

C. Eligible Applicants

Assistance will be provided only to the health departments of States or their bona fide agents 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, the Republic of Palau, and federally recognized Indian tribal governments.

Recipients funded under CDC Program Announcement 02172, (Surveillance and Epidemiologic Research of Duchenne and Becker Muscular Dystrophy and Other Single Gene Disorders) currently involved in type 1 projects are not eligible. See Attachment II for a list of the States currently funded.

To be eligible, applicants must document a study population of at least 30,000 live births per year within a State, a contiguous area of a State (such as the catchment of a local health agency), or an area comprising a combination of States, based on U.S. Census Data. In addition, a copy of the state Legislation that allows the authority for state Health Departments to collect information on birth defects, genetic diseases or related conditions needs to be included.

This information should be placed directly behind the face page of the application. Applications that fail to submit the evidence requested above will be considered non-responsive and returned without review.

Note: Title 2 of the United States Code, Section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, or loan.

D. Funding

Availability of Funds

Approximately \$1,000,000 is available in FY 2003 to fund up to two awards. It is expected that up to two awards will be made, ranging from \$400,000 to \$500,000. It is expected that the award will begin on or about September 1, 2003, and will be made for a 12-month budget period within a two-year project period. Funding estimates may change.

Continuation awards within the project period will be made on the basis of satisfactory programmatic progress and the availability of funds.

Recipient Financial Participation

Matching funds are not required for this program.

Funding Preference

Relative to and consistent with the technical merit of the application, funding preference will be given to applicants who complement the existing funded programs by balancing the geographic and racial/ethnic diversity of the multi-state collaborative effort.

E. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1. Recipient Activities. CDC will be responsible for the activities listed under 2. CDC Activities.

1. Recipient Activities:

a. Develop, implement and evaluate methods and approaches which will improve or expand the capacity of the applicant's existing surveillance system to ascertain cases and generate timely population-based data of DBMD and its complications. Make any necessary modifications to the surveillance system to comply with the Collaborative DBMD Project case definitions. The Collaborative DBMD Project case definitions and other information developed by the current grantees may be obtained from the programmatic technical assistance point-of-contact in the "Where to Obtain Additional Information" section.

b. Establish or enhance collaborative relationships with appropriate stakeholders, *i.e.*, specialty treatment centers (*e.g.*, MDA clinics, other muscular dystrophy clinics), state or regional chapters or associations related to genetic conditions, hospitals, emergency care centers, private physicians, managed care organizations, clinical and diagnostic laboratories that provide diagnosis of genetic conditions (*e.g.*, creatine kinase measurements, muscle biopsy analysis, genetic analysis, *etc.*), and others.

c. Collaborate with other funded recipients to design and develop one common protocol for all recipients to implement and evaluate as described in Attachment III. The Collaborative DBMD Project current draft protocol and other information developed by the current grantees may be obtained from the programmatic technical assistance point-of-contact in the "Where to Obtain Additional Information" section.

d. Implement active case ascertainment of DBMD among reporting sources to determine the prevalence of the genetic condition(s) in the defined geographic area, including a complete count of all prevalent cases, including ages birth to 21 years, and supplemented in later years by newly diagnosed cases.

e. Describe the source, frequency, and type of preventive and medical care among persons with DBMD among three populations: (a) Those who access care at specialty clinics (*e.g.*, MDA or other muscular dystrophy clinics), (b) those who receive their care elsewhere, and (c) those who are not receiving care or are undiagnosed.

f. Determine the prevalence of related complications.

g. Conduct population-based long-term follow-up of persons with DBMD to relate health outcomes to the source, frequency, and type of preventive and therapeutic care.

h. Obtain buccal samples or other biologics, as agreed-upon by awardees, from children with DBMD and other family members.

i. Evaluate and disseminate the findings.

2. CDC Activities:

a. Provide technical assistance in designing, developing, and evaluating methodologies and approaches used for population-based surveillance of genetic conditions.

b. Provide technical assistance in the collection, management, and analysis of surveillance data related to genetic conditions.

c. Provide technical assistance in the development and planning of the study protocol. Provide final approval for the study protocol.

d. Provide technical assistance in the analysis and reporting of aggregate surveillance data collected from funded initiatives; coordinate and consolidate the transfer of tabulated data, analyses, and conclusions among recipients.

e. Provide technical assistance to national, state, or regional programs in the use of data to develop or improve care programs for genetic conditions.

f. Provide technical assistance to recipients in developing a plan for the collection, storage and access of biologic samples.

g. Provide technical assistance to recipients in the evaluation and dissemination of the findings.

F. Content

Letter of Intent (LOI)

A LOI is requested for this program. The Program Announcement title and number must appear in the LOI. The narrative should be no more than two, double-spaced pages, printed on one side, with one inch margins and 12 point font. The LOI will not be used to eliminate potential applicants, but it will enable CDC to determine the level of interest in this announcement, and plan the review more efficiently. The LOI should include the following