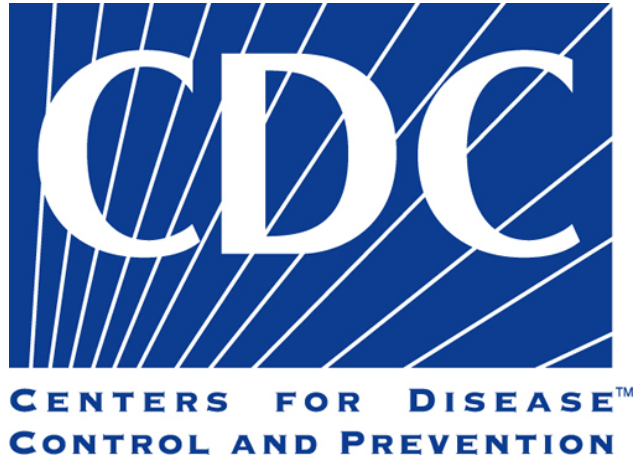




Centers for Disease Control and Prevention

NATIONAL CENTER ON BIRTH DEFECTS AND DEVELOPMENTAL DISABILITIES

Surveillance of Muscular Dystrophies

CDC-RFA-DD-24-0064

05/08/2024

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Part I. Overview

Applicants must go to the synopsis page of this announcement at www.grants.gov and click on the "Subscribe" button link to ensure they receive notifications of any changes to CDC-RFA-DD-24-0064. Applicants also must provide an e-mail address to www.grants.gov to receive notifications of changes.

A. Federal Agency Name:

Centers for Disease Control and Prevention (CDC)

B. Notice of Funding Opportunity (NOFO) Title:

Surveillance of Muscular Dystrophies

C. Announcement Type: New - Type 1:

This announcement is only for non-research activities supported by CDC. If research is proposed, the application will not be considered. For purposes of this NOFO, research is defined as set forth in 45 CFR 75.2 and, for further clarity, as set forth in 42 CFR 52.2 (see eCFR :: 45 CFR 75.2 -- Definitions and <https://www.gpo.gov/fdsys/pkg/CFR-2007-title42-vol1/pdf/CFR-2007-title42-vol1-sec52-2.pdf>). In addition, for purposes of research involving human subjects and available exceptions for public health activities, please see 45 CFR 46.102(l) ([https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.102#p-46.102\(l\)](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.102#p-46.102(l))).

D. Agency Notice of Funding Opportunity Number:

CDC-RFA-DD-24-0064

E. Assistance Listings Number:

93.073

F. Dates:

1. Due Date for Letter of Intent (LOI):

The LOI date will generate once the Synopsis is published if Days or a Date are entered.

Recommended but not Required

A letter of intent is recommended, but not required. The purpose of an LOI is to allow CDC program staff to estimate the number of and plan for the review of submitted applications.

LOI must be sent via email to:

Kandi Givner

CDC, NCBDDD

Email address: xla7@cdc.gov

2. Due Date for Applications:

05/08/2024

11:59 p.m. U.S. Eastern Standard Time, at www.grants.gov.

3. Due Date for Informational Conference Call

An informational call for potential applicants will take place on March 28, 2024, from 2:00-3:00 PM Eastern Daylight Time (EDT). The call will be held via Zoom:

Join ZoomGov Meeting

<https://cdc.zoomgov.com/j/1609494004?pwd=THBoa2ptZ2M5WDlJSzIrbUlKZmRXZz09>

Meeting ID: 160 949 4004

Passcode: z!4+Aryx

One tap mobile

+16692545252,,1609494004#,,,,*37061257# US (San Jose)

+16468287666,,1609494004#,,,,*37061257# US (New York)

Dial by your location

- +1 669 254 5252 US (San Jose)
- +1 646 828 7666 US (New York)
- +1 646 964 1167 US (US Spanish Line)
- +1 669 216 1590 US (San Jose)
- +1 415 449 4000 US (US Spanish Line)
- +1 551 285 1373 US (New Jersey)

Meeting ID: 160 949 4004

Passcode: 37061257

Find your local number: <https://cdc.zoomgov.com/u/abX4DfedWI>

Join by SIP

- 1609494004@sip.zoomgov.com

Join by H.323

- 161.199.138.10 (US West)
- 161.199.136.10 (US East)

Meeting ID: 160 949 4004

Passcode: 37061257

G. Executive Summary:

Summary Paragraph

The purpose of this NOFO is to conduct longitudinal, population-based surveillance of select muscular dystrophies (MD) [Duchenne MD (DMD), Becker MD (BMD), myotonic dystrophy (DM), facioscapulohumeral muscular dystrophy (FSHD), limb-girdle MD (LGMD), congenital MD (CMD), Emery-Dreifuss MD (EDMD), and distal MD] to describe key health outcomes and health inequities, with the goal of improving the health of individuals living with muscular dystrophies. This NOFO has three components to achieve the purpose of the program: Component A is the core surveillance component and will fund longitudinal data collection, analysis, and dissemination of results. Component B will fund one applicant to conduct abstractor training and activities that improve quality of the surveillance data. Component C is an optional component in which recipients will either 1) develop and evaluate novel approaches to case finding or longitudinal data collection (e.g., through machine learning algorithms, automated data extraction) or 2) describe the use of MD-specific ICD-10-CM codes by source. The goals of Components B and C are to improve accuracy and efficiency in case finding and data collection to improve data quality and timeliness. Surveillance data will be analyzed and results disseminated to determine prevalence, mortality/survival, care utilization, differences in access to care and new treatments, disease progression, comorbidities, and factors that lead to better outcomes.

a. Eligible Applicants:

Open Competition

b. NOFO Type:

CA (Cooperative Agreement)

c. Approximate Number of Awards

10

5-7 (Component A); 1 (Component B); 2 (Component C)

d. Total Period of Performance Funding:

\$15,200,000

e. Average One Year Award Amount:

\$380,000

Component A: \$450-500,000 per year

Component B: \$100,000 per year

Component C: \$100,000 per year

f. Total Period of Performance Length:

4 year(s)

g. Estimated Award Date:

September 01, 2024

h. Cost Sharing and / or Matching Requirements:

No

Part II. Full Text

A. Funding Opportunity Description

1. Background

a. Overview

Muscular dystrophies (MDs) are a group of rare inherited disorders characterized by progressive and irreversible muscle weakness and wasting. They 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 surveillance is needed to estimate prevalence, morbidity, and mortality, and to describe the variability and disparities in access to care and treatments received among individuals with MD. Epidemiological data also support the establishment and evaluation of policies and health care services and enable assessment of health equity and outcomes among people affected by MD.

CDC's surveillance for muscular dystrophies started in 2002 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. Initially, surveillance focused on the most common muscular dystrophies, Duchenne muscular dystrophy (DMD) and Becker muscular dystrophy (BMD). During this first phase of MD surveillance, the **Muscular Dystrophy Surveillance, Tracking, and Research Network (MD STARnet)** was developed. The network collected, analyzed and published MD surveillance data, leading to an improved understanding of DMD and BMD. Topics covered in publications thus far include prevalence, survival/mortality, delays in diagnosis, disparities in diagnosis and care received, and association of treatments on disease progression (Sahay, Paramsothy, Thomas, Mann, Butterfield). Surveillance of MDs later expanded, under the MD STARnet surveillance efforts, to include surveillance of myotonic dystrophy (DM), facioscapulohumeral MD (FSHD), limb-girdle MD (LGMD), congenital MD (CMD), Emory-Dreifuss MD (EDMD), distal MD, and oculopharyngeal MD (OPMD)—and described the sociodemographic and key clinical attributes of these populations (Do, Wallace). Currently, several analyses are underway to describe prevalence, diagnosis, survival, and health services and treatments received in these populations. Additional years of surveillance data are needed to understand changes that have occurred in the prevalence and health of these populations especially considering recent advances in diagnosis and treatment.

The approach of this NOFO will be to conduct longitudinal, population-based surveillance of MDs, building on the methods and lessons learned from previous surveillance of MDs. This NOFO will support the development and implementation of surveillance of MDs across the

lifespan - , collection and analysis of surveillance data and dissemination of results. This NOFO has three components: Component A is the core surveillance component and will fund data collection, analysis, and dissemination. Component B will fund one applicant to conduct abstractor training and activities that improve quality of the surveillance data. Component C is an optional component in which recipients will either 1) develop and evaluate novel approaches to case finding or longitudinal data collection (e.g., through machine learning algorithms, automated data extraction) or 2) describe the use of MD-specific ICD-10-CM codes by source.

b. Statutory Authorities

Sections 317C and 317Q of the Public Health Service Act (42 U.S.C. Sections 247b-4 and 247 b-18).

c. Healthy People 2030

N/A

d. Other National Public Health Priorities and Strategies

The strategies and activities of this NOFO are consistent with the missions of the National Center on Birth Defects and Developmental Disabilities (NCBDDD) and the Division of Birth Defects and Infant Disorders (DBDID):

NCBDDD mission:

- Improving the health of people living with disabilities
- Helping children live to the fullest by understanding developmental disabilities.

DBDID mission:

- Identify and address preventable causes of birth defects, infant disorders, and related conditions.
- Promote and improve the health of people living with birth defects, infant disorders, and related conditions.

e. Relevant Work

Since 2002, MD STARnet has improved the understanding of the impact of MD on affected individuals and their families through collection, analysis, and dissemination of population-based data to stakeholder audiences. The current NOFO will build upon the work done by MD STARnet by using MD STARnet methodology to conduct surveillance for individuals with MD. More information about MD STARnet can be found at: [Muscular Dystrophy Research and Tracking | CDC](#).

2. CDC Project Description

a. Approach

Bold indicates period of performance outcome.

CDC-RFA-DD-24-0064 Logic Model: Surveillance of Muscular Dystrophies

Bold indicates period of performance outcome

Strategies and Activities	Short-term Outcomes	Intermediate Outcomes	Long-Term Outcomes
Component A	Component A	Component A	Components A, B, & C
<p><u>Surveillance Capacity</u></p> <p>Conduct longitudinal, population-based data collection on individuals with muscular dystrophy</p> <p>Access clinical and administrative data sources for case identification and data collection</p> <p><u>Data Management and Reporting</u></p> <p>Use standardized database provided by CDC for data collection and submit individual-level data with limited identifiers to CDC for pooling</p> <p>Routinely monitor data quality and improve quality as needed</p> <p><u>Dissemination:</u></p> <p>Collaborate with CDC and other grantees in the analysis of surveillance data and dissemination of findings to</p>	<p>Increased awareness and understanding among providers, patients, caregivers about:</p> <ul style="list-style-type: none"> • disease prevalence • mortality/survival • care utilization • access to care and new treatments • disease progression and comorbidities • factors that lead to better outcomes 	<p>Improved ability of policymakers to make data-informed decisions</p> <p>Improved ability to develop effective secondary prevention strategies to reduce the public health impact of MDs</p> <p>Improvements in clinical care for individuals with MD</p>	<p>Improved health for individuals with MDs</p> <p>Prolonged survival for individuals with MDs</p> <p>Improved quality of life for individuals with MDs and their families</p>

stakeholder audiences			
Component B	Components A, B, and C	Components A, B and C	
<u>Abstractor training and data quality improvement</u> Train, certify, and conduct ongoing training of abstractors Plan and implement activities that improve quality of surveillance data	Improved accuracy and efficiency in case finding and data collection	Improved data quality and availability of data for action	
Component C	Component C		
<u>Efficiencies in Data Collection</u> Develop, implement, and evaluate novel approaches to case-	Improved understanding of the accuracy of ICD codes in identifying individuals with MD		

finding and data collection			
Develop and implement study to evaluate the use of MD-specific ICD-10 codes by source			

i. Purpose

The purpose of this NOFO is to conduct longitudinal, population-based surveillance of select muscular dystrophies [Duchenne MD (DMD), Becker MD (BMD), myotonic dystrophy (DM), facioscapulohumeral muscular dystrophy (FSHD), limb-girdle MD (LGMD), congenital MD (CMD), Emery-Dreifuss MD (EDMD), and distal MD] to describe key health outcomes and

health inequities, with the goal of identifying opportunities to improve the health of all individuals living with muscular dystrophies.

ii. Outcomes

Recipients are expected to demonstrate measurable progress toward addressing the following short and intermediate outcomes in the logic model:

Component A

- Increased awareness and understanding among providers, patients, caregivers about:
 - disease prevalence
 - mortality/survival
 - care utilization
 - access to care and new treatments
 - disease progression and comorbidities
 - factors that lead to better outcomes

Components A, B, and C

- Improved accuracy and efficiency in case finding and data collection
- Improved data quality and availability of data for action

Component C

- Improved understanding of the accuracy of ICD codes in identifying individuals with MD

iii. Strategies and Activities

The strategies and activities of this NOFO include those that are listed in the Strategies and Activities column in the logic model above and are restated here with additional detail. Each recipient will conduct all activities within their component and is expected to collaborate and coordinate across NOFO recipients as part of a multidisciplinary collaborative. The purpose of Component B is to provide support to Component A. The purpose of optional Component C is to develop efficient methods of case ascertainment and data collection that could be applied across NOFO recipient sites.

Component A

Surveillance Capacity

- Conduct longitudinal, population-based data collection on individuals with muscular dystrophies.
 - Build on surveillance methods developed as part of MD STARnet, to identify individuals with MDs (DMD, BMD, DM, FSHD, LGMD, CMD, EDMD, and Distal MD). Eligibility criteria include:
 - Health encounter on or after January 1, 2015
 - Residency in the surveillance area at any time after January 1, 2015
 - Diagnosis of eligible MD
 - Collect data from medical records including:
 - Demographics (e.g., birth month/year, death month/year, insurance, employment status, educational attainment)

- Diagnosis (signs and symptoms, screening and diagnostic tests)
 - Key clinical assessments, interventions, medications, and procedures related to MD care (e.g., neuromuscular, cardiac, pulmonary, endocrine, neurobehavioral)
- Build new and maintain existing relationships with state agencies and institutions to conduct and enhance case ascertainment and data collection activities (e.g., public health authority to conduct surveillance for MDs, access to administrative data, access to data from birth defects and other surveillance systems).
- Engage in data modernization activities including testing novel approaches to data collection developed by CDC or recipient of Component C.
- Utilize MD surveillance protocols previously developed as part of MD STARnet to develop a site-specific surveillance manual or standard operating procedure and update as needed.
- Access clinical and administrative data sources for case identification and data collection
 - Access multiple sources, such as neuromuscular, specialty care and other outpatient clinics, hospitals; administrative data (e.g., vital records, Medicaid/Medicare, hospital discharge); or other sources available to funding recipients to generate an accurate and complete population-based cohort for the surveillance area.
 - Use clinic sources to determine other healthcare sources where individuals with MD receive specialty care (e.g., cardiac and pulmonary care) and collect data at these sources.
 - Recipients whose geographic areas share a physical border should collaborate to obtain medical record data of individuals who receive care in the other's surveillance area.
 - Use address tracing services to obtain address histories on eligible cases.

Data Management and Reporting

- Use standardized database and applications provided by CDC for data collection and submit individual-level data with limited identifiers, including but not limited to date of birth (month/year), date of death (month/year), and clinic visits/procedures (month/year) to CDC.
 - Abstract data from medical and vital records into standardized database.
 - Provide data to CDC on community indicators (e.g., socio-economic status) by linking to census data.
 - Provide individual-level data to CDC. Pooled analytic data sets for each MD that contain limited identifiers will be provided to all recipients.
- Routinely monitor data quality and improve quality as needed.
 - Participate in initial and ongoing abstractor training and data quality activities. Applicant should plan for abstractors to travel to Component B recipient site for initial, focused, comprehensive training and annual trainings in conjunction with Principal Investigator meetings.
 - Clean local data and perform data quality checks according to protocols.

Dissemination

- Collaborate with CDC and other grantees in the analysis of surveillance data and dissemination of findings to stakeholder audiences.
 - Collaborate with CDC and other grantees in identifying knowledge gaps and prioritizing analyses.
 - Propose and describe at least 3 project ideas that are expected to be developed into manuscripts.
 - Present project results at least 3 times at national conferences, professional societies or other meetings that include target audiences (i.e., clinicians, industry representatives, patient advocacy groups, families and individuals with MD, regional communities, researchers, and/or public health professionals). Presentation of results could include webinars, oral or poster presentations at conferences or other methods designed to reach target audiences.
 - Conduct secondary analysis for at least 1 other research project led by another recipient or CDC.
 - Participate in the development of analytic variables.
 - Participate in analyses, abstracts, and manuscripts led by other recipient or CDC investigators that require epidemiologic, clinical, analytical, and other expertise available in that site. Build and maintain partnerships with the regional and local MD community (e.g., patient advocacy groups, clinicians who treat patients with MD) to inform community about surveillance results. Collaborate with CDC and national MD partners to inform community about surveillance results.

Component B

Abstractor training and data quality improvement

- Train, certify and provide ongoing training to abstractors in the standardized collection of data from medical records.
- Conduct data quality activities (e.g., inter-rater reliability exercises) to improve data quality of data collection from medical records.
- Develop, modify, and update training materials and manuals.
- Communicate regularly with abstractors through leading monthly abstractor calls and providing assistance to recipient sites as needed. Provide technical assistance as needed through participation in committees, workgroups, and Principal Investigator meetings.

Component C

Efficiencies in Data Collection

- Develop, implement, and evaluate novel approaches to case-finding and data collection.
 - Develop data extraction tool (e.g., machine learning algorithms, natural language processing, automated data extraction/integration) to reduce abstractor effort and time to abstract cases.
 - Pilot data extraction using clinic sources within site(s) and compare with current method of data abstraction.

- Develop documentation that clearly describes the functionality of the data extraction tool, with specifics on use of machine learning and natural language processing.
- Develop and implement study to evaluate the use of MD-specific ICD-10 codes by source.
 - Development a plan to collect MD ICD-10 codes for eligible individuals by source where cases were ascertained.
 - Collect data to determine the use of MD-specific ICD-10 codes by source.
 - Analyze data and publish findings.

1. Collaborations

a. With other CDC programs and CDC-funded organizations:

Each recipient will conduct all required activities indicated for their respective component and is expected to collaborate and coordinate with other recipients and CDC. Applicants must describe how they plan to work with other recipients and CDC to achieve the outcomes of the NOFO. Anticipated collaborations include implementation of data sharing, pooling of data across recipient sites, coordination of methods for data collection, determining case status, participating in abstractor training and data quality activities, engaging in data modernization activities, evaluating progress, analyzing data and disseminating results, and participating on committees and workgroups. Applicants will also collaborate with CDC and national patient advocacy groups to disseminate results from analysis of MD surveillance data.

A Data Use Agreement (DUA) is generally not needed between a NOFO recipient and CDC, since the NOFO itself serves that function. If a DUA is needed with CDC and/or other NOFO recipients, the recipient must document that within the proposal. If the NOFO recipient currently has DUAs in place they plan to extend or renew, those should be noted and a copy of the DUA provided. NOFO recipients will need to collaborate with CDC to develop and sign new DUAs within the first 6 months of the award, using CDC's DUA template.

b. With organizations not funded by CDC:

Recipients are expected to maintain existing partnerships and establish new partnerships as needed. Recipients will maintain or build partnerships with their state health departments or other state agencies to maintain or establish public health authority for MD surveillance, 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. Formal agreements already in place that are related to conducting surveillance and accessing records should be included with the application. Applicants should provide MOU/MOAs, DUAs, or other documentation to indicate the applicant has access to source records. Applicant must name the file as appropriate (e.g., MOU/MOA, DUA) and upload as a PDF, Word, or Excel file format at www.grants.gov. Renewal or development of new MOUs/MOAs or DUAs are expected to be finalized within 6 months of the award date. Recipients should also maintain and establish partnerships with local and regional patient advocacy groups and clinicians who treat individuals with MD to assist in disseminating results from surveillance data.

2. Population(s) of Focus

The target population for this NOFO includes all individuals with one of the eight eligible types of MD residing in the surveillance area. Applicants will identify a geographic area (e.g., a state or area within a state) with a population of at least 3 million people. Eligible individuals with DMD, BMD, DM, FSHD, LGMD, CMD, EDMD, or Distal MD must have a health encounter on or after January 1, 2015 and reside in the surveillance area at any time after January 1, 2015.

This NOFO, including funding and eligibility, is not limited based on, and does not discriminate on the basis of race, color, national origin, disability, age, sex (including gender identity, sexual orientation, and pregnancy) or other constitutionally protected statuses.

a. Health Disparities

The goal of health equity is for everyone to have a fair and just opportunity to attain their highest level of health. Achieving this requires focused and ongoing societal efforts to address historical and contemporary injustices; overcome economic, social, and other obstacles to health and healthcare; and eliminate preventable health disparities.

Broadly defined, social determinants of health are non-medical factors that influence health outcomes. They are the conditions in which people are born, grow, work, live, and age, and the wider set of forces and systems shaping the conditions of daily life. These forces (e.g., racism, climate) and systems include economic policies and systems, development agendas, social norms, social policies, and political systems. See content below and in other sections (e.g., Approach, Collaborations, Populations of Focus) for information on how this specific NOFO affects social determinants of health.

A health disparity is a preventable difference in the burden of disease, injury, violence, or opportunities to achieve optimal health that are experienced by populations that have been socially, economically, geographically, and environmentally disadvantaged. Health disparities are inextricably linked to a complex blend of social determinants that influence which populations are most disproportionately affected by these diseases and conditions.

This NOFO will provide data on the prevalence, diagnosis, and clinical care of individuals with MD among sub-populations (e.g., sex, race/ethnicity, urban vs. rural areas). Understanding any differences by these factors will help inform policies that address access to care for all individuals with MD.

iv. Funding Strategy

This NOFO includes three components. Component A includes the core surveillance and dissemination activities. Component B includes enhanced activities of abstractor training and data quality improvement. Component C is an optional component; awards will be subject to availability of funding. Component A is required for all applicants. Component B is not required for all applicants, however there are enhanced activities under Component B and one applicant should be awarded Component B. Component C is optional. Component A applicants may apply for both Components B and C or can apply for either Component B or C. The annual award range for Component A is \$450,000-\$500,000. The annual funding ceiling for Components B and C is \$100,000. Funding for Component C is anticipated to be for 2-3 years of the project period.

b. Evaluation and Performance Measurement

i. CDC Evaluation and Performance Strategy

The evaluation and performance measurement strategy will be used to assess the performance of the overall project. Measures are subject to change. Evaluation and performance measures must be tracked by recipients and reported to CDC as requested. Measures are meant to be collective across recipients unless otherwise indicated. Applicants must include an evaluation plan that aligns with the strategies and activities in the logic model, includes performance measures, describes personnel assigned to activities, includes a timeline, describes anticipated outcomes, and describes use of evaluation results for program improvement.

CDC and recipients will use findings from these measures to: 1) ensure program implementation and continuous system improvement and 2) demonstrate achievement of activities and short-term outcomes. Information will lead to improvements in implementation of current and future longitudinal surveillance activities and demonstrate progress toward reaching program goals.

CDC has provided example process and outcome measures that can be used by recipients to describe how they will monitor and report performance measurement data.

Process measures

Component A:

Surveillance capacity

- Current MOAs/MOUs, DUAs, and other agreements that enable access to sources and ability to conduct population-based surveillance provided in the application, as needed
- Updated or new MOA/MOUs, DUAs, and other agreements provided within 6 months of award, as needed
- IRB protocols approved or exempted from review with 6 months of award.
- Site-specific surveillance manual or standard operating procedure based on MD STARnet protocol is developed within 6 months of award and updated as needed
- Number of staff hired and trained within 6 months of award
- Number of clinic sources contacted and case lists obtained
- Address tracing service identified and purchased

Data Management and Reporting

- Standardized database received and installed
- Training on use of database completed
- Number of cases abstracted by source
- Number of cases assigned case definition
- Timely response to CDC in performing periodic data quality checks
- Link birth, death, and census data prior to data submission
- Number of data sets sent to CDC

Dissemination

- Number of recipient-led analyses completed
- Number of recipient-led presentations to target audiences
- Number of recipient-led manuscripts submitted for journal peer-review
- Number of projects involved as co-author for projects led by other recipients

Component B:

Abstractor training and data quality improvement

- Number of abstractors trained and certified
- Number of data quality activities conducted
- Over 90% agreement (or other metric) for data fields in inter-rater reliability exercises
- Number of training materials and manuals developed or modified

Component C:

Efficiencies in Data Collection

- Study methods or tool developed
- Number of abstractions completed by tool
- Number of discrepant results comparing abstractions from tool and current methods
- Number of MD ICD codes by source for each case
- Manuscript published describing use of new MD ICD codes across sources or development of data collection tool

Outcome measures

Components A and C:

- Reduced time in abstracting cases when implementing data collection tool
- Number and description of conferences/meetings and number of attendees where results are presented
- Altmetrics scores of publications

Data Management Plan:

All recipients will conduct data collection for core surveillance activities. At periodic intervals, recipients will submit standardized data to CDC. Once the data are received by CDC, it is subject to applicable federal law, including for purposes of data sharing. CDC will pool data with limited identifiers (i.e., dates) from all sites into pooled analytic datasets which will be furnished to all recipients. A subset of this dataset may be requested by outside investigators in the form of a public-use dataset containing no personally identifying information and constructed to minimize the possibility of identification of individuals. CDC will coordinate with recipients on which data elements to make publicly available, but it is a requirement of all federally funded programs to comply with the CDC Data Management and Sharing Policy (<http://www.cdc.gov/maso/Policy/ReleasingData.pdf>) to furnish data for public use, so all recipients are required to make these data available in an established manner.

For Component A, applicants must include a draft data management plan that includes:

- A description of the data to be collected or generated
- The standards to be used for the collected or generated data

- Mechanisms for, or limitations to, providing access to the data, including a description for the provisions for the protection of privacy, confidentiality, security, and intellectual property, or other rights
- Statement of the use of data standards that ensure all documentation describes the method of collection and what the data represent
- Plans for archiving and long-term preservation of the data, or explaining why long-term preservation and access are not justified
- Other additional requirements based on the program

During the project period, CDC will provide guidance and technical assistance to recipients for updating or revising DMP, as needed.

Since Component B does not involve the generation or collection of public health data, a Data Management Plan is not required. For projects proposed under Component C, a DMP will be required if the project involves the generation or collection of public health data.

ii. Applicant Evaluation and Performance Measurement Plan

Applicants must provide an evaluation and performance measurement plan that demonstrates how the recipient will fulfill the requirements described in the CDC Evaluation and Performance Measurement and Project Description sections of this NOFO. At a minimum, the plan must describe:

- How applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement, including, as applicable to the award, how findings will contribute to reducing or eliminating health disparities and inequities.
- How key program partners will participate in the evaluation and performance measurement planning processes.
- Available data sources, feasibility of collecting appropriate evaluation and performance data, and other relevant data information (e.g., performance measures proposed by the applicant).
- How evaluation findings will be disseminated to communities and populations of interest in a manner that is suitable to their needs.
- Plans for updating the Data Management Plan (DMP) as new pertinent information becomes available. If applicable, throughout the lifecycle of the project. Updates to DMP should be provided in annual progress reports. The DMP should provide a description of the data that will be produced using these NOFO funds; access to data; data standards ensuring released data have documentation describing methods of collection, what the data represent, and data limitations; and archival and long-term data preservation plans. For more information about CDC's policy on the DMP, see <https://www.cdc.gov/grants/additional-requirements/ar-25.html>.

Where the applicant chooses to, or is expected to, take on specific evaluation studies, the applicant should be directed to:

- Describe the type of evaluations (i.e., process, outcome, or both).
- Describe key evaluation questions to be addressed by these evaluations.

- Describe other information (e.g., measures, data sources).

Recipients will be required to submit a more detailed Evaluation and Performance Measurement plan, including a DMP, if applicable, within the first 6 months of award, as described in the Reporting Section of this NOFO.

d. Work Plan

Applicants are required to provide a work plan that provides both a high-level overview of the entire four-year period of performance and a detailed description of the first year of the award. The work plan must demonstrate how the outcomes, strategies, activities, timelines, and staffing/collaborations work together. Information on performance measures should be included in the work plan.

The proposed Project Period Timeline:

- Year 1: Update/finalize MOUs/DUAs and protocols, finalize research questions and variables, pilot database, begin data collection for FSHD
- Year 2: Conduct data collection for FSHD and DMD/BMD
- Year 3: Conduct data collection for LGMD, CMD, EDMD, and distal MD and DM
- Year 4: Finish data collection for DM

For each component, the First-Year Work Plan should include:

- Program strategies
- Program activities
- Performance Measures
- Timeframe
- Persons responsible
- Activity completion date

A sample workplan that includes the first strategy and activities as an example is below:

Strategy	Activity	Performance Measure	Person Responsible	Timeframe	Activity Completion Date
Surveillance Capacity	Conduct longitudinal data collection on individuals with muscular dystrophy				
	Access clinical and administrative data sources for case identification				

	and data collection				
--	------------------------	--	--	--	--

For each component, the Four-Year Overview of the Project Work Plan should include intended strategies, activities, outputs, and outcomes for the entire four-year period of performance.

c. Organizational Capacity of Recipients to Implement the Approach

All applicants must demonstrate their existing or potential capacity to successfully execute all proposed strategies and activities to meet the project requirements of each funding component to which they are applying. Applicants should indicate their understanding and capacity to share data with CDC as described in the NOFO. Applicants should address infrastructure (the applicant organization's physical space, equipment, and capacity to work remotely), partnership development, evaluation and performance monitoring, financial reporting, budget management and administration, personnel management (including developing staffing plans, and developing and training workforce), and expertise and experience related to all component-specific project focus areas. Furthermore, applicants must be fully capable of managing the required procurement efforts, including the ability to write and award contracts in accordance with 45 CFR Part 75.

Key capacity considerations for Component A to address in the application:

- Applicants must describe their experience related to the content area and provide documentation of current operational capacity to conduct multiple source surveillance using methodology similar to that used in MD STARnet. Each applicant must provide evidence (e.g., MOU/MOA, DUA, or letter of support) from the state government or governing body (e.g., health system, university) that they would have access to health records, if funded, and be able to submit individual-level data with limited identifiers to CDC. Public health authority to conduct surveillance for MD is strongly encouraged.
- Applicants must describe their resources and staffing levels. The exact personnel and percentage of time allotted will vary by site. However, there are basic project staff requirements, including having actively involved principal investigator(s), project coordinator, epidemiologist, record abstractors (at least one full-time equivalent), clinician reviewer, data analysts, and data management/programmer support.
- Applicants must demonstrate that they have adequate technical and facility resources to meet the project's goals, including informational technology (IT) infrastructure such as the capacity to maintain a database application (e.g., SQL Server) on a local network server.

Key capacity considerations for Component B to address in the application:

- Applicants must describe their experience in conducting abstractor training and data quality improvement activities. They must describe resources and staffing roles and responsibilities.

Key capacity considerations for Component C to address in the application:

- Applicants must describe their experience related to the content area of their proposed project (e.g., development of machine learning algorithms/data extraction tools). They must also describe resources and staffing roles and responsibilities.

e. CDC Monitoring and Accountability Approach

Monitoring activities include routine and ongoing communication between CDC and recipients, site visits, and recipient reporting (including work plans, performance, and financial reporting). Consistent with applicable grants regulations and policies, CDC expects the following to be included in post-award monitoring for grants and cooperative agreements:

- Tracking recipient progress in achieving the desired outcomes.
- Ensuring the adequacy of recipient systems that underlie and generate data reports.
- Creating an environment that fosters integrity in program performance and results.

Monitoring may also include the following activities deemed necessary to monitor the award:

- Ensuring that work plans are feasible based on the budget and consistent with the intent of the award.
- Ensuring that recipients are performing at a sufficient level to achieve outcomes within stated timeframes.
- Working with recipients on adjusting the work plan based on achievement of outcomes, evaluation results and changing budgets.
- Monitoring performance measures (both programmatic and financial) to assure satisfactory performance levels.

Monitoring and reporting activities that assist grants management staff (e.g., grants management officers and specialists, and project officers) in the identification, notification, and management of high-risk recipients.

CDC and recipients will collaborate on development of measures for performance monitoring. Emphasis will be placed on process measures for monthly reporting and on outcome measures for yearly reporting. CDC will provide feedback on process measures during site-specific monthly calls and on aggregated (all-site) outcome measures during coordinating committee calls and PI meetings.

f. CDC Program Support to Recipients

CDC staff will be substantially involved beyond site visits and regular performance and financial monitoring during the period of performance of this cooperative agreement. Substantial involvement means that the recipient can expect federal programmatic partnerships in carrying out the efforts under the award. The CDC program will work in partnership with the recipient to ensure the success of the cooperative agreement by providing:

i. Technical Assistance

- Assist recipients with surveillance activities including surveillance protocols, the operationalization of case definitions, and providing data dictionaries and other resources
- Provide technical consultation regarding surveillance methods including data collection and abstraction, quality assurance, evaluation, case review, analyses, and reporting
- Hold monthly calls and periodic site visits as needed with recipients to monitor performance and provide technical assistance

- Share data collection systems and provide technical support to qualified data management/programmer staff
- Provide tools and guidance for extracting data with limited identifiers for submission to CDC
- Pool data from all sites and distribute datasets to recipients
- Assist in the analyses, interpretation, and reporting of findings in the literature
- Provide updated information on relevant CDC, US Department of Health and Human Services (HHS), and other policies and regulations that affect the programs

ii. Information Sharing among Recipients:

- Facilitate implementation and updating of data sharing guidelines.
- Maintain a platform (i.e. SharePoint) which allows documents and other key project materials to be shared among sites.
- Coordinate and facilitate discussion on committee conference calls (e.g., coordinating, data sharing, data management); develop agendas and provide meeting minutes; follow-up with sites on action items from calls.
- Organize and lead an annual in-person (Atlanta) or virtual Principal Investigator meeting.

B. Award Information

1. Funding Instrument Type:

CA (Cooperative Agreement)

CDC's substantial involvement in this program appears in the CDC Program Support to Recipients Section.

2. Award Mechanism:

U01

3. Fiscal Year:

2024

Estimated Total Funding:

\$15,200,000

4. Approximate Total Fiscal Year Funding:

\$3,800,000

Component A: \$2,250,000 – \$3,500,000 per year

Component B – \$100,000 per year

Component C – fund if available: \$200,000 per year

This amount is subject to the availability of funds.

5. Approximate Period of Performance Funding:

\$15,200,000

Component A: \$9,000,000 – \$14,000,000

Component B – \$400,000

Component C – fund if available: \$800,000

6. Total Period of Performance Length:

4 year(s)

7. Expected Number of Awards:

10

5-7 (Component A); 1 (Component B); 2 (Component C)

8. Approximate Average Award:

\$380,000

Per Budget Period

Component A: \$450-500,000 per year

Component B: \$100,000 per year

Component C: \$100,000 per year

9. Award Ceiling:

\$700,000

Per Budget Period

Component A: \$500,000 per year

Component B: \$100,000 per year

Component C: \$100,000 per year

10. Award Floor:

\$250,000

Per Budget Period

Component A: \$250,000

Component B: \$50,000

Component C: \$50,000

11. Estimated Award Date:

September 01, 2024

12. Budget Period Length:

12 month(s)

Throughout the period of performance, CDC will continue the award based on the availability of funds, the 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 total number of years for which federal support has been approved (period of performance) will be shown in the “Notice of Award.” This information does not constitute a commitment by

the federal government to fund the entire period. The total period of performance comprises the initial competitive segment and any subsequent non-competitive continuation award(s).

13. Direct Assistance

Direct Assistance (DA) is not available through this NOFO.

If you are successful and receive a Notice of Award, in accepting the award, you agree that the award and any activities thereunder are subject to all provisions of 45 CFR Part 75, currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

C. Eligibility Information

1. Eligible Applicants

Eligibility Category:

00 (State governments)

01 (County governments)

02 (City or township governments)

04 (Special district governments)

05 (Independent school districts)

06 (Public and State controlled institutions of higher education)

07 (Native American tribal governments (Federally recognized))

08 (Public housing authorities/Indian housing authorities)

11 (Native American tribal organizations (other than Federally recognized tribal governments))

12 (Nonprofits having a 501(c)(3) status with the IRS, other than institutions of higher education)

13 (Nonprofits without 501(c)(3) status with the IRS, other than institutions of higher education)

20 (Private institutions of higher education)

22 (For profit organizations other than small businesses)

23 (Small businesses)

25 (Others (see text field entitled "Additional Information on Eligibility" for clarification))

99 (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:

Government Organizations:

State (includes the District of Columbia)

Local governments or their bona fide agents

Territorial governments or their bona fide agents in the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau

State controlled institutions of higher education

American Indian or Alaska Native tribal governments (federally recognized or state-recognized)

American Indian or Alaska native tribally designated organizations

Other:

Private colleges and universities

Community-based organizations

Faith-based organizations

2. Additional Information on Eligibility

For Component A:

- 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.
- Applicant must provide evidence that they have effectively conducted surveillance for MD or rare diseases/birth defects and document access to sources needed for surveillance to occur (provide surveillance report or other documentation).

For Component B or C:

- 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.

3. Justification for Less than Maximum Competition

N/A

4. Cost Sharing or Matching

Cost Sharing / Matching Requirement:

No

5. Maintenance of Effort

Maintenance of effort is not required for this program.

D. Application and Submission Information

1. Required Registrations

An organization must be registered at the three following locations before it can submit an application for funding at www.grants.gov.

PLEASE NOTE: Effective April 4, 2022, applicants must have a Unique Entity Identifier (UEI) at the time of application submission (SF-424, field 8c). The UEI is generated as part of SAM.gov registration. Current SAM.gov registrants have already been assigned their UEI and can view it in SAM.gov and Grants.gov. Additional information is available on the [GSA website](https://www.gsa.gov), [SAM.gov](https://sam.gov), and [Grants.gov- Finding the UEI](https://www.grants.gov).

a. Unique Entity Identifier (UEI):

All applicant organizations must obtain a Unique Entity Identifier (UEI) number associated with your organization's physical location prior to submitting an application. A UEI number is a unique twelve-digit identification number assigned through SAM.gov registration. Some organizations may have multiple UEI numbers. Use the UEI number associated with the location of the organization receiving the federal funds.

b. System for Award Management (SAM):

The SAM is the primary registrant database for the federal government and the repository into which an entity must submit information required to conduct business as a recipient. All applicant organizations must register with SAM, and will be assigned a SAM number and a Unique Entity Identifier (UEI). All information relevant to the SAM number must be current at all times during which the applicant has an application under consideration for funding by CDC. If an award is made, the SAM information must be maintained until a final financial report is submitted or the final payment is received, whichever is later. The SAM registration process can require 10 or more business days, and registration must be renewed annually. Additional information about registration procedures may be found at [SAM.gov](https://sam.gov) and the [SAM.gov Knowledge Base](https://sam.gov).

c. [Grants.gov](https://www.grants.gov): The first step in submitting an application online is registering your organization at www.grants.gov, the official HHS E-grant Web site. Registration information is located at the "Applicant Registration" option at www.grants.gov.

All applicant organizations must register at www.grants.gov. The one-time registration process usually takes not more

than five days to complete. Applicants should start the registration process as early as possible.

Step	System	Requirements	Duration	Follow Up
1	System for Award	1. Go to SAM.gov and create an Electronic Business Point of Contact (EBiz POC) (You will	7-10 Business Days but may take longer and must be renewed once a year	For SAM Customer Service

	Management (SAM)	need to have an active SAM account before you can register on grants.gov). The UEI is generated as part of your registration.		Contact https://fsd.gov/fsd-gov/home.do Calls: 866-606-8220
2	Grants.gov	1. Set up an account in Grants.gov, then add a profile by adding the organization's new UEI number. 2. The EBiz POC can designate user roles, including Authorized Organization Representative (AOR). 3. AOR is authorized to submit applications on behalf of the organization in their workspace.	Allow at least one business day (after you enter the EBiz POC name and EBiz POC email in SAM) to receive a UEI (SAM) which will allow you to register with Grants.gov and apply for federal funding.	Register early! Applicants can register within minutes.

2. Request Application Package

Applicants may access the application package at www.grants.gov. Additional information about applying for CDC grants and cooperative agreements can be found here: <https://www.cdc.gov/grants/applying/pre-award.html>

3. Application Package

Applicants must download the SF-424, Application for Federal Assistance, package associated with this funding opportunity at www.grants.gov.

4. Submission Dates and Times

If the application is not submitted by the deadline published in the NOFO, it will not be processed. Office of Grants Services (OGS) personnel will notify the applicant that their application did not meet the deadline. The applicant must receive pre-approval to submit a paper application (see Other Submission Requirements section for additional details). If the applicant is authorized to submit a paper application, it must be received by the deadline provided by OGS.

a. Letter of Intent Deadline (must be emailed)

Due Date for Letter Of Intent 04/08/2024

04/08/2024

A letter of intent is recommended, but not required. The purpose of an LOI is to allow CDC program staff to estimate the number of and plan for the review of submitted applications.

LOI must be sent via email to:

Kandi Givner

CDC, NCBDDD

Email address: xla7@cdc.gov

b. Application Deadline

Due Date for Applications 05/08/2024

05/08/2024

11:59 pm U.S. Eastern Time, at www.grants.gov. If Grants.gov is inoperable and cannot receive applications, and circumstances preclude advance notification of an extension, then applications must be submitted by the first business day on which Grants.gov operations resume.

Due Date for Informational Conference Call

An informational call for potential applicants will take place on March 28, 2024, from 2:00-3:00 PM Eastern Daylight Time (EDT). The call will be held via Zoom:

Join ZoomGov Meeting

<https://cdc.zoomgov.com/j/1609494004?pwd=THBoa2ptZ2M5WDlJSzIrbUlKZmRXZz09>

Meeting ID: 160 949 4004

Passcode: z!4+Aryx

One tap mobile

+16692545252,,1609494004#,,,*37061257# US (San Jose)

+16468287666,,1609494004#,,,*37061257# US (New York)

Dial by your location

- +1 669 254 5252 US (San Jose)
- +1 646 828 7666 US (New York)
- +1 646 964 1167 US (US Spanish Line)
- +1 669 216 1590 US (San Jose)
- +1 415 449 4000 US (US Spanish Line)
- +1 551 285 1373 US (New Jersey)

Meeting ID: 160 949 4004

Passcode: 37061257

Find your local number: <https://cdc.zoomgov.com/u/abX4DfedWI>

Join by SIP

- 1609494004@sip.zoomgov.com

Join by H.323

- 161.199.138.10 (US West)
- 161.199.136.10 (US East)

Meeting ID: 160 949 4004

Passcode: 37061257

5. Pre-Award Assessments

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 in Grants.gov under "Other Attachment Forms." The document should be labeled: "Report on Programmatic, Budgetary, and Commitment Overlap."

6. Content and Form of Application Submission

Applicants are required to include all of the following documents with their application package at www.grants.gov.

7. Letter of Intent

Is a LOI:

Recommended but not Required

A letter of intent is recommended, but not required. The purpose of an LOI is to allow CDC program staff to estimate the number of and plan for the review of submitted applications.

The LOI must be sent via email to:

Kandi Givner

CDC, NCBDDD

Email address: xla7@cdc.gov

8. Table of Contents

(There is no page limit. The table of contents is not included in the project narrative page limit.): The applicant must provide, as a separate attachment, the "Table of Contents" for the entire submission package.

Provide a detailed table of contents for the entire submission package that includes all of the documents in the application and headings in the "Project Narrative" section. Name the file "Table of Contents" and upload it as a PDF, Word, or Excel file format under "Other Attachment Forms" at www.grants.gov.

9. Project Abstract Summary

A project abstract is included on the mandatory documents list and must be submitted at www.grants.gov. The project abstract must be a self-contained, brief summary of the proposed project including the purpose and outcomes. This summary must not include any proprietary or confidential information. Applicants must enter the summary in the "Project Abstract Summary" text box at www.grants.gov.

10. Project Narrative

Multi-component NOFOs may have a maximum of 15 pages for the “base” (subsections of the Project Description that the components share with each other, which may include target population, inclusion, collaboration, etc.); and up to 4 additional pages per component for

Project Narrative subsections that are specific to each component.

Text should be single spaced, 12 point font, 1-inch margins, and number all pages. Page limits include work plan; content beyond specified limits may not be reviewed.

Applicants should use the federal plain language guidelines and Clear Communication Index to respond to this Notice of Funding Opportunity Announcement. Note that recipients should also use these tools when creating public communication materials supported by this NOFO. Failure to follow the guidance and format may negatively impact scoring of the application.

a. Background

Applicants must provide a description of relevant background information that includes the context of the problem (See CDC Background).

b. Approach

i. Purpose

Applicants must describe in 2-3 sentences specifically how their application will address the problem as described in the CDC Background section.

ii. Outcomes

Applicants must clearly identify the outcomes they expect to achieve by the end of the period of performance. Outcomes are the results that the program intends to achieve. All outcomes must indicate the intended direction of change (e.g., increase, decrease, maintain). (See the logic model in the Approach section of the CDC Project Description.)

iii. Strategies and Activities

Applicants must provide a clear and concise description of the strategies and activities they will use to achieve the period of performance outcomes. Applicants must select existing evidence-based strategies that meet their needs, or describe in the Applicant Evaluation and Performance

Measurement Plan how these strategies will be evaluated over the course of the period of performance. (See CDC Project Description: Strategies and Activities section.)

1. Collaborations

Applicants must describe how they will collaborate with programs and organizations either internal or external to CDC. Applicants must address the Collaboration requirements as described in the CDC Project Description.

2. Population(s) of Focus and Health Disparities

Applicants must describe the specific population(s) of focus in their jurisdiction and explain how to achieve the goals of the award and/or alleviate health disparities. The applicants must also address how they will include specific populations that can benefit from the program that is described in the Approach section. Applicants must address the Population(s) of Focus and Health Disparities requirements as described in the CDC Project Description, including (as applicable to this award) how to address health disparities in the design and implementation of the proposed program activities.

c. Applicant Evaluation and Performance Measurement Plan

Applicants must provide an evaluation and performance measurement plan that demonstrates how the recipient will fulfill the requirements described in the CDC Evaluation and Performance Measurement and Project Description sections of this NOFO. At a minimum, the plan must describe:

- How applicant will collect the performance measures, respond to the evaluation questions, and use evaluation findings for continuous program quality improvement. The Paperwork Reduction Act of 1995 (PRA): Applicants are advised that any activities involving information collections (e.g., surveys, questionnaires, applications, audits, data requests, reporting, recordkeeping and disclosure requirements) from 10 or more individuals or non-Federal entities, including State and local governmental agencies, and funded or sponsored by the Federal Government are subject to review and approval by the Office of Management and Budget. For further information about CDC's requirements under PRA see <https://www.cdc.gov/os/integrity/reducepublicburden/index.htm>.
- How key program partners will participate in the evaluation and performance measurement planning processes.
- Available data sources, feasibility of collecting appropriate evaluation and performance data, data management plan (DMP), and other relevant data information (e.g., performance measures proposed by the applicant).

Where the applicant chooses to, or is expected to, take on specific evaluation studies, they should be directed to:

- Describe the type of evaluations (i.e., process, outcome, or both).
- Describe key evaluation questions to be addressed by these evaluations.
- Describe other information (e.g., measures, data sources).

Recipients will be required to submit a more detailed Evaluation and Performance Measurement plan (including the DMP elements) within the first 6 months of award, as described in the Reporting Section of this NOFO.

d. Organizational Capacity of Applicants to Implement the Approach

Applicants must address the organizational capacity requirements as described in the CDC Project Description.

11. Work Plan

(Included in the Project Narrative's page limit)

Applicants must prepare a work plan consistent with the CDC Project Description Work Plan section. The work plan integrates and delineates more specifically how the recipient plans to carry out achieving the period of performance outcomes, strategies and activities, evaluation and performance measurement.

12. Budget Narrative

Applicants must submit an itemized budget narrative. When developing the budget narrative, applicants must consider whether the proposed budget is reasonable and consistent with the purpose, outcomes, and program strategy outlined in the project narrative. The budget must include:

- Salaries and wages
- Fringe benefits
- Consultant costs
- Equipment
- Supplies
- Travel
- Other categories
- Contractual costs
- Total Direct costs
- Total Indirect costs

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 MTDC 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.

If applicable and consistent with the cited statutory authority for this announcement, applicant entities may use funds for activities as they relate to the intent of this NOFO to meet national

standards or seek health department accreditation or reaccreditation through the Public Health Accreditation Board (see: <http://www.phaboard.org>). Applicant entities to whom this provision applies include state, local, territorial governments (including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau), or their bona fide agents, political subdivisions of states (in consultation with states), federally recognized or state-recognized American Indian or Alaska Native tribal governments, and American Indian or Alaska Native tribally designated organizations. Activities include those that enable a public health organization to deliver public health services such as activities that ensure a capable and qualified workforce, up-to-date information systems, and the capability to assess and respond to public health needs. Use of these funds must focus on achieving a minimum of one national standard that supports the intent of the NOFO. Proposed activities must be included in the budget narrative and must indicate which standards will be addressed.

Vital records data, including births and deaths, are used to inform public health program and policy decisions. If applicable and consistent with the cited statutory authority for this NOFO, applicant entities are encouraged to collaborate with and support their jurisdiction's vital records office (VRO) to improve vital records data timeliness, quality and access, and to advance public health goals. These goals may include supporting vital records offices participating in the Vital Records and Health Statistics Accreditation Program, certifying vital records offices to meet industry standards. Recipients may, for example, use funds to support efforts to build VRO capacity through partnerships; provide technical and/or financial assistance to improve vital records timeliness, quality or access; provide financial assistance to support accreditation related fees and/or support staff time to coordinate accreditation activities; or support vital records improvement efforts, as approved by CDC.

Applicants must name this file "Budget Narrative" and can upload it as a PDF, Word or Excel file format at www.grants.gov. If requesting indirect costs in the budget, a copy of the indirect cost-rate agreement is required. If the indirect costs are requested, include a copy of the current negotiated federal indirect cost rate agreement or a cost allocation plan approval letter for those Recipients under such a plan. Applicants must name this file "Indirect Cost Rate" and upload it at www.grants.gov.

13. Employee Whistleblower Rights and Protections

Employee Whistleblower Rights and Protections: All recipients of an award under this NOFO will be subject to a term and condition that applies the requirements set out in 41 U.S.C. § 4712, "Enhancement of contractor protection from reprisal for disclosure of certain information" and 48 Code of Federal Regulations (CFR) section 3.9 to the award, which includes a requirement that recipients and subrecipients inform employees in writing (in the predominant native language of the workforce) of employee whistleblower rights and protections under 41 U.S.C. § 4712. For more information see: <https://oig.hhs.gov/fraud/whistleblower/>.

13a. Funds Tracking

Proper fiscal oversight is critical to maintaining public trust in the stewardship of federal funds. Effective October 1, 2013, a new HHS policy on subaccounts requires the CDC to set up

payment subaccounts within the Payment Management System (PMS) for all new grant awards. Funds awarded in support of approved activities and drawdown instructions will be identified on the Notice of Award in a newly established PMS subaccount (P subaccount). Recipients will be required to draw down funds from award-specific accounts in the PMS. Ultimately, the subaccounts will provide recipients and CDC a more detailed and precise understanding of financial transactions. The successful applicant will be required to track funds by P-accounts/sub accounts for each project/cooperative agreement awarded.

Applicants are encouraged to demonstrate a record of fiscal responsibility and the ability to provide sufficient and effective oversight. Financial management systems must meet the requirements as described 45 CFR 75 which include, but are not limited to, the following:

- Records that identify adequately the source and application of funds for federally-funded activities.
- Effective control over, and accountability for, all funds, property, and other assets.
- Comparison of expenditures with budget amounts for each Federal award.
- Written procedures to implement payment requirements.
- Written procedures for determining cost allowability.
- Written procedures for financial reporting and monitoring.

13b. Copyright Interests Provisions

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.

13c. Data Management Plan

As identified in the Evaluation and Performance Measurement section, applications involving data collection or generation must include a Data Management Plan (DMP) as part of their

evaluation and performance measurement plan unless CDC has stated that CDC will take on the responsibility of creating the DMP. The DMP describes plans for assurance of the quality of the public health data through the data's lifecycle and plans to deposit the data in a repository to preserve and to make the data accessible in a timely manner. See web link for additional information: <https://www.cdc.gov/grants/additional-requirements/ar-25.html>.

14. Funding Restrictions

Restrictions that must be considered while planning the programs and writing the budget are:

- Recipients may not use funds for research.
- Recipients may not use funds for clinical care except as allowed by law.
- Recipients may use funds only for reasonable program purposes, including personnel, travel, supplies, and services.
- Generally, recipients may not use funds to purchase furniture or equipment. Any such proposed spending must be clearly identified in the budget.
- Reimbursement of pre-award costs generally is not allowed, unless the CDC provides written approval to the recipient.
- Other than for normal and recognized executive-legislative relationships, no funds may be used for:
 - publicity or propaganda purposes, for the preparation, distribution, or use of any material designed to support or defeat the enactment of legislation before any legislative body
 - the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before any legislative body
- See [Additional Requirement \(AR\) 12](#) for detailed guidance on this prohibition and [additional guidance on anti-lobbying restrictions for CDC recipients](#).
- The direct and primary recipient in a cooperative agreement program must perform a substantial role in carrying out project outcomes and not merely serve as a conduit for an award to another party or provider who is ineligible.

15. Intergovernmental Review

This NOFO is not subject to executive order 12372, Intergovernmental Review of Federal Programs. No action is needed.

16. Other Submission Requirements

a. Electronic Submission: Applications must be submitted electronically by using the forms and instructions posted for this notice of funding opportunity at www.grants.gov. Applicants can complete the application package using Workspace, which allows forms to be filled out online or offline. Application attachments can be submitted using PDF, Word, or Excel file formats. Instructions and training for using Workspace can be found at www.grants.gov under the "Workspace Overview" option.

b. Tracking Number: Applications submitted through www.grants.gov are time/date stamped electronically and assigned a tracking number. The applicant's Authorized Organization Representative (AOR) will be sent an e-mail notice of receipt when www.grants.gov receives the application. The tracking number documents that the application has been submitted and initiates the required electronic validation process before the application is made available to CDC.

c. Validation Process: Application submission is not concluded until the validation process is completed successfully. After the application package is submitted, the applicant will receive a "submission receipt" e-mail generated by www.grants.gov. A second e-mail message to applicants will then be generated by www.grants.gov that will either validate or reject the submitted application package. This validation process may take as long as two business days. Applicants are strongly encouraged to check the status of their application to ensure that submission of their package has been completed and no submission errors have occurred. Applicants also are strongly encouraged to allocate ample time for filing to guarantee that their application can be submitted and validated by the deadline published in the NOFO. Non-validated applications will not be accepted after the published application deadline date.

If you do not receive a "validation" e-mail within two business days of application submission, please contact www.grants.gov. For instructions on how to track your application, refer to the e-mail message generated at the time of application submission or review the Applicants section on www.grants.gov.

d. Technical Difficulties: If technical difficulties are encountered at www.grants.gov, applicants should contact Customer Service at www.grants.gov. The www.grants.gov Contact Center is available 24 hours a day, 7 days a week, except federal holidays. The Contact Center is available by phone at 1-800-518-4726 or by e-mail at support@grants.gov. Application submissions sent by e-mail or fax, or on CDs or thumb drives will not be accepted. Please note that www.grants.gov is managed by HHS.

e. Paper Submission: If technical difficulties are encountered at www.grants.gov, applicants should call the www.grants.gov Contact Center at 1-800-518-4726 or e-mail them

at support@grants.gov for assistance. After consulting with the Contact Center, if the technical difficulties remain unresolved and electronic submission is not possible, applicants may e-mail CDC GMO/GMS, before the deadline, and request permission to submit a paper application.

Such requests are handled on a case-by-case basis.

An applicant's request for permission to submit a paper application must:

1. Include the www.grants.gov case number assigned to the inquiry
2. Describe the difficulties that prevent electronic submission and the efforts taken with the www.grants.gov Contact Center to submit electronically; and
3. Be received via e-mail to the GMS/GMO listed below at least three calendar days before the application deadline. Paper applications submitted without prior approval will not be considered. If a paper application is authorized, OGS will advise the applicant of specific instructions for submitting the application via email.

E. Review and Selection Process

1. Review and Selection Process: Applications will be reviewed in three phases

a. Phase 1 Review

All applications will be initially reviewed for eligibility and completeness by the Office of Grants Services. Complete applications will be reviewed for responsiveness by Grants Management Officials and Program Officials. Non-responsive applications will not advance to Phase II review. Applicants will be notified that their applications did not meet eligibility and/or published submission requirements.

b. Phase II Review

NOFO reviewers will follow CDC's merit review process by evaluating eligible and responsive applications in accordance with the criteria below. Reviewers may be external to the federal government (non-federal personnel), federal personnel, or a mix of federal and non-federal personnel.

i. Approach

ii. Evaluation and Performance Measurement

iii. Applicant's Organizational Capacity to Implement the Approach

Not more than thirty days after the Phase II review is completed, applicants will be notified electronically if their application does not meet eligibility or published submission requirements.

i. Approach

Maximum Points: 40

Component A: To what extent does the applicant:

- Describe the public health problem and how their application will address it? (5 points)
- Demonstrate their ability and experience in conducting population-based surveillance of MD or other rare disease/birth defect including documenting access to sources needed for surveillance? (6 points)
- Describe an approach to meet the overall strategy and activities of this NOFO and intent to adhere to the methodology required by CDC? (6 points)
- Describe the surveillance area and target population? Is the applicant's target population composed of at least 3 million people? Does the target population include a large minority population? (6 points)
- Describe sources of data including which sources of clinical and administrative data the applicant will have access to for the project? (6 points)
- Describe how they plan to disseminate surveillance data? (6 points)
- Present a work plan that is aligned with the strategies/activities, outcomes, and performance measures in the approach and is consistent with the content and format proposed by CDC? (5 points)

Component B: To what extent does the applicant:

- Describe their ability and previous experience in conducting abstractor training and data quality activities? (12 points)
- Describe plans for conducting initial and ongoing abstractor training and periodic data quality activities (e.g., inter-rater reliability) (12 points)
- Describe developing, maintaining, and updating, training materials and user manuals (5 points)
- Describe leading a monthly abstractor call and participating on other committees as needed to provide expertise regarding data abstraction (5 points)
- Present a work plan that is aligned with the strategies/activities, outcomes, and performance measures in the approach and is consistent with the content and format proposed by CDC? (6 points)

Component C: To what extent does the applicant:

- Describe the problem and how their application will address it? (10 points)
- Describe an approach to meet the overall strategy and activities of the NOFO? (10 points)
- Describe sources of data including which sources of clinical and administrative data the applicant will have access to for the project? (10 points)
- Present a work plan that is aligned with the strategies/activities, outcomes, and performance measures in the approach and is consistent with the content and format proposed by CDC? (10 points)

ii. Evaluation and Performance Measurement

Maximum Points: 25

All components:

To what extent does the applicant's evaluation performance and measuring plan measure:

- Monitoring and evaluation procedures and the ability to collect data on the process and outcome measures specified? (10 points)
- The ability to report on process and outcome measures and demonstrate the outcomes of the NOFO? (10 points)
- How evaluation and performance measures will be used to monitor progress and for continuous improvement of the NOFO activities? (5 points)

iii. Applicant's Organizational Capacity to Implement the Approach

Maximum Points: 35

Component A: To what extent does the applicant:

- Describe relevant experience conducting surveillance for MD or other rare diseases/birth defects and capacity (management, administrative, technical, and facility resources) to achieve the outcomes of project? (10 points)
- To what extent does the applicant provide a staffing plan and project management structure that will be sufficient to meet the outcomes of the project and that clearly defines staff roles (and provides an organizational chart)? Staffing should include personnel with expertise in surveillance and epidemiology, medical record abstraction

data management, and data analysis at a level of effort sufficient to achieve the outcomes of the project. (10 points)

- Describe their authority to conduct surveillance for MD and provide agreements with departments of public health and local data sources (e.g., MOU/MOA, DUA, letters of support) to access data sources needed for their proposed activities? (10 points)
- Describe how they will collaborate with programs and organizations either internal or external to CDC that can support accomplishment of the objectives of this NOFO? (5 points)

Component B and C: To what extent does the applicant:

- Describe relevant experience with the topic area to achieve the outcomes of project? (10 points)
- Demonstrate that they have adequate technical and facility resources to meet the project's goals? (10 points)
- Provide a staffing plan and project management structure that will be sufficient to meet the outcomes of the project and that clearly defines staff roles? (10 points)
- Describe how they will collaborate with programs and organizations either internal or external to CDC that can support accomplishment of the objectives of this NOFO? (5 points)

Budget

Maximum Points: 0

The budget is not scored. The budget will be evaluated for the extent to which it is reasonable, clearly justified, and consistent with the intended use of the cooperative agreement funds.

c. Phase III Review

In general, applications will be funded in order by score and rank determined by the review panel, but the following factors also may affect the funding decision.

- Demonstrated ability of recipient to be able to access sources within site that will enable creation of a population-based cohort of individuals with MD.
- Applicant's ability to share data with CDC to include in pooled analytic datasets that will be accessed by other project sites.

Components A, B, and C will be scored separately. Only applicants that are funded under Component A will be considered for Component B or C funding.

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 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 review of risk may impact reward eligibility.

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.

Additionally, we may ask for additional information prior to the award based on the results of the CDC's risk review.

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.

2. Announcement and Anticipated Award Dates

Estimated award announcement date: 8/1/2024

Estimated award date 8/15/2024 via Notice of Award

Budget/project period start date: 9/1/2024

F. Award Administration Information

1. Award Notices

Recipients will receive an electronic copy of the Notice of Award (NOA) from CDC OGS. The NOA shall be the only binding, authorizing document between the recipient and CDC. The NOA will be signed by an authorized GMO and emailed to the Recipient Business Officer listed

in application and the Program Director.

Any applicant awarded funds in response to this Notice of Funding Opportunity will be subject to annual SAM Registration and Federal Funding Accountability And Transparency Act Of 2006 (FFATA) requirements.

Unsuccessful applicants will receive notification of these results by e-mail with delivery receipt.

2. Administrative and National Policy Requirements

Generally applicable ARs:

- [AR-9: Paperwork Reduction Act Requirements](#)
- [AR-10: Smoke-Free Workplace Requirements](#)
- [AR-11: Healthy People 2030](#)
- [AR-12: Lobbying Restrictions](#)
- [AR-14: Accounting System Requirements](#)
- [AR-16: Security Clearance Requirement](#)
- [AR-21: Small, Minority, And Women-owned Business](#)
- [AR-24: Health Insurance Portability and Accountability Act Requirements](#)
- [AR-25: Data Management and Access](#)
- [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-32: Enacted General Provisions](#)
- [AR-37: Prohibition on certain telecommunications and video surveillance services or equipment for all awards issued on or after August 13, 2020](#)

Organization-specific ARs:

- [AR-8: Public Health System Reporting Requirements](#)
- [AR-15: Proof of Non-profit Status](#)
- [AR-23: Compliance with 45 CFR Part 87](#)

If you receive an award, you must follow all applicable nondiscrimination laws. You agree to this when you register in [SAM.gov](#). You must also submit an Assurance of Compliance ([HHS-690](#)). To learn more, see the [HHS Office for Civil Rights website](#).

3. Reporting

Reporting provides continuous program monitoring and identifies successes and challenges that recipients encounter throughout the period of performance. Also, reporting is a requirement for recipients who want to apply for yearly continuation of funding. Reporting helps CDC and recipients because it:

- Helps target support to recipients;

- Provides CDC with periodic data to monitor recipient progress toward meeting the Notice of Funding Opportunity outcomes and overall performance;
- Allows CDC to track performance measures and evaluation findings for continuous quality and program improvement throughout the period of performance and to determine applicability of evidence-based approaches to different populations, settings, and contexts; and
- Enables CDC to assess the overall effectiveness and influence of the NOFO.

The table below summarizes required and optional reports. All required reports must be sent electronically to GMS listed in the “Agency Contacts” section of the NOFO copying the CDC Project Officer.

Report	When?	Required?
Recipient Evaluation and Performance Measurement Plan, including Data Management Plan (DMP)	6 months into award	Yes
Annual Performance Report (APR)	No later than 120 days before the end of the budget period. Serves as the yearly continuation application.	Yes
Data on Performance Measures	N/A	No
Federal Financial Reporting Forms	90 days after the end of the budget period	Yes
Final Performance and Financial Report	90 days after end of period of performance	Yes

a. Recipient Evaluation and Performance Measurement Plan (required)

With support from CDC, recipients must elaborate on their initial applicant evaluation and performance measurement plan. This plan must be no more than 20 pages; recipients must submit the plan 6 months into the award. HHS/CDC will review and approve the recipient’s monitoring and evaluation plan to ensure that it is appropriate for the activities to be undertaken as part of the agreement, for compliance with the monitoring and evaluation guidance established by HHS/CDC, or other guidance otherwise applicable to this Agreement.

Recipient Evaluation and Performance Measurement Plan (required): This plan should provide additional detail on the following:

Performance Measurement

- Performance measures and targets
- The frequency that performance data are to be collected.
- How performance data will be reported.
- How quality of performance data will be assured.

- How performance measurement will yield findings to demonstrate progress towards achieving NOFO goals (e.g., reaching specific populations or achieving expected outcomes).
- Dissemination channels and audiences.
- Other information requested as determined by the CDC program.

Evaluation

- The types of evaluations to be conducted (e.g. process or outcome evaluations).
- The frequency that evaluations will be conducted.
- How evaluation reports will be published on a publicly available website.
- How evaluation findings will be used to ensure continuous quality and program improvement.
- How evaluation will yield findings to demonstrate the value of the NOFO (e.g., effect on improving public health outcomes, effectiveness of NOFO, cost-effectiveness or cost-benefit).
- Dissemination channels and audiences.

HHS/CDC or its designee will also undertake monitoring and evaluation of the defined activities within the agreement. The recipient must ensure reasonable access by HHS/CDC or its designee to all necessary sites, documentation, individuals and information to monitor, evaluate and verify the appropriate implementation the activities and use of HHS/CDC funding under this Agreement.

b. Annual Performance Report (APR) (required)

The recipient must submit the APR via www.Grantsolutions.gov no later than 120 days prior to the end of the budget period. This report must not exceed 45 pages excluding administrative reporting. Attachments are not allowed, but web links are allowed.

This report must include the following:

- **Performance Measures:** Recipients must report on performance measures for each budget period and update measures, if needed.
- **Evaluation Results:** Recipients must report evaluation results for the work completed to date (including findings from process or outcome evaluations).
- **Work Plan:** Recipients must update work plan each budget period to reflect any changes in period of performance outcomes, activities, timeline, etc.
- **Successes**
 - Recipients must report progress on completing activities and progress towards achieving the period of performance outcomes described in the logic model and work plan.
 - Recipients must describe any additional successes (e.g. identified through evaluation results or lessons learned) achieved in the past year.
 - Recipients must describe success stories.
- **Challenges**

- Recipients must describe any challenges that hindered or might hinder their ability to complete the work plan activities and achieve the period of performance outcomes.
- Recipients must describe any additional challenges (e.g., identified through evaluation results or lessons learned) encountered in the past year.
- **CDC Program Support to Recipients**
 - Recipients must describe how CDC could help them overcome challenges to complete activities in the work plan and achieving period of performance outcomes.
- **Administrative Reporting** (No page limit)
 - SF-424A Budget Information-Non-Construction Programs.
 - Budget Narrative – Must use the format outlined in "Content and Form of Application Submission, Budget Narrative" section.
 - Indirect Cost Rate Agreement.

The recipient must submit the Annual Performance Report via <https://www.grantsolutions.gov> 120 days prior to the end of the budget period.

c. Performance Measure Reporting (optional)

CDC programs may require more frequent reporting of performance measures than annually in the APR. If this is the case, CDC programs must specify reporting frequency, data fields, and format for recipients at the beginning of the award period.

d. Federal Financial Reporting (FFR) (required)

The annual FFR form (SF-425) is required and must be submitted 90 days after the end of the budget period through the Payment Management System (PMS). The report must include only 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 by the due date may adversely affect the future funding of the project. If the information cannot be provided by the due date, recipients are required to submit a letter of explanation to OGS and include the date by which the Grants Officer will receive information.

e. Final Performance and Financial Report (required)

The Final Performance Report is due 120 days after the end of the period of performance. The Final FFR is due 120 days after the end of the period of performance and must be submitted through the Payment Management System (PMS). CDC programs must indicate that this report should not exceed 40 pages. This report covers the entire period of performance and can include information previously reported in APRs. At a minimum, this report must include the following:

- Performance Measures – Recipients must report final performance data for all process and outcome performance measures.

- Evaluation Results – Recipients must report final evaluation results for the period of performance for any evaluations conducted.
- Impact/Results/Success Stories – Recipients must use their performance measure results and their evaluation findings to describe the effects or results of the work completed over the period of performance, and can include some success stories.
- A final Data Management Plan that includes the location of the data collected during the funded period, for example, repository name and link data set(s)
- Additional forms as described in the Notice of Award (e.g., Equipment Inventory Report, Final Invention Statement).

No additional forms necessary

4. Federal Funding Accountability and Transparency Act of 2006 (FFATA)

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 awards, contracts, loans, other assistance, and payments through a single publicly accessible Web site, <http://www.USASpending.gov>.

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 applicants: 1) information on executive compensation when not already reported through the SAM, and 2) similar information on all sub-awards/subcontracts/consortiums over \$30,000.

For the full text of the requirements under the FFATA and HHS guidelines, go to:

- <https://www.gpo.gov/fdsys/pkg/PLAW-109publ282/pdf/PLAW-109publ282.pdf>,
- https://www.fsrcs.gov/documents/ffata_legislation_110_252.pdf
- <http://www.hhs.gov/grants/grants/grants-policies-regulations/index.html#FFATA>.

5. Reporting of Foreign Taxes (International/Foreign projects only)

A. Valued Added Tax (VAT) and Customs Duties – Customs and import duties, consular fees, customs surtax, valued added taxes, and other related charges are hereby authorized as an allowable cost for costs incurred for non-host governmental entities operating where no applicable tax exemption exists. This waiver does not apply to countries where a bilateral agreement (or similar legal document) is already in place providing applicable tax exemptions and it is not applicable to Ministries of Health. Successful applicants will receive information on VAT requirements via their Notice of Award.

B. The U.S. Department of State requires that agencies collect and report information on the amount of taxes assessed, reimbursed and not reimbursed by a foreign government against commodities financed with funds appropriated by the U.S. Department of State, Foreign Operations and Related Programs Appropriations Act (SFOAA) (“United States foreign assistance funds”). Outlined below are the specifics of this requirement:

1) Annual Report: The recipient must submit a report on or before November 16 for each foreign country on the amount of foreign taxes charged, as of September 30 of the same year, by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant during the prior United States fiscal year (October 1 – September 30), and the amount reimbursed and unreimbursed by the foreign government. [Reports are required even if the recipient did not pay any taxes during the reporting period.]

2) Quarterly Report: The recipient must quarterly submit a report on the amount of foreign taxes charged by a foreign government on commodity purchase transactions valued at 500 USD or more financed with United States foreign assistance funds under this grant. This report shall be submitted no later than two weeks following the end of each quarter: April 15, July 15, October 15 and January 15.

3) Terms: For purposes of this clause:

“Commodity” means any material, article, supplies, goods, or equipment;

“Foreign government” includes any foreign government entity;

“Foreign taxes” means value-added taxes and custom duties assessed by a foreign government on a commodity. It does not include foreign sales taxes.

4) Where: Submit the reports to the Director and Deputy Director of the CDC office in the country(ies) in which you are carrying out the activities associated with this cooperative agreement. In countries where there is no CDC office, send reports to VATreporting@cdc.gov.

5) Contents of Reports: The reports must contain:

a. recipient name;

b. contact name with phone, fax, and e-mail;

c. agreement number(s) if reporting by agreement(s);

d. reporting period;

e. amount of foreign taxes assessed by each foreign government;

f. amount of any foreign taxes reimbursed by each foreign government;

g. amount of foreign taxes unreimbursed by each foreign government.

6) Subagreements. The recipient must include this reporting requirement in all applicable subgrants and other subagreements.

6. Termination

CDC may impose other enforcement actions in accordance with 45 CFR 75.371- Remedies for Noncompliance, as appropriate.

The Federal award may be terminated in whole or in part as follows:

- (1) By the HHS awarding agency or pass-through entity, if the non-Federal entity fails to comply with the terms and conditions of the award;
- (2) By the HHS awarding agency or pass-through entity for cause;
- (3) By the HHS awarding agency or pass-through entity with the consent of the non-Federal entity, in which case the two parties must agree upon the termination conditions, including the effective date and, in the case of partial termination, the portion to be terminated; or
- (4) By the non-Federal entity upon sending to the HHS awarding agency or pass-through entity written notification setting forth the reasons for such termination, the effective date, and, in the case of partial termination, the portion to be terminated. However, if the HHS awarding agency or pass-through entity determines in the case of partial termination that the reduced or modified portion of the Federal award or subaward will not accomplish the purposes for which the Federal award was made, the HHS awarding agency or pass-through entity may terminate the Federal award in its entirety.

G. Agency Contacts

CDC encourages inquiries concerning this NOFO.

Program Office Contact

For programmatic technical assistance, contact:

First Name:

Kandi

Last Name:

Givner

Project Officer

Department of Health and Human Services

Centers for Disease Control and Prevention

Address:

4770 Buford Hwy

S106-3

Atlanta, GA 30341

Telephone:

(404) 498-2694

Email:

xla7@cdc.gov

Grants Management Office Information

For financial, awards management, or budget assistance, contact:

First Name:

Randall

Last Name:

Slaven
Grants Management Specialist
Department of Health and Human Services
Office of Grants Services

Address:

Telephone:
(404) 718-5568

Email:
jlf0@cdc.gov

For assistance with **submission difficulties related to** www.grants.gov, contact the Contact Center by phone at 1-800-518-4726.

Hours of Operation: 24 hours a day, 7 days a week, except on federal holidays.

CDC Telecommunications for persons with hearing loss is available at: TTY 1-888-232-6348

H. Other Information

Following is a list of acceptable attachments **applicants** that can be uploaded as a PDF, Word, or Excel file format as part of their application at www.grants.gov. Applicants may not attach documents other than those listed; if other documents are attached, applications will not be reviewed.

- Project Abstract
- Project Narrative
- Budget Narrative
- Report on Programmatic, Budgetary and Commitment Overlap
- Table of Contents for Entire Submission

For international NOFOs:

- SF424
- SF424A
- Funding Preference Deliverables

Optional attachments, as determined by CDC programs:

Resumes / CVs

Position descriptions

Letters of Support

Organization Charts

Non-profit organization IRS status forms, if applicable

Indirect Cost Rate, if applicable

Memorandum of Agreement (MOA)

Memorandum of Understanding (MOU)

Bona Fide Agent status documentation, if applicable

Applicants must submit a Project Narrative with the application forms. Applicants must name this file “Project Narrative” and upload it at www.grants.gov. The Project Narrative must include all of the following headings (including sub-headings): Background, Approach, Applicant Evaluation and Performance Measurement Plan, Organizational Capacity of Applicants to Implement the Approach, and Work Plan. The Project Narrative must be succinct, self-explanatory, and in the order outlined in this section. It must address outcomes and activities to be conducted over the entire period of performance as identified in the CDC Project Description section.

Cost sharing or matching funds are not required for this program. Although no statutory matching requirement for this NOFO exists, leveraging other resources and related ongoing efforts to promote sustainability is strongly encouraged.

I. Glossary

Activities: The actual events or actions that take place as a part of the program.

Administrative and National Policy Requirements, Additional Requirements (ARs):

Administrative requirements found in 45 CFR Part 75 and other requirements mandated by statute or CDC policy. All ARs are listed in the Template for CDC programs. CDC programs must indicate which ARs are relevant to the NOFO; recipients must comply with the ARs listed in the NOFO. To view brief descriptions of relevant provisions, see <https://www.cdc.gov/grants/additional-requirements/index.html>. Note that 2 CFR 200 supersedes the administrative requirements (A-110 & A-102), cost principles (A-21, A-87 & A-122) and audit requirements (A-50, A-89 & A-133).

Approved but Unfunded: Approved but unfunded refers to applications recommended for approval during the objective review process; however, they were not recommended for funding by the program office and/or the grants management office.

Assistance Listings: A government-wide collection of federal programs, projects, services, and activities that provide assistance or benefits to the American public.

Assistance Listings Number: A unique number assigned to each program and NOFO throughout its lifecycle that enables data and funding tracking and transparency

Award: Financial assistance that provides support or stimulation to accomplish a public purpose. Awards include grants and other agreements (e.g., cooperative agreements) in the form of money, or property in lieu of money, by the federal government to an eligible applicant.

Budget Period or Budget Year: The duration of each individual funding period within the period of performance. Traditionally, budget periods are 12 months or 1 year.

Carryover: Unobligated federal funds remaining at the end of any budget period that, with the approval of the GMO or under an automatic authority, may be carried over to another budget

period to cover allowable costs of that budget period either as an offset or additional authorization. Obligated but liquidated funds are not considered carryover.

Community engagement: The process of working collaboratively with and through groups of people to improve the health of the community and its members. Community engagement often involves partnerships and coalitions that help mobilize resources and influence systems, improve relationships among partners, and serve as catalysts for changing policies, programs, and practices.

Competing Continuation Award: A financial assistance mechanism that adds funds to a grant and adds one or more budget periods to the previously established period of performance (i.e., extends the “life” of the award).

Continuous Quality Improvement: A system that seeks to improve the provision of services with an emphasis on future results.

Contracts: An award instrument used to acquire (by purchase, lease, or barter) property or services for the direct benefit or use of the Federal Government.

Cooperative Agreement: A financial assistance award with the same kind of interagency relationship as a grant except that it provides for substantial involvement by the federal agency funding the award. Substantial involvement means that the recipient can expect federal programmatic collaboration or participation in carrying out the effort under the award.

Cost Sharing or Matching: Refers to program costs not borne by the Federal Government but by the recipients. It may include the value of allowable third-party, in-kind contributions, as well as expenditures by the recipient.

Direct Assistance: A financial assistance mechanism, which must be specifically authorized by statute, whereby goods or services are provided to recipients in lieu of cash. DA generally involves the assignment of federal personnel or the provision of equipment or supplies, such as vaccines. DA is primarily used to support payroll and travel expenses of CDC employees assigned to state, tribal, local, and territorial (STLT) health agencies that are recipients of grants and cooperative agreements. Most legislative authorities that provide financial assistance to STLT health agencies allow for the use of DA. <https://www.cdc.gov/grants/additional-requirements/index.html>.

Equity: The consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment (from Executive Order 13985).

Evaluation (program evaluation): The systematic collection of information about the activities, characteristics, and outcomes of programs (which may include interventions, policies, and specific projects) to make judgments about that program, improve program effectiveness, and/or inform decisions about future program development.

Evaluation Plan: A written document describing the overall approach that will be used to guide an evaluation, including why the evaluation is being conducted, how the findings will likely be used, and the design and data collection sources and methods. The plan specifies what will be done, how it will be done, who will do it, and when it will be done. The NOFO evaluation plan is

used to describe how the recipient and/or CDC will determine whether activities are implemented appropriately and outcomes are achieved.

Federal Funding Accountability and Transparency Act of 2006 (FFATA): Requires that information about federal awards, including awards, contracts, loans, and other assistance and payments, be available to the public on a single website at www.USAspending.gov.

Fiscal Year: The year for which budget dollars are allocated annually. The federal fiscal year starts October 1 and ends September 30.

Grant: A legal instrument used by the federal government to transfer anything of value to a recipient for public support or stimulation authorized by statute. Financial assistance may be money or property. The definition does not include a federal procurement subject to the Federal Acquisition Regulation; technical assistance (which provides services instead of money); or assistance in the form of revenue sharing, loans, loan guarantees, interest subsidies, insurance, or direct payments of any kind to a person or persons. The main difference between a grant and a cooperative agreement is that in a grant there is no anticipated substantial programmatic involvement by the federal government under the award.

Grants.gov: A "storefront" web portal for electronic data collection (forms and reports) for federal grant-making agencies at www.grants.gov.

Grants Management Officer (GMO): The individual designated to serve as the HHS official responsible for the business management aspects of a particular grant(s) or cooperative agreement(s). The GMO serves as the counterpart to the business officer of the recipient organization. In this capacity, the GMO is responsible for all business management matters associated with the review, negotiation, award, and administration of grants and interprets grants administration policies and provisions. The GMO works closely with the program or project officer who is responsible for the scientific, technical, and programmatic aspects of the grant.

Grants Management Specialist (GMS): A federal staff member who oversees the business and other non-programmatic aspects of one or more grants and/or cooperative agreements. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with regulations and guidelines, negotiating grants, providing consultation and technical assistance to recipients, post-award administration and closing out grants.

Health Disparities: Preventable differences in the burden of disease, injury, violence, or opportunities to achieve optimal health that are experienced by populations that have been socially, economically, geographically, and environmentally disadvantaged.

Health Equity: The state in which everyone has a fair and just opportunity to attain their highest level of health. Achieving this requires focused and ongoing societal efforts to address historical and contemporary injustices; overcome economic, social, and other obstacles to health and healthcare; and eliminate preventable health disparities.

Health Inequities: Particular types of health disparities that stem from unfair and unjust systems, policies, and practices and limit access to the opportunities and resources needed to live the healthiest life possible.

Healthy People 2030: National health objectives aimed at improving the health of all Americans by encouraging collaboration across sectors, guiding people toward making informed health decisions, and measuring the effects of prevention activities.

Inclusion: The act of creating environments in which any individual or group can be and feel welcomed, respected, supported, and valued to fully participate. An inclusive and welcoming climate embraces differences and offers respect in words and actions for all people.

Indirect Costs: Costs that are incurred for common or joint objectives and not readily and specifically identifiable with a particular sponsored project, program, or activity; nevertheless, these costs are necessary to the operations of the organization. For example, the costs of operating and maintaining facilities, depreciation, and administrative salaries generally are considered indirect costs.

Letter of Intent (LOI): A preliminary, non-binding indication of an organization's intent to submit an application.

Lobbying: Direct lobbying includes any attempt to influence legislation, appropriations, regulations, administrative actions, executive orders (legislation or other orders), or other similar deliberations at any level of government through communication that directly expresses a view on proposed or pending legislation or other orders, and which is directed to staff members or other employees of a legislative body, government officials, or employees who participate in formulating legislation or other orders. Grass roots lobbying includes efforts directed at inducing or encouraging members of the public to contact their elected representatives at the federal, state, or local levels to urge support of, or opposition to, proposed or pending legislative proposals.

Logic Model: A visual representation showing the sequence of related events connecting the activities of a program with the programs' desired outcomes and results.

Maintenance of Effort: A requirement contained in authorizing legislation, or applicable regulations that a recipient must agree to contribute and maintain a specified level of financial effort from its own resources or other non-government sources to be eligible to receive federal grant funds. This requirement is typically given in terms of meeting a previous base-year dollar amount.

Memorandum of Understanding (MOU) or Memorandum of Agreement (MOA):

Document that describes a bilateral or multilateral agreement between parties expressing a convergence of will between the parties, indicating an intended common line of action. It is often used in cases where the parties either do not imply a legal commitment or cannot create a legally enforceable agreement.

Nonprofit Organization: Any corporation, trust, association, cooperative, or other organization that is operated primarily for scientific, educational, service, charitable, or similar purposes in the public interest; is not organized for profit; and uses net proceeds to maintain, improve, or expand the operations of the organization. Nonprofit organizations include institutions of higher education, hospitals, and tribal organizations (that is, Indian entities other than federally recognized Indian tribal governments).

Notice of Award (NoA): The official document, signed (or the electronic equivalent of signature) by a Grants Management Officer that: (1) notifies the recipient of the award of a grant; (2) contains or references all the terms and conditions of the grant and Federal funding limits and

obligations; and (3) provides the documentary basis for recording the obligation of Federal funds in the HHS accounting system.

Objective Review: A process that involves the thorough and consistent examination of applications based on an unbiased evaluation of scientific or technical merit or other relevant aspects of the proposal. The review is intended to provide advice to the persons responsible for making award decisions.

Outcome: The results of program operations or activities; the effects triggered by the program. For example, increased knowledge, changed attitudes or beliefs, reduced tobacco use, reduced morbidity and mortality.

Performance Measurement: The ongoing monitoring and reporting of program accomplishments, particularly progress toward pre-established goals, typically conducted by program or agency management. Performance measurement may address the type or level of program activities conducted (process), the direct products and services delivered by a program (outputs), or the results of those products and services (outcomes). A “program” may be any activity, project, function, or policy that has an identifiable purpose or set of objectives.

Period of performance –formerly known as the project period - : The time during which the recipient may incur obligations to carry out the work authorized under the Federal award. The start and end dates of the period of performance must be included in the Federal award.

Period of Performance Outcome: An outcome that will occur by the end of the NOFO's funding period

Plain Writing Act of 2010: The Plain Writing Act of 2010 requires that federal agencies use clear communication that the public can understand and use. NOFOs must be written in clear, consistent language so that any reader can understand expectations and intended outcomes of the funded program. CDC programs should use NOFO plain writing tips when writing NOFOs.

Program Official: Person responsible for developing the NOFO; can be either a project officer, program manager, branch chief, division leader, policy official, center leader, or similar staff member.

Program Strategies: Strategies are groupings of related activities, usually expressed as general headers (e.g., Partnerships, Assessment, Policy) or as brief statements (e.g., Form partnerships, Conduct assessments, Formulate policies).

Public Health Accreditation Board (PHAB): A nonprofit organization that works to promote and protect the health of the public by advancing the quality and performance of public health departments in the U.S. through national public health department accreditation
<http://www.phaboard.org>.

Social Determinants of Health: The non-medical factors that influence health outcomes. The conditions in which people are born, grow, work, live, and age, and the wider set of forces and systems shaping the conditions of daily life. These forces (e.g., racism, climate) and systems include economic policies and systems, development agendas, social norms, social policies, and political systems. <https://www.cdc.gov/about/sdoh/index.html>

Statute: An act of the legislature; a particular law enacted and established by the will of the legislative department of government, expressed with the requisite formalities. In foreign or civil

law any particular municipal law or usage, though resting for its authority on judicial decisions, or the practice of nations.

Statutory Authority: Authority provided by legal statute that establishes a federal financial assistance program or award.

System for Award Management (SAM): The primary vendor database for the U.S. federal government. SAM validates applicant information and electronically shares secure and encrypted data with federal agencies' finance offices to facilitate paperless payments through Electronic Funds Transfer (EFT). SAM stores organizational information, allowing www.grants.gov to verify identity and pre-fill organizational information on grant applications.

Technical Assistance: Advice, assistance, or training pertaining to program development, implementation, maintenance, or evaluation that is provided by the funding agency.

UEI: The Unique Entity Identifier (UEI) number is a twelve-digit number assigned by SAM.gov. When applying for Federal awards or cooperative agreements, all applicant organizations must obtain a UEI number as the Universal Identifier. UEI number assignment is free. If an organization does not know its UEI number or needs to register for one, visit www.sam.gov.

Work Plan: The summary of period of performance outcomes, strategies and activities, personnel and/or partners who will complete the activities, and the timeline for completion. The work plan will outline the details of all necessary activities that will be supported through the approved budget.