

ICR Non-Substantive CHANGE REQUEST MEMO

ICR Title

OMB NO. 0920-1433

Expiration Date 05/31/2027

Summary:

The screener and discussion guide for the Congenital Heart Defects (CHD) focus groups have been modified to accommodate an expanded CHD audience made up of those who have recently been in cardiac care but have experienced a gap in care in the past. This audience will be recruited for their own separate focus groups as part of the original 16 focus groups planned for individuals with CHD.

- Updated CHD Screening Tool
 - The previous version screened out individuals who had received cardiac care within the past 3 years. The screener will now allow these individuals to be recruited if at some point in the past, they went 3 or more years without receiving care.
 - This change expands the pool of potential participants to draw from which will bolster recruitment efforts. Hearing from these individuals about their experiences with an extended gap in care aligns with the original project goals and will be valuable perspectives to include.
- Created a new version of the CHD Focus Group Discussion Guide for the new “Recently In Care” audience
 - Some of the language in the guide has been updated to be appropriate for the new audience and their historical gap in care. Additionally, a few questions have been modified or added to explore their reasons for leaving cardiac care, factors that lead to their return to care, and experiences transitioning back to care. The overall structure and length of the guide remains unchanged from the original.

Attachments:

- Attachment 3: CHD Screening Tool
- Attachment 36: CHD Focus Group Discussion Guide – Recently in Care (New)

Background & Justification:

Previously, the CHD focus groups were only being conducted with individuals with CHD who had not received cardiac care in the previous 3 or more years. The changes outlined here would expand the CHD recruitment criteria to include individuals who experienced a gap in cardiac care of 3 or more years at any point in the past. This would allow individuals who have recently received care to participate as long as they previously experienced a gap in care.

There are two main benefits to this change:

1. Since CHD participants are exclusively being recruited from a list of individuals who have participated in previous CDC data collections on this topic (CH STRONG), fully recruiting enough participants to fill the 16 originally planned focus groups has been difficult. Expanding the recruitment parameters to include those who've experienced a gap in care in the past will help bolster recruitment efforts.
2. This expanded audience offers an opportunity to learn from individuals who have returned to care about their experiences with the process and the factors that influenced their return to care. These align well with the core goal of the project which is to obtain firsthand perspectives on the types of care adults with MD, SB, and CHD receive with a special focus on medical care (including specialist care) and barriers and facilitators to accessing, receiving, or reengaging in care as well as their experiences around the transition from pediatric to adult care.

These changes will not affect the total number of focus groups conducted nor will it increase the burden associated with the project.

ICR Non-Substantive CHANGE REQUEST MEMO

Effect of Proposed Changes on Current Approved Instruments:

Form	Current/Question Item	Requested Change
Attachment 3: CHD Screening Tool	<p>Q5 - When was the last time you saw a cardiac specialist or healthcare provider who specializes in cardiac care or care of your heart?</p> <ul style="list-style-type: none"> a. Less than 6 months ago TERMINATE b. 6 months to 11 months ago TERMINATE c. 1 to 2 years ago TERMINATE d. 3 to 5 years ago e. More than 5 years ago f. Never TERMINATE g. Don't know or can't remember TERMINATE 	<p>Q5 - When was the last time you saw a cardiac specialist or healthcare provider who specializes in cardiac care or care of your heart?</p> <ul style="list-style-type: none"> a. Less than 6 months ago TERMINATE b. 6 months to 11 months ago TERMINATE c. 1 to 2 years ago TERMINATE d. 3 to 5 years ago e. More than 5 years ago f. Never TERMINATE g. Don't know or can't remember TERMINATE <p><u>IF Q5 = a, b, OR c, CODE RESPONDENTS AS "RECENTLY IN CARE"</u></p> <p><u>IF Q5 = d OR e, CODE RESPONDENTS AS "NOT RECENTLY IN CARE"</u></p>
	New question.	<p><u>Q6 - IF Q5 = a, b, c What is the longest stretch of time you have gone without seeing a cardiac specialist or healthcare provider who specializes in cardiac care or care of your heart?</u></p> <ul style="list-style-type: none"> a. <u>Less than 6 months</u> TERMINATE b. <u>6 months to 11 months</u> TERMINATE c. <u>1 to 2 years</u> TERMINATE d. <u>3 to 5 years</u> e. <u>More than 5 years</u> f. <u>Don't know or can't remember</u> TERMINATE
Attachment 36: CHD Focus Group Discussion Guide	Throughout - Language changes	Wording has been modified throughout to be appropriate for an audience that has been out of cardiac care for 3 or more years in the past, but may have recently

ICR Non-Substantive CHANGE REQUEST MEMO

		<p>received care.</p> <p>For example, in the Return to Cardiac Care section: <i>As we mentioned earlier, you have all been invited to this focus group because <u>at some point in the past,</u> you have had not been to a cardiac specialist for 3 or more years. not been recently seen by a cardiac specialist to get a check-up on your heart.</i></p>
	<p>Q11 - Could you share your reasons for not receiving cardiac care since then?</p> <p>a. How did the prospect of seeking cardiac care make you feel?</p>	<p>Moved from <i>Cardiac Healthcare Experience</i> to <i>Return to Cardiac Care</i> section.</p> <p>Q14 - Could you share your reasons for not receiving cardiac care during that period?</p> <p>a. How did you feel about not receiving care?</p>
	<p>Q12 - Have you ever tried to get cardiac care, but couldn't?</p> <p>a. Can you describe any barriers you might have encountered related to getting cardiac care in the past?</p>	<p>Moved from <i>Cardiac Healthcare Experience</i> to <i>Return to Cardiac Care</i> section.</p> <p>Q15 - Did you ever try to get cardiac care during this time, but couldn't?</p> <p>b. Can you describe any barriers you might have encountered related to getting cardiac care during this period?</p>
	<p>Q13 - What has been your experience, if any, with finding a clinic or doctor for your CHD?</p> <p>PROBES</p> <p>i. <i>How did you find the clinic or doctor for your CHD? Was it easy or difficult for you to find them?</i></p>	<p>Moved from <i>Cardiac Healthcare Experience</i> to <i>Return to Cardiac Care</i> section.</p> <p>Q18 - What was your experience with finding a clinic or doctor for your CHD after the gap in care?</p> <p>PROBES</p> <p>i. <i>How did you find the clinic or doctor for your CHD? Was it easy or difficult for you to find them?</i></p>
	<p>Q16 - Have you ever experienced any potential problems or symptoms with your heart that you think might have been related</p>	<p>Q13 - Have you ever experienced any potential problems or symptoms with your heart that you think might have been related</p>

ICR Non-Substantive CHANGE REQUEST MEMO

	<p>to your CHD?</p> <p>a. Is there a reason why you haven't followed up with a cardiologist about this?</p>	<p>to your CHD?</p> <p>a. What did you do in response to these problems or symptoms, if anything?</p>
	<p>New question.</p>	<p>Q16 - Did you face any other challenges that resulted from not receiving cardiac care during this time? If so, please describe.</p> <p>PROBES</p> <p>i. Did you have issues getting medications you might have needed for your CHD? Did you have any health problems that might have been avoided (complications during pregnancy, emergency visits, etc.) if you had received cardiac care?</p>
	<p>New question.</p>	<p>Q17 - What motivated you to seek cardiac care after the gap?</p> <p>PROBES</p> <p>i. Was there a specific moment or experience that prompted you to seek care?</p> <p>ii. Did anyone else do something to motivate you? A cardiac specialist? A healthcare provider? Your family?</p>
	<p>New question.</p>	<p>Q19 - What was your experience with receiving cardiac care after the gap?</p> <p>a. Did you run into any problems?</p> <p>b. Was there anything that made this transition back into care easier?</p>

Effect on Burden Estimate:

There is no change in burden. The burden from the expanded audience will be entirely accounted for by the approved burden for the CHD audience. No more than 410 individuals will be screened and no more than 80 individuals will participate in focus groups, which is what was originally approved. While the new proposed "Recently in Care" focus group guide will have additional probes, it will still run the same time as the other focus groups (105 minutes). Moderators will adjust their pacing if needed to ensure that each focus group remains within the allotted 105-minute timeframe.

ICR Non-Substantive CHANGE REQUEST MEMO

Form	Approved Burden	Requested Burden
Attachment 3: CHD Screening Tool	68 hours (10 mins per response x 410 respondents)	68 hours
Attachment 36: CHD Focus Group Discussion Guide	140 hours (105 mins per response x 80 respondents)	140 hours
Total		
	208	208