hours: 852 Costs: \$ 17,184.84