Focus Groups Among Adults with or Caring for Individuals with Congenital Heart Defects (CHD), Muscular Dystrophy (MD), and Spina Bifida (SB).

Request for OMB approval of a New Information Collection

Mach 13, 2024

Supporting Statement A

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Goal of the project: The purpose of this project is to conduct focus groups among adults with or caring for individuals with congenital heart defects (CHD), muscular dystrophy (MD), and spina bifida (SB) to obtain firsthand perspectives on the types of care individuals receive with a special focus on: receipt of and access to medical care and barriers and facilitators to accessing, receiving, or reengaging care; the journey to diagnosis; and the transition period from pediatric to adult care (for persons diagnosed during childhood).

Intended use of the resulting data: Data from this project will enable federal, state, and local governments and organizations to understand the perceived barriers to specialty care for adults with CHD, MD, and SB, allocate resources, establish programs accordingly, address gaps in the literature, inform future surveillance, research, and data collection, and gather individual perspectives that may be shared with clinicians and inform clinical care.

Methods to be used to collect: This is a qualitative project. Data will be collected from a maximum of 46 virtual focus groups consisting of 5-8 participants each, by condition type. Each virtual focus group will last 90 minutes.

The subpopulation to be studied: CHD focus groups will be comprised of adults (≥18 years) born with CHD who have previously participated in the Congenital Heart Survey to Recognize Outcomes, Needs and well-beinG (CH STRONG), agreed to follow-up contact, and have remained out of cardiac care for three or more years at the time of recruitment screening.

MD and SB focus groups will be comprised of adults (≥18 years) with MD or SB or adult caregivers of individuals with MD or SB.

How the data will be analyzed: Focus group recordings will be transcribed, coded, and synthesized. The de-identified data will be sent to the CDC along with a summary report for each of the three conditions.

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 Office of Management and Budget (OMB) approval is three 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. 247b) (Attachment 31).

Background Information

Congenital Heart Defects

Congenital heart defects are the most common type of structural birth defects in the United States, affecting approximately 1 in 110 live-born children, and are a leading cause of birth defect-associated infant mortality, morbidity, and healthcare costs. CHD mortality has decreased over the past few

decades due to advances in diagnosis and medical interventions. As a result, more individuals are living into adulthood with CHD, a lifelong condition that can result in an increasing need for specialist care and clinical interventions over time. There is a lack of information on adults that are lost to cardiac care since most data sources only have access to patients that have been hospitalized or that are currently in cardiac care. A better understanding of the factors that contribute to adults not remaining in or seeking cardiac care will fill an important knowledge gap and could help shape future interventions to bring this population back to cardiac care.

Muscular Dystrophies

Muscular dystrophies are a group of rare inherited disorders characterized by progressive and irreversible muscle weakness and wasting.[i] The nine major types of MD (Duchenne and Becker [DBMD], myotonic dystrophy [DM], congenital [CMD], limb girdle [LGMD], Emory-Dreifuss [EDMD], facioscapulohumeral [FSHD], distal, and oculopharyngeal [OPMD]) vary by age of onset, muscle groups affected, genes involved, severity, and progression of disease. In 2002, CDC implemented the Muscular Dystrophy Surveillance, Tracking, and Research Network (MD STARnet [DD-19-002]).[ii] Now in its fourth funding cycle, MDSTARnet has conducted surveillance and collected epidemiologic and clinical data on people with DBMD, DM, FSHD, LGMD, CMD, OPMD, EDMD, and distal MD and has published numerous articles in scientific journals. However, qualitative data on the experiences of individuals with certain types of MD (DBMD, DM, FSHD, LGMD, and CMD) or their caregivers are limited. The MD portion of this collection will focus on gathering qualitative information to better understand the personal experiences of adults (≥18 years) with DBMD, FSHD, DM, and LGMD as well as adult caregivers of youth (<18 years) with DBMD, congenital or juvenile onset DM, and CMD. Specifically, qualitative data on barriers to accessing and receiving care, the journey to diagnosis, and for those diagnosed early in life the transition into adulthood will help to address a gap in the literature and inform future research and surveillance efforts.

Spina Bifida

Spina bifida is among the most common disabling birth defects in the United States. Based on national data from 2010-2014, the estimated birth prevalence for spina bifida is 3.9 per 10,000 live births.[iii] SB impacts different organ systems, resulting in the need for various types of clinical specialists. In 2008, CDC implemented the National Spina Bifida Patient Registry (NSBPR; [DD-19-001]) with SB clinics across the United States.[iv] In 2014, CDC funded a subset of NSBPR clinics to establish and implement the "Urologic Management to Preserve Initial Renal Function Protocol for Young Children with Spina Bifida" (UMPIRE Protocol; [DD-14-002]).[v] NSBPR and UMPIRE have generated numerous publications on clinical interventions, health outcomes, and lessons learned. However, increases in survival for individuals with SB have prompted the need for greater understanding of the complexities involved in their clinical and psychological care. Qualitative data on individual and caregiver experiences with SB, including barriers to accessing specialty care, managing one's skin health and bowel and bladder function, and the transition from childhood to adulthood (for those with MD diagnosed prior to adulthood) are needed to guide future SB surveillance and research projects as well as the care of those aging into adulthood.

2. Purpose and Use of Information Collection

The purpose of this Information Collection Request (ICR) is to recruit individuals for virtual focus groups and gather qualitative data from adults with or caring for individuals with congenital heart defects (CHD), muscular dystrophies (MD), and spina bifida (SB). This data will be collected by KRC Research, a contracted research firm, over the course of the study (two years and three months) and will provide firsthand perspectives on the types of care individuals receive with a special focus on receipt of and access to medical care and barriers and facilitators to accessing, receiving, or reengaging care; the journey to diagnosis; and the transition from pediatric to adult care (for persons diagnosed during childhood). This information may be used to address gaps in knowledge, inform future surveillance, research, and data collection, and gather patient and caregiver perspectives that may be shared with clinicians and inform clinical care.

3. Use of Improved Information Technology and Burden Reduction

Data will be collected via online focus groups through a web-based platform, meaning that participants will be able to use their own internet-connected personal devices and internet connections to participate. All focus groups will be conducted by professional moderators from KRC Research. All focus groups will be audio recorded to ensure participant responses are captured accurately and transcribed. Questions included in the participant screeners and focus group moderator guides have been limited to only those relevant to the audience of focus to reduce burden on respondents.

4. Efforts to Identify Duplication and Use of Similar Information

Congenital Heart Defects

In 2012, CDC convened a panel of CHD experts to discuss how to use limited resources to address major gaps in information among individuals of all ages born with CHD. Gaps the group identified were the need for information on healthcare access and utilization and continuation of care from adolescence to adulthood among individuals of all ages with CHD, since existing U.S. data did not address these. Since then, CDC has held regular calls with its partner organizations focused on CHD, both individually and through the Congenital Heart Public Health Consortium (e.g., National Heart Lung and Blood Institute (NHLBI), March of Dimes, American Heart Association, CHD patient-parent advocacy organizations), to inform them of our current and future work on the topic. During a call with these partners in 2022, we discussed conducting focus groups on people with CHD who had fallen out of cardiology care. Prior research has shown that there is a subpopulation of individuals with CHD that have fallen out of cardiology care, yet little is known about what would have encouraged them to remain in cardiology care and what can be done to bring them back into cardiology care. These groups agreed that information related to this population is missing and they did not know of another organization, aside from CDC, having access to this group of people.

There is limited data on adults living with CHD who have fallen out of cardiac care, and the available information is strictly among those who returned to care. Currently, there is no information on adults with CHD who remain out of care and what might bring them back into cardiac care. Understanding what may bring adults with CHD back into care, aside from an urgent cardiac need, would help in

developing interventions, as well as improving access and retention to cardiac care, ultimately improving long-term health and wellbeing.

Muscular Dystrophies and Spina Bifida

Barriers to accessing and receiving care, the journey to diagnosis, and the transition into adulthood have been identified by NCBDDD's Rare Disorders and Health Outcomes Team as priority research topics for MD and SB. Supplementing epidemiologic and clinical data with qualitative information on the personal experiences of individuals and caregivers will help to guide future MD surveillance and research projects. A preliminary literature review identified few qualitive studies focusing on individuals with MD or their caregivers, especially for types of MD other than DBMD in the United States.[vi,vii] Similarly, few qualitative studies among individuals with SB are available, especially for individuals or caregivers in the United States.[viii,ix]

5. Impact on Small Businesses or Other Small Entities

This data collection will not involve small businesses.

6. Consequences of Collecting the Information Less Frequently

This is a one-time information collection.

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

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

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

A. A 60-day Federal Register Notice was published in the *Federal Register* on April 7, 2023, vol. 88, No. 67, pp. 20888-20890 (Attachment 32). CDC did receive one public comment related to this notice (Attachment 33). The comment was both non-substantive and anonymous and did not warrant a response.

B. KRC Research, a contracted research firm, has been consulted in the development of the research plan, sampling parameters, participants screeners (Attachments 3, 12, 23), and focus group guides (Attachments 6, 16, 27). Under the supervision of CDC, KRC will ultimately conduct all data collection related to the proposed evaluation. Data collection will include recruiting and screening participants into the formative research, and conducting 46 focus groups among adults with or caring for individuals with CHD, MD, or SB.

9. Explanation of Any Payment or Gift to Respondents

Focus group participants will receive a monetary incentive of $75 for their participation. Such an incentive is a standard practice in the market research industry and helps to ensure efficient recruitment

and higher participation among qualified and scheduled participants. The amount is also standard for a general public audience participating in a 90-minute focus group. The incentive is also intended to offset the cost of personal or professional time taken to participate.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The research determination for this project has declared it "Not Research – Public Health Surveillance" and therefore exempt from IRB review (Attachment 34). The CDC Office of the Chief Information Officer has determined that the Privacy Act does not apply to this information collection request. A Privacy Impact Assessment is included as part of this submission (Attachment 35). KRC Research will manage recruitment and data collection for this initiative. All project files, including but not limited to meeting notes, participant communication materials, data collection instruments, focus group audio recordings, transcriptions, code books, data files, and summary reports, will be stored on KRC's secure Microsoft cloud environment. No one outside of KRC will have access to this data. Files that contain sensitive or private information, such as participant PII, will be both password-protected and encrypted for safe storage and transmission. Only authorized members of KRC's team with a legitimate need will have access to these files.

During recruiting, KRC Research will share de-identified MD and SB participant lists with CDC, which will have all personally identifiable information (PII), including names and addresses, removed. These lists will only include sociodemographic data and other relevant characteristics collected from screeners for the purpose of describing the composition of focus groups. For the CHD recruitment lists, the names and addresses of participants will be included in the submission in order to update CDC's existing list of CH STRONG participants. Participants drawn from this list have all agreed to be recontacted. No recordings of the focus groups will be shared with CDC, and transcripts shared with CDC will have names and any other identifiable information redacted from them. All findings will be reported in aggregate only.

The screening instruments for this data collection are provided as attachments (Attachments 3, 12, 23). These screening instruments will be used to evaluate the qualification of potential focus group participants. The screening instruments and introductory communications materials (Attachments 1, 2, 8, 9, 10, 11, 19, 20, 21, 22) will include information about privacy. After an individual agrees to participate in screening and has qualified for focus group scheduling, they will be given a separate consent form that reiterates privacy policies. The participant will be required to sign the form (Attachment 30) (electronic submission is allowed) and deliver a copy to the recruiting and data collection team in order to participate. The participant will be reminded that participation is entirely voluntary throughout the entire process.

During the introduction to each focus group, the trained moderator will review key parts of the privacy agreement:

1. This discussion is completely voluntary. Participants may choose to leave the discussion and/or not answer a question at any time for any reason.

2. KRC's evaluation team will take every precaution to protect participant identity and ensure privacy unless otherwise determined by law. This includes keeping names and answers to questions private and keeping contact information separate from any responses.
3. Results of the focus groups will be presented in aggregate, and names will not be used in any reports.
4. Discussions will be audio-recorded and notes will be taken during the discussion. All information, notes, and audio recordings will be locked in a file cabinet or password protected. Only evaluation staff will be able to access the information.

Data will be kept private to the extent allowed by law.

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

Institutional Review Board (IRB)

The human subjects contact for this project has declared it "Not Research – Public Health Surveillance" and therefore exempt from IRB review.

Justification for Sensitive Questions

Screening questions will ask about demographic and health-related information. Using these screening questions is a necessary component of recruiting the right audiences of those with MD, SB, or CHD or those who care for individuals with MD or SB. Similarly, research questions about health-related experiences asked during focus groups are necessary to understand the respondents' journeys with the conditions.

To reduce fear or stigma of disclosing sensitive information, several steps will be taken:

- Respondents will be told all information provided will be treated in a secure manner and will not be disclosed unless otherwise compelled by law.
- Respondents will be informed that participation is voluntary and that they need not answer any question that makes them feel uncomfortable or that they simply do not wish to answer.
- Respondents will be asked to use first names only when speaking about their experiences or the experiences of others.
- Respondents within a given focus group will all share the same health condition or be caregivers for individuals with the same condition.
- Moderators are trained to ask questions in a sensitive, nonjudgmental manner, and to handle any subsequent discussion skillfully.
- Respondents will be provided with the contact information of the project director in case they have any questions or concerns.

12. Estimates of Annualized Burden Hours and Costs

A. Estimated Annualized Burden Hours

CHD Focus Groups (16 groups)

We estimate that up to 410 individuals (137 annualized) will be screened for focus group participation and complete a screening questionnaire. The screening questionnaire will be filled out once per respondent and the completion of the screening questionnaire will take approximately 10 minutes per respondent, for a total burden of 23 annualized hours. We expect to seat 5 participants per focus group and estimate approximately 80 participants (27 annualized) will participate in the focus group discussions as a whole. The focus groups will be conducted once per participant and completion of the focus group will take 105 minutes total (15 minutes of preparation and technology checks plus 90 minutes for the discussion), for a total burden of 47 annualized hours. Overall total burden hours are 70. There are no costs to respondents other than their time.

MD Focus Groups (21 groups)

We estimate that up to 210 individuals (70 annualized) will be screened for focus group participation and complete a screening questionnaire. The screening questionnaire will be filled out one time per respondent and the completion of the screening questionnaire will take approximately 10 minutes per respondent, for a total burden of 12 annualized hours. We expect to seat between 5 to 8 participants per focus group and estimate that approximately 137 participants (46 annualized) will participate in the focus group discussions as a whole. The focus groups will be conducted one time per participant and completion of the focus group will take 105 minutes total (15 minutes of preparation and technology checks and 90 minutes for the discussion), for a total burden of 81 annualized hours. Overall total burden hours are 93. There are no costs to respondents other than their time.

SB Focus Groups (9 groups)

We estimate that up to 90 individuals (30 annualized) will be screened for focus group participation and complete a screening questionnaire. The screening questionnaire will be filled out one time per respondent and the completion of the screening questionnaire will take approximately 10 minutes per respondent, for a total burden of 5 annualized hours. We expect to seat between 5 to 8 participants per focus group and estimate that approximately 60 (20 annualized) participants will participate in the focus group discussions as a whole. The focus groups will be conducted one time per participant and completion of the focus group will take 105 minutes total (15 minutes of preparation and technology checks plus 90 minutes for the discussion), for a total burden of 35 annualized hours. Overall total burden hours are 40. There are no costs to respondents other than their time.

The total annual burden hours for all audiences is 203 hours. The breakdown of hours is summarized in the table below. Previously, in the 60-day Federal Register Notice, the burden hours were 533 hours (not annualized). The hours have been increased to account for the additional time added by asking participants to arrive 15 minutes early to focus groups to be checked in by a technician.

Table 1. Annualized Burden

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hrs.)	Total Burden (in hrs.)
Adults with a CHD that have been out of cardiac care for ≥ 3.	CHD Screening Tool	137	1	10/60	23
Adults with a CHD that have been out of cardiac care for ≥ 3.	CHD Focus Group Guide	27	1	105/60	47
Adults with MD or adult caregivers of individuals with MD	MD Screening Tool	70	1	10/60	12
Adults with MD or adult caregivers of individuals with MD	MD Focus Group Guide	46	1	105/60	81
Adults with SB or adult caregivers of individuals with SB	SB Screening Tool	30	1	10/60	5
Adults with SB or adult caregivers of individuals with SB	SB Focus Group Guide	20	1	105/60	35
Total					**203**

B. Estimated Annualized Burden Costs

There will be no anticipated costs to respondents other than their time. Each focus group participant will receive $75 as a token of appreciation for their time.

Annualized burden costs are summarized in the table below. The hourly wage estimates are based on the U.S Bureau of Labor Statistics, May 2022 National Occupational Employment and Wage Estimates (available at http://www.bls.gov/oes/current/oes_nat.htm). The median hourly wage rate for all occupations ($22.26) was used. The total estimated cost burden is $4,518.78.

Table 2. Cost Burden Associated with Information Collection

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Adults with a CHD that have been out of cardiac care for ≥ 3 years.	CHD Screening Tool	23	$22.26	$511.98
Adults with a CHD that have been out of cardiac care for ≥ 3 years.	CHD Focus Group Guide	47	$22.26	$1,046.22
Adults with MD or adult caregivers of individuals with MD	MD Screening Tool	12	$22.26	$267.12

Adults with MD or adult caregivers of individuals with MD	MD Focus Group Guide	81	$22.26	$1,803.06
Adults with SB or adult caregivers of individuals with SB	SB Screening Tool	5	$22.26	$111.30
Adults with SB or adult caregivers of individuals with SB	SB Focus Group Guide	35	$22.26	$779.10
Total				**$4,518.78**

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

There are no costs to respondents other than their time to participate.

14. Annualized Cost to the Government

The annualized cost to the Federal Government to collect this information is $**254,329.72**. Table 3 below describes the cost in more detail.

All data collection activities will be conducted by KRC Research, a contracted firm. KRC's work includes recruitment, screening, scheduling, management of consent forms, conducting focus groups, transcription and data cleaning, and reporting. Contractor costs cover the work of a team working with CDC on this initiative and include 2,302 hours of labor total. A breakdown is available below:

- 45 hours for a President
- 66 hours for Executive Vice Presidents
- 257 hours for Senior Vice Presidents
- 295 hours for Account Directors
- 220 hours for Recruiting Staff
- 1,419 hours for Research Analysts

Hours and costs are tabulated based on existing contractor hourly rates. Contractor expenses are based on competitively bid prices for panel recruitment / screening and transcription, plus cost of incentives.

Oversight and review of all materials and reports will be conducted by 7 federal government employees, including 4 Health Scientists, GS-13, 2 Health Scientists, GS-14, and 1 Senior Service Fellow, GS-15. Their work will include providing oversight to KRC Research on the purpose and objectives of the project; guidance and feedback on recruitment, screening, and data collection instruments; submitting the project for OMB approval; meeting regularly with KRC Research staff to discuss the project's progress and answer any questions; reviewing the transcripts and summary report; and sharing topline findings internally with CDC staff. The estimate includes 388 total hours for each job title for the life cycle of the project.

Estimated federal employee cost is tabulated based on these employees' current hourly wages (locality-adjusted GS pay table for Atlanta-area workers, step 10):

- Health Scientist, GS-13: 388 hours @ $64.79/hour * 4 employees = $100,554.08

- Health Scientist, GS-14: 388 hours @ $76.56/hour * 2 employees = $59,410.56
- Senior Service Fellow, GS-15: 388 hours @ $87.93/hour * 1 employee = $34,116.84

- Total = $194,081.48

Table 3. Estimated Annualized Cost to the Government per Activity

Cost Category	**Estimated Annualized Cost**
Contractor personnel costs: costs to oversee recruit, conduct focus groups	$86,764.03
Contractor personnel costs: costs to report on results	$18,538.53
Contractor expenses: recruitment panel, transcription, incentives	$84,333.33
Federal government personnel costs: oversight, report review	$64,693.83
Total	**$254,329.72**

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

A. Project Time Schedule

This initiative is expected to take two years and three months from start to finish. Seven months will be spent building participant pools and three months will be spent screening, recruiting, and scheduling. Conducting the focus groups will take six months and analysis and reporting will take nine months. A timeline is in Table 4.

Table 4. Project Time Schedule

High-Level Timeline												
BEGINNING CONTRACT YEAR SEPTEMBER 2023-SEPTEMBER 2024	**2023**				**2024**							
	O	**N**	**D**	**J**	**F**	**M**	**A**	**M**	**J**	**J**	**A**	**S**
1.1 Kickoff call												
1.2 Work plan												
2.1, 2.3 Finalize Instruments												
2.2 Finalize recruitment plan												
2.4 Data management plan												
3 OMB Package												
4.1 Tracking and tracing eligible CHD participants												
5.1-5.3 Screen, recruit, and schedule for MD, SB, and CHD groups												

BEGINNING CONTRACT YEAR SEPTEMBER 2024 – SEPTEMBER	**2024**			**2025**								
	O	**N**	**D**	**J**	**F**	**M**	**A**	**M**	**J**	**J**	**A**	**S**

5.1-5.3 Screen, recruit, and schedule for MD, SB, and CHD groups												
6.2 Conduct focus groups												
7.1 Submission of focus group transcriptions												

BEGINNING CONTRACT YEAR SEPTEMBER 2025 – SEPTEMBER 2026	2025			2026								
	O	N	D	J	F	M	A	M	J	J	A	S
7.2.1 Submit proposed themes and codes												
7.2.3 Coding reliability analyses												
7.3 Submit coded dataset												
7.4 Submit summary report												

B. Publication

CDC plans on disseminating and publishing the results from the data collection under this package to address existing knowledge gaps and inform decisions related to patient and caregiver needs. They intend to use findings in academic publications, conference and internal presentations, and to inform the development of clinician materials and toolkits. Sharing the results will help CDC and key stakeholders understand how the experiences and beliefs of individuals with CHD, MD, and SB and their caregivers impact their behaviors. An explanation of the analysis and reporting process is detailed below.

Analysis

All focus groups' audio will be transcribed verbatim in English by a vetted and trusted transcription company. Once transcribed, KRC will review each transcript to ensure there are no inconsistencies, and that the discussion was recorded accurately. All PII will be redacted from transcriptions and moderator notes before being shared with CDC on a rolling basis during data collection.

Immediately following the conclusion of all forty-six (46) focus groups, KRC will use the qualitative data analysis software NVivo to prepare a codebook from the transcripts with eleven (11) sets of codes, one for each condition segment. To create codes for analysis, each segment's transcripts will be examined for recurring themes, patterns, and concepts. Additionally, KRC will identify themes across audience groups and condition types for a holistic and comprehensive view of patient and caregiver perspectives and experiences. KRC will submit proposed codes in a codebook to CDC for review and approval and will work with CDC to revise the codebook as needed. Once approved, focus group transcripts will be coded in full according to the codebook.

After coding, KRC will perform an inter-coder reliability analysis. The process will involve different KRC Analysts coding the same set of transcripts individually and then comparing and reviewing the coded transcripts to determine the percentage of codes that are identical. Should significant discrepancies occur, the coders will discuss and decide which code should be used. A final summary of the inter-coder reliability analysis, including percentage agreement and Cohen's kappa coefficient for

each segment will be shared with CDC, as well as a final coded dataset. The final analysis will focus on synthesizing the identified themes for each condition segment and across segments.

Reporting

Based on the analysis of the coded themes, KRC will create a summary report of all 46 focus groups, organized by condition type (CHD, MD, and SB). This report will summarize the firsthand perspectives of each focus group segment with a focus on their medical care, barriers and facilitators to accessing receiving or reengaging in care, experiences around the transition from pediatric to adult care, experiences with clinics that provide care according to specific care considerations, and their journey to diagnosis. The report will also include aggregated demographic data collected from the screener to present the composition of focus groups. No PII will be included in the report.

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

The display of the OMB Expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

Attachments

1. CHD Email
2. CHD Mailer
3. CHD Screening Tool
4. CHD Participant Selection Email
5. CHD Calendar Invite Email
6. CHD Focus Group Guide
7. CHD Thank You Email
8. MD Email Caregiver
9. MD Email Individual
10. MD Mailer Caregiver
11. MD Mailer Individual
12. MD Screening Tool
13. MD Participant Selection Email
14. MD Calendar Invite Email Caregiver
15. MD Calendar Invite Email Individual
16. MD Focus Group Guide
17. MD Thank You Email Caregiver
18. MD Thank You Email Individual
19. SB Email Caregiver
20. SB Email Individual
21. SB Mailer Caregiver
22. SB Mailer Individual

23. SB Screening Tool
24. SB Participant Selection Email
25. SB Calendar Invite Email Caregiver
26. SB Calendar Invite Email Individual
27. SB Focus Group Guide
28. SB Thank You Email Caregiver
29. SB Thank You Email Individual
30. Consent Form
31. Authorizing Legislation
32. 60-Day FRN
33. 60-Day FRN Public Comment
34. Human Subjects Determination
35. Privacy Impact Assessment

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