U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Print Date: 3/14/23

Title: Focus groups among adults with or caring for individuals with congenital heart defects (CHD), muscular dystrophy (MD), and spina bifida (SB)

Project Id: 0900f3eb820e6f9b

Accession #: NCBDDD-RDHOT-1/23/23-988e4

Project Contact: Hollie A Clark

Organization: NCBDDD/DBDID/BDMR/RDHOT

Status: **Pending Regulatory Clearance**

Intended Use: **Project Determination**

Estimated Start Date: 09/25/2023

Estimated Completion Date: 09/24/2026

CDC/ATSDR HRPO/IRB Protocol #:

OMB Control #:

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research / Other *45 CFR 46.102(l)* Program Evaluation Quality Assurance / Improvement	3/9/23	Campbell_Scott (sic3) CIO HSC

PRA: **PRA Applies**		3/9/23	Herron_Adrienne R. (xwj9) OMB / PRA

Description & Funding

Description

Priority:	Standard
Date Needed:	03/21/2023
Determination Start Date:	03/09/23
Description:	This surveillance project will conduct focus groups to obtain firsthand perspectives on the types of care adults (18 years and older) 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; experiences around the transition from pediatric to adult care; experiences with clinics that provide care according to specific care considerations; and the journey to diagnosis. Also, for MD and SB, perspectives will be gathered from caregivers of children or adults with specific condition types. Each focus group will be virtual (i.e., conducted using chat and recording-enabled videoconferencing software).
IMS/CIO/Epi-Aid/Lab-Aid/Chemical Exposure Submission:	No
IMS Activation Name:	Not selected
Primary Priority of the Project:	Not selected
Secondary Priority(s) of the Project:	Not selected
Task Force Associated with the Response:	Not selected
CIO Emergency Response Name:	Not selected
Epi-Aid Name:	Not selected
Lab-Aid Name:	Not selected
Assessment of Chemical Exposure Name:	Not selected
Goals/Purpose	The purpose of this project is to conduct focus groups among adults living 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; the transition period from pediatric to adult care (for persons diagnosed during childhood); and experiences with clinics that provide care according to specific care considerations.
Objective:	The objective of this surveillance project is to obtain data that 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.

Does this project include interventions, services, or policy change work aimed at improving the health of groups who have been excluded or marginalized and /or decreasing disparities?:	No
Project does not incorporate elements of health equity science:	Not Selected
Measuring Disparities:	Not Selected
Studying Social Determinants of Health (SDOH):	Yes
SDOH Economic Stability:	Not Selected
SDOH Education:	Not Selected
SDOH Health Care Access:	Yes
SDOH Neighborhood and Environment:	Not Selected
SDOH Social and Community Context:	Not Selected
SDOH Indices:	Not Selected
Other SDOH Topics:	Not Selected
Assessing Impact:	Not Selected
Methods to Improve Health Equity Research and Practice:	Not Selected
Other:	Not Selected
Activities or Tasks:	New Collection of Information, Data, or Biospecimens
Target Populations to be Included/Represented:	Other - Adults with a congenital heart defect, muscular dystrophy, or spina bifida
Tags/Keywords:	Heart Defects, Congenital ; Muscular Dystrophies ; Spina Bifida Cystica ; Focus Groups ; Health Services Accessibility
CDC's Role:	Activity originated and designed by CDC staff, or conducted at the specific request of CDC, or CDC staff will approve study design and data collection as a condition of any funding provided ; CDC employees or agents will obtain or use anonymous or unlinked data or biological specimens ; CDC employees will participate as co-authors in presentation(s) or publication(s) ; CDC is providing funding
Method Categories:	Focus Group
	CDC project staff will submit a task order to the Office of the Associate Director#s blanket purchase agreement (OADC BPA) and via technical review panel, select a vendor to perform project activities. OADC BPA vendors include large and small businesses with the capacity and capabilities to perform focus groups (see: https://intranet.cdc.gov/oadc/create-it/access-to-communication-services-through-gsa-schedules.html). CDC will draft preliminary eligibility screeners and focus group discussion guides and work with the contractor to finalize these items. The contractor will develop a work plan, recruitment plan, and data management plan for review and final approval by CDC project staff. For CHD focus groups the contractor will recruit adults 19 years and older who participated in the Congenital Heart Survey to Recognize Outcomes, Needs and well-beinG (CH STRONG). Between 2016 and 2019, CH STRONG was administered to adults ages 19-38 with a confirmed CHD diagnosis, born in Arizona, Arkansas, and 5-county Metro-

Methods:	Atlanta, Georgia. CH STRONG assessed many factors, including access to care and healthcare utilization. Through survey responses we will identify a subpopulation of respondents whose last cardiology encounter was ?3 years before survey completion, who agreed to follow-up contact, and who provided a mailing and/or email address. The CDC will provide the contractor with the residential address and/or email information for individuals who are eligible to be contacted for focus group participation. For MD and SB focus groups, the contractor will implement the final recruitment plan developed for the project. The contractor will conduct virtual focus groups for each condition and participant type (i.e., individual with the condition or a caregiver), for a total of 46 focus groups. For CHD, 16 focus groups will be conducted with participants that have a CHD and have been out of cardiac care for three or more years. For MD and SB, the contractor will perform 30 focus groups with adults 18 years or older, including 3 with individuals with Duchenne or Becker muscular dystrophy (DBMD); 3 with adult caregivers (i.e., parent or other household member) of children (younger than 18 years) with DBMD; 3 with individuals with facioscapulohumeral dystrophy (FSHD); 3 with individuals with myotonic dystrophy (DM); 3 with individuals with limb girdle muscular dystrophy (LGMD); 3 with adult caregivers (i.e., parent or other household member) of children with congenital or juvenile onset myotonic dystrophy (DM); 3 with adult caregivers (i.e., parent or other household member) of children with congenital MD (CMD); 3 with participants with SB (excluding spina bifida occulta); 3 with adult caregivers (i.e., parent or other household member) of children (younger than 18 years) with SB (excluding spina bifida occulta); and 3 with adult caregivers (i.e., parent or other household member) of adults (18 years and older) with SB (excluding spina bifida occulta).
Collection of Info, Data or Biospecimen:	For this project, a contractor will collect qualitative data via 46 virtual focus groups consisting of 5-8 participants each. Focus group recordings will be transcribed, coded, and synthesized. The de-identified data will be submitted to the CDC along with final CHD, MD, and SB summary reports void of personal identifiers (e.g., void of name, date of birth, county of residence, or other identifying information).
Expected Use of Findings/Results and their impact:	Findings will be presented at internal CDC meetings, to partners, and at national conferences and submitted for publications in peer-reviewed journals. Findings may improve understanding of individual's perspectives of healthcare access and utilization, barriers to specialty care, transition of care, and the needs and experiences of individuals with CHD, MD, or SB.
Could Individuals potentially be identified based on Information Collected?	Yes
Will PII be captured (including coded data)?	Yes
Does CDC have access to the identifiers (including coded data)?:	Yes
Is this project covered by an Assurance of Confidentiality?	No
Does this activity meet the criteria for a Certificate of Confidentiality (CoC)?	No
Is there a formal written agreement prohibiting the release of identifiers?	No

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount
CDC Contract	Multiple Award Blanket Purchase Agreement (BPA) for Health Marketing Support Services for the CDCs Office of the Associate Director for Communication (OADC)		2020	5	100000000.00

HSC Review

HSC Attributes

Program Evaluation Yes

Quality Assurance / Improvement Yes

Regulation and Policy

Do you anticipate this project will be submitted to the IRB office No

Estimated number of study participants

Population - Children Protocol Page #:

Population - Minors Protocol Page #:

Population - Prisoners Protocol Page #:

Population - Pregnant Women Protocol Page #:

Population - Emancipated Minors Protocol Page #:

Suggested level of risk to subjects

Do you anticipate this project will be exempt research or non-exempt research

Requested consent process waviers

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection
Alteration of authorization under HIPPA Privacy Rule	No Selection

Requested Waivers of Documentation of Informed Consent

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection

Consent process shown in an understandable language

Reading level has been estimated	No Selection
Comprehension tool is provided	No Selection
Short form is provided	No Selection
Translation planned or performed	No Selection
Certified translation / translator	No Selection
Translation and back-translation to/from target language(s)	No Selection
Other method	No Selection

Clinical Trial

Involves human participants	No Selection
Assigned to an intervention	No Selection
Evaluate the effect of the intervention	No Selection
Evaluation of a health related biomedical or behavioral outcome	No Selection
Registerable clinical trial	No Selection

Other Considerations

Exception is requested to PHS informing those bested about HIV serostatus	No Selection
Human genetic testing is planned now or in the future	No Selection
Involves long-term storage of identfiable biological specimens	No Selection
Involves a drug, biologic, or device	No Selection
Conducted under an Investigational New Drug exemption or Investigational Device Exemption	No Selection

Institutions & Staff

Institutions

Institutions yet to be added .....

Staff

Staff Member	SIQT Exp. Date	CITI Biomedical Exp. Date	CITI Social & Behavioral Exp. Date	CITI Good Clinical Practice Exp. Date	Staff Role	Email	Phone	Organization
Catharine Riley	12/22/2024				Co-Investigator	xan2@cdc.gov	404-498-3330	RARE DISORDERS AND HEALTH OUTCOMES TEAM
Hollie Clark	02/10/2025	03/27/2023	03/13/2026		Contract Officer Representative	hdc3@cdc.gov	404-639-3983	RARE DISORDERS AND HEALTH OUTCOMES TEAM
Jennigije Reefhuis	04/06/2025	10/05/2024			Co-Investigator	nzr5@cdc.gov	404-498-3917	EPIDEMIOLOGY TEAM
Shannon Moss	10/15/2024	10/19/2024	10/19/2024		Co-Investigator	sez7@cdc.gov	404-639-1314	EPIDEMIOLOGY TEAM
Sherry Farr-mus	11/28/2025		12/30/2024		Co-Investigator	bwa0@cdc.gov	404-498-3877	LIFESPAN SURVEILLANCE & RESEARCH TEAM

Data

DMP

Proposed Data Collection Start Date: 9/25/23

Proposed Data Collection End Date: 9/24/26

Proposed Public Access Level: Restricted

Restricted Details:

Data Use Type: Data Sharing Agreement

Data Use Type URL:

Data Use Contact:

Public Access Justification: MD, SB, and CHD are rare diseases for which the constellation of clinical characteristics and diagnoses can be very unique and potentially identifiable. These data will be restricted to ensure that they will not be used in any way except for statistical reporting and analysis; will not be shared with anyone without approval from project collaborators; will not be used to learn the identity of any person or establishment; and that reasonable measures will be used to protect all individual-level data from eye observation, theft, or accidental loss or misplacement. Access will be granted if a researcher's proposal is approved by the project publication committee, is sponsored by a principal investigator, and after a Confidentiality and Data Use Acknowledgement form has been signed and returned to CDC project staff.

How Access Will Be Provided for Data: The contractor selected to collect data for this project will be identified based on offers submitted by OADC BPA vendors (see https://intranet.cdc.gov/oadc/create-it/access-to-communication-services-through-gsa-schedules.html). OADC BPA vendors are required to have current Federal Wide Assurance and adhere to any OMB, IRB, and Privacy Act requirements. From the OADC BPA, p. 13: "The Contractor shall be responsible for properly protecting all information used, gathered, or developed as a result of work under a resulting BPA. In addition, the Contractor shall protect all Government data, files, equipment, etc. by treating the information as sensitive. Sensitive but unclassified information, data, and/or equipment will only be disclosed to authorized personnel as described in the Task Order. The Contractor shall ensure that appropriate administrative, technical, and physical safeguards are established to ensure the security and confidentiality of this information, data, and/or equipment is properly protected. When no longer required, this information, data, and/or equipment shall be returned to Government control; destroyed; or held until otherwise directed by the Contracting Officer. Items returned to the Government shall be hand carried or mailed to the Contracting Officer#s Representative. The Contractor shall destroy unneeded items by burning, shredding or any other method that precludes the reconstruction of the material." CDC will receive de-identified data from the focus groups, along with summary documents of findings. These data and documents will be kept on password protected systems only accessible by the contract organization and CDC project staff.

Plans for Archival and Long Term Preservation:

Spatiality

Spatiality (Geographic Locations) yet to be added .....

Dataset

Dataset Title	Dataset Description	Data Publisher /Owner	Public Access Level	Public Access Justification	External Access URL	Download URL	Type of Data Released	Collection Start Date	Collection End Date
Dataset yet to be added...									

Supporting Info

Current	CDC Staff Member and Role	Date Added	Description	Supporting Info Type	Supporting Info
Current	Clark_Hollie A. (hdc3) Project Contact	02/06/2023	OADC BPA RFQ template /Performance Work Statement for "Focus groups among adults with or caring for individuals with congenital heart defects, muscular dystrophies, and spina bifida"	Statement of Work	MD SB CHD FGs_OADC BPA RFQ_02032023.docx