

Centers for Disease Control

National Center on Birth Defects and Developmental Disabilities Extramural Research Program Office

The Muscular Dystrophy Surveillance, Tracking, and Research Network (MD STARnet)
RFA-DD-19-002
Application Due Date: 02/13/2019

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RFA-DD-19-002
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Part 1. Overview Information

Participating Organization(s)

Centers for Disease Control

Components of Participating Organizations

National Center on Birth Defects and Developmental Disabilities Extramural Research Program Office (NCBDDD ERPO)
National Center on Birth Defects and Developmental Disabilities (NCBDDD)

Notice of Funding Opportunity (NOFO) Title

The Muscular Dystrophy Surveillance, Tracking, and Research Network (MD STARnet)

Activity Code

U01

Notice of Funding Opportunity Type

New

Agency Notice of Funding Opportunity Number

RFA-DD-19-002

Assistance Listings (CFDA) Number(s)

93.315

Category of Funding Activity:

Health

NOFO Purpose

The purpose of this NOFO is to better understand the public health and clinical impacts of living with muscular dystrophies (MDs) by conducting longitudinal, population-based surveillance and research of eligible MDs (Duchenne MD, Becker MD, myotonic dystrophy, facioscapulohumeral MD, limb-girdle MD, congenital MD, Emery-Dreifuss MD, oculopharyngeal MD, and distal MD).

Key Dates

Publication Date:	**To receive notification of any changes to RFA-DD-19-002, return to the synopsis page of this announcement at www.grants.gov and click on the "Send Me Change Notification Emails" link. An email address is needed for this service.**
Letter of Intent Due Date:	**01/14/2019**
Application Due Date:	**02/13/2019**

On-time submission requires that electronic applications be error-free and made available to CDC for processing from the NIH eRA system on or before the deadline date. Applications must be submitted to and validated successfully by Grants.gov no later than 5:00 PM U.S. Eastern Time. Applications must be submitted using the Application Submission System &

Interface for Submission Tracking (ASSIST) module which is a web-based service used for the preparation and submission of grant applications to CDC through Grants.gov. ASSIST provides the ability for applicants to prepare their applications online, and offers the applicant additional capabilities including the ability to preview the application image, validate the application against required business rules, and prepopulate data from an applicant organization's records, therefore identifying issues earlier in the application submission process.

Note: HHS/CDC grant submission procedures do not provide a grace period beyond the application due date time to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e., error correction window).

Scientific Merit Review:	**04/10/2019**
Secondary Review:	**05/20/2019**
Estimated Start Date:	**09/01/2019**
Expiration Date:	**02/14/2019**
Due Dates for E.O. 12372:	**Executive Order 12372 does not apply to this program.**

Required Application Instructions

ELECTRONIC APPLICATION SUBMISSION VIA ASSIST IS PREFERRED

It is recommended that applicants use ASSIST for the electronic preparation and submission of applications through Grants.gov to CDC. ASSIST is an alternative method to prepare and submit applications, and provides many features to facilitate the application submission process which improves data quality (e.g., pre-population of organization data, pre-submission validation of business rules, and preview of the application image used for review). Use of the Grants.gov downloadable Adobe application packages and submission process will still be supported.

It is critical that applicants follow the instructions in the SF 424 (R&R) Application Guide except where instructed to do otherwise in this NOFO. Conformance to all requirements (both in the Application Guide and the NOFO) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Note: The Research Strategy component of the Research Plan is limited to 25 pages.

Applications that do not comply with these instructions may be delayed or not accepted for review.

Telecommunications for the Hearing Impaired: TTY 1-888-232-6348

(See Part 2, Section IV, 7. Page Limitations).

Executive Summary

Purpose. The purpose of this NOFO is to better understand the public health and clinical impacts of living with muscular dystrophies (MDs) by conducting longitudinal, population-based surveillance and research of eligible MDs (Duchenne MD, Becker MD, myotonic dystrophy, facioscapulohumeral MD, limb-girdle MD, congenital MD, Emery-Dreifuss MD, oculopharyngeal MD, and distal MD).

This NOFO has five components to achieve the purpose of the program:

- **Component A – Core-Current:** Current MD STARnet sites will continue to conduct surveillance for eligible MDs, collect clinical data on existing cohorts, and conduct research studies on surveillance populations. Applicants must be a current MD STARnet site to apply for Component A.
- **Component B – Core-New:** New MD STARnet sites will build a program to conduct MD surveillance, identify and collect data on eligible MD populations, and conduct research studies on surveillance populations. Applicants proposing a new MD STARnet site may apply for Component B. Component B applicants should contribute to the diversity of the MD surveillance population by including large target populations of specific minority groups (e.g. non-Hispanic Blacks, Asians, and Hispanics).
- **Component C – Enhanced-Dissemination:** Analysis of MD STARnet data and dissemination of results through publications in peer-reviewed journals and presentations at stakeholder meetings. **Only Component A** applicants are eligible to apply for Component C.
- **Component D – Enhanced-Data Coordinating Center:** Data coordinating center (DCC) that supports activities involving data collection, quality improvement, cleaning, pooling, and release for the network. **Component A and B** applicants are eligible to apply for Component D.
- **Component E – Enhanced-Abstractor:** Center that conducts abstractor training and data quality activities for the network. **Only Component A** applicants are eligible to apply for Component E.
- **Mechanism of Support.** Cooperative Agreement
- **Funds Available and Anticipated Number of Awards.** Component A: It is anticipated that up to six awards will be made to up to six recipients for up to $375,000 each in FY 2019. Component B: It is anticipated that up to two awards will be made to up to two recipients for up to $350,000 each in FY 2019. Component C: It is anticipated that up to five awards will be made to up to five recipients for up to $80,000 each in FY 2019. Component D: It is anticipated that one award will be made to a single recipient for up to $250,000 in FY 2019. Component E: It is anticipated that one award will be made to a single recipient for up to $80,000 in FY 2019. Awards issued under this NOFO are contingent upon availability of funds and a sufficient number of meritorious applications. Because the nature and scope of the proposed research will vary from application to application, it is also anticipated that the size and duration of each award may also vary. The total amount awarded and the number of awards will depend upon the number, quality, duration and cost of the applications received.
- **Budget and Project Period.** The estimated total funding for all components (direct and indirect) for the first budget period, 9/1/2019 – 8/31/2020, is $3,250,000. The estimated

total funding for all components (direct and indirect) for the entire project period, 9/1/2019 – 8/31/2024, is $16,250,000.

- **Application Research Strategy Length:** Page limits for the Research Strategy are clearly specified in Section IV. Application and Submission Information.
- **Eligible Institutions/Organizations.** Institutions/organizations listed in Section III, 1.A. are eligible to apply.
- **Eligible Project Directors/Principal Investigators (PDs/PIs).** Individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution/organization to develop an application for support. NOTE: CDC does not make awards to individuals directly. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply.
- **Number of PDs/PIs.** Applications may include more than one PI; however, the first PI listed on the application will be the "contact PI" for all correspondence. Any additional PIs are permitted, but would be referred to as Co-PIs.
- **Number of Applications.** Only one application per institution (normally identified by having a unique DUNS Number) per component is allowed for this NOFO. Applicants must submit separate applications if applying to more than one Component. All eligible applicants for Component A can also apply for Component C, D, or E. To apply for component C, D, or E, eligible applicants must apply for Component A. To apply for Component D, eligible applicants must apply for Component B.
- **Application Type.** New
- **Special Date(s).** CDC will conduct one conference call for prospective applicants on December 14, 2018 from 2:00 pm - 3:30 pm, EST. The conference call number is 1-855-644-0229 and Conference ID: 5069266. This session will provide information about the NOFO and will answer questions pertinent to preparing applications in response to this NOFO.
- **Application Materials.** See Section IV.1 for application materials. Please note that Form D is to be used when downloading the application package. http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general-forms-d.pdf%20
- **Hearing Impaired.** Telecommunications for the hearing impaired are available at: TTY: 1-888-232-6348.

Part 2. Full Text

Section I. Funding Opportunity Description

Statutory Authority

This program is authorized under Section 301(a) and 317C of the Public Health Service Act, [42 U.S.C. Section 241(a)).and 247-4], as amended.

1. Background and Purpose

In the U.S. population, approximately 7,000 rare diseases affect an estimated 25 million people. Many of these conditions have severe, lifelong health effects which usually lead to premature disability and even death. Muscular dystrophies (MDs) are a group of rare inherited disorders

characterized by progressive and irreversible muscle weakness and wasting. The nine major types of MD (Duchenne, Becker, myotonic dystrophy, congenital, limb girdle, Emory-Dreifuss, facioscapulohumeral, distal, and oculopharyngeal) vary by age of onset, muscle groups affected, genes involved, severity, and progression of disease. Although MDs have been studied in numerous clinic-based groups, population-based epidemiologic studies are needed to more accurately estimate prevalence, morbidity, and mortality, and to describe the variability in access to care and treatments received among individuals with MD. Epidemiological data also support the establishment and evaluation of policies, health care services, and health outcomes among people affected by MD.

To obtain epidemiologic data, surveillance for muscular dystrophies started in 2002 with the development of the Muscular Dystrophy Surveillance, Tracking, and Research Network (MD STARnet) after passage of the MD CARE Act of 2001, which authorized CDC to award grants and cooperative agreements to public or nonprofit entities for a national surveillance program for muscular dystrophies. From 2002 through 2011, the goal of MD STARnet was to identify and collect information on all people with Duchenne muscular dystrophy (DMD) and Becker muscular dystrophy (BMD), the most common types of MD in children, to determine prevalence, types of care received, factors that affect outcomes, and the needs and quality of life of patients and families affected by these MDs[1]. During that time, up to six sites (i.e. award recipients) participated in surveillance of DMD and BMD. In 2011, the number of sites was reduced to four and surveillance was expanded to include a total of nine types of MD to test the ability of the existing network to conduct surveillance for other MDs. Pilot data showed that the MD STARnet infrastructure could be used to identify and collect epidemiologic and clinical data on people with other types of MD (myotonic dystrophy (DM), facioscapulohumeral MD (FSHD), limb-girdle MD (LGMD), congenital MD (CMD), oculopharyngeal MD (OPMD), Emery-Dreifuss MD (EDMD), and distal MD)[2]. Building on the pilot, in 2014, three of the original sites and three new sites were awarded funds to conduct population-based surveillance for nine MDs (DMD, BMD, DM, FSHD, LGMD, CMD, OPMD, EDMD, and distal MD). The focus of the past five years has been to establish three new MD STARnet sites, modify protocols and eligibility criteria for each of the nine MDs, expand data collection to include more extensive clinical data on all MDs, and publish and disseminate results of data collected through previous funding cycles (on primarily DMD/BMD).

The purpose of this NOFO is to better understand the public health and clinical impacts of living with MD by conducting longitudinal, population-based surveillance and research of eligible MDs (DMD, BMD, DM, FSHD, LGMD, CMD, EDMD, OPMD, and distal MD). The current cycle will focus on identifying eligible MD cases, conducting longitudinal follow-up and research, analyzing data, and publishing and disseminating the results. Current MD STARnet sites will collect data to estimate prevalence and survival and additional clinical data on existing MD cohorts. New MD STARnet sites will focus on identifying eligible MD cases and collecting data to estimate prevalence, survival and track key clinical indicators. Identification of cases through population-based surveillance will enable existing and new sites to conduct research on these populations. This information is expected to advance understanding of diagnosed prevalence, disease progression and survival; clinical care and interventions and their alignment with recommended care; disparities in access to care; the association of treatment with outcomes, and the impact of MD on the lives of affected individuals and their families.

The following objectives address the purpose of the NOFO:

1. Conduct longitudinal, population-based surveillance and follow-up on individuals with eligible muscular dystrophies.

    a. For current MD STARnet sites:

        - Eligibility criteria will be expanded and basic demographic, clinical data, and vital records information will be collected for DM, FSHD, LGMD, CMD, EDMD, and distal MD to enable better estimation of clinically diagnosed prevalence and survival. For DM, FSHD, LGMD, CMD, EDMD, and distal MD, sites will also continue to collect clinical information for those cases with definitive diagnoses and/or family history to better understand disease progression, care and clinical interventions and their alignment with recommended care, disparities in access to care, and association of clinical treatment on outcomes.
        - DMD/BMD cohorts will continue to be followed to determine changes over time in prevalence and survival, and to further describe disease progression, care and clinical interventions and their alignment with the DMD care considerations, disparities in access to care, and association of clinical treatment on outcomes.

    b. New MD STARnet sites will use MD STARnet methods to identify eligible MD cases and collect data to determine prevalence, survival, and track key clinical indicators.

    c. Current and new MD STARnet sites will determine a method for collecting ICD-10 codes and conduct research to validate implementation of the new codes for DMD/BMD and FSHD.

2. Conduct research with populations identified through surveillance to address knowledge gaps (e.g. quality of life, pregnancy and fertility issues, and burden of care) that cannot be investigated well through surveillance methods.

3. Analyze, publish, and disseminate surveillance and research studies that address knowledge gaps in diagnosed prevalence, disease progression and survival; clinical care and interventions and their alignment with recommended care; disparities in access to care; the association of clinical treatment with outcomes; and the impact of MD on the lives of affected individuals and their families.

Although new MD STARnet sites added during the last funding cycle have been contributing data on minority populations, more data on these populations are needed to better understand the impact of MD on affected individuals and their families among minority populations (e.g. non-Hispanic Blacks, Asians, and Hispanics). As a result, potential applicants with large populations of one or more racial/ethnic minority groups are encouraged to apply for Component B.

Healthy People 2020 and other National Strategic Priorities

The CDC and NCBDDD are committed to achieving the health promotion and disease

prevention objectives of "Healthy People 2020". This NOFO addresses the following “Healthy People 2020” priority areas:

1. Ensure that federal, state, tribal, and local health agencies have the necessary infrastructure to effectively provide essential public health services

    - PHI-13: Increase the proportion of tribal, state, and local public health agencies that provide or assure comprehensive epidemiology services to support essential public health services

2. Improve access to comprehensive, quality health care services.

    - AHS-6: Reduce the proportion of individuals who are unable to obtain or delay in obtaining necessary medical care, dental care, or prescription medicines

3. Promote the health and well-being of people with disabilities.

    - DH-4: Reduce the proportion of adults with disabilities aged 18 years and older who experience delays in receiving primary and periodic preventive care due to specific barriers

The goals and objectives of this NOFO are consistent with the missions of NCBDDD and Division of Human Development and Disability (DHDD):

1. Performance goals for the National Center on Birth Defects and Developmental Disabilities:

    - Improving the health and well-being of people with disabilities
    - Helping children to develop and reach their full potential
    - Promoting health and well-being among people of all ages with disabilities

2. Priorities of the Division of Human Development and Disability

    - Improve developmental outcomes of children
    - Reduce disparities in health care access for people with disabilities

Public Health Impact

Surveillance and public health research resulting from this NOFO can be used to inform and improve policies that benefit people affected with MD. Analysis of MD STARnet data can identify trends and gaps where further research or intervention is needed. Patient advocacy groups, federal and state agencies, and clinicians can use these new data to determine where resources and care are most needed and determine appropriate interventions to improve clinical care or access to clinical care.

Relevant Work

Over the past 12 years, MD STARnet has published data on Duchenne and Becker muscular dystrophies examining prevalence, diagnostic delay, steroid use and trends, growth and other important topics that address the original research objectives [3]. A full list of publications is

available on request (see Scientific/Research Contact under Section VII. Agency Contacts).

Under the current award, MD STARnet sites developed a coordinated muscular dystrophy research agenda using literature reviews to determine knowledge gaps. The purpose of the research agenda is to focus data collection and dissemination of results on important knowledge gaps in muscular dystrophy that can be addressed using data from MD STARnet. Key knowledge gaps that are not easily investigated using MD STARnet data collected from medical records and administrative data (e.g. vital records, hospital discharge data) may be considered as topics for surveys or other research methods. This research agenda can be shared upon request (see Scientific/Research Contact under Section VII. Agency Contacts).

2. Approach

This NOFO has five components to achieve the purpose of the program:

- **Component A – Core-Current:** Current MD STARnet sites will continue to conduct surveillance for eligible MDs, collect clinical data on existing cohorts, and conduct research studies on surveillance populations. Applicants must be a current MD STARnet site to apply for Component A.
- **Component B – Core-New:** New MD STARnet sites will build a program to conduct MD surveillance, identify and collect data on eligible MD populations, and conduct research studies on surveillance populations. Applicants proposing a new MD STARnet site may apply for Component B. Component B applicants should contribute to the diversity of the MD surveillance population by including large target populations of specific minority groups (e.g. non-Hispanic Blacks, Asians, and Hispanics).
- **Component C – Enhanced-Dissemination:** Analysis of MD STARnet data and dissemination of results through publications in peer-reviewed journals and presentations at stakeholder meetings. **Only Component A** applicants are eligible to apply for Component C; however, applying for Component C is optional.
- **Component D – Enhanced-Data Coordinating Center:** Data coordinating center (DCC) that supports activities involving data collection, quality improvement, pooling, and release for the network. **Component A or B** applicants are eligible to apply for Component D.
- **Component E – Enhanced-Abstractor:** Center that conducts abstractor training and data quality activities for the network. **Only Component A** applicants are eligible to apply for Component E.

A separate application is required for each Component.

Objectives/Outcomes

Component A – Core-Current:

1. Continue to conduct longitudinal, population-based surveillance for MD by using existing MD STARnet methods to identify and gather data on individuals with eligible MDs

a. Collaborate with other Component A and B recipients and CDC to refine the variables collected. Reduce the number of variables to those reliably collected from medical records and administrative data (e.g. vital records, hospital discharge data) that can address questions in the research agenda

b. Access clinic and administrative data sources to maximize ascertainment of eligible MD cases and define population-based cohorts that can be recruited for additional research studies through methods such as phone interviews or surveys

c. Conduct new and follow-up abstraction on eligible MD cases

i. Eligible DMD/BMD cases:

a. Date of birth on or after January 1, 2000

b. Residency in a site at any time after January 1, 2000

c. Diagnosis of DMD or BMD

ii. Expand eligibility of the following MD cohorts (DM, FSHD, LGMD, CMD, EDMD, and Distal MD) to better address prevalence and mortality

a. Eligible cases:

i. Health encounter on or after January 1, 2008

ii. Residency in the surveillance area at any time after January 1, 2008

iii. Diagnosis of DM, FSHD, LGMD, CMD, EDMD, or Distal MD

1. For cases without confirmatory diagnosis or family history (possible cases), collect enough data to establish eligibility, case definition, and mortality (causes and age at death). Collect mortality data from medical and vital records (State vital records and National Death Index searches)

2. For cases with confirmatory diagnosis and/or family history (definite or probable cases), abstract additional clinical information

iii. Abstract data from clinical and administrative data sources (e.g. vital records, hospital discharge data) that can be used to address priority topic areas in the MD research agenda (i.e. diagnosed prevalence; disease progression and survival; clinical care and interventions and their alignment with recommended care; disparities in access to care; the association of treatment with outcomes; and the impact of MD on the lives of affected individuals and their families)

d. Collect ICD-10 codes on all cases to evaluate how well the new codes for DMD/BMD and FSHD, which were implemented in October 2018, identify cases

e. Clean local data according to protocol, and contribute to a pooled data set by contributing individual level data with limited identifiers to the data coordinating center

f. Participate as co-authors in the development of manuscripts that use MD STARnet data; leading manuscript development is optional

g. Conduct follow-up abstraction for DMD/BMD cohort in year 4 (for MD research

and surveillance sites that have data on cases born between 1982-1999)

i. With CDC, refine the variables by abstracting reliability collected clinical variables that can answer research questions defined in the research agenda

ii. Abstract a minimum of five years follow-up data on DMD/BMD cohort of cases born between 1982-1999

iii. Clean and send de-identified, locally collected data to the Data Coordinating Center (DCC)

2. Develop research methods and tools (i.e. surveys, interviews) and conduct research within sites

a. In collaboration with other sites and CDC, determine topic(s) for research using the newly created MD research agenda, and develop research methods and tools. Studies that address topics relevant to more than one MD will be prioritized

b. Conduct research with MD populations identified through surveillance and contribute to a pooled data set by collecting and cleaning individual level data with limited identifiers and sending them to the DCC

i. Note: Applicants should take into account the time required for developing methods and tool(s) and for OMB approval

c. Participate in activities to engage the study population and promote participation in research studies (e.g., periodically disseminating newsletters to potential study participants about research findings)

3. Build new and maintain existing relationships with MD partners and stakeholders to enhance and promote surveillance and research efforts

a. Involve appropriate partners, such as health care organizations/providers, professional clinical societies, patient advocacy groups, and other organizations who serve people with MDs to assist with or promote the collection of data

b. Collaborate and coordinate with state agencies and partner organizations to enhance case ascertainment and data collection activities (e.g. getting access to administrative data and data from birth defects and other surveillance systems to assist with case identification)

c. With assistance from CDC, collaborate with muscular dystrophy registries on data linkages and data sharing agreements to more thoroughly describe the health care and health outcomes of individuals with MD

Component B – Core-New:

1. Conduct longitudinal, population-based surveillance for MD by using existing MD STARnet methods[1,2] to identify and gather data on individuals with eligible MDs

a. Collaborate with other Component A and B recipients and CDC to refine the variables collected. Reduce the number of variables to those reliably collected from medical records and administrative data (e.g. vital records, hospital discharge data) that can address questions in the research agenda

b. Access clinic and administrative data sources to maximize ascertainment of eligible MD cases and define population-based cohorts that can be recruited for additional research studies through methods such as phone interviews or surveys

c. Identify and abstract information on eligible MD cases and collect the data elements sufficient to address prevalence and survival (i.e. data to establish eligibility, case definition (diagnostic data), and mortality (causes and age at death)). For select MDs, collect additional data elements related to key clinical indicators. (The selected MDs for which clinical indicators will be tracked will be determined by CDC and recipient.)

i. Eligible DMD/BMD cases:

1. Date of birth on or after January 1, 2000
2. Residency in a site at any time after January 1, 2000
3. Diagnosis of DMD or BMD

ii. Eligible DM, FSHD, LGMD, CMD, EDMD, OPMD and distal MD cases:

1. Health encounter after January 1, 2008
2. Residency in a site at any time after January 1, 2008
3. Diagnosis of DM, FSHD, LGMD, CMD, EDMD, OPMD or distal MD

d. Collect ICD-10 codes on all cases to evaluate how well the new codes for DMD/BMD and FSHD, which were implemented in October 2018, identify cases

e. Clean local data according to protocol, and contribute to a pooled data set by contributing individual level data with limited identifiers to the DCC

f. Participate as co-authors in the development of manuscripts that use MD STARnet data; leading manuscript development is optional

2. Develop research methods and tools (i.e. surveys, interviews) and conduct research within site

a. In collaboration with other sites and CDC, determine topic(s) for research using MD research agenda, and develop research methods and tools. Studies that address topics relevant to more than one MD will be prioritized

b. Conduct research with MD populations identified through surveillance and contribute to a pooled data set by sending individual level data with limited identifiers to the DCC

i. Note: Applicants should take into account the time required for developing methods and tool(s) and for OMB approval

c. Participate in activities to engage the study population and promote participation in research studies (e.g., periodically disseminating newsletters to potential study participants about research findings)

3. Build new and maintain existing relationships with MD partners and stakeholders to enhance and promote surveillance and research efforts

a. Involve appropriate partners, such as health care organizations/providers, professional clinical societies, patient advocacy groups, and other organizations who serve people with MDs to assist with or promote the collection of data

b. Collaborate and coordinate with state agencies and partner organizations to enhance case ascertainment and data collection activities (e.g. getting access to administrative data and data from birth defects and other surveillance systems to assist with case identification)

c. With assistance from CDC, collaborate with MD registries on data linkages and data sharing agreements to more thoroughly describe the health care and health outcomes of individuals with MD

Component C – Enhanced-Dissemination:

1. Analyze surveillance data and disseminate research results through peer-reviewed publications and presentations to target audiences using data from the 2014 – 2019 funding cycle

a. Use the coordinated research agenda for the different MDs (currently under development), analyze and publish results addressing gaps in knowledge identified as high priority

b. Publish at least 5 papers in peer-reviewed journals for the total period of funding

c. Present results of data analyses at least 5 times at national conferences, professional societies or other meetings that include target audiences (i.e., clinicians, industry representatives, families and individuals with MD, scientists and researchers, and/or public health professionals) for the total period of funding

d. Conduct secondary analysis for at least three research projects led by other sites or CDC

e. Participate in analyses, abstracts, and manuscripts led by other MD sites or CDC investigators that require epidemiologic, clinical, analytical, and other expertise available in the site

Component D – Enhanced-DCC:

1. Develop, modify, and/or maintain customized off the shelf (COTS) software applications (e.g. data cleaning, clinical review), databases, and related documentation (e.g. data manager manual, codebooks for data sets) that enable data collection and analysis of surveillance and research data for MD

2. Distribute applications, databases, and COTS software required for abstraction, clinical review, and data analysis to Component A and B recipients (software should be customizable off the shelf products that other recipients can easily obtain and support)

3. Provide end-user technical assistance to sites (e.g. data managers, abstractors, clinical reviewers) in using applications, databases and software via communication such as conference calls, and calls and e-mails with sites. Travel to new sites to provide additional support, if necessary

4. Perform extensive data cleaning efforts along with guiding and supporting local sites in

data cleaning activities. Complete and document data cleaning methods, procedures, and timelines for completion

5. Work with data analysts from all sites to standardize variables

6. Manage the pooling of multiple site-specific data sets and release analytic data sets to CDC and other sites

7. Create, modify, and update all calculated variables determined by the coordinating and/or data sharing committees and provide detailed methodology/documentation for each. New calculated variables may be suggested or initially developed by other sites in conducting analyses for manuscripts; however the creation, modification and updating of the calculated variables will solely be the responsibility of the DCC

8. Create and maintain detailed records (codebooks, survey instruments, and other materials) on data collection methodology for surveillance and other research activities (i.e., surveys or interviews)

9. In codebooks for each MD, identify and flag variables that have changed since the previous data collections (i.e. V8, DMD/BMD (DOB 200+, DMD/BMD legacy, new data collections). Create cross-walks between datasets

10. Maintain or contribute to a shared web portal or website housing relevant documents and files to assist sites in surveillance and research activities

11. Provide technical assistance to sites and participating in workgroups, committees, and in-person meetings

12. Participate in activities required by the federal government including the Security Assessment and Authorization (SA&A) process [formerly know as the Certification and Accreditation (C&A) process] from the Office of the Chief Information Security Officer (OCISO) and production of restricted use data sets with accompanying documentation

Component E – Enhanced-Abstractor:

1. Train and certify abstractors in the standardized collection of data from medical records. Travel to sites may be necessary to train new abstractors

2. Provide ongoing training to abstractors to maintain the standardization of data collection from medical records. Conduct conference calls and in-person trainings as needed

3. Create and implement a plan to periodically re-sample a portion of all abstracted records to assess inter-abstractor reliability

4. Provide technical assistance as needed through participation in committees, workgroups, in-person meetings and direct communication with sites

OMB/PRA approval will be required for research studies (described in Components A and B objective 2). CDC and recipients will identify and design the Components A and B research studies. Studies that collect data on 10 or more people are required to have OMB approval unless one of several exemptions apply. Data will not be collected without the Office of

Management and Budget's (OMB) approval. CDC will lead and submit the application for OMB approval.

References:

[1]Miller LA, Romitti PA, Cunniff C et al. The Muscular Dystrophy Surveillance Tracking and Research Network (MD STARnet): surveillance methodology. Birth Defects Res A Clin Mol Teratol. 2006 Nov;76(11):793-7.

[2] Do T, Street, N, Donnelly J et al. Muscular Dystrophy Surveillance, Tracking, and Research Network pilot: Population-based surveillance of major muscular dystrophies at four U.S. sites, 2007-2011. Birth Defects Res. 2018 Aug 2. doi: 10.1002/bdr2.1371.

[3] Sahay K, Smith T, Conway KM et al. A Review of MD STARnet's Research Contributions to Pediatric-Onset Dystrophinopathy in the United States; 2002-2017. J Child Neurol. 2018 Oct 22: doi: 10.1177/0883073818801704. [Epub ahead of print]

Target Population

The target populations for all components are individuals with muscular dystrophies (DMD, BMD, DM, FSHD, LGMD, CMD, EDMD, OPMD and distal MD) who meet eligibility criteria. Applicants for Component B sites are expected to contribute to the racial and ethnic diversity of the MD surveillance population by including relatively large populations of specific minority groups (e.g., non-Hispanic Blacks, Asians, or Hispanics).

Collaboration/Partnerships

Component A:

Recipient is expected to maintain existing partnerships and establish new partnerships as needed. These partnerships include patient advocacy groups and clinicians who treat patients with MD to promote surveillance and research efforts with the populations they serve and to disseminate surveillance information to individuals with MD and their families. Recipient will maintain or build partnerships with their state health department or other state agencies to facilitate access to administrative data and to communicate information gathered from surveillance that can be useful to states in tracking their patient populations and informing changes in policy and services. Recipient will partner with clinics and hospitals to conduct medical record abstraction and describe the types of relationships that currently exist or they plan to establish. CDC is pursuing collaborations with registries to establish linkages and data use agreements to more thoroughly describe the health care and health outcomes for individuals with MD. Recipient is expected to work with CDC and registries to achieve this goal. Recipient is also expected to collaborate with other recipients and CDC under this award.

Component B:

Recipient is expected to maintain existing partnerships and build new partnerships as needed, with particular emphasis on minority populations. These partnerships include patient advocacy groups and clinicians who treat patients with MD to promote surveillance and research efforts with the populations they serve and to disseminate surveillance information to individuals with

MD and their families. Letters of support from potential partners should be provided in the appendix of the application. Recipient must already have or plan to form strong partnerships with relevant other state health department organizational units or state agencies and/or their state health department that could facilitate access to administrative data, support efforts to designate MD as a reportable condition in their state (if not already), use aggregate surveillance information to track health and care received, and inform policy and interventions. Agreements or letters of support for the ability to access and link data should be provided in the appendix. Recipient will partner with clinics and hospitals to conduct medical record abstraction and describe the types of relationships that currently exist or that they plan to establish. CDC is pursuing collaborations with registries to establish linkages and data use agreements to more thoroughly describe the health care and health outcomes for individuals with MD. Recipient is expected to work with CDC and registries to achieve this goal. Recipient is also expected to collaborate with other recipients and CDC under this award.

Component C:

Recipient will be expected to lead and collaborate with other MD STARnet investigators, CDC, and outside investigators on analysis and dissemination of the results of surveillance and research activities to stakeholders.

Components D:

Recipient will be expected to collaborate with other recipients and CDC. The DCC will be responsible for providing COTS software, databases, and relevant documentation and support of these applications for all sites. Recipient must be able to collect and pool, MD STARnet data that is collected by individual sites.

Component E:

Recipient for the abstractor training and data quality activities is expected to collaborate with other recipients and CDC. The recipient will work with abstractors and investigators in all sites to ensure that the abstraction activities are successfully conducted.

Evaluation/Performance Measurement

For Components A and B, recipients are expected to use clinical data and administrative data (e.g. vital records, hospital discharge data) to ascertain all eligible MD cases and to collect the longitudinal data needed to describe the population of people with MD. For surveillance, recipient should attempt to identify all cases of eligible MDs residing within their surveillance catchment areas . Sites will be evaluated by comparing the number of cases collected by site with the expected number of cases based on existing prevalence estimates. Before the beginning of data collection at the start of the funding period, a workgroup composed of CDC and representatives from sites will review the variables to be collected to determine those that are most reliable, previously used, and necessary to answer the research questions identified in the research agenda, to modify and streamline the database. Data subsequently collected should be periodically evaluated for missing entries, quality, and ability to answer priority research

questions through periodic analyses and presentations at Principal Investigators' (PI) meetings.

The Component C recipient will analyze and publish at least 5 peer-reviewed manuscripts and give 5 presentations at professional society meetings on high priority topic areas from the MD research agenda during the funding period. Recipient will also be expected to participate in projects led by other investigators and CDC including conducting secondary analysis for three projects.

The Component D recipient will be evaluated on the usability of the COTS software, the readiness and quality of the pooled data sets, the clarity of the data documentation.

The Component E recipient will be evaluated on the deliverables such as certifying all abstractors, reducing inter-rater variability and identifying areas where more training is needed.

Translation Plan

For Component C, the recipient will be required to collaborate with CDC and other recipients to ensure results of MD surveillance and research activities are publicly available to stakeholders (e.g. patient advocacy groups, federal and state agencies, clinicians, and researchers). Recipient and CDC are expected to follow the MD research agenda (currently under development) to address priority topics on knowledge gaps in MD. Broadly, topics included in the research agenda are diagnosed prevalence, disease progression and survival, clinical care, interventions and their alignment with recommended care, disparities in access to care, association of clinical treatment with outcomes, and the impact of MD on the lives of affected individuals and their families. Component A and C recipients will be expected to participate as co-authors in manuscripts.

Section II. Award Information

Funding Instrument Type: Cooperative Agreement

A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.

Application Types Allowed:

New - An application that is submitted for funding for the first time. Includes multiple submission attempts within the same round.

Estimated Total Funding: $16,250,000

The estimated total funding for all components (direct and indirect) for the first budget period,

9/1/2019 – 8/31/2020, is $3,250,000:

Component A: The estimated total funding (direct and indirect) for the first budget period is up to $375,000 each in FY 2019. Award Floor amount is $0 and Award Ceiling amount is $375,000.

Component B: The estimated total funding (direct and indirect) for the first budget period is up to $350,000 each in FY 2019. Award Floor amount is $0 and Award Ceiling amount is $350,000.

Component C: The estimated total funding (direct and indirect) for the first budget period is up to $80,000 each in FY 2019. Award Floor amount is $0 and Award Ceiling amount is $80,000.

Component D: The estimated total funding (direct and indirect) for the first budget period is up to $250,000 in FY 2019. Award Floor amount is $0 and Award Ceiling amount is $250,000.

Component E: The estimated total funding (direct and indirect) for the first budget period is up to $80,000 in FY 2019. Award Floor amount is $0 and Award Ceiling amount is $80,000.

The estimated total funding for all components (direct and indirect) for the entire project period, 9/1/2019 – 8/31/2024, is $16,250,000.

Anticipated Number of Awards: 15

Component A: It is anticipated that up to six awards will be made to up to six recipients.

Component B: It is anticipated that up to two awards will be made to up to two recipients.

Component C: It is anticipated that up to five awards will be made to up to five recipients.

Component D: It is anticipated that one award will be made to a single recipient.

Component E: It is anticipated that one award will be made to a single recipient.

Awards issued under this NOFO are contingent on the availability of funds and submission of a sufficient number of meritorious applications.

Award Ceiling: $375,000 Per Budget Period
Award Floor: $0 Per Budget Period
Total Period of Performance Length: 5 year(s)

Throughout the Period of Performance, CDC's commitment to continuation of awards will depend on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and CDC's determination that continued funding is in the best interest of the Federal government.

HHS/CDC grants policies as described in the HHS Grants Policy Statement (http://www.hhs.gov/ sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf) will apply to the applications submitted and awards made in response to this NOFO.

Section III. Eligibility Information

1. Eligible Applicants

Eligibility Category: State governments

County governments
City or township governments
Special district governments
Independent school districts
Public and State controlled institutions of higher education
Native American tribal governments (Federally recognized)
Public housing authorities/Indian housing authorities
Native American tribal organizations (other than Federally recognized tribal governments)
Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education
Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education
Private institutions of higher education
For profit organizations other than small businesses
Small businesses
Others (see text field entitled "Additional Information on Eligibility" for clarification)
Unrestricted (i.e., open to any type of entity above), subject to any clarification in text field entitled "Additional Information on Eligibility"

Additional Eligibility Category:

2. Foreign Organizations

Foreign Organizations are not eligible to apply.

Foreign components of U.S. Organizations are not eligible to apply.

For this announcement, applicants may not include collaborators or consultants from foreign institutions. All applicable federal laws and policies apply.

3. Special Eligibility Requirements

For an applicant to be considered they must be responsive to the information here.

Component A – Core-Current:

- Applicants must document current funding under RFA DD-14-001 Surveillance and Research of Muscular Dystrophies and Neuromuscular Disorders.

Component B – Core-New:

- Applicants must propose a study site that should be a specific geographic area with a population of at least 3 million people including a large minority population (e.g. African American, Asian, or Hispanic).

Component C – Enhanced-Dissemination:

- Applicants must submit an application for Component A to apply for Component C.
- To be funded for Component C, the applicant must also be funded for Component A.
- Applicants should document that they have applied for Component A.

Component D – Enhanced-DCC:

- Applicants must submit an application for Component A or B to apply for Component D.
- To be funded for Component D, the applicant must also be funded for Component A or B.
- Applicants should document that they have applied for Component A or B.

Component E – Enhanced-Abstractor:

- Applicants must submit an application for Component A to apply for Component E.
- To be funded for Component E, the applicant must also be funded for Component A.
- Applicants should document that they have applied for Component A.

If your application is incomplete or non-responsive to the special eligibility requirements listed in this section, it will not enter the review process.

4. Justification for Less than Maximum Competition

N/A

5. Responsiveness

Component A – Core-Existing:

- Applicants must provide a statement that the applicant institution is currently funded under DD-14-001 Surveillance and Research of Muscular Dystrophies and Neuromuscular Disorders and provide cooperative agreement number.

Component B – Core-New:

- Applicant must show evidence that their proposed site has a population of at least 3 million people and provide the distribution of this population by race and ethnicity. Evidence can be in the form of tables or figures based on census estimates within the last 5 years showing total population for the proposed study area with the distribution by race and ethnicity.

Component C – Enhanced-Dissemination and Component E – Enhanced-Abstractor:

- Applicants must demonstrate that they have applied for Component A. Evidence can include a copy of the face page of the application for Component A.

Component D – Enhanced-DCC:

- Applicants must demonstrate that they have applied for Component A or B. Evidence can include a copy of the face page of the application for Component A or B.

Component E – Enhanced-Abstractor:

- Applicants must demonstrate that they have applied for Component A. Evidence can include a copy of the face page of the application for component A.

If an application is incomplete or non-responsive to these requirements, it will not enter the review process. Applications will be deemed unresponsive if the proposed budget is greater than the ceiling amounts in this NOFO.

6. Required Registrations

Applicant organizations must complete the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. Applicants must have a valid Dun and Bradstreet Universal Numbering System (DUNS) number in order to begin each of the following registrations.

- (Foreign entities only): Special Instructions for acquiring a Commercial and Governmental Entity (NCAGE) Code: https:// eportal.nspa.nato. int/ AC135Public/

Docs/ US%20Instructions%2 0for%20NSPA%20NCAGE.pdf

- System for Award Management (SAM) – must maintain current registration in SAM (the replacement system for the Central Contractor Registration) to be renewed annually, https://www.sam.gov/portal/SAM/.
- Grants.gov
- eRA Commons

All applicant organizations must register with Grants.gov. Please visit www.Grants.gov at least 30 days prior to submitting your application to familiarize yourself with the registration and submission processes. The "one-time" registration process will take three to five days to complete. However, it is best to start the registration process at least two weeks prior to application submission.

All Program Directors/Principal Investigators (PD/PIs) must also work with their institutional officials to register with the eRA Commons or ensure their existing Principle Investigator (PD/PI) eRA Commons account is affiliated with the eRA commons account of the applicant organization. All registrations must be successfully completed and active before the application due date. Applicant organizations are strongly encouraged to start the eRA Commons registration process at least four (4) weeks prior to the application due date. ASSIST requires that applicant users have active eRA Commons account in order to prepare an application. It also requires that the applicant organization's Signing Official have an active eRA Commons Signing Official account in order to initiate the submission process. During the submission process, ASSIST will prompt the Signing Official to enter their Grants.gov Authorized Organizational Representative (AOR) credentials in order to complete the submission, therefore the applicant organization must ensure that their Grants.gov AOR credentials are active.

7. Universal Identifier Requirements and System for Award Management (SAM)

All applicant organizations **must obtain** a DUN and Bradstreet (D&B) Data Universal Numbering System (DUNS) number as the Universal Identifier when applying for Federal grants or cooperative agreements. The DUNS number is a nine-digit number assigned by Dun and Bradstreet Information Services. An AOR should be consulted to determine the appropriate number. If the organization does not have a DUNS number, an AOR should complete the US D&B D-U-N-S Number Request Web Form or contact Dun and Bradstreet by telephone directly at 1-866-705-5711 (toll-free) to obtain one. A DUNS number will be provided immediately by telephone at no charge. Note this is an organizational number. Individual Program Directors/Principal Investigators do not need to register for a DUNS number. Additionally, all applicant organizations must register in the **System for Award Management (SAM)**. Organizations must maintain the registration with current information at all times during which it has an application under consideration for funding by CDC and, if an award is made, until a final financial report is submitted or the final payment is received, whichever is later. SAM is the primary registrant database for the Federal government and is the repository into which an entity must provide information required for the conduct of business as a recipient. Additional information about registration procedures may be found at the SAM internet site at https://www.sam.gov/index.html.
If an award is granted, the recipient organization **must** notify potential sub-recipients that no organization may receive a subaward under the grant unless the organization has provided its

DUNS number to the recipient organization.

8. Eligible Individuals (Project Director/Principal Investigator) in Organizations/Institutions

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Project Director/Principal Investigator (PD/PI) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for HHS/CDC support.

9. Cost Sharing

This FOA does not require cost sharing as defined in the HHS Grants Policy Statement (http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

10. Number of Applications

As defined in the HHS Grants Policy Statement, (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf), applications received in response to the same Notice of Funding Opportunity generally are scored individually and then ranked with other applications under peer review in their order of relative programmatic, technical, or scientific merit. HHS/CDC will not accept any application in response to this NOFO that is essentially the same as one currently pending initial peer review unless the applicant withdraws the pending application.

Only one application per institution (normally identified by having a unique DUNS Number) per component is allowed for this NOFO. Applicants must submit separate applications if applying to more than one Component. All eligible applicants for Component A may also apply for Component C, D, or E. All eligible applicants for component B can also apply for Component D. To apply for Component C, D, or E, eligible applicants must apply for Component A. To apply for Component D, eligible applicants must apply for Component B.

Section IV. Application and Submission Information

1. Address to Request Application Package

In order to use ASSIST, applicants must visit https://public.era.nih.gov/assist where you can login using your eRA Commons credentials, and enter the Notice of Funding Opportunity Number to initiate the application, and begin the application preparation process.
If you experience problems accessing or using ASSIST, you can refer to the ASSIST Online Help Site at: https://era.nih.gov/erahelp/assist. Additional support is available from the NIH eRA Service desk via:

- E-mail: http://grants.nih.gov/support/index.html
- Phone: 301-402-7469 or (toll-free) 1-866-504-9552. The NIH eRA Service desk is available Monday - Friday, 7 a.m. to 8 p.m. Eastern Time, excluding federal holidays.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF-424 (R&R) Application Guide http://grants.nih.gov/grants/how-to-apply-application-guide.htm and here: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf, except where instructed in this Notice of Funding Opportunity to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review. The package associated with this NOFO includes all applicable mandatory and optional forms. Please note that some forms marked optional in the application package are required for submission of applications for this NOFO. Follow the instructions in the SF-424 (R&R) Application Guide to ensure you complete all appropriate "optional" components.
When using ASSIST, all mandatory forms will appear as separate tabs at the top of the Application Information screen; applicants may add optional forms available for the NOFO by selecting the Add Optional Form button in the left navigation panel.

In conjunction with the SF424 (R&R) components, CDC grant applicants should also complete and submit additional components titled "PHS398." Note the PHS398 should include assurances and certifications, additional data required by the agency for a complete application. While these are not identical to the PHS398 application form pages, the PHS398 reference is used to distinguish these additional data requirements from the data collected in the SF424 (R&R) components. A complete application to CDC will include SF424 (R&R) and PHS398 components. A complete application to CDC will include SF424 (R&R) and PHS398 components. These forms can be downloaded from http://grants.nih.gov/grants/forms.htm

3. Letter of Intent

Due Date for Letter of Intent: **01/14/2019**

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows CIO staff to estimate the potential review workload and plan the review.

By the date listed in Part 1. Overview Information, prospective applicants are asked to submit a letter of intent that includes the following information:

- Name of the Applicant
- Descriptive title of proposed research
- Name, address, and telephone number of the PD(s)/PI(s)
- Names of other key personnel
- Participating institutions
- Number, title, and component of this funding opportunity

The letter of intent should be sent to:

Marcella Law

Scientific Program Official

Extramural Research Program Operations and Services

Centers for Disease Control and Prevention

4770 Buford Highway, NE

Mailstop F-80

Atlanta, GA 30342

Telephone: (770)-488-5416

Email: mah7@cdc.gov

4. Required and Optional Components

A complete application has many components, both required and optional. The forms package associated with this NOFO in Grants.gov includes all applicable components for this NOFO, required and optional. In ASSIST, all required and optional forms will appear as separate tabs at the top of the Application Information screen.

5. PHS 398 Research Plan Component

The SF424 (R&R) Application Guide includes instructions for applicants to complete a PHS 398 Research Plan that consists of components. Not all components of the Research Plan apply to all Notices of Funding Opportunities (NOFOs). Specifically, some of the following components are for Resubmissions or Revisions only. See the SF 424 (R&R) Application Guide https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/generalforms-e.pdf and https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf for additional information. Please attach applicable sections of the following Research Plan components as directed in Part 2, Section 1 (Notice of Funding Opportunity Description).
Follow the page limits stated in the SF 424 unless otherwise specified in the NOFO. As applicable to and specified in the NOFO, the application should include the bolded headers in this section and should address activities to be conducted over the course of the entire project, including but not limited to:

1. **Introduction to Application** (for Resubmission and Revision ONLY) - provide a clear description about the purpose of the proposed research and how it addresses the specific requirements of the NOFO.
2. **Specific Aims** – state the problem the proposed research addresses and how it will result in public health impact and improvements in population health.
3. **Research Strategy** – the research strategy should be organized under 3 headings: Significance, Innovation and Approach. Describe the proposed research plan, including staffing and time line.
4. **Progress Report Publication List** (for Continuation ONLY)

Other Research Plan Sections

5. **Vertebrate Animals**
6. **Select Agent Research**

7. **Multiple PD/PI Leadership Plan.**
8. **Consortium/Contractual Arrangements**
9. **Letters of Support**
10. **Resource Sharing Plan(s)**
11. **Authentication of Key Biological and/or Chemical Resources**
12. **Appendix**

All instructions in the SF424 (R&R) Application Guide https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf and here: https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf must be followed along with any additional instructions provided in the NOFO.
Applicants that plan to collect public health data must submit a Data Management Plan (DMP) in the Resource Sharing Plan section of the PHS 398 Research Plan Component of the application. A DMP is required for each collection of public health data proposed. Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds.
The DMP may be outlined in a narrative format or as a checklist but, at a minimum, should include:
• Descriptions of the data to be produced in the proposed project
• How access will be provided to the data (including provisions for protection of privacy, confidentiality, security, intellectual property, or other rights)
• Use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use
• Plans for archival and long-term preservation of the data, or explaining why long-term preservation and access cannot be justified
Examples of DMPs may be found here: University of California https://dmp.cdlib.org/, or USGS, http://www.usgs.gov/datamanagement/plan/dmplans.php

RESEARCH PLAN

The applicant's research plan should address activities that will be conducted over the 5 year project period. The Research Plan narrative is comprised of components 2 and 3 above. NOTE: that the research Strategy is divided into three parts: 1) Significance, 2) Innovation, and 3) Approach.

The applicant's research plan should include the following items:

Component A – Core-Current:

Background:

1. Describe your experience in conducting surveillance for MD.
    - Describe sources for surveillance of MD and explain facilitators and barriers in using these sources for identifying cases. Describe new sources/plans for identifying remaining cases that are not seeking care at large neuromuscular clinics
    - Describe your site's authority to conduct surveillance for MDs providing references to state laws and rules and documentation such as signed letters or

agreements
    - Describe if and how your site has used surveillance data to identify the need for, design, target, or evaluate public health interventions
2. Identify and explain existing key partnerships within the state and plans to build relationships that facilitate access to administrative data. Also identify key partnerships that can potentially use surveillance data to track health and services and inform policy and interventions. Applicants should provide agreements or letters of support.
3. Describe existing partnerships and plans for building new partnerships with the MD community including patient advocacy groups and clinicians who treat patients with MD. Explain how these partnerships can be used to promote surveillance and research efforts and dissemination of surveillance data to the populations they serve. Applicants should provide letters of support from partners.

Approach:

1. Describe your site's readiness to implement project activities according to the objectives of the NOFO. Provide a timeline for activities and distinguishable benchmarks for monitoring the progress of the project.
2. Describe the geographic area and population of your site and distribution of population by age, race, ethnicity, percentage below the federal poverty line, urban/suburban/rural residence and, if relevant, other prominent demographic characteristics.
3. Estimate the number of expected cases for each type of eligible MD based on prevalence estimates in published literature and eligibility criteria in the objectives. Provide the actual number of cases of MD abstracted to date within your site by MD type during the 2014-2019 funding cycle by gender, race, and ethnicity and compare to expected number of cases.
4. Describe your approach for case ascertainment and data collection.

    - Describe the clinics and hospitals treating patients with MD where abstracting of medical records will occur. Identify the clinics and hospitals with which data collection relationships have been established and those that need to be approached. Discuss potential barriers to accessing medical records in the clinics and hospitals.
    - Describe plans for obtaining medical record information from clinical facilities bordering your site that care for patients with MD residing in your site. Include plans for how you will work with other MD STARnet sites that border your site to obtain clinical record data of each site's eligible cases.
    - Describe ability and resources needed to expand case ascertainment for DM, FSHD, LGMD, CMD, EDMD, and distal MD.

5. Describe the administrative data systems (i.e. vital records, national death index, hospital discharge and/or emergency room data, Medicaid) to which you will have access to for this project and explain the type of data these systems will provide. Applicants should provide letters of support or other documentation of the ability to access administrative data.

6. Propose and describe at least two topics that address knowledge gaps in MD that could be best addressed through research methods such as surveys or phone interviews.

7. Describe the capacity of your site to conduct surveys, phone interviews, or similar research.

Staffing:

1. Demonstrate research capacity by describing staff expertise, including track record of senior staff in conducting surveillance and research, authoring publications, and mentoring junior staff.
2. Provide evidence of a clear management and staffing plan. Include a description of project staff's role, responsibility, and expertise in:
    - Coordination of surveillance system activities
    - Data management, clinical review, data abstraction
    - Development of research methods and tools
    - Implementation of the research (i.e. survey or phone interview)

Component B – Core-New:

Background:

1. Describe your site's experience conducting surveillance for rare disorders:
    - Describe your site's authority for conducting surveillance
    - Describe sources used for surveillance and explain facilitators, deterrents, and barriers in using these sources for identifying cases
    - Describe steps your site has taken to locate cases that are lost to follow-up and facilitators and barriers to locating these cases
    - Describe your experience disseminating findings to professional as well as patient advocacy and other groups orally and in writing (e.g., presentations to clinical groups; presentations at meetings of patient advocacy groups, articles in patient and/or provider newsletters, etc., and papers published in peer-reviewed medical and/or public health journals)
    - Describe if and how your site has used surveillance data to identify the need for, design, target, or evaluate public health interventions.
2. Describe how your site has the ability to conduct population-based surveillance for MDs within a specified geographic area. Describe agreements in place and provide references to state laws, rules, and other documentation such as signed letters or agreements.
3. Explain whether MD is a reportable condition in your site and if so, to what age limit. If MD is not reportable in your site, explain your plan for pursuing this activity
4. Identify and explain existing key partnerships at the state and plans to build relationships that facilitate access to administrative data and could support efforts to designate MD as a reportable condition in your state state (if not already). Also identify key partners that can potentially use surveillance data to track health and services and inform policy and interventions. Applicants should provide agreements or letters of support
5. Describe existing partnerships and plans for building new partnerships with the MD community including patient advocacy groups and clinicians who treat patients with MD. Explain how these partnerships can be used to promote surveillance and research efforts and dissemination of surveillance data to the populations they serve. Applicants should provide letters of support from partners

Approach:

1. Describe your site's readiness to implement project activities according to the objectives of the NOFO. Provide a timeline for activities and distinguishable benchmarks for monitoring the progress of the project.
2. Describe the proposed study population in terms of geographic area and size of population (must have at least 3 million total), annual birth cohort, and distribution of population by age, race and ethnicity (must have large population of African Americans, Hispanics, or Asians), percentage below the federal poverty line, urban/suburban/rural residence and, if relevant, other prominent demographic characteristics. The population should be of sufficient size to be able to address the specific objectives of the NOFO.
3. Estimate the number of expected cases for each type of eligible MD based on prevalence estimates in published literature and eligibility criteria in the objectives.
4. Propose four MDs for which additional clinical indicators will be collected.
5. Describe your approach for case ascertainment and data collection.
    - Describe the clinics and hospitals treating patients with MD where abstracting of medical records will occur. Identify the clinics and hospitals with which data collection relationships have been established and/or those that need to be approached. Discuss potential barriers to accessing medical records in the clinics and hospitals.
    - Describe plans for obtaining medical record information from clinical facilities bordering your site that care for patients with MD residing in your site. Include plans for how you will work with other MD STARnet sites that border your site to obtain clinical record data of each site's eligible cases.
6. Describe the administrative data systems (i.e. vital records, national death index, hospital discharge and/or emergency room data, Medicaid) to which you will have access to for this project and explain the type of data these systems will provide. Provide letters of support or other documentation of the ability to access administrative data.
7. Propose and describe two topics that address knowledge gaps in MD that could be best addressed through research methods such as surveys or phone interviews.
8. Describe the capacity of your site to conduct surveys, phone interviews, or similar research.

Staffing:

1. Demonstrate research capacity by describing staff expertise, including track record of senior staff in conducting surveillance and research, authoring publications, and mentoring junior staff.
2. Provide evidence of a clear management and staffing plan. Include a description of project staff's role, responsibility, and expertise in:
    - Coordination of surveillance system activities (Principal investigator, coordinator)
    - Data management and data abstraction (data manager, abstractors)
    - Development of research methods and tools (co-investigators)
    - Implementation of the research (i.e. survey or phone interview)

Component C –Enhanced-Dissemination

1. Describe your experience disseminating orally and in writing findings to professional, patient advocacy, and other stakeholder audiences.
2. Provide a list of and describe projects on muscular dystrophy your site has conducted/is conducting using MD STARnet data, administrative data, or other study data.
    - Describe publications that have yielded high priority information to advance the scientific knowledge of the MD community.
3. Identify and describe the experience of staff who will be conducting data analysis and dissemination including their experience conducting complex analyses (i.e. longitudinal data analysis).
4. Propose and describe at least five projects that your site will develop into manuscripts. Provide at least five potential professional society or patient advocacy group meetings where they will be presented. Provide a proposed timeline for completion.
5. Describe staff roles and responsibilities for producing the manuscripts and presenting at meetings and conferences.

Component D – Enhanced-DCC:

1. Describe previous experience navigating information security regulations and obtaining authorization to operate (ATO) (if applicable). Describe a plan and staffing for navigating security regulations and obtaining authorization to operate.
2. Describe staff roles and responsibilities, including experience hosting a data coordinating center (DCC) for muscular dystrophies or other conditions.
3. Describe how the DCC will provide support to all sites for the applications, databases, and software for the data collection. This should include a plan for developing or modifying and sharing existing COTS software, applications, and database for longitudinal data collection of MDs. (Software should be off the shelf products that other recipients can easily obtain and support.)
4. Describe a plan for:

    - Performing extensive data cleaning efforts along with guiding and supporting local sites in data cleaning activities. Completing and documenting data cleaning methods and procedures
    - Compiling monthly reports
    - Securing and protecting data
    - Managing the pooling of site-specific data and release analytic data sets.
    - Creating and maintaining detailed records (codebooks, survey instruments, and other materials) on data collection and processing methodology for surveillance and other research activities (i.e., surveys or interviews)
    - Creating cross-walks between datasets (i.e. V8, DMD/BMD (DOB 200+, DMD/BMD legacy, new data collections) and including in the codebooks for each MD
    - Creating, modifying and updating all calculated variables after release of each data set and providing detailed methodology/documentation for each.
    - Developing or modifying data managers' manual
    - Providing technical support to site data managers and to the network

- Leading the data managers in a monthly conference call
- Hosting an internal surveillance system website and FTP site
- Participating in activities required by the federal government such as the SA&A process from the Office of the Chief Information Security Officer (OCISO)

5. Describe timelines to accomplish project goals and objectives.

Component E – Enhanced-Abstractor:

1. Describe staff roles and responsibilities including any previous experience conducting abstractor training and data quality improvement activities.
2. Describe a plan to oversee abstractor training and data quality activities for all sites. In the application include plans for the following items:
   - Training and certifying abstractors
   - Planning and conducting ongoing training and data quality exercises for abstractors
   - Assessing abstractor reliability by reviewing 5% of records
   - Developing, maintaining and updating abstractor training and user manuals
   - Leading and writing minutes of monthly abstractor conference calls
   - Participating on other committees as needed to provide expertise regarding abstraction data
   - Preparing an annual report for the coordinating committee on QA/QC activities conducted and recommended
3. Describe timelines to accomplish project goals and objectives.

6. Appendix

Do not use the appendix to circumvent page limits. A maximum of 10 PDF documents are allowed in the appendix. Additionally, up to 3 publications may be included that are not publically available. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

Documentation such as 1) laws that state MD is a reportable condition in the surveillance area, 2) public health authority for conducting MD surveillance, and 3) agreements to use administrative data should be included in the appendix.

7. Page Limitations

All page limitations described in this individual NOFO must be followed. For this specific NOFO, the Research Strategy component of the Research Plan narrative is limited to 25 pages. Supporting materials for the Research Plan narrative included as appendices may not exceed 10 PDF files with a maximum of 35 pages for all appendices.

8. Format for Attachments

Designed to maximize system-conducted validations, multiple separate attachments are required for a complete application. When the application is received by the agency, all submitted forms and all separate attachments are combined into a single document that is used by peer reviewers and agency staff. Applicants should ensure that all attachments are uploaded to the system.

CDC requires all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted in the SF424 (R&R) Application Guide https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf and here: https://apply07.grants.gov/apply/forms/sample/SF424B-V1.1.pdf.

9. Submission Dates & Times

Part I. Overview Information contains information about Key Dates. Applicants are strongly encouraged to allocate additional time and submit in advance of the deadline to ensure they have time to make any corrections that might be necessary for successful submission. This includes the time necessary to complete the application resubmission process that may be necessary, if errors are identified during validation by Grants.gov and the NIH eRA systems. The application package is not complete until it has passed the Grants.gov and NIH eRA Commons submission and validation processes.

Organizations must submit applications using the ASSIST web-based application preparation and submission process.

ASSIST will validate applications before submission. If the system detects errors, then the applicant must correct errors before their application can be submitted.

Applicants are responsible for viewing their application in ASSIST after submission to ensure accurate and successful submission through Grants.gov. If the submission is not successful and post-submission errors are found, then those errors must be corrected and the application resubmitted in ASSIST.

Applicants are able to access, view, and track the status of their applications in the eRA Commons.

Information on the submission process is provided in the SF-424 (R&R) Application Guidance and ASSIST User Guide at https://era.nih.gov/files/ASSIST_user_guide.pdf.

Note: HHS/CDC grant submission procedures do not provide a grace period beyond the grant application due date time to correct any error or warning notices of noncompliance with application instructions that are identified by Grants.gov or eRA systems (i.e. error correction window).

Applicants who encounter problems when submitting their applications must attempt to resolve them by contacting the NIH eRA Service desk at:
Toll-free: 1-866-504-9552; Phone: 301-402-7469
http://grants.nih.gov/support/index.html
Hours: Mon-Fri, 7 a.m. to 8 p.m. Eastern Time (closed on federal holidays)

Problems with Grants.gov can be resolved by contacting the Grants.gov Contact Center at:
Toll-free: 1-800-518-4726
https://www.grants.gov/web/grants/support.html
support@grants.gov
Hours: 24 hours a day, 7 days a week (closed on federal holidays)

If the applicant encounters problems that prevent the ability to submit an application which cannot be resolved by Grants.gov or NIH eRA Service Desks, then applicants must contact CDC Technical Information Management Section (TIMS) at 770-488-2700; ogstims@cdc.gov for guidance at least 3 calendar days before the deadline date. Therefore, it is important that applicants complete the application submission process well in advance of the due date time.

After submission of your application package, applicants will receive a "submission receipt" email generated by Grants.gov. Grants.gov will then generate a second e-mail message to applicants which will either validate or reject their submitted application package. A third and final e-mail message is generated once the applicant's application package has passed validation and the grantor agency has confirmed receipt of the application.

Unsuccessful Submissions: If an application submission was unsuccessful, the **applicant** must:

1. Track submission and verify the submission status (tracking should be done initially regardless of rejection or success).

    a. If the status states "**rejected**", do #2a or #2b

2. Check emails from both Grants.gov and NIH eRA Commons for rejection notices.

    a. If the deadline has passed, he/she should email the Grants Management contact listed in the Agency Contacts section of this announcement and ogstims@cdc.gov explaining why the submission failed.
    b. If there is time before the deadline, correct the problem(s) and resubmit as soon as possible.

Due Date for Applications: **02/13/2019**

Electronically submitted applications must be submitted no later than 5:00 p.m., ET, on the listed application due date.

10. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review (http:// www. whitehouse.gov/ omb/ grants_spoc).

11. Funding Restrictions

All HHS/CDC awards are subject to the federal regulations, 45 CFR 75, terms and conditions, and other requirements described in the HHS Grants Policy Statement. Pre-award costs may be allowable as an expanded authority, but only if authorized by CDC.
In accordance with the United States Protecting Life in Global Health Assistance policy, all non-governmental organization (NGO) applicants acknowledge that foreign NGOs that receive funds provided through this award, either as a prime recipient or subrecipient, are strictly prohibited, regardless of the source of funds, from performing abortions as a method of family planning or engaging in any activity that promotes abortion as a method of family planning, or to provide financial support to any other foreign non-governmental organization that conducts such activities. See Additional Requirement (AR) 35 for applicability (https://www.cdc.gov/grants/additionalrequirements/ar-35.html).
For more information on expanded authority and pre-award costs, go to: https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf.
CDC requires that mechanisms for, and cost of, public health data sharing be included in grants,

cooperative agreements, and contracts. The cost of sharing or archiving public health data may also be included as part of the total budget requested for first-time or continuation awards. Fulfilling the data-sharing requirement must be documented in a Data Management Plan (DMP) that is developed during the project planning phase prior to the initiation of generating or collecting public health data and must be included in the Resource Sharing Plan(s) section of the PHS398 Research Plan Component of the application.
Applicants who contend that the public health data they collect or create are not appropriate for release must justify that contention in the DMP submitted with their application for CDC funds (for example, privacy and confidentiality considerations, embargo issues).
Recipients who fail to release public health data in a timely fashion will be subject to procedures normally used to address lack of compliance (for example, reduction in funding, restriction of funds, or award termination) consistent with 45 CFR 74.62 or other authorities as appropriate. For further information, please
see: https://www.cdc.gov/grants/additionalrequirements/ar-25.html for revised AR-25.

Funds will be restricted until:

- IRB and OMB/PRA approvals are obtained.
- Human Subjects Education Requirement documentation is provided for any new key personnel or other significant contributors involved in the design or conduct or research involving human subjects.

CDC and sites will identify and develop the Component A and B research studies. Applicants are advised that any activities involving standard information collection (i.e., surveys, questionnaires, data requests, etc.) from 10 or more non-federal individual/entities are subject to Paperwork Reduction Act (PRA) requirements. CDC will coordinate an OMB/PRA approval request.

Reimbursement of pre-award costs is not allowed. All HHS/CDC awards are subject to the terms and conditions, cost principles, and other requirements described in the HHS Grants Policy Statement.

For more information on expanded authority and pre-award costs, go to: http://www.hhs.gov/asfr/ogapa/aboutog/hhsgps107.pdf or speak with your Grants Management Specialist (GMS).

12. Other Submission Requirements and Information

Risk Assessment Questionnaire Requirement
CDC is required to conduct pre-award risk assessments to determine the risk an applicant poses to meeting federal programmatic and administrative requirements by taking into account issues such as financial instability, insufficient management systems, non-compliance with award conditions, the charging of unallowable costs, and inexperience. The risk assessment will include an evaluation of the applicant's CDC Risk Questionnaire, located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, as well as a review of the applicant's history in all available systems; including OMB-designated repositories of government-wide eligibility and financial integrity systems (see 45 CFR

75.205(a)), and other sources of historical information. These systems include, but are not limited to: FAPIIS (https://www.fapiis.gov/), including past performance on federal contracts as per Duncan Hunter National Defense Authorization Act of 2009; Do Not Pay list; and System for Award Management (SAM) exclusions.
CDC requires all applicants to complete the Risk Questionnaire, OMB Control Number 0920-1132 annually. This questionnaire, which is located at https://www.cdc.gov/grants/documents/PPMR-G-CDC-Risk-Questionnaire.pdf, along with supporting documentation must be submitted with your application by the closing date of the Notice of Funding Opportunity Announcement. If your organization has completed CDC's Risk Questionnaire within the past 12 months of the closing date of this NOFO, then you must submit a copy of that questionnaire, or submit a letter signed by the authorized organization representative to include the original submission date, organization's EIN and DUNS.

When uploading supporting documentation for the Risk Questionnaire into this application package, clearly label the documents for easy identification of the type of documentation. For example, a copy of Procurement policy submitted in response to the questionnaire may be labeled using the following format: Risk Questionnaire Supporting Documents _ Procurement Policy.

Duplication of Efforts
Applicants are responsible for reporting if this application will result in programmatic, budgetary, or commitment overlap with another application or award (i.e. grant, cooperative agreement, or contract) submitted to another funding source in the same fiscal year. Programmatic overlap occurs when (1) substantially the same project is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific objective and the project design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source. Budgetary overlap occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source. Commitment overlap occurs when an individual's time commitment exceeds 100 percent, whether or not salary support is requested in the application. Overlap, whether programmatic, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted. Any overlap will be resolved by the CDC with the applicant and the PD/PI prior to award. Report Submission: The applicant must upload the report under "Other Attachment Forms." The document should be labeled: "Report on Programmatic, Budgetary, and Commitment Overlap."

Application Submission
Applications must be submitted electronically following the instructions described in the SF 424 (R&R) Application Guide. **PAPER APPLICATIONS WILL NOT BE ACCEPTED.**

Applicants must complete all required registrations before the application due date. Section III.6 "Required Registrations" contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically (http://grants.nih.gov/grants/guide /url_ redirect.htm? id=11144).

Important reminders:
All PD/PIs must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF 424(R&R) Application Package. Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to CDC.
The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management (SAM). Additional information may be found in the SF424 (R&R) Application Guide.
If the applicant has an FWA number, enter the 8-digit number. Do not enter the letters "FWA" before the number. If a Project/Performance Site is engaged in research involving human subjects, the applicant organization is responsible for ensuring that the Project/Performance Site operates under and appropriate Federal Wide Assurance for the protection of human subjects and complies with 45 CFR Part 46 and other CDC human subject related policies described in Part II of the SF 424 (R&R) Application Guide and in the HHS Grants Policy Statement.

See more resources to avoid common errors and submitting, tracking, and viewing applications:

- http://grants.nih.gov/grants/ElectronicReceipt/avoiding_errors.htm
- http://grants.nih.gov/grants/ElectronicReceipt/submit_app.htm
- https://era.nih.gov/files/ASSIST_user_guide.pdf
- http://era.nih.gov/erahelp/ASSIST/

Upon receipt, applications will be evaluated for completeness by the CDC Office of Grants Services (OGS) and responsiveness by OGS and the Center, Institute or Office of the CDC. Applications that are incomplete and/or nonresponsive will not be reviewed.

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the CDC mission (http:// www.cdc.gov/ about/ organization/ mission.htm), all applications submitted to the CDC in support of public health research are evaluated for scientific and technical merit through the CDC peer review system.

Overall Impact
Reviewers will provide an overall impact/priority score to reflect their assessment of the

likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria
Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Components A, B, and C:

- Did the applicant explain the public health burden that the site will address?
- Did the applicant adequately demonstrate understanding of the need for this site and the planned activities for the targeted population(s)?
- Did the applicant demonstrate a clear understanding of the requirements, objectives, and purpose of this NOFO?
- Will successful implementation of the proposed project substantially contribute to improved understanding of the impact of muscular dystrophies over the life course?
- Does the applicant adequately demonstrate or provide a compelling argument for the potential impact of their proposed research in the US? Do they successfully address how the findings can improve the lives of those affected by MD?

Investigator(s)

Are the PD/PIs, collaborators, and other researchers well suited to the project? Have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Components A-E:

- Does the applicant demonstrate an accomplished and collaborative team that can successfully accomplish the goals and objectives of their proposal?
- Are the roles of project staff well defined?
- Are the expertise, experience, and skills of project personnel appropriate to their roles on the project?
- Are the personnel sufficient given the nature and scope of the project?

- If applicable, can staff and consultants be identified and hired in a timely manner?

Components A and B:

- Do the investigators have experience in conducting surveillance (e.g. birth defects, rare disorders, muscular dystrophy)?
- Are personnel with expertise in surveillance and epidemiology, data collection, survey and interview methods, and medical record abstraction included?

Component C:

- Do the investigators have experience publishing MD STARnet data and communicating research findings to key stakeholders?
- Have investigators led publications that has served to advance the scientific knowledge in the field of muscular dystrophy?
- Does the staff include analysts who have demonstrated expertise in analyzing MD STARnet data and/or have experience conducting longitudinal data analysis?
- Have investigators published public health or clinical data on muscular dystrophies in peer-reviewed journals?
- Does the site have experience presenting and communicating MD STARnet data to health care providers and patient communities?
- Does the applicant include sufficient plans for presenting MD STARnet findings at professional society and patient advocacy group meetings?

Component D:

- Does the applicant demonstrate the experience and/or capacity to host a data coordinating center?
- Does the applicant describe previous experience navigating security regulations and obtaining authorization to operate?
- Does the applicant describe a plan and staffing for navigating security regulations and obtaining authorization to operate?
- Does the applicant have extensive experience in developing, modifying, and/or maintaining customized off the shelf (COTS) software applications, cleaning and pooling data, and creating databases and related documentation?
- Does the applicant have experience providing technical assistance related to data collection and processing?

Component E:

- Does the applicant have extensive experience training medical record abstractors in the abstraction of medical record data related to MD, and monitoring quality of abstraction?
- Does the applicant have an abstractor experienced with abstraction of data related to MD and who has a clinical background?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Components A and B:

- Does the applicant propose to use innovative methods for case ascertainment? Do the proposed innovations have the potential to improve case identification or enhance surveillance?

Component D:

- Does the applicant describe innovative approaches to data management?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?
If the project involves clinical research, are there plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Component A:

- Does the applicant provide an estimate of the number of cases of DMD/BMD and DM expected in their site and the actual number of cases identified to date during the last funding cycle (2014-2019)? Does the applicant demonstrate the ability to successfully identify cases within their surveillance area?

Components A and B:

- Does the applicant describe their experience in conducting population-based surveillance of MD, rare diseases, or other conditions in their site?
- Does the applicant describe their ability to conduct population-based surveillance for MDs? Does the applicant adequately describe planned efforts toward designating MD a a reportable condition in their state, if applicable? Do they state their legal authority or agreements to access data sources needed for their proposed activities?
- Does the applicant provide an adequate plan with feasible methods to carry out all of the proposed objectives? Does the plan cover the entire project period? Will the applicant be able to implement project activities immediately?
- Does the applicant describe sources of data including which sources of administrative data the applicant will have access to for the project? Does the applicant describe what

data will be pooled and shared with CDC and other recipients? Were limitations to data sharing, if any, discussed?
- Is a timeline and milestones provided for activities that will accomplish the objectives? Is the timeline reasonable? Will the timeline allow the applicant to accomplish the goals of the site?

Component B:

- Is the applicant's target population composed of at least 3 million people?
- Does the applicant's target population include a large minority population (African Americans, Hispanics, or Asians)?

Component C:

- Does the applicant propose topics that address key gaps in knowledge for the required manuscripts and a timeline for data analyses and publications?
- Does the applicant describe potential professional society conferences and patient advocacy group meetings where they will present results of manuscripts?

Component D:

- How well does the applicant's approach address each of the following?
    - Performing extensive data cleaning efforts along with guiding and supporting local sites in data cleaning activities. Completing and documenting data cleaning methods and procedures
    - Compiling monthly reports
    - Securing and protecting data
    - Managing the pooling of site-specific data and releasing analytic data sets.
    - Creating and maintaining detailed records (codebooks, survey instruments, and other materials) on data collection and processing methodology for surveillance and other research activities (i.e., surveys or interviews)
    - Creating cross-walks between datasets (i.e. V8, DMD/BMD (DOB 200+, DMD/BMD legacy, new data collections) and including the codebooks for each MD.
    - Creating, modifying and updating all calculated variables after release of each data set and providing detailed methodology/documentation for each
    - Developing or modifying data managers' manual
    - Providing technical support to site data managers and to the network
    - Leading the data managers in a monthly conference call
    - Hosting an internal surveillance system website and FTP site
    - Participating in activities required by the federal government such as the SA&A (formerly known as the C&A) process from the Office of the Chief Information Security Officer (OCISO)

Component E:

- How well does the applicant's approach address each of the following?
    - Training and certifying abstractors
    - Planning and conducting ongoing training and data quality exercises for abstractors
    - Assessing abstractor reliability by reviewing 5% of records
    - Developing, maintaining and updating abstractor training and user manuals
    - Leading and writing minutes of monthly abstractor conference calls
    - Participating on other committees as needed to provide expertise regarding abstraction data
    - Preparing an annual report for the coordinating committee on QA/QC activities conducted and recommended

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Components A and B:

- Has the applicant demonstrated key partnerships that can support accomplishment of the objectives of this NOFO?
- Has the applicant demonstrated access to administrative datasets to maximize case ascertainment?
- Are existing and potential partnerships and collaborations with various entities discussed? Are letters of support or memoranda of understanding, etc. provided and demonstrate existing collaborations are sufficient to accomplish the objectives of the NOFO?

2. Additional Review Criteria

As applicable for the project proposed, *reviewers will evaluate* the following additional items while determining scientific and technical merit, and in providing an overall impact/priority score, but *will not give separate scores* for these items.

Protections for Human Subjects

If the research involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the

justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the HHS/CDC Requirements under AR-1 Human Subjects Requirements (https://www.cdc.gov/grants/additionalrequirements/ar-1.html).

If your proposed research involves the use of human data and/or biological specimens, you must provide a justification for your claim that no human subjects are involved in the Protection of Human Subjects section of the Research Plan.

Inclusion of Women, Minorities, and Children
When the proposed project involves clinical research, the committee will evaluate the proposed plans for inclusion of minorities and members of both genders, as well as the inclusion of children. For additional information on review of the Inclusion section, please refer to the policy on the Inclusion of Women and Racial and Ethnic Minorities in Research (https://www.cdc.gov/maso/Policy/Policy_women.pdf and the policy on the Inclusion of Persons Under 21 in Research (https://www.cdc.gov/maso/Policy/policy496.pdf).

Vertebrate Animals
The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (https://grants.nih.gov/grants/olaw/VAChecklist.pdf).

Biohazards
Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Dual Use Research of Concern
Reviewers will identify whether the project involves one of the agents or toxins described in the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern, and, if so, whether the applicant has identified an IRE to assess the project for DURC potential and develop mitigation strategies if needed.

For more information about this Policy and other policies regarding dual use research of concern, visit the U.S. Government Science, Safety, Security (S3) website at: http://www.phe.gov/s3/dualuse. Tools and guidance for assessing DURC potential may be found at: http://www.phe.gov/s3/dualuse/Pages/companion-guide.aspx.

3. Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact/priority score.

As applicable for the project proposed, reviewers will consider each of the following items, but *will not give scores* for these items, and should not consider them in providing an overall impact/priority score.

Resource Sharing Plan(s)
HHS/CDC policy requires that recipients of grant awards make research resources and data readily available for research purposes to qualified individuals within the scientific community after publication. Please see: https://www.cdc.gov/grants/additionalrequirements/ar-25.html

New additional requirement: CDC requires recipients for projects and programs that involve data collection or generation of data with federal funds to develop and submit a Data Management Plan (DMP) for each collection of public health data.

Investigators responding to this Notice of Funding Opportunity should include a detailed DMP in the Resource Sharing Plan(s) section of the PHS 398 Research Plan Component of the application. The AR-25 outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.

The DMP should be developed during the project planning phase prior to the initiation of collecting or generating public health data and will be submitted with the application. The submitted DMP will be evaluated for completeness and quality at the time of submission.

The DMP should include, at a minimum, a description of the following:

• Type of data to be produced in the proposed project;
• Mechanisms for providing access to and sharing of the data (including provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights);
• Use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use; and
• Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified.

Applications submitted without the required DMP may be deemed ineligible for award unless submission of DMP is deferred to a later period depending on the type of award, in which case, funding restrictions may be imposed pending submission and evaluation.

Budget and Period of Support
Reviewers will consider whether the budget and the requested period of support are fully

justified and reasonable in relation to the proposed research. The applicant can obtain guidance for completing a detailed justified budget on the CDC website, at the following Internet address: http://www.cdc.gov/grants/interestedinapplying/applicationresources.html
The budget can include both direct costs and indirect costs as allowed.
Indirect costs could include the cost of collecting, managing, sharing and preserving data.
Indirect costs on grants awarded to foreign organizations and foreign public entities and performed fully outside of the territorial limits of the U.S. may be paid to support the costs of compliance with federal requirements at a fixed rate of eight percent of modified total direct costs exclusive of tuition and related fees, direct expenditures for equipment, and subawards in excess of $25,000. Negotiated indirect costs may be paid to the American University, Beirut, and the World Health Organization.
Indirect costs on training grants are limited to a fixed rate of eight percent of MTDC exclusive of tuition and related fees, direct expenditures for equipment, and sub-awards in excess of $25,000.
If requesting indirect costs in the budget based on a federally negotiated rate, a copy of the indirect cost rate agreement is required. Include a copy of the current negotiated federal indirect cost rate agreement or cost allocation plan approval letter.

4. Review and Selection Process

Applications will be evaluated for scientific and technical merit by an appropriate peer review group, in accordance with CDC peer review policy and procedures, using the stated review criteria.
As part of the scientific peer review, all applications:

- Will receive a written critique.

Applications will be assigned to the appropriate HHS/CDC Center, Institute, or Office.
Applications will compete for available funds with all other recommended applications submitted in response to this NOFO. Following initial peer review, recommended applications will receive a second level of review. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.

- Will undergo a selection process in which all responsive applications will be discussed and assigned an overall impact/priority score.

- Component A: Ability to successfully find cases with the site as demonstrated by the similarity of the estimates of expected and actual number of DMD/BMD and DM cases.

- Component B: Racial/ethnic diversity of the surveillance population.

Review of risk posed by applicants.
Prior to making a Federal award, CDC is required by 31 U.S.C. 3321 and 41 U.S.C. 2313 to review information available through any OMB-designated repositories of government-wide eligibility qualification or financial integrity information as appropriate. See also suspension and debarment requirements at 2 CFR parts 180 and 376.

In accordance 41 U.S.C. 2313, CDC is required to review the non-public segment of the OMB-designated integrity and performance system accessible through SAM (currently the Federal Recipient Performance and Integrity Information System (FAPIIS)) prior to making a Federal award where the Federal share is expected to exceed the simplified acquisition threshold, defined in 41 U.S.C. 134, over the period of performance. At a minimum, the information in the system for a prior Federal award recipient must demonstrate a satisfactory record of executing programs or activities under Federal grants, cooperative agreements, or procurement awards; and integrity and business ethics. CDC may make a Federal award to a recipient who does not fully meet these standards, if it is determined that the information is not relevant to the current Federal award under consideration or there are specific conditions that can appropriately mitigate the effects of the non-Federal entity's risk in accordance with 45 CFR §75.207.

CDC's framework for evaluating the risks posed by an applicant may incorporate results of the evaluation of the applicant's eligibility or the quality of its application. If it is determined that a Federal award will be made, special conditions that correspond to the degree of risk assessed may be applied to the Federal award. The evaluation criteria is described in this Notice of Funding Opportunity.

In evaluating risks posed by applicants, CDC will use a risk-based approach and may consider any items such as the following:

(1) Financial stability;
(2) Quality of management systems and ability to meet the management standards prescribed in this part;
(3) History of performance. The applicant's record in managing Federal awards, if it is a prior recipient of Federal awards, including timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous Federal awards, and if applicable, the extent to which any previously awarded amounts will be expended prior to future awards;
(4) Reports and findings from audits performed under subpart F 45 CFR 75 or the reports and findings of any other available audits; and
(5) The applicant's ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities.

CDC must comply with the guidelines on government-wide suspension and debarment in 2 CFR part 180, and require non-Federal entities to comply with these provisions. These

provisions restrict Federal awards, subawards and contracts with certain parties that are debarred, suspended or otherwise excluded from or ineligible for participation in Federal programs or activities.

5. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) and other pertinent information via the eRA Commons.

Section VI. Award Administration Information

1. Award Notices

Any applications awarded in response to this NOFO will be subject to the DUNS, SAM Registration, and Transparency Act requirements. If the application is under consideration for funding, HHS/CDC will request "just-in-time" information from the applicant as described in the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the Grants Management Officer is the authorizing document and will be sent via email to the grantee's business official.

Recipient must comply with any funding restrictions as described in Section IV.11. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be allowable as an expanded authority, but only if authorized by CDC.

2. CDC Administrative Requirements

Overview of Terms and Conditions of Award and Requirements for Specific Types of Grants

Administrative and National Policy Requirements, Additional Requirements (ARs) outline the administrative requirements found in 45 CFR Part 75 and the HHS Grants Policy Statement and other requirements as mandated by statute or CDC policy. Recipients must comply with administrative and national policy requirements as appropriate. For more information on the Code of Federal Regulations, visit the National Archives and Records Administration: http://www.access.gpo.gov/nara/cfr/cfr-table- search.html.

Specific requirements that apply to this NOFO are the following:

AR-1: Human Subjects Requirements

AR-2: Inclusion of Women and Racial and Ethnic Minorities in Research

AR-7: Executive Order 12372 Review

AR-9: Paperwork Reduction Act Requirements

AR-10: Smoke-Free Workplace Requirements

AR-11: Healthy People 2010

AR-12: Lobbying Restrictions

AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities

AR-14: Accounting System Requirements

AR-16: Security Clearance Requirement

AR-21: Small, Minority, And Women-owned Business

AR-22: Research Integrity

AR-24: Health Insurance Portability and Accountability Act Requirements

AR-25: Data Management and Access ?new requirement

AR-26: National Historic Preservation Act of 1966

AR-28: Inclusion of Persons Under the Age of 21 in Research

AR-29: Compliance with EO13513, ?Federal Leadership on Reducing Text Messaging while Driving?, October 1, 2009

AR-30: Information Letter 10-006, - Compliance with Section 508 of the Rehabilitation Act of 1973

AR-31: Research Definition

AR-32: Appropriations Act, General Provisions

AR-36: ; Certificates of Confidentiality

AR-25: Data Management and Access

CDC requires recipients for projects that involve the collection or generation of data with federal funds to develop, submit and comply with a Data Management Plan (DMP) for each collection or generation of public health data undertaken as part of the award and, to the extent appropriate, provide access to and archiving/long-term preservation of collected or generated data.

Data Management Plan

Consistent with the terms of and activities expected under the notice of funding opportunity (NOFO), recipients must develop and submit a DMP generally during the project planning phase, but in any event, prior to the initiation of generating or collecting public health data. Accordingly, the DMP may be evaluated during the application, study proposal, or project review process or during other times in the project period. For NOFOs that involve already defined projects which include data collection or generation at the time of application, applications submitted without the required DMP may be deemed non-responsive for award. For NOFOs where CDC specifies that submission of the DMP is deferred to a later period, funding restrictions may be imposed pending submission and evaluation of the DMP. For awards where data collection or generation activities may become necessary during the project

period, DMPs will be required to be submitted and evaluated during the project period of the award. These DMPs also will be required to comply with this AR. In all instances described above, the reviewing officials have to approve an acceptable DMP. Costs associated with developing and implementing a DMP, including costs of sharing, archiving and long-term preservation, may be included in the budget submissions for grants and cooperative agreements.

A DMP for each collection and/or generation of public health data funded by this award should include the following information:

- A description of the data to be collected or generated in the proposed project;
- Standards to be used for the collected or generated data;
- Mechanisms for or limitations to providing access to and sharing of the data (include a description of provisions for the protection of privacy, confidentiality, security, intellectual property, or other rights). This section should address access to identifiable and de-identified data (see below for additional information about access);
- Statement of the use of data standards that ensure all released data have appropriate documentation that describes the method of collection, what the data represent, and potential limitations for use; and
- Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified. This section should address archiving and preservation of identifiable and de-identified data (see below for additional information regarding archiving).

Access to and Archiving of the Data

Recipients whose terms of award do not include submitting data to CDC are expected to plan and prepare for access to and archiving/long-term preservation of collected and/or generated data within the funding period, as set forth below. The final version of a collected and/or generated data set intended for release or sharing should be made available within thirty (30) months after the end of the data collection or generation, except surveillance data which should be made accessible within a year of the end of a collection cycle. In addition, recipients should ensure the quality of data they make accessible and seek to provide the data in a nonproprietary format. Recipients who fail to release public health data in a timely fashion may be subject to procedures normally used to address lack of compliance consistent with applicable authorities, regulations, policies or terms of their award.

For public use de-identified (removal of sensitive identifiable or potentially identifiable information) datasets, an accompanying data dictionary, and other documentation relevant to use of the data set should be deposited in a sustainable repository to provide access to the data. Data that cannot be de-identified can be provided on request under a data-use agreement.

Recipients will be required to inform the appropriate CDC point-of-contact identified in the award via an update to their DMP of the location of the deposited data. The DMP is a living

document that should be updated throughout the life cycle of data.

For data underlying scientific publication, recipients should make the data available coincident with publication of the paper, unless the data set is already available via a release or sharing mechanism. At a minimum, release of the data set should consist of a machine-readable version of the data tables shown in the paper.

Requirements set forth in this policy are not intended to conflict with or supersede applicable grants regulations related to agency access to recipient data and records.

For more information on the Code of Federal Regulations, visit the National Archives and Records Administration at: http://www.archives.gov/.

3. Additional Policy Requirements

The following are additional policy requirements relevant to this NOFO:

HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items and Printing Publications This policy supports the Executive Order on Promoting Efficient Spending (EO 13589), the Executive Order on Delivering and Efficient, Effective, and Accountable Government (EO 13576) and the Office of Management and Budget Memorandum on Eliminating Excess Conference Spending and Promoting Efficiency in Government (M-35-11). This policy apply to all new obligations and all funds appropriated by Congress. For more information, visit the HHS website at: https://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/index.html.

Federal Funding Accountability and Transparency Act of 2006 Federal Funding Accountability and Transparency Act of 2006 (FFATA), P.L. 109–282, as amended by section 6202 of P.L. 110–252, requires full disclosure of all entities and organizations receiving Federal funds including grants, contracts, loans and other assistance and payments through a single, publicly accessible website, www.usaspending.gov. For the full text of the requirements, please review the following website: https://www.fsrs.gov/.

Plain Writing Act The Plain Writing Act of 2010, Public Law 111-274 was signed into law on October 13, 2010. The law requires that federal agencies use "clear Government communication that the public can understand and use" and requires the federal government to write all new publications, forms, and publicly distributed documents in a "clear, concise, well-organized" manner. For more information on this law, go to: http://www.plainlanguage.gov/plLaw/index.cfm.

Pilot Program for Enhancement of Employee Whistleblower Protections All applicants will be subject to a term and condition that applies the terms of 48 CFR section 3.908 to the award and requires that grantees inform their employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. 4712.

Copyright Interests Provision This provision is intended to ensure that the public has access to the results and accomplishments of public health activities funded by CDC. Pursuant to applicable grant regulations and CDC's Public Access Policy, Recipient agrees to submit into the National Institutes of Health (NIH) Manuscript Submission (NIHMS) system an electronic version of the final, peer-reviewed manuscript of any such work developed under this award upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. Also at the time of submission, Recipient and/or the Recipient's submitting author must specify the date the final manuscript will be publicly accessible through PubMed Central (PMC). Recipient and/or Recipient's submitting author must also post the manuscript through PMC within twelve (12) months of the publisher's official date of final publication; however the author is strongly encouraged to make the subject manuscript available as soon as possible. The recipient must obtain prior approval from the CDC for any exception to this provision.
The author's final, peer-reviewed manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. Recipient and its submitting authors working under this award are responsible for ensuring that any publishing or copyright agreements concerning submitted articles reserve adequate right to fully comply with this provision and the license reserved by CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for this award, recipient must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS identification number for up to three (3) months after the publication date and the PubMed Central identification number (PMCID) thereafter.

Language Access for Persons with Limited English Proficiency Recipients of federal financial assistance from HHS must administer their programs in compliance with federal civil rights law. This means that recipients of HHS funds must ensure equal access to their programs without regard to a person's race, color, national origin, disability, age and, in some circumstances, sex and religion. This includes ensuring your programs are accessible to persons with limited English proficiency. Recipients of federal financial assistance must take the reasonable steps to provide meaningful access to their programs by persons with limited English proficiency.

Dual Use Research of Concern On September 24, 2014, the US Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern was released. Grantees (foreign and domestic) receiving CDC funding on or after September 24, 2015 are subject to this policy. Research funded by CDC involving the agents or toxins named in the policy, must be reviewed to determine if it involves one or more of the listed experimental effects and if so, whether it meets the definition of DURC. This review must be completed by an Institutional Review Entity (IRE) identified by the funded institution.

Recipients also must establish an Institutional Contact for Dual Use Research (ICDUR). The award recipient must maintain records of institutional DURC reviews and completed risk mitigation plans for the term of the research grant, cooperative agreement or contract plus three years after its completion, but no less than eight years, unless a shorter period is required by law

or regulation.

If a project is determined to be DURC, a risk/benefit analysis must be completed. CDC will work collaboratively with the award recipient to develop a risk mitigation plan that the CDC must approve. The USG policy can be found at http://www.phe.gov/s3/dualuse.

Non-compliance with this Policy may result in suspension, limitation, restriction or termination of USG funding, or loss of future USG funding opportunities for the non-compliant USG-funded research project and of USG funds for other life sciences research at the institution, consistent with existing regulations and policies governing USG funded research, and may subject the institution to other potential penalties under applicable laws and regulations.

Data Management Plan(s)
CDC requires that all new collections of public health data include a Data Management Plan (DMP). For purposes of this announcement, "public health data" means digitally recorded factual material commonly accepted in the scientific community as a basis for public health findings, conclusions, and implementation.

This new requirement ensures that CDC is in compliance with the following; Office of Management and Budget (OMB) memorandum titled "Open Data Policy–
Managing Information as an Asset" (OMB M-13-13); Executive Order 13642 titled "Making Open and Machine Readable the New Default for Government Information"; and the Office of Science and Technology Policy (OSTP) memorandum titled "Increasing Access to the Results of Federally Funded Scientific Research" (OSTP Memo).

The AR-25 https://www.cdc.gov/grants/additionalrequirements/ar-25.html outlines the components of a DMP and provides additional information for investigators regarding the requirements for data accessibility, storage, and preservation.
Certificates of Confidentiality: Institutions and investigators are responsible for determining whether research they conduct is subject to Section 301(d) of the Public Health Service (PHS) Act. Section 301(d), as amended by Section 2012 of the 21st Century Cures Act, P.L. 114-255 (42 U.S.C. 241(d)), states that the Secretary shall issue Certificates of Confidentiality (Certificates) to persons engaged in biomedical, behavioral, clinical, or other research activities in which identifiable, sensitive information is collected. In furtherance of this provision, CDC supported research commenced or ongoing after December 13, 2016 in which identifiable, sensitive information is collected, as defined by Section 301(d), is deemed issued a Certificate and therefore required to protect the privacy of individuals who are subjects of such research. Certificates issued in this manner will not be issued as a separate document, but are issued by application of this term and condition to this award. See Additional Requirement 36 to ensure compliance with this term and condition. The link to the full text is at:
https://www.cdc.gov/grants/additionalrequirements/ar-36.html.

4. Cooperative Agreement Terms and Conditions

The following special terms of award are in addition to, and not in lieu of, otherwise applicable U.S. Office of Management and Budget (OMB) administrative guidelines, U.S. Department of

Health and Human Services (DHHS) grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), and other HHS, PHS, and CDC grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement, an "assistance" mechanism (rather than an "acquisition" mechanism), in which substantial CDC programmatic involvement with the recipients is anticipated during the performance of the activities. Under the cooperative agreement, the HHS/CDC purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; CDC Project Officer are not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the recipients for the project as a whole, although specific tasks and activities may be shared among the recipients and HHS/CDC as defined below.

The PD(s)/PI(s) will have the primary responsibility for:

Components A and B (current and new MD STARnet sites):

- Oversight of all management, administrative, data security, and scientific aspects of the project
- Maintain an effective and adequate management and staffing plan
- Continue to build and maintain partnerships with stakeholders
- Efforts to designate MD a reportable condition in their state, if applicable
- Serve on Coordinating Committee and other workgroups as requested; participate in monthly conference calls, and participate in up to two in-person PI meetings per year.
- Assign staff to attend conference calls and PI meetings as relevant to their duties
- Obtain/maintain approvals of protocol(s) through designated Institutional Review Board (IRB), assure the protocol(s) (is/are) conducted in compliance with the terms and conditions of the IRB, and amend protocol(s) as needed. Provide approval letters to CDC
- Assure and maintain the confidentiality of all surveillance and study data
- Foster and maintain regular communication with the other recipients and CDC project staff
- Link administrative data to medical record abstraction data and share data with limited identifiers with other sites and CDC through collaboration with the DCC
- OMB/PRA requirements may apply to the research studies. If the Paperwork Reduction Act applies, collaborate with CDC-led effort to develop an information collection request for OMB review and approval

Component C: Dissemination

- Oversight of staff who conduct data analyses and who develop abstracts, presentations, and manuscripts
- Identification of 5 potential manuscript topics that include high priority topics from the MD research agenda (currently under development)
- Maintain and adequate staffing plan to ensure publication and presentations requirements are met

- Serve on a Data Sharing Committee, and other workgroups as requested; participate in monthly conference calls

Component D: Data Coordinating Center

- Oversight of all management, administrative, data security, and scientific aspects of the project
- Maintain an effective and adequate management and staffing plan
- Provide technical assistance to all sites for the applications, databases, and software required for data collection and analysis. For new sites, this may require travel
- Develop or modify existing software, applications, and databases to conduct surveillance and research for MDs
- Compile monthly abstraction reports
- Perform extensive data cleaning efforts along with guiding and supporting local sites in data cleaning activities. Completing and documenting data cleaning methods and procedures
- Secure and protect pooled data from all sites
- Manage the pooling of site-specific data and release of analytic data sets
- Create and maintain detailed records (codebooks, survey instruments, and other materials) on data collection methodology for surveillance and other research activities (i.e., surveys or interviews)
- Create cross-walks between datasets (i.e. V8, DMD/BMD (DOB 200+, DMD/BMD legacy, new data collections) and include in the codebooks for each MD
- Develop, maintain and make revisions as necessary to manuals
- Lead and record a monthly data manager conference call
- Participate on other committees as needed to provide expertise regarding data management issues
- Maintain or contribute to a shared web portal or website housing relevant documents and files
- Create and modify calculated variables and update these for each data set
- Participate in activities required by the federal government including the Security Assessment and Authorization process (SA&A) [formerly known as the Certification and Accreditation (C&A) process] from the Office of the Chief Information Security Officer (OCISO) and production of restricted use data sets with accompanying documentation
- Provide to the CDC copies of all data including at minimum:
    - Data collected via the COTS system
    - All calculated variables generated by the recipient.
    - Program code necessary to rebuild systems. This should also include documented exporting & QC processes, data dictionaries, codebooks, background application code, script, and stored procedures.
    - Provide technical support and system software requirements to rebuild systems resulting in fully operational systems at the completion of the process.

Component E: Abstractor

- Oversee abstractor training and data quality activities for all sites
- Train and certify new abstractors. May require travel to sites for training
- Plan and conduct ongoing training and data quality exercises for all abstractors including conference calls, virtual meetings, and in-person trainings
- Assess abstractor reliability by reviewing 5% of records
- Develop, maintain and update abstractor training and user manuals
- Lead and record monthly abstractor conference calls
- Participate on other committees as needed to provide expertise regarding abstraction data
- Prepare an annual report for the coordinating committee on data quality activities conducted and recommended

Recipients will retain custody of and have primary rights to the data and software developed under these awards, subject to Government rights of access consistent with current DHHS, PHS, and CDC policies.

CDC staff have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

There are two separate CDC scientific roles: Scientific Collaborator (SC) and the Scientific Program Official (SPO).

In this cooperative agreement, a NCBDDD SC is a partner with scientific and programmatic involvement during the conduct of the project through technical assistance, advice, and coordination. The SC will:

- Assist recipients with building partnerships with stakeholders
- Provide expertise and guidance on the content, implementation, and, if needed, revision of the project-developed protocols
- Hold monthly calls and periodic site visits as needed with recipients to determine the adequacy of the research and to monitor performance against approved project objectives
- Support the recipient's activities in data management, analysis and dissemination.
- Provide technical assistance to resolve problems in case ascertainment and data collection procedures
- Assist in the analyses, interpretation, and reporting of findings in the literature.
- Obtain and maintain IRB approvals as required by CDC when CDC is engaged in research involving human subjects
- Lead the Coordinating Committee and a Data Sharing Committee by chairing the committees and leading the monthly conference calls
- Organize and lead up to two annual in-person Principal Investigator meetings hosted either at CDC facilities in Atlanta or at a recipient site location
- Coordinate and facilitate discussion on conference calls; develop agendas and provide meeting minutes; follow-up with sites on action items from calls. Facilitate communication among committees and sites
- Provide technical assistance for health communications, including plain language resources and CDC's Clear Communications Index

- Provide technical assistance to site as requested with dissemination of research using MD STARnet data

Additionally, an HHS/CDC Project Officer or other HHS/CDC staff will provide day-to-day programmatic, administrative, and fiscal management in support of the project as defined above.

Additionally, an HHS/CDC agency Program Official will be responsible for the normal scientific and programmatic stewardship of the award. The SPO will be:

- Named in the Notice of Grant Award (NGA) as the Program Official to provide oversight and assure overall scientific and programmatic stewardship of the award;
- Monitor performance against approved project objectives; and
- Assure assessment of the public health impact of the research conducted under this funding opportunity announcement and promote translation of promising practices, programs, interventions, and other results from the research.

Areas of Joint Responsibility include:

- Implementation of surveillance methods to conduct population-based, longitudinal surveillance on all types of muscular dystrophy across the participating sites.
- Participation in the coordinating committee and other committees or workgroups composed of CDC and other recipients.
- Collaboration on data analyses, publications, and other forms of sharing results.

5. Reporting

Recipients will be required to complete Research Performance Progress Report (RPPR) in eRA Commons at least annually (see https://grants.nih.gov/grants/rppr/index.htm; https://grants.nih.gov/grants/forms/report_on_grant.htm) and financial statements as required in the HHS Grants Policy Statement.

A final progress report, invention statement, equipment inventory list and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the HHS Grants Policy Statement.

Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity depend upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.
Compliance with this law is primarily the responsibility of the Federal agency. However, two elements of the law require information to be collected and reported by recipients:

1) Information on executive compensation when not already reported through the SAM Registration; and
2) Similar information on all sub-awards/ subcontracts/ consortiums over $25,000. It is a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later.
All recipients of applicable CDC grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over $25,000. See the HHS Grants Policy Statement (https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf).

A. Submission of Reports
The Recipient Organization must provide HHS/CDC with an original, plus one hard copy of the following reports:

1. **Yearly Non-Competing Grant Progress Report**, is due 90 to 120 days before the end of the current budget period. The RPPR form (https://grants.nih.gov/grants/rppr/index.htm; https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf) is to be completed on the eRA Commons website. The progress report will serve as the non-competing continuation application. Although the financial plans of the HHS/CDC CIO(s) provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports) and the determination that continued funding is in the best interest of the Federal government.

2. **Annual Federal Financial Report (FFR) SF 425** (https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm) is required and must be submitted through eRA Commons **within 90 days after the end of the calendar quarter in which the budget period ends**.

3. **A final progress report**, invention statement, equipment/inventory report, and the final FFR are required **90 days after the end of the period of performance**.

B. Content of Reports

1. Yearly Non-Competing Grant Progress Report: The grantee's continuation application/progress should include:

- Description of Progress during Annual Budget Period: Current Budget Period Progress reported on the RPPR form in eRA Commons (https://grants.nih.gov/grants/rppr/index.htm). Detailed narrative report for the current budget period that directly addresses progress towards the Measures of Effectiveness

included in the current budget period proposal.
- Research Aims: list each research aim/project

a) Research Aim/Project: purpose, status (met, ongoing, and unmet), challenges, successes, and lessons learned
b) Leadership/Partnership: list project collaborations and describe the role of external partners.

- Translation of Research (1 page maximum). When relevant to the goals of the research project, the PI should describe how the significant findings may be used to promote, enhance, or advance translation of the research into practice or may be used to inform public health policy. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups, researchers, and other potential users. The PI should identify the research findings that were translated into public health policy or practice and how the findings have been or may be adopted in public health settings. Or, if they cannot be applied yet, this section should address which research findings may be translated, how these findings can guide future research or related activities, and recommendations for translation. If relevant, describe how the results of this project could be generalized to populations and communities outside of the study. Questions to consider in preparing this section include:

- How will the scientific findings be translated into public health practice or inform public health policy?
- How will the project improve or effect the translation of research findings into public health practice or inform policy?
- How will the research findings help promote or accelerate the dissemination, implementation, or diffusion of improvements in public health programs or practices?
- How will the findings advance or guide future research efforts or related activities?

- Public Health Relevance and Impact (1 page maximum). This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project relate beyond the immediate study to improved practices, prevention or intervention techniques, inform policy, or use of technology in public health. Questions to consider in preparing this section include:
- How will this project lead to improvements in public health?
- How will the findings, results, or recommendations been used to influence practices, procedures, methodologies, etc.?
- How will the findings, results, or recommendations contributed to documented or projected reductions in morbidity, mortality, injury, disability, or disease?

- Current Budget Period Financial Progress: Status of obligation of current budget period funds and an estimate of unobligated funds projected provided on an estimated FFR.

- New Budget Period Proposal:
- Detailed operational plan for continuing activities in the upcoming budget period, including updated Measures of Effectiveness for evaluating progress during the upcoming budget period. Report listed by Research Aim/Project.
- Project Timeline: Include planned milestones for the upcoming year (be specific and provide deadlines).

- New Budget Period Budget: Detailed line-item budget and budget justification for the new budget period. Use the CDC budget guideline format.

- Publications/Presentations: Include publications/presentations resulting from this CDC grant only during this budget period. If no publication or presentations have been made at this stage in the project, simply indicate “Not applicable: No publications or presentations have been made."

- IRB Approval Certification: Include all current IRB approvals to avoid a funding restriction on your award. If the research does not involve human subjects, then please state so. Please provide a copy of the most recent local IRB and CDC IRB, if applicable. If any approval is still pending at time of APR due date, indicate the status in your narrative.

- Update of Data Management Plan: The DMP is considered a living document that will require updates throughout the lifecycle of the project. Investigators should include any updates to the project’s data collection such as changes to initial data collection plan, challenges with data collection, and recent data collected. Applicants should update their DMP to reflect progress or issues with planned data collection and submit as required for each reporting period.

- Additional Reporting Requirements:

https://era.nih.gov/docs/Commons_UserGuide.pdf

2. Annual Federal Financial Reporting The Annual Federal Financial Report (FFR) SF 425 is required and must be submitted through eRA Commons within 90 days after the end of the calendar quarter in which the budget period ends. The FFR should only include those funds authorized and disbursed during the timeframe covered by the report. The final FFR must indicate the exact balance of unobligated funds and may not reflect
any unliquidated obligations. There must be no discrepancies between the
final FFR expenditure data and the Payment Management System's (PMS) cash transaction data.
Failure to submit the required information in a timely manner may adversely affect the future funding of this project. If the information cannot be provided by the due date, you are required to submit a letter explaining the reason and date by which the Grants Officer will receive the information.

The due date for final FFRs will continue to be 90 days after the Period of Performance end date.
Recipients must submit closeout reports in a timely manner. Unless the Grants Management Officer (GMO) of the awarding Institute or Center approves an extension, recipients must submit a final FFR, final progress report, and Final Invention Statement and Certification within 90 days of the end of grant period. Failure to submit timely and accurate final reports may affect future funding to the organization or awards under the direction of the same Project Director/Principal Investigator (PD/PI).

FFR (SF 425) instructions for CDC recipients are now available at https://grants.nih.gov/grants/forms/report_on_grant/federal_financial_report_ffr.htm. For further information, contact GrantsInfo@nih.gov. Additional resources concerning the eFSR/FFR system, including a User Guide and an on-line demonstration, can be found on the eRA Commons Support Page: https://grants.nih.gov/support/index.html

FFR Submission: The submission of FFRs to CDC will require organizations to register with eRA Commons (Commons) (https:// commons. era.nih.gov/ commons/). CDC recommends that this one time registration process be completed at least 2 weeks prior to the submittal date of a FFR submission.

Organizations may verify their current registration status by running the "List of Commons Registered Organizations" query found at: https://era.nih.gov/registration_accounts.cfm. Organizations not yet registered can go to https://commons.era.nih.gov/commons for instructions. It generally takes several days to complete this registration process. This registration is independent of Grants.gov and may be done at any time.

The individual designated as the PI on the application must also be registered in the Commons. The PI must hold a PI account and be affiliated with the applicant organization. This registration must be done by an organizational official or their delegate who is already registered in the Commons. To register PIs in the Commons, refer to the eRA Commons User Guide found at: https://era.nih.gov/docs/Commons_UserGuide.pdf.

3. Final Reports: Final reports should provide sufficient detail for CDC to determine if the stated outcomes for the funded research have been achieved and if the research findings resulted in public health impact based on the investment. The grantee's final report should include:

- Research Aim/Project Overview: The PI should describe the purpose and approach to the project, including the outcomes, methodology and related analyses. Include a discussion of the challenges, successes and lessons learned. Describe the collaborations/partnerships and the role of each external partner.

- Translation of Research Findings: The PI should describe how the findings will be translated and how they will be used to inform policy or promote, enhance or advance the impact on public health practice. This section should be understandable to a variety of audiences, including policy makers, practitioners, public health programs, healthcare institutions, professional organizations, community groups,

researchers and other potential end users. The PI should also provide a discussion of any research findings that informed policy or practice during the course of the period of performance. If applicable, describe how the findings could be generalized and scaled to populations and communities outside of the funded project.

- Public Health Relevance and Impact: This section should address improvements in public health as measured by documented or anticipated outcomes from the project. The PI should consider how the findings of the project related beyond the immediate study to improved practices, prevention or intervention techniques, or informed policy, technology or systems improvements in public health.

- Publications; Presentations; Media Coverage: Include information regarding all publications, presentations or media coverage resulting from this CDC funded activity. Please include any additional dissemination efforts that did or will result from the project.

- Final Data Management Plan: Applicants must include an updated final Data Management Plan that describes the data collected, the location of where the data is stored (example: a repository), accessibility restrictions (if applicable), and the plans for long term preservation of the data.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts
Grants.gov Customer Support (Questions regarding Grants.gov registration and submission, downloading or navigating forms)
Contact Center Phone: 800-518-4726
Email: support@grants.gov
Hours: 24 hours a day, 7 days a week; closed on Federal holidays

eRA Commons Help Desk (Questions regarding eRA Commons registration, tracking application status, post submission issues, FFR submission)
Phone: 301-402-7469 or 866-504-9552 (Toll Free)
TTY: 301-451-5939
Email: commons@od.nih.gov
Hours: Monday - Friday, 7am - 8pm U.S. Eastern Time

CDC Technical Information Management Section (TIMS)
Telephone 770-488-2700
Email: ogstims@cdc.gov
Hours: Monday - Friday, 7am – 4:30pm U.S. Eastern Standard Time

Scientific/Research Contact(s)

Marcella Law
Scientific Program Official
Extramural Research Program Operations and Services
Centers for Disease Control and Prevention
4770 Buford Highway, NE
Mailstop F-80
Atlanta, GA 30342
Telephone: (770)-488-5416
Email: mah7@cdc.gov

Peer Review Contact(s)

Jaya Raman, Ph.D.
Scientific Review Official
Extramural Research Program Operations and Services
Centers for Disease Control and Prevention
4770 Buford Highway, NE
Mailstop F-80
Atlanta, GA 30342
Telephone: (770)-488-6511
Email: kva@cdc.gov

Financial/Grants Management Contact(s)

Heidi Williams or Sharon Cassell
Grants Management Specialist
Office of Grant Services
Centers for Disease Control and Prevention
2920 Brandywine Road, GHSecB, Team 1
Atlanta, GA 30341
Telephone: Heidi, 770.488.2626 or Sharon, 770.488.2703

Email: Heidi, isa2@cdc.gov or Sharon, zpr0@cdc.gov

Section VIII. Other Information

Other CDC Notices of Funding Opportunities can be found at www.grants.gov.
All awards are subject to the terms and conditions, cost principles, and other considerations described in the HHS Grants Policy Statement.

Authority and Regulations
Awards are made under the authorization of Sections of the Public Health Service Act as amended and under the Code Federal Regulations.