administrative process, that meets the requirements of this subpart, for reviewing, investigating, and reporting allegations of misconduct in science in connection with PHS-sponsored biomedical and behavioral research conducted at the applicant institution or sponsored by the applicant; and (2) Will comply with its own administrative process and the requirements of this subpart.''

Section 50.103(b) of the regulation states that: ''An applicant or recipient institution shall make an annual submission to the [ORI] as follows: (1) The institution's assurance shall be submitted to the [ORI], on a form prescribed by the Secretary, * * * and updated annually thereafter * * * (2) An institution shall submit, along with its annual assurance, such aggregate information on allegations, inquiries, and investigations as the Secretary may prescribe.'' An additional policy is added in the year 2000 that ''requires research institutions to provide training in the responsible conduct of research to all staff engaged in research or research training with PHS funds.

AR–24 Health Insurance Portability and Accountability Act Requirements

Recipients of this grant award should note that pursuant to the Standards for Privacy of Individually Identifiable Health Information promulgated under the Health Insurance Portability and Accountability Act (HIPAA) (45 CFR parts 160 and 164) covered entities may disclose protected health information to public health authorities authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions. The definition of a public health authority includes a person or entity acting under a grant of authority from or contract with such public agency. CDC considers this project a public health activity consistent with the Standards for Privacy of Individually Identifiable Health Information and CDC will provide successful recipients a specific grant of public health authority for the purposes of this project.

AR–25 Release and Sharing of Data

The Data Release Plan is the Grantee's assurance that the dissemination of any and all data collected under the CDC data sharing agreement will be released as follows:

a. In a timely manner.

b. Completely, and as accurately as possible.

c. To facilitate the broader community.

d. Developed in accordance with CDC policy on Releasing and Sharing Data, April 16, 2003, *http://www.cdc.gov/od/foia/policies/sharing.htm,* and in full compliance with the 1996 Health Insurance Portability and Accountability Act (HIPPA), (where applicable), The Office of Management and Budget Circular A110, (2000) revised 2003, *http://www.whitehouse.gov/omb/query.html?col=omb&qt=Releasing+and+Sharing+of+Data* and Freedom of Information Act (FOIA) *http://www.4.law.cornell.edu/uscode/5/5/552/html.*

Applications must include a copy of the applicant's Data Release Plan. Applicants should provide CDC with appropriate documentation on the reliability of the data. Applications submitted without the required Plan may be ineligible for award. Award will be made when reviewing officials have approved an acceptable Plan. The successful applicant and the Program Manager will determine the documentation format. CDC recommends data is released in the form closest to micro data and one that will preserve confidentiality.

Authority and Regulations

This program is described in the Catalog of Federal Domestic Assistance at *http://www.cfda.gov/* and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under the authorization of 399B of the Public Health Service Act (PHS Act), 42 U.S.C. 280e, 399C of the PHS Act, 42 U.S.C. 280e–1, 399D of the PHS Act, 42 U.S.C. 280e–2, 317(k)(2) of the PHS Act, 42 U.S.C. 247b(k)(2), and 301(a) of the PHS Act, 42 U.S.C. 241(a). All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The NIH Grants Policy Statement can be found at *http://grants.nih.gov/grants/policy/policy.htm.*

Dated: May 31, 2005.

William P. Nichols,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 05–11254 Filed 6–6–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Incidence, Natural History, and Quality of Life of Diabetes in Youth

Part I—Overview Information

Department of Health and Human Services

Issuing Organization

Centers for Disease Control and Prevention (CDC), (*http://www.cdc.gov/*).

Participating Organizations

Centers for Disease Control and Prevention (CDC), (*http://www.cdc.gov/*).

National Institutes of Health (NIH), (*http://www.nih.gov/*).

Components of Participating Organizations

National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), (*http://www.cdc.gov/nccdphp/*), Division of Diabetes Translation (DDT), (*http://www.cdc.gov/diabetes/*).

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), (*http://www.niddk.nih.gov/*).

Title: Incidence, Natural History, and Quality of Life of Diabetes in Youth.

Announcement Type: New.

Request For Applications (RFA) Number: RFA–DP–05–069.

Catalog of Federal Domestic Assistance Number: 93.945.

Key Dates: Release Date: May 11, 2005.

Letters of Intent Receipt Date: May 25, 2005.

Application Receipt Date: June 24, 2005.

Earliest Anticipated Start Date: August 31, 2005.

Expiration Date: June 25, 2005.

Due Dates for E.O. 12372: Not Applicable.

Additional Overview Content

Executive Summary

• This RFA has two components, A and B:

Component A solicits applications for conducting multi-center, population-based research studies aimed at: assessing the incidence and secular trends of diabetes in youth; enhancing our knowledge of the natural history of diabetes and its complications in children; conducting research on health care utilization, processes of care, and quality of life of youth with diabetes;

and developing and validating classification schemes of diabetes in youth suitable for public health surveillance.

Component B solicits applications for a study Coordinating Center (CC) to provide the data management and analysis to support this multi-center research study.

• The participating organizations plan on contributing $4.1 million in FY 2005 to fund up to six new cooperative agreement awards for Component A and one cooperative agreement award for Component B.

• This funding opportunity will use the cooperative agreement funding mechanism (CDC U58).

• Applications may be submitted by: for-profit organizations, non-profit organizations; public or private institutions such as universities, colleges, hospitals, and laboratories; units of State government; domestic institutions; and faith- or community-based organizations, including Native American tribal organizations.

• Any individuals with the skills, knowledge, and resources necessary to carry out the proposed research are invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups, as well as individuals with disabilities, are always encouraged to apply for CDC funding announcements.

• An applicant may submit only one application for either Component A or B, but not both under this funding announcement.

• Applications must be prepared using the ''Application for a DHHS Public Health Service Grant'' (PHS 398, rev. 9/04). The PHS 398 instructions and forms are available at *http://grants.nih.gov/grants/forms.htm.*

• Telecommunications for the hearing impaired is available at: TTY 301–451–0088.

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Part II—Full Text of Announcement

Section I. Funding Opportunity Description

The purpose of this RFA is to support research that will expand the preliminary findings of a five year research project, SEARCH for Diabetes in Youth, and enhance our understanding of the natural history, complications, and risk factors of diabetes mellitus with onset in childhood and adolescence. This program addresses the ''Healthy People 2010'' focus area of Diabetes.

Measurable outcomes of the program will be in alignment with the following performance goal for the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP): To increase the capacity of state diabetes control programs to address the prevention of diabetes and its complications at the community level.

1. Research Objectives

Nature of the Research Opportunity

This RFA builds upon a five year research project, SEARCH for Diabetes in Youth, and solicits applications in the form of cooperative agreements to conduct research that will expand the preliminary findings from SEARCH and enhance our understanding of the natural history, complications, and risk factors of diabetes mellitus with onset in childhood and adolescence. A second component of this RFA is the funding of a data management, analysis, and study Coordinating Center (CC) that will collaborate with award recipients and the NCCDPHP.

Background

Diabetes mellitus, a leading cause of end-stage renal disease, blindness, non-traumatic amputation, and cardiovascular disease, is one of the most prevalent severe chronic diseases of childhood in the United States. Until recently, diabetes diagnosed in children and adolescents was almost entirely considered to be type 1, which is usually attributed to the destruction of the beta cells of the pancreas leading to an absolute deficiency of insulin. However, in the last two decades diabetes in children and adolescents has emerged as a complex disorder with heterogeneity in its pathogenesis, clinical presentation, and outcomes.

In adolescents, especially those from minority race/ethnic U.S. groups, type 2 diabetes appears to be increasing. Type 1 diabetes incidence is also increasing worldwide; however, type 1 diabetes registries in the U.S. have reported conflicting results. Knowledge of the magnitude of diabetes in adolescents and children, the rate of increase, and the clinical course and evolution of different forms of diabetes in children and youth is limited.

In 2000, CDC in collaboration with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH) under Program Announcement #00097 (Uniform Population-Based Approach to Case Ascertainment, Typology, Surveillance, and Research on Childhood Diabetes) established a 5-year research project to assess the burden of diabetes with onset in childhood and adolescence in the U.S. The goals of this project (now called SEARCH for Diabetes in Youth) were to: (1) Identify prevalent and incident cases of diabetes among individuals under age 20 years in order to estimate population prevalence and incidence rates; (2) develop gold standards for the classification of diabetes type in youth; and (3) describe and compare clinical presentation and characteristics of type 1, type 2, and other types of diabetes.

Six SEARCH research centers, located across the U.S., were funded to conduct this study. Approximately 5.5 million children aged < 20 years (~6% of the <20 years U.S. population), with wide racial/ethnic, socioeconomic, and geographic representation, have been under surveillance at the SEARCH

research centers to estimate diabetes prevalence and incidence by age, sex, race/ethnicity, and diabetes type.

Scientific Knowledge To Be Achieved Through this Funding Opportunity

Data from SEARCH reveal important preliminary findings that warrant further scientific study:

- The incidence of diabetes in U.S. youth is higher at all the SEARCH sites and among all age groups than had been expected based on estimates from previous diabetes registries. However, this does not necessarily imply that the incidence has increased. Differences in case definition and in ascertainment methodology, or changes in screening patterns, may partly explain the higher incidence estimated by SEARCH. In order to assess temporal trends, it is necessary to monitor diabetes incidence in youth for a longer period of time using consistent methodology for case ascertainment and classification.
- Some subjects not only exhibit the clinical features of type 2 diabetes, but also have positive diabetes autoantibody status (a characteristic of type 1 autoimmune diabetes). This finding demonstrates the limits of the current diabetes classification scheme in youth and the need to better understand the natural history and long-term evolution of diabetes in youth, especially those with features of both type 1 and type 2 diabetes.

This RFA will fund research that will expand our understanding of the natural history, complications, and risk factors of diabetes with onset in childhood and adolescence. Additional research will also provide consistency and ensure sustainable and simplified criteria for case ascertainment and classification for surveillance purposes, across centers, across populations, and over time. This approach will constitute an essential basis for assembling large numbers of incident cases for additional clinical, epidemiological, health care, or therapeutic research into childhood diabetes.

Experimental Approach and Research Objectives

Using an established standardized multi-center, population-based approach in a diverse population, the objectives of this research program under Component A are to:

- Assess the incidence of diabetes with onset in childhood and adolescence by age, gender, and race/ethnicity.
- Describe the natural history of diabetes in youth, including the occurrence of diabetes micro- and macro-vascular complications and their risk factors.
- Assess the impact of quality of diabetes care in youth on short- and long-term diabetes outcomes, including quality of life.
- Develop and validate simple and low-cost case definition and classification of diabetes in youth that can be used for public health surveillance.

Component B will establish a data management, analysis, and study Coordinating Center (CC) to collaborate with award recipients from Component A and with the NCCDPHP. The objectives of this research program under Component B are for the CC to:

- Create and maintain a central data repository and create protocols and mechanisms to secure transmission of data and relevant data management reports between the CC and the study sites.
- Ensure the training and certification of staff at the study sites on measurement and study procedures as outlined in the protocol and manual of operations.
- Provide statistical and other analytic support to the multi-center study.
- Act, directly or through a subcontractor, as a central laboratory for the analyses of specimens from the study sites and ensure rapid transmission of the results.

See *Section VIII, Other Information—Required Federal Citations,* for policies related to this announcement.

Section II. Award Information

1. Mechanism(s) of Support

This funding opportunity will use the CDC (U58) cooperative agreement award mechanism for both Component A and B. The applicant will be solely responsible for planning, directing, and executing the proposed project. In the cooperative agreement mechanism, the Principal Investigator retains the primary responsibility and dominant role for planning, directing, and executing the proposed project, with NCCDPHP staff being substantially involved, as a partner with the Principal Investigator, as described under the *Section VI. 2. Administrative and National Policy Requirements,* ''Cooperative Agreement Terms and Conditions of Award''.

This funding opportunity uses the just-in-time budget concepts. It requires the summary budget information provided in the application package, including the budget justification and support, written in the form, format, and the level of detail as specified in the budget guidelines. You may access the latest version of the budget guidelines by accessing the following web site: *http://www.cdc.gov/od/pgo/funding/budgetguide2004.htm.*

This RFA is a one-time solicitation. The total project period for an application submitted in response to this RFA may not exceed five years.

2. Funds Available

The participating organizations, NCCDPHP and NIDDK, intend to commit approximately $4.4 million in FY 2005 to fund up to six competitive cooperative agreements under Component A and one competitive cooperative agreement under Component B in response to this RFA. An applicant under Component A may request a project period of up to five years and a budget for total costs between $450,000 and $650,000 per year. An applicant under Component B may request a project period of up to five years and a budget for total costs up to $1.1 million per year.

The earliest anticipated start date is August 31, 2005 with performance periods between September 2005 and September 2010.

Although the financial plans of the NCCDPHP and NIDDK provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the Federal Government.

Section III. Eligibility Information

1. Eligible Applicants

1.A. Eligible Institutions

You may submit an application if your organization has any of the following characteristics:

- Public nonprofit organizations
- Private nonprofit organizations
- For profit organizations
- Universities
- Colleges
- Research institutions
- Hospitals
- Community-based organizations
- Faith-based organizations
- Federally recognized Indian tribal governments
- Indian tribes
- Indian tribal organizations
- State and local governments or their Bona Fide Agents (this includes 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)

A Bona Fide Agent is an agency/organization identified by the state as eligible to submit an application under the state eligibility in lieu of a state application. If you are applying as a bona fide agent of a state or local government, you must provide a letter from the state or local government as documentation of your status. Place this documentation behind the first page of your application form.

Institution eligibility is limited to those with broad research capacity and access to the data sources that are representative of the overall U.S. population, including the specific populations targeted in this announcement.

1.B. Eligible Individuals

Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for CDC programs.

2. Cost Sharing or Matching

Cost sharing is not required.

3. Other—Special Eligibility Criteria

For Component A, the following criteria will be used to determine an applicant's eligibility:

- Access to a research infrastructure and an established population-based childhood diabetes registry. Evidence should be provided in the form of summaries of existing data collected in the last five years which shows incidence and prevalence of diabetes in youth by age, sex, race/ethnicity, and diabetes type. In addition, a description of an already established cohort of youth with diabetes including age, race/ethnicity, socio-economic status, and diabetes type distribution should be included.
- Experience in the recruitment and retention of youth with diabetes, especially those from older adolescent populations, racial/ethnic minorities, and socio-economic disadvantaged populations.
- A minimum of five years experience collaborating with other partners in a multi-center study that included a common protocol, development of methods and procedures, design of instruments, the collection, analysis and interpretation of data, and dissemination of results. Evidence of previous collaborations with other institutional partners should be provided in the form of letters of support, publications, reports, and abstracts.

For Component B (Coordinating Center), the following criteria will be used to determine an applicant's eligibility:

- A minimum of five years experience in directing and operating a coordinating center for collaborative, population-based, large-scale epidemiological research projects that included coordination of multi-site studies, development of training/certification programs, monitoring site performance and progress of studies, and providing governance support.
- Experience in providing data management, analysis, and statistical support to multi-site research studies that included development and management of a multi-site database, the design, analysis, and interpretation of data, and the development/production of data summaries and statistical reports.
- Experience with working with centralized laboratories and tracking of specimens.

Investigators may submit one application for either Component A or B, but not both under this funding announcement.

If your application is incomplete or non-responsive to the special requirements listed in this section, it will not be entered into the review process and you will be notified that your application did not meet submission requirements. Applicants that request a funding amount greater than the ceiling of the award range will be considered non-responsive.

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.

Section IV. Application and Submission Information

1. Address To Request Application Information

The PHS 398 application instructions are available at *http://grants.nih.gov/grants/funding/phs398/phs398.html* in an interactive format. Applicants must use the currently approved version of the PHS 398. If you do not have access to the Internet, or if you have difficulty accessing the forms on-line, you may contact the CDC Procurement and Grants Office Technical Information Management Section (PGO–TIM) staff at: 770/488–2700, E-mail: *PGOTIM@cdc.gov.*

2. Content and Form of Application Submission

Applications must be prepared using the most current PHS 398 research grant application instructions and forms. Applications must have a D&B Data Universal Numbering System (DUNS) number as the universal identifier when applying for Federal grants or cooperative agreements. The D&B number can be obtained by calling 866/705–5711 or through the web site at *http://www.dnb.com/us/.* The D&B number should be entered on line 11 of the face page of the PHS 398 form.

The title and number of this funding opportunity must be typed on line 2 of the face page of the application form and the YES box must be checked.

3. Submission Dates and Times

Applications must be received on or before the receipt date described below (*Section IV.3.A*).

3.A. Receipt, Review and Anticipated Start Dates

Letter of Intent Receipt Date: Add Information Here.

Application Receipt Date: Month XX, 2005.

Peer Review Date: Add Information Here.

Earliest Anticipated Start Date: August 31, 2005.

Explanation of Deadlines: All requested information must be received in the CDC Procurement and Grants Office by 4 p.m. Eastern Time on the deadline date.

If you submit your LOI or application by the United States Postal Service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery by the closing date and time. If CDC receives your submission after closing due to: (1) Carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, you will be given the opportunity to submit documentation of the carrier's guarantee. If the documentation verifies a carrier problem, CDC will consider the submission as having been received by the deadline.

This announcement is the definitive guide on LOI and application content, submission address, and deadline. It supersedes information provided in the application instructions. If your application does not meet the deadline above, it will not be eligible for review, and will be discarded. You will be notified that you did not meet the submission requirements.

CDC will not notify you upon receipt of your submission. If you have a question about the receipt of your LOI or application, first contact your courier. If you still have a question, contact the PGO–TIM staff at: 770/488–2700. Before calling, please wait two to three days after the submission deadline. This will allow time for submissions to be processed and logged.

3.A.1. Letter of Intent

CDC requests that you send a Letter of Intent (LOI) if you intend to apply for this funding announcement. Although an LOI is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows NCCDPHP staff to estimate the potential reviewer workload and plan the review.

LOI Format

- Two page maximum, one side only
- One-inch margins, 12 point font, single spaced

LOI Contents

- Number and title of this funding opportunity (RFA)
- Descriptive title of proposed research
- Name, address, e-mail, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating Institutions

The LOI should be mailed, faxed, or emailed by Month XX, 2005 to

Office of Extramural Research, NCCDPHP, Centers for Disease Control and Prevention, 4770 Buford Highway NE, Mailstop K–92, Atlanta, GA 30341. Phone: 770/488–8390. Fax: 770/488–8046. E-mail: *OER@cdc.gov.*

3.B. Sending an Application to the CDC

Applications must be prepared using the PHS 398 research grant application instructions and forms as described above. Submit a signed, typewritten original of the application, including the checklist, and two signed photocopies in one package to: Technical Information Management—RFA DP–05–069, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

At the time of submission, three additional copies of the complete application, including the appendix material, must be sent to: Brenda Colley Gilbert, Ph.D., M.S.P.H., Office of Extramural Research, NCCDPHP, Centers for Disease Control and Prevention, 4770 Buford Highway NE, Mailstop K–92, Atlanta, GA 30341. FedEx Address: Brenda Colley Gilbert, Ph.D., M.S.P.H., Office of Extramural Research, NCCDPHP, Koger Center/Williams Building, 2877 Brandywine Road, Room 5516, Atlanta, GA 30341.

For further assistance contact the CDC Procurement and Grants Office, Technical Information Management Section: Telephone 770/488–2700, E-mail *pgotim@cdc.gov.*

3.C. Application Processing

Applications must be received on or before the application receipt date described above (*Section IV.3.A.*). If an application is received after that date, it will be returned to the applicant without review.

Upon receipt, applications will be evaluated for completeness by the Procurement and Grants Office (PGO) and responsiveness by the NCCDPHP. Incomplete and non-responsive applications will not be reviewed.

4. Intergovernmental Review

Executive Order 12372 does not apply to this program.

5. Funding Restrictions

Restrictions, which must be taken into account while writing your budget, are as follows:

- Funds relating to the conduct of research will not be released until the appropriate assurances and Institutional Review Board approvals are in place.
- Reimbursement of pre-award costs is not allowed.

If you are requesting indirect costs in your budget, you must include a copy of your indirect cost rate agreement. If your indirect cost rate is a provisional rate, the agreement should be less than 12 months of age.

6. Other Submission Requirements

For Component A of this RFA the general instructions in the PHS 398 should be followed; however, the applicant should include:

- Copies of publications, reports, and abstracts on the epidemiology of diabetes with onset in childhood and adolescence authored by the Principal Investigator or co-principal investigator and published within the last five years.
- Plans for recruiting children and adolescents with diabetes and retaining them for long-term follow-up, especially those from racial/ethnic minorities and socio-economically disadvantaged populations.
- Strategies for the follow-up of the incident cases and prevalent cases of childhood diabetes for studying the natural history of the disease and the long-term impact of quality of diabetes care.
- Letters of support from collaborating partners specifying the commitment of the parties involved including the terms of access to data and populations and any specified limits to collaboration.

For Component B (Coordinating Center) of this RFA the general instructions in the PHS 398 should be followed; however, the applicant should include:

- Evidence that the applicant has the staffing and facilities to implement the program at the time of the award. The cost of coordinating at least four annual meetings with the Principal Investigators of the study sites and the Steering Committee must be included in the budget.
- A proposed organizational structure for facilitating and supporting, scientifically and administratively, a collaborative, multi-center research study.
- Examples of materials and methods used to recruit and retain children and adolescents in health care research.
- A description of the research infrastructure and physical facilities for developing a central database.
- Examples of innovative analytic approaches to evaluating research data from multi-site studies.
- Examples of detailed data management and quality control procedures, including methods for assuring privacy and maintaining confidentiality, methods for sending and receiving data, descriptions and examples of data forms and questionnaires, and descriptions of software/computer programs.
- A description of the approach that will be used for soliciting and evaluating proposals for centralized laboratories and/or reading centers.

Principal Investigators must include a research plan of the activities to be conducted over the entire project period and a Data Release Plan that addresses the dissemination of any and all data collected in their application. This announcement also requires summary budget information provided in the application package, including the budget justification and support, written in the form, format, and the level of detail as specified in the budget guidelines. You may access the latest version of the budget guidelines by accessing the following Web site: *http://www.cdc.gov/od/pgo/funding/budgetguide2004.htm.*

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

Section V. Application Review Information

1. Criteria

Applicants are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures of effectiveness must relate to the performance goals stated in Section I. Funding Opportunity Description of this announcement. Measures must be objective and quantitative, and must measure the intended outcome. These measures of effectiveness must be submitted with the application and will be an element of evaluation.

The goals of CDC-supported research are to advance the understanding of biological systems, improve the control and prevention of disease and injury, and enhance health. In the written comments, reviewers will be asked to evaluate the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals.

The following will be considered in making funding decisions:

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

Preference may be given to applications based on evidence of accessibility to populations with racial/ethnic and socio-economic diversity necessary to achieve socio-economic and racial/ethnic representation of the U.S. population.

2. Review and Selection Process

Upon receipt, applications will be reviewed for completeness by PGO and responsiveness by the NCCDPHP. Incomplete and/or non-responsive applications will not be reviewed. Applicants will be notified that their application did not meet submission requirements.

Applications that are complete and responsive to the announcement will be evaluated for scientific and technical merit by an external peer review group in accordance with the review criteria stated below.

As part of the initial merit review, all applications will:

- Undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed and assigned a priority score.
- Receive a written critique within 30 days after the review.

Scored applications will receive a second level review by the NCCDPHP Secondary Review Committee. The review process will follow the policy requirements as stated in the GPD 2.04 [*http://198.102.218.46/doc/gpd204.doc*].

The following review criteria will be addressed and considered in assigning the overall score, weighting them as appropriate for each application. Note that an application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

1. *Significance.* Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of these studies on the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

2. *Approach.* Are the conceptual or clinical framework, design, methods, and analyses adequately developed, well integrated, well reasoned, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

For Component A: Does the application adequately describe: (a) The population source (including size, age, ethnicity, medical insurance status, socio-economic status, and geographic distribution); (b) the partnership/network(s) which will provide access to information on the cases of diabetes within this population source; (c) access to racial and ethnic minority and socio-economically disadvantaged populations; (d) data sources (hospital and non-hospital) that will be used; (e) how the population size (denominator) will be ascertained for estimation of incidence and secular trends over the five years of study; and (f) strategies for the follow-up of the incident cases and prevalent cases of childhood diabetes for studying the natural history of the disease and the long-term impact of quality of diabetes care?

For Component B: Does the applicant describe the approach that would be used for soliciting and evaluating proposals for centralized laboratories and/or reading centers?

3. *Innovation.* Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools, or technologies for this area?

4. *Investigators.* Are the investigators appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers? Does the investigative team bring complementary and integrated expertise to the project (if applicable)?

For Component A: Does the Principal Investigator or the co-principal investigator have a history of conducting competitively funded peer reviewed research on the epidemiology of diabetes with onset in childhood and adolescence within the last five years? Is there evidence of prior experience in working collaboratively to carry out a population-based, multi-center study or standard protocol? Does the applicant's project team include significant expertise in pediatric endocrinology, epidemiology of diabetes and its micro- and macro-vascular complications, and/or health care research?

For Component B: Is the Principal Investigator an experienced biostatistician, epidemiologist, physician, or other professional with experience in directing a coordinating center for a collaborative, population-based, large-scale epidemiological research project? Does the applicant's project team include senior statistical staff that will devote substantial time to developing data analysis methods for use in the study? Does the applicant demonstrate experience in developing materials and methods for the recruitment and retention of children and adolescents?

5. *Environment.* Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed studies benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

For Component A: Is there an institutional research infrastructure to carry out large, complex, population-based projects, as well as facilities to perform in-person visits, and handle and process biological samples?

For Component B: Is there a description of the applicant's physical facilities, data management and computer resources, and facilities for data retrieval and storage?

2.A. Additional Review Criteria

In addition to the above criteria, the following items will continue to be considered in the determination of scientific merit and the priority score:

Protection of Human Subjects from Research Risk: Federal regulations (45

CFR Part 46) require that applications and proposals involving human subjects be evaluated and that they reference the risk to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained (*http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm*). The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed (see the Research Plan, Section E on Human Subjects in the PHS Form 398).

Inclusion of Women, Minorities and Children in Research: Does the application adequately address the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research? This includes: (1) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation; (2) The proposed justification when representation is limited or absent; (3) A statement as to whether the design of the study is adequate to measure differences when warranted; and (4) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits. Plans for the recruitment and retention of subjects will also be evaluated (see the Research Plan, Section E on Human Subjects in the PHS Form 398).

2.B. Additional Review Considerations

Budget: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research. The priority score should not be affected by the evaluation of the budget.

3. Anticipated Announcement and Award Dates

CDC expects to make awards on or about August 31, 2005.

Section VI. Award Administration Information

1. Award Notices

After the peer review of applications is complete, Principal Investigators will receive a written critique called a Summary Statement. Those applications under consideration for funding will receive a call or e-mail from the Grants Management Specialist (GMS) of the Procurements and Grants Office (PGO) for additional information.

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization. The NoA signed by the Grants Management Officer (GMO) is the authorizing document. This document will be mailed and/or emailed to the institutional fiscal official identified in the application.

Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. See Also *Section IV.5. Funding Restrictions.*

2. Administrative and National Policy Requirements

The Code of Federal Regulations 45 CFR Part 74 and Part 92 have details about policy requirements. For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: *http://www.access.gpo.gov/nara/cfr/cfr-table-search.html.* The following additional requirements can be found in Section VIII. Other Information of this document or on the CDC website at the following Internet address: *http://www.cdc.gov/od/pgo/funding/ARs.htm.* These will be incorporated into the award statement and will be provided to the Principal Investigator, as well as to the appropriate institutional official, at the time of award.

2.A. Cooperative Agreement Terms and Conditions of Award

The following special terms of award are in addition to, and not in lieu of, otherwise applicable OMB administrative guidelines, HHS grant administration regulations at 45 CFR Parts 74 and 92 (Part 92 is applicable when State and local Governments are eligible to apply), and other HHS, PHS, and CDC grant administration policies.

The administrative and funding instrument used for this program will be the cooperative agreement (CDC U58), an ''assistance'' mechanism (rather than an ''acquisition'' mechanism), in which substantial NCCDPHP programmatic involvement with the awardees is anticipated during the performance of the activities. Under the cooperative agreement, the NCCDPHP's purpose is to support and stimulate the recipients' activities by involvement in and otherwise working jointly with the award recipients in a partnership role; it is not to assume direction, prime responsibility, or a dominant role in the activities. Consistent with this concept, the dominant role and prime responsibility resides with the awardees for the project as a whole, although specific tasks and activities may be shared among the awardees and the NCCDPHP as defined above.

2.A.1. Principal Investigator Rights and Responsibilities

The Principal Investigator under Component A will have the primary responsibility for:

1. Participating in the Steering Committee, the primary governing body of the study and comprised of the Principal Investigators from each study site (*see* section 2.A.3).

2. Establishing and maintaining networks or partnerships with health care providers and health care systems that have access to information on cases of childhood diabetes.

3. Participating in the methodology and protocol development of the study, on-going data collection and follow up, quality control, data analysis and interpretation, and the preparation of peer-reviewed publications for presentation of findings.

4. Collaborating with other study investigators and following common protocol(s) and manuals of operations developed by the Steering Committee.

5. Maintaining an effective and adequate management and staffing plan.

6. Assuring and maintaining the confidentiality of all study data.

7. Performing joint analysis with aggregate data and communicating scientifically via publications, abstracts, and presentations, the main and secondary findings pertaining to the goals of the study.

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

The Principal Investigator under Component B (Coordinating Center) will have the primary responsibility for:

1. Promoting and facilitating a multi-center and collaborative environment among the award recipients.

2. Facilitating the formation of a Steering Committee (SC) consisting of the Principal Investigators from each study site. The SC will have a minimum of four meetings each year and regular teleconferences throughout the year. The SC may create sub-committees as appropriate to accomplish its goals.

3. Coordinating the statistical analyses and data management aspects of the study. The CC will have both scientific and administrative functions.

4. Reviewing the study protocol and assisting in the development of the statistical design for the multi-center study, analyzing study results, and reviewing all manuscripts for statistical considerations. Based on input from the

Steering Committee, the CC will prepare and update the protocols and manuals of operation, provide materials to aid in patient recruitment and retention, and ensure the training and certification of staff at the study sites as outlined in the study protocol.

5. Establishing a database to accommodate data generated by each study site, developing a data transmission system, and assessing data quality and completeness throughout the study. The CC will provide for central registration of all individuals enrolled in the study.

6. Establishing, directly or through subcontracts, central laboratories and reading centers, as determined by the Steering Committee.

7. Providing statistical reports on the progress of the study at Steering Committee meetings and facilitating communication among investigators, including scheduling meetings and conference calls, developing agendas and documenting minutes, and maintaining membership rosters and committee lists.

The Principal Investigator of the CC will be a member of the Steering Committee. The Coordinating Center will not retain custody of or have primary rights to the data and software developed under this award. Primary rights to collected data will remain with the awardees under Component A.

2.A.2. NCCDPHP Responsibilities

For both Component A and B, a NCCDPHP Project Scientist will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

1. Support the grantees' activities by collaborating and providing scientific and public health consultation and assistance in the development of activities related to the cooperative agreement.

2. Assist in facilitating communication among grantees' for the development of common multi-center protocol(s), quality control, interim data monitoring, data analysis, interpretation, reporting, and coordination.

3. Ensure adherence of human subjects requirements, and approval of study protocol by appropriate local IRBs, for all cooperating institutions participating in the research study.

4. Serve as a consultant to the Steering Committee.

5. Facilitate the process for obtaining Certificates of Confidentiality in the form of 301(d), as appropriate.

6. Collaborate to produce technical reports or manuscripts for peer-reviewed publications, as appropriate. Provide assistance for joint analysis with aggregate data.

An External Advisory Committee (EAC) will be appointed by the NCCDPHP. It will consist of a Chair and scientists with expertise in epidemiology, biostatistics, and diabetes. Clinical scientists knowledgeable about diabetes, but who are not participating at a designated Research Center, may be invited to assess the study protocol.

The EAC will evaluate the protocol proposed by the Steering Committee based on the importance of the question to be addressed, scientific merit of the experimental design, feasibility, and consistency with NCCDPHP mission and policies. The EAC will provide a written critique of the protocol and a final recommendation to the Steering Committee and the NCCDPHP. During the implementation phase of the protocol, the EAC will monitor each research center for adherence to the study protocol and progress towards study goals. The EAC will have the authority to recommend protocol or procedural changes or early termination of any award for poor performance.

The EAC is advisory to both the NCCDPHP and the Steering Committee. The Chairperson of the Steering Committee and the Principal Investigator of the CC will attend annual EAC meetings.

The CDC reserves the right to terminate or curtail the study (or an individual award) in the event of substantial shortfall in participant recruitment, follow-up, data reporting, quality control, or other major breach of the protocol. The CDC can also terminate or curtail the study (or an individual award) if human subject safety or ethical issues dictate a premature termination. The CDC may also terminate the project if there is failure to develop or implement a mutually agreeable collaborative protocol.

Additionally, an agency program official or NCCDPHP program director will be responsible for the normal scientific and programmatic stewardship of the award and will be named in the award notice.

2.A.3. Collaborative Responsibilities

The Steering Committee, the main governing board of the study, will be comprised of the Principal Investigator from each study site, the Principal Investigator of the CC, and a NCCDPHP Project Scientist serving as consultant. A chairperson will be selected from the non-federal Steering Committee members. The chairperson must have proven evidence of leadership ability and be able to make an adequate time commitment to the cooperative agreement.

The Steering Committee will meet initially to develop the protocol and throughout the year to discuss the progress of the study. It will have primary responsibility for developing common research designs, protocols and manuals of operations, facilitating the conduct and monitoring of studies, and reporting study results. The Steering Committee must approve the protocol, changes to protocols, and manuals of operation. The Principal Investigator of each study site will be responsible for the execution of the protocol and will provide progress reports to the Steering Committee. The Steering Committee will also develop policies relating to access to patient data and specimens and ancillary studies. It will establish guidelines for presentations at scientific meetings and for writing and publishing manuscripts on the findings of the study.

Each full member of the Steering Committee will have one vote. Grantee members of the Steering Committee will be required to accept and implement policies approved by the Steering Committee. To promote the development of a collaborative program among awardees, Principal Investigators are expected to attend Steering Committee meetings and participate in conference calls on a regular basis.

3. Reporting

Grantees must provide CDC with an original, plus two hard copies of the following reports:

1. Interim progress report, (use form PHS 2590, OMB Number 0925–0001, rev. 5/2001 as posted on the CDC website) no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application and must contain the following elements:

a. Current Budget Period Activities Objectives.

b. Current Budget Period Financial Progress.

c. New Budget Period Program Proposed Activity Objectives.

d. Budget.

e. Measures of Effectiveness.

f. Additional Requested Information.

2. Annual Progress Report, due 90 days after the end of the budget period.

3. Financial status report, no more than 90 days after the end of the budget period.

4. Final financial and performance reports, no more than 90 days after the end of the project period.

5. Data collected must be released to the public no later than two years after the end of the budget period as specified in the application's Data Release Plan and in accordance with CDC policy on Releasing and Sharing Data.

These reports must be mailed to the Grants Management Specialist listed in the ''Agency Contacts'' section of this announcement.

Section VII. Agency Contacts

We encourage your inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues:

1. General Questions: Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341. Telephone: 770/488–2700. E-mail: *PGOTIM@cdc.gov*.

2. Scientific/Research Contacts: Brenda Colley Gilbert, Ph.D., M.S.P.H., Office of Extramural Research, NCCDPHP, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway NE, Mailstop K–92, Atlanta, GA 30341. Telephone: 770/488–8390. E-mail: *BColleyGilbert@cdc.gov*.

3. Peer Review Contacts: Scientific Review Administrator, Office of Extramural Research, NCCDPHP, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway NE, Mailstop K–92, Atlanta, GA 30341. Telephone: 770/488–8390. E-mail: *OER@cdc.gov*.

4. Financial or Grants Management Contacts: Sylvia Dawson, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), Koger Office Park, Colgate Building, Mail-Stop E–14, 2920 Brandywine Road, Atlanta, GA 30341–5539. Telephone: 770/488–2771. E-mail: *SDawson@cdc.gov*.

Section VIII. Other Information

Required Federal Citations

AR–1

Human Subjects Requirements

If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services (DHHS) Regulations (Title 45 Code of Federal Regulations Part 46) regarding the protection of human research subjects. All awardees of CDC grants and cooperative agreements and their performance sites engaged in human subjects research must file an assurance of compliance with the Regulations and have continuing reviews of the research protocol by appropriate institutional review boards. In order to obtain a Federalwide Assurance (FWA) of Protection for Human Subjects, the applicant must complete an on-line application at the Office for Human Research Protections (OHRP) website or write to the OHRP for an application. OHRP will verify that the Signatory Official and the Human Subjects Protections Administrator have completed the OHRP Assurance Training/Education Module *before* approving the FWA. Existing Multiple Project Assurances (MPAs), Cooperative Project Assurances (CPAs), and Single Project Assurances (SPAs) remain in full effect until they expire or until December 31, 2003, whichever comes first.

To obtain a FWA contact the OHRP at: *http://ohrp.osophs.dhhs.gov/irbasur.htm* OR If your organization is not Internet-active, please obtain an application by writing to: Office for Human Research Protections (OHRP), Department of Health and Human Services, 6100 Executive Boulevard, Suite 3B01, MSC 7501, Rockville, Maryland 20892–7507. (For Express or Hand Delivered Mail, Use Zip Code 20852)

Note: In addition to other applicable committees, Indian Health Service (IHS) institutional review committees must also review the project if any component of IHS will be involved with or will support the research. If any American Indian community is involved, its tribal government must also approve the applicable portion of that project.

AR–2

Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

It is the policy of the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC/ATSDR-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian or Alaska Native, Asian, Black or African American, Hispanic or Latino, Native Hawaiian or Other Pacific Islander. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity, and/or sex of subjects. Further guidance to this policy is contained in the **Federal Register**, Vol. 60, No. 179, pages 47947–47951, and dated Friday, September 15, 1995.

AR–8

Public Health System Reporting Requirements

This program is subject to the Public Health System Reporting Requirements. Under these requirements, all community-based non-governmental organizations submitting health services applications must prepare and submit the items identified below to the head of the appropriate State and/or local health agency(s) in the program area(s) that may be impacted by the proposed project no later than the application deadline date of the Federal application. The appropriate State and/or local health agency is determined by the applicant. The following information must be provided:

A. A copy of the face page of the application (SF 424).

B. A summary of the project that should be titled ''Public Health System Impact Statement'' (PHSIS), not exceed one page, and include the following: A description of the population to be served. A summary of the services to be provided. A description of the coordination plans with the appropriate state and/or local health agencies.

If the State and/or local health official should desire a copy of the entire application, it may be obtained from the State Single Point of Contact (SPOC) or directly from the applicant.

AR–9

Paperwork Reduction Act Requirements

Under the Paperwork Reduction Act, projects that involve the collection of information from 10 or more individuals and funded by a grant or a cooperative agreement will be subject to review and approval by the Office of Management and Budget (OMB).

AR–10

Smoke-Free Workplace Requirements

CDC strongly encourages all recipients to provide a smoke-free workplace and to promote abstinence from all tobacco products. Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care,

or early childhood development services are provided to children.

AR–11

Healthy People 2010

CDC is committed to achieving the health promotion and disease prevention objectives of ''Healthy People 2010,'' a national activity to reduce morbidity and mortality and improve the quality of life. For the conference copy of ''Healthy People 2010,'' visit the internet site: *http://www.health.gov/healthypeople.*

AR–12

Lobbying Restrictions

Applicants should be aware of restrictions on the use of HHS funds for lobbying of Federal or State legislative bodies. Under the provisions of 31 U.S.C. Section 1352, recipients (and their sub-tier contractors) are prohibited from using appropriated Federal funds (other than profits from a Federal contract) for lobbying congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement, or loan. This includes grants/cooperative agreements that, in whole or in part, involve conferences for which Federal funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby.

In addition, no part of CDC appropriated funds, shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State or local legislature, except in presentation to the Congress or any State or local legislature itself. No part of the appropriated funds shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State or local legislature.

Any activity designed to influence action in regard to a particular piece of pending legislation would be considered ''lobbying.'' That is lobbying for or against pending legislation, as well as indirect or ''grass roots'' lobbying efforts by award recipients that are directed at inducing members of the public to contact their elected representatives at the Federal or State levels to urge support of, or opposition to, pending legislative proposals is prohibited. As a matter of policy, CDC extends the prohibitions to lobbying with respect to local legislation and local legislative bodies.

The provisions are not intended to prohibit all interaction with the legislative branch, or to prohibit educational efforts pertaining to public health. Clearly there are circumstances when it is advisable and permissible to provide information to the legislative branch in order to foster implementation of prevention strategies to promote public health. However, it would not be permissible to influence, directly or indirectly, a specific piece of pending legislation. It remains permissible to use CDC funds to engage in activity to enhance prevention; collect and analyze data; publish and disseminate results of research and surveillance data; implement prevention strategies; conduct community outreach services; provide leadership and training, and foster safe and healthful environments.

Recipients of CDC grants and cooperative agreements need to be careful to prevent CDC funds from being used to influence or promote pending legislation. With respect to conferences, public events, publications, and ''grassroots'' activities that relate to specific legislation, recipients of CDC funds should give close attention to isolating and separating the appropriate use of CDC funds from non-CDC funds. CDC also cautions recipients of CDC funds to be careful not to give the appearance that CDC funds are being used to carry out activities in a manner that is prohibited under Federal law.

AR–14

Accounting System Requirements

The services of a certified public accountant licensed by the State Board of Accountancy or the equivalent must be retained throughout the project as a part of the recipient's staff or as a consultant to the recipient's accounting personnel. These services may include the design, implementation, and maintenance of an accounting system that will record receipts and expenditures of Federal funds in accordance with accounting principles, Federal regulations, and terms of the cooperative agreement or grant.

Capability Assessment

It may be necessary to conduct an on-site evaluation of some applicant organization's financial management capabilities prior to or immediately following the award of the grant or cooperative agreement. Independent audit statements from a Certified Public Accountant (CPA) for the preceding two fiscal years may also be required.

AR–15

Proof of Non-profit Status

Proof of nonprofit status must be submitted by private nonprofit organizations with the application. Any of the following is acceptable evidence of nonprofit status: (a) A reference to the applicant organization's listing in the Internal Revenue Service's (IRS) most recent list of tax-exempt organizations described in section 501(c)(3) of the IRS Code; (b) a copy of a currently valid IRS tax exemption certificate; (c) a statement from a State taxing body, State Attorney General, or other appropriate State Official certifying that the applicant organization has a nonprofit status and that none of the net earnings accrue to any private shareholders or individuals; (d) a certified copy of the organization's certificate of incorporation or similar document that clearly establishes nonprofit status; (e) any of the above proof for a State or national parent organization and a statement signed by the parent organization that the applicant organization is a local nonprofit affiliate.

AR–16

Security Clearance Requirement

All individuals who will be performing work under a grant or cooperative agreement in a CDC-owned or leased facility (on-site facility) must receive a favorable security clearance, and meet all security requirements. This means that all awardee employees, fellows, visiting researchers, interns, etc., no matter the duration of their stay at CDC must undergo a security clearance process.

AR–22

Research Integrity

The signature of the institution official on the face page of the application submitted under this Program Announcement is certifying compliance with the Department of Health and Human Services (DHHS) regulations in Title 42 Part 50, Subpart A, entitled ''Responsibility of PHS Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science.''

The regulation places several requirements on institutions receiving or applying for funds under the PHS Act that are monitored by the DHHS Office of Research Integrity's (ORI) Assurance Program. For examples:

Section 50.103(a) of the regulation states: ''Each institution that applies for or receives assistance under the Act for

any project or program which involves the conduct of biomedical or behavioral research must have an assurance satisfactory to the Secretary (DHHS) that the applicant: (1) Has established an administrative process, that meets the requirements of this subpart, for reviewing, investigating, and reporting allegations of misconduct in science in connection with PHS-sponsored biomedical and behavioral research conducted at the applicant institution or sponsored by the applicant; and (2) Will comply with its own administrative process and the requirements of this Subpart.''

Section 50.103(b) of the regulation states that: ''an applicant or recipient institution shall make an annual submission to the [ORI] as follows: (1) The institution's assurance shall be submitted to the [ORI], on a form prescribed by the Secretary, * * * and updated annually thereafter * * * (2) An institution shall submit, along with its annual assurance, such aggregate information on allegations, inquiries, and investigations as the Secretary may prescribe.''

An additional policy is added in the year 2000 that ''requires research institutions to provide training in the responsible conduct of research to all staff engaged in research or research training with PHS funds.

AR–23

Compliance With Executive Order 13279

Faith-based organization are eligible to receive federal financial assistance, and their applications are evaluated in the same manner and using the same criteria as those for non-faith-based organizations in accordance with Executive Order 13279, Equal Protection of the Laws for Faith-Based and Community Organizations. All applicants should, however, be aware of restrictions on the use of direct financial assistance from the Department of Health and Human Services (DHHS) for inherently religious activities. Under the provisions of Title 45, Parts 74, 87, 92 and 96, organizations that receive direct financial assistance from DHHS under any DHHS program may not engage in inherently religious activities, such as worship, religious instruction, or proselytization as a part of the programs or services funded with direct financial assistance from DHHS. If an organization engages in such activities, it must offer them separately, in time or location, from the programs or services funded with direct DHHS assistance, and participation must be voluntary for the beneficiaries of the programs or services funded with such assistance. A religious organization that participates in the DHHS funded programs or services will retain its independence from Federal, State, and local governments, and may continue to carry out its mission, including the definition, practice, and expression of its religious beliefs, provided that it does not use direct financial assistance from DHHS to support inherently religious activities such as those activities described above. A faith-based organization may, however, use space in its facilities to provide programs or services funded with financial assistance from DHHS without removing religious art, icons, scriptures, or other religious symbols. In addition, a religious organization that receives financial assistance from DHHS retains its authority over its internal governance, and it may retain religious terms in its organization's name, select its board members on a religious basis, and include religious references in its organization's mission statements and other governing documents in accordance with all program requirements, statutes, and other applicable requirements governing the conduct of DHHS funded activities. For further guidance on the use of DHHS direct financial assistance see Title 45, Code of Federal Regulations, Part 87, Equal Treatment for Faith-Based Organizations, and visit the Internet site: *http://www.whitehouse.gov/government/fbci/.*

AR–24

Health Insurance Portability and Accountability Act Requirements

Recipients of this grant award should note that pursuant to the Standards for Privacy of Individually Identifiable Health Information promulgated under the Health Insurance Portability and Accountability Act (HIPAA) (45 CFR Parts 160 and 164) covered entities may disclose protected health information to public health authorities authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions. The definition of a public health authority includes a person or entity acting under a grant of authority from or contract with such public agency. CDC considers this project a public health activity consistent with the Standards for Privacy of Individually Identifiable Health Information and CDC will provide successful recipients a specific grant of public health authority for the purposes of this project.

AR–25

Release and Sharing of Data

The Data Release Plan is the Grantee's assurance that the dissemination of any and all data collected under the CDC data sharing agreement will be released as follows:

a. In a timely manner.

b. Completely, and as accurately as possible.

c. To facilitate the broader community.

d. Developed in accordance with CDC policy on Releasing and Sharing Data, April 16, 2003, *http://www.cdc.gov/od/foia/policies/sharing.htm,* and in full compliance with the 1996 Health Insurance Portability and Accountability Act (HIPPA), (where applicable), The Office of Management and Budget Circular A110, (2000) revised 2003, *www.whitehouse.gov/omb/query.html?col=omb&qt=Releasing+and+Sharing+of+Data and Freedom of Information Act (FOIA), www.4.law.cornell.edu/uscode/5/5/552/html.*

Applications must include a copy of the applicant's Data Release Plan. Applicants should provide CDC with appropriate documentation on the reliability of the data. Applications submitted without the required Plan may be ineligible for award. Award will be made when reviewing officials have approved an acceptable Plan. The successful applicant and the Program Manager will determine the documentation format. CDC recommends data is released in the form closest to micro data and one that will preserve confidentiality.

Authority and Regulations

This program is described in the Catalog of Federal Domestic Assistance at *http://www.cfda.gov/* and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under the authorization of 317(k)(2) of the Public Health Service Act (PHS Act), 42 U.S.C. 247b(k)(2) and 301(a) of the PHS Act, 42 U.S.C. 241(a). All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The NIH Grants Policy Statement can be found at *http://grants.nih.gov/grants/policy/policy.htm.*

Dated: June 1, 2005.

William P. Nichols,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 05–11253 Filed 6–6–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Study Team for the Los Alamos Historical Document Retrieval and Assessment (LAHDRA) Project

The Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) announces the following meeting.

Name: Public Meeting of the Study Team for the Los Alamos Historical Document Retrieval and Assessment Project.

Time and Date: 5 p.m.–7 p.m., (mountain time), June 23, 2005.

Place: Cities of Gold Hotel in Pojoaque (15 miles north of Santa Fe on U.S. 84/285), 10–A Cities of Gold Road, Santa Fe, New Mexico 87506, telephone: 505–455–0515.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

Background: Under a Memorandum of Understanding (MOU) signed in December 1990 with the Department of Energy (DOE) and replaced by MOUs signed in 1996 and 2000, the Department of Health and Human Services (HHS) was given the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities, workers at DOE facilities, and other persons potentially exposed to radiation or to potential hazards from non-nuclear energy production use. HHS delegated program responsibility to CDC. In addition, a memo was signed in October 1990 and renewed in November 1992, 1996, and in 2000, between the Agency for Toxic Substances and Disease Registry (ATSDR) and DOE. The MOU delineates the responsibilities and procedures for ATSDR's public health activities at DOE sites required under sections 104, 105, 107, and 120 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or ''Superfund''). These activities include health consultations and public health assessments at DOE sites listed on, or proposed for, the Superfund National Priorities List and at sites that are the subject of petitions from the public; and other health-related activities such as epidemiologic studies, health surveillance, exposure and disease registries, health education, substance-specific applied research, emergency response, and preparation of toxicological profiles.

Purpose: This study group is charged with locating, evaluating, cataloguing, and copying documents that contain information about historical chemical or radionuclide releases from facilities at the Los Alamos National Laboratory since its inception. The purpose of this meeting is to review the goals, methods, and schedule of the project, discuss progress to date, provide a forum for community interaction, and serve as a vehicle for members of the public to express concerns and provide advice to CDC.

Matters to be Discussed: Agenda items include a presentation from the National Center for Environmental Health (NCEH) and its contractor regarding the status of project work. There will be time for public input, questions, and comments.

Agenda items are subject to change as priorities dictate.

Contact Person For Additional Information: Phillip R. Green, Public Health Advisor, Radiation Studies Branch, NCEH, CDC, 1600 Clifton Road, N.E. (MS–E39), Atlanta, GA 30333, telephone 404/498–1717, fax 404/498–1811.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and ATSDR.

Dated: June 2, 2005.

Diane Allen,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 05–11363 Filed 6–6–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Designation of a Class of Employees for Addition to the Special Exposure Cohort

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (''HHS'') gives notice of a decision to designate a class of employees at the Iowa Army Ammunition Plant (IAAP), in Burlington, Iowa as an addition to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000. On May 20, 2005, the Secretary of HHS designated the following class of employees as an addition to the SEC:

Employees of the Department of Energy (DOE) or DOE contractors or subcontractors employed by the Iowa Army Ammunition Plant, Line 1, during the period from March 1949 through 1974 who were employed for a number of work days aggregating at least 250 work days either solely under this employment or in combination with work days within the parameters (excluding aggregate work day requirements) established for other classes of employees included in the SEC.

This designation will become effective on June 19, 2005, unless Congress provides otherwise prior to the effective date. After this effective date, HHS will publish a notice in the **Federal Register** reporting the addition of this class to the SEC or the result of any action by Congress.

FOR FURTHER INFORMATION CONTACT: Larry Elliott, Director, Office of Compensation Analysis and Support, National Institute for Occupational Safety and Health, 4676 Columbia Parkway, MS C–46, Cincinnati, OH 45226, Telephone 513–533–6800 (this is not a toll-free number). Information requests can also be submitted by e-mail to OCAS@CDC.GOV

Dated: May 27, 2005.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Administration for Native Americans; Grants and Cooperative Agreements; Notice of Availability

Funding Opportunity Title: Environmental Mitigation.

Announcement Type: Initial.

Funding Opportunity Number: HHS–2005–ACF–ANA–NM–0019.

CFDA Number: 93.582.