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

Print Date: 11/9/22

Title: MD STARnet Muscular Dystrophy Survey

Project Id: 0900f3eb8201d456

Accession #: NCBDDD-RDHOT-9/27/22-e865d

Project Contact: Natalie Street

Organization: NCBDDD/DBDID/BDMR/RDHOT

Status: **Pending Regulatory Clearance**

Intended Use: **Project Determination**

Estimated Start Date: 01/09/2023

Estimated Completion Date: 08/31/2024

CDC/ATSDR HRPO/IRB Protocol #:

OMB Control #:

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Non-Exempt Human Subjects Research when CDC is not engaged *45 CFR 46.102(a) HHS/OHRP 2008 Engagement Guidance at III B(1-11)*	10/28/22	Campbell_Scott (sic3) CIO HSC
PRA: **PRA Applies**		10/31/22	Herron_Adrienne R. (xwj9) OMB / PRA

Description & Funding

Description

Priority:	Standard
Date Needed:	11/10/2022
Determination Start Date:	10/31/22
Description:	The Muscular Dystrophy Surveillance Tracking and Research Network (MD STARnet) collects data and disseminates results to better understand the public health and clinical impact of living with muscular dystrophies (MD). MD STARnet will be conducting a survey to describe the experiences of COVID-19 disease and flu vaccination, pain, fatigue, pregnancy, and infertility of adults living with MD.
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 research study is to better understand the experiences of COVID-19 disease and flu vaccination, pain, fatigue, pregnancy, and infertility of adults (18 and over) with MD. Adults with one of eight types of MD identified through the surveillance portion of MD STARnet will be eligible to participate in the survey. Eligible muscular dystrophies include Duchenne muscular dystrophy (DMD), Becker muscular dystrophy (BMD), myotonic dystrophy (DM), facioscapulohumeral MD (FSHD), limb-girdle MD (LGMD), congenital MD (CMD), Emery-Dreifuss MD (EDMD), and distal MD.
Objective:	Objectives 1.What is the percentage of adults with MDs who had COVID-19 disease? What was their level of symptom severity and care received? 2.What is the percentage of adults with MDs who received COVID-19 and seasonal influenza vaccinations? What are the reasons they have not received these vaccinations? 3.What is the percentage of adult individuals with MD (DM, FSHD, LGMD, DMD, BMD, CMD, EDMD, Distal MD) who report pain and fatigue? How does it differ by employment, education, and income? 4.What medications and/or practices are used to manage pain and fatigue? 5.What are the differences in frequency, location, intensity, and interference of pain with daily living among people with different MDs? 6.What are the most common pregnancy complications and outcomes among adult women with MD? 7.How do MD symptoms change during or after pregnancy? 8.What are the fertility issues in adult men and women with MD and the treatments or interventions provided?
Does this project include interventions, services, or policy change work aimed at improving the health of	No

groups who have been excluded or marginalized and /or decreasing disparities?:	
Project does not incorporate elements of health equity science:	Not Selected
Measuring Disparities:	Yes
Studying Social Determinants of Health (SDOH):	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 ; Research with Humans
Target Populations to be Included/Represented:	Patient ; Other - Individuals with one of eight types of muscular dystrophy who are 18 years of age and older
Tags/Keywords:	Muscular Dystrophy, Duchenne ; Muscular Dystrophy, Emery-Dreifuss ; Muscular Dystrophy, Facioscapulohumeral ; Muscular Dystrophies, Limb-Girdle ; Muscular Dystrophies ; Myotonic Dystrophy ; Surveys and Questionnaires ; Pain ; Fatigue ; Pregnancy ; Infertility
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 employees will provide substantial technical assistance or oversight ; CDC is NOT a recipient or provider of private data, specimens, materials or services ; CDC is providing funding
Method Categories:	Survey
Methods:	MD STARnet grantees will identify adults with eligible MDs from the surveillance portion of MD STARnet and recruit them via mail to participate in a survey to assess their experiences of COVID-19 disease and flu vaccination, pain, fatigue, pregnancy, and infertility. Individuals eligible for the survey will be identified through each site#s local MD STARnet surveillance database. Eligibility criteria include: #18 years of age and older as of the start of the study #Diagnosed with one of the eight types of eligible MDs (DM, FSHD, DMD, BMD, LGMD, CMD, EDMD, and distal MD) #Definite or probable MD STARnet case classification #Current resident of site (as of last clinic visit) # Reads English or Spanish The MD STARnet Data Coordinating Center (DCC) will develop and maintain the web-based survey using Research Electronic Data Capture (REDCap). Each site will have access to the REDCap survey database for purposes of tracking survey completion amongst their site#s respondents and for inputting paper and phone survey responses. Unique, anonymous REDCap IDs, personal URL, and QR codes will be created for each eligible subject and linked to an existing surveillance ID (pooled index case ID). Personal information of potential participants is maintained at each MD STARnet site and will only be accessible by that site#s staff and not shared with the DCC, CDC, and other sites. The survey will not ask for direct identifiers. Upon completion of data collection, the DCC will make pooled survey data available to all sites and CDC. CDC will obtain de-identified data for analysis that does not include the ID that links the survey with the surveillance data.
Collection of Info, Data or Biospecimen:	Data will be collected via a web-based, paper, or phone survey. Two versions of the survey were developed: one for males and one for females. The female and male surveys are identical except for questions in the section on pregnancy and infertility. The male survey takes approximately 15 minutes and the female survey is approximately 20 minutes to complete. Recruitment will take place through a series of mailed letters and reminder calls. The survey will be primarily web-based, but a paper option will also be available. Participants may also have the survey read to them over the phone by study staff. Participants will be able to indicate

their survey mode of preference by sending back an enclosure form. Sites have asked IRBs for a waiver of written consent -- consent will be implied if the participant completes the survey. Participants will receive a $25 token of appreciation upon survey completion. The survey will be available in English and Spanish.

Expected Use of Findings/Results and their impact:

Results of this survey address gaps in knowledge on the topics of COVID-19, flu, pain, fatigue, pregnancy, and infertility in the muscular dystrophy population. Survey results can be used to inform and improve care and policies that benefit people affected with MD and can identify areas where further research or intervention is needed. Patient advocacy groups, federal and state agencies, and clinicians can use these research results to determine where resources and care are most needed and develop the appropriate interventions to improve clinical care or access to it.

Could Individuals potentially be identified based on Information Collected?

No

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award	Budget Amount
CDC Cooperative Agreement	The Muscular Dystrophy Surveillance Tracking and Research Network	DD19-002	2019	5	

HSC Review

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

Name	FWA #	FWA Exp Date	IRB Title	IRB Exp Date	Funding #
New York State Dept of Hlth	FWA00003700	09/23/26	New York State Dept of Hlth IRB #1 - Behavioral Science	10/06/23	DD19-002
Rsch Triangle Inst	FWA00003331	01/26/26	Research Triangle Inst IRB #1	10/12/24	DD19-002
South Carolina Dept Hlth & Environmental Control	FWA00003803	08/30/22	South Carolina Dept of Hlth & Environmental Control IRB #1	01/08/22	DD19-002
U of Florida	FWA00005790	10/15/24	U of Florida IRB #1	08/03/23	DD19-002
U of Iowa (The)	FWA00003007	07/25/22	U of Iowa IRB #01 - NR - Biomedical	05/05/24	DD19-002
University of Utah	FWA00003745	11/16/25			DD19-002
Virginia Commonwealth U	FWA00005287	09/04/25	Virginia Commonwealth U IRB #2 Panel A	10/08/24	DD19-002

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
Hollie Clark	02/10/2025	03/27/2023			Co-Investigator	hdc3@cdc.gov	404-639-3983	INFORMATION INTEGRATION TEAM
Joyce Alese	02/10/2024	02/10/2024			Co-Investigator	qvg8@cdc.gov	- -	RARE DISORDERS AND HEALTH OUTCOMES TEAM
Natalie Street	11/16/2024				Program Lead	ntl2@cdc.gov	404-498-3001	RARE DISORDERS AND HEALTH OUTCOMES TEAM
Pangaja Paramsothy	09/29/2024	05/09/2025			Co-Investigator	pfp5@cdc.gov	404-498-0368	RARE DISORDERS AND HEALTH OUTCOMES TEAM
Yinding Wang	09/16/2023	05/26/2025			Statistician	nnz6@cdc.gov	404-498-5114	RARE DISORDERS AND HEALTH OUTCOMES TEAM

Data

DMP

Proposed Data Collection Start Date: 1/9/23

Proposed Data Collection End Date: 8/31/23

Proposed Public Access Level: Restricted

Restricted Details:

Data Use Type: Other -

Data Use Type URL:

Data Use Contact: mdstarnet@cdc.gov

Public Access Justification: As muscular dystrophies are rare diseases, there is the potential to identify individuals using a combination of different variables.

How Access Will Be Provided for Data: Outside investigators may request to collaborate on development of a manuscript using MD STARnet data. These investigators may access de-identified aggregate data that is produced during manuscript development. If the outside investigator's request is approved by the MD STARnet data sharing committee (DSC) and a CDC or core site sponsor is identified, investigators will be

	provided with a copy of the DSC guidelines and will collaborate with CDC or a core site to develop the necessary documents to submit a research proposal to the DSC.
Plans for Archival and Long Term Preservation:	The Data Coordinating Center at Research Triangle International will maintain the survey data set that includes index case IDs. CDC will maintain a copy of the survey data that does NOT include index case IDs plus the accompanying documentation, and other project materials on password-protected firewalled servers, with access to folders restricted to the CDC MD STARnet staff. Additionally, the CDC will collaborate with funded sites to develop plans to preserve the data and handle data requests once the Data Sharing Committee is dissolved.

Spatiality

Country	State/Province	County/Region
United States	Virginia	
United States	Utah	
United States	South Carolina	
United States	New York	
United States	North Carolina	
United States	Iowa	
United States	Florida	

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
	Street_Natalie (ntl2) Project Contact	10/28/2022	Survey protocol with appendices	Protocol	Protocol Draft.10.28.22.CDC.docx
	Street_Natalie (ntl2) Project Contact	10/28/2022	MD STARnet Muscular Dystrophy Survey - Male Version	Data Collection Form	md starnet male paper survey 8_16_22.OMB.docx
	Street_Natalie (ntl2) Project Contact	10/28/2022	MD STARnet Muscular Dystrophy Survey - Female Version	Data Collection Form	md starnet female paper survey 8_16_22.OMB.docx