

expected to benefit by initiating research programs that may lead to future research efforts and similar consortia on their own. The public will benefit from CDC-established additional linkages to frontier research efforts dealing with quality of laboratory services impacting patient outcome and the increased knowledge gained in evaluating and improving the critical components of laboratory testing that impact public health.

Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under A. (Recipient Activities), and CDC will be responsible for the activities under B. (CDC Activities).

A. Recipient Activities

1. Either alone or through their constituents, carry out the research projects that were developed as stated in the application for assistance and as evaluated and prioritized by both CDC and the recipient.

2. Provide leadership in the design and implementation of research methodologies and protocols used to assess quality of laboratory testing and patient outcome.

3. Provide leadership in optimal data collection and analysis using the best epidemiological, statistical, and mathematical approaches available. Participant identification information may be omitted from these data if the consortium manager or research director is able to respond to questions concerning the validity of the data without providing participant information.

4. Use a mechanism for the sharing of the raw and analyzed data both within the consortium and with CDC.

5. Prepare manuscripts, along with the principal investigators of the individual projects if appropriate, for peer-reviewed publications that describe the results of some or all of the activities listed above. Manuscripts should benefit the public; the papers must also note the source of the funding for the project.

B. CDC Activities

1. Assist in the selection of projects that have the greatest public health concerns and in the evaluation of the detailed projects after their solicitation.

2. Provide technical input in the refinement of research protocol and methodologies proposed by the recipients and individual researchers including data collection, statistical analyses, and epidemiological approaches.

3. Collaborate in the development of a mutually defined data set standard for transmission of raw data, analyzed data, and reports within the consortium and with CDC.

4. Provide technical input and participate in the presentation of data at professional forums, meetings, and conferences as needed.

5. Provide technical assistance and input in the preparation of manuscripts related to the activities of the funded projects.

Evaluation Criteria

Applications will be reviewed and evaluated according to the following criteria:

1. Responsiveness of the overall application and its constituent projects to the objectives of the cooperative agreement including: a) applicant's understanding of the objectives of the proposed cooperative agreement and each proposed project; b) relevance of the projects to the stated objectives; c) public health benefits of the proposed research projects; and d) relationship to previous studies if applicable. (25 points)

2. Ability to provide staff, knowledge, and other resources required to provide oversight of the investigators—responsibilities in the individual projects. Of paramount importance are the assessed quality of the individual projects and ability of the individual investigators to carry out the functions as stated in their projects. The qualifications and time allocations of key personnel to be assigned to the cooperative agreement as well as the facilities, equipment, and other resources available to provide oversight of the constituent projects. (30 points)

3. The methods to be used in carrying out the responsibilities of the cooperative agreement and the projects contained therein and the steps to be taken in the planning and implementation of the projects. Scope of the studies in addition to the statistical and epidemiological methods to be used if applicable. (35 points)

4. Schedule for the activities of the cooperative agreement and the individual projects therein and methods for evaluating the accomplishments including detailed research plan to meet the objectives of the projects. (10 points)

5. In addition, consideration will be given to the extent to which the budget is reasonable, clearly justified, and consistent with the intended use of the funds. (Not scored)

Executive Order 12372 Review

This program is not subject to the Executive Order 12372 review.

Public Health Reporting Requirements

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance number is 93.283.

Other Requirements

Paperwork Reduction Act

Projects that involve the collection of information from ten or more individuals and funded by the cooperative agreement will be subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Human Subjects

If any of the proposed projects involves research on human subjects, the applicant must comply with the Department of Health and Human Services Regulations, 45 CFR part 46, regarding the protection of human subjects. Assurance must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and form provided in the application kit. In addition to other applicable committees, Indian Health Service (IHS) institutional review committees also must review the project if any component of IHS will be involved or will support the research. If any Native American community is involved, its tribal government must also approve that portion of the project applicable to it.

Application Submission and Deadline

The original and two copies of the application Form PHS 5161-1 (OMB Control Number 0937-0189) must be submitted to Henry S. Cassell III, Acting Chief, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 300, Atlanta, Georgia 30305, Attention: Marsha D. Driggins, Grants Management Specialist, Mailstop E16, on or before August 7, 1995.

1. **Deadline:** Applications shall be considered as meeting the deadline if they are either: (a) Received on or before the deadline date; or (b) Sent on or before the deadline date and received in time for submission to the objective review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or