the environmental analysis for the redevelopment of the St. Es West Campus must be postmarked no later than July 5, 2005, and sent to the following address: General Services Administration, National Capital Region, Attention: Denise Decker, NEPA Lead, 301 7th Street, SW, Room 7600, Washington, DC 20407. Fax (202) 708—7671. *denise.decker@gsa.gov.*

Dated: May 31, 2005.

Patricia T. Ralston,

Acting Director, Portfolio Management.

[FR Doc. 05–11242 Filed 6–6–05; 8:45 am]

BILLING CODE 6820–23–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Breast and Prostate Cancer Data Quality and Patterns of Care Study

Announcement Type: New.

Funding Opportunity Number: CDC–RFA–DP05–071.

Catalog of Federal Domestic Assistance Number: 93.395.

Key Dates:

Release Date: May 11, 2005.

Letters of Intent Receipt Date: May 27, 2005.

Application Receipt Date: June 28, 2005.

Earliest Anticipated Start Date: August 31, 2005.

Expiration Date: June 29, 2005.

Due Dates for E.O. 12372:

Not applicable.

I. Funding Opportunity Description

Executive Summary

• This RFA will support up to six registries to conduct enhanced surveillance and operations research utilizing population-based data from the National Program of Cancer Registries (NPCR). The research will focus on improving the completeness, timeliness, quality, and use of first course of treatment and stage data, and on describing patterns of care for female breast cancer and prostate cancer. A long term goal is to strengthen the capacity of NPCR funded state cancer registries to use their data to improve aspects of cancer care.

• It is estimated that approximately $2 million will be available each year to fund up to six registries. A total of approximately $6 million will be available for the entire three year project period.

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

• Eligible organizations include NPCR funded cancer registries, or their designated agent, meeting United States Cancer Statistics (USCS) publication criteria for the diagnosis year 2000 or 2001. For-profit organizations, non-profit organizations, public and private institutions, units of State government, and domestic institutions that can provide evidence of an active collaboration with their respective NPCR funded cancer registry are also eligible to apply.

• 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 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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I. Funding Opportunity Description

The purpose of this RFA is to support research focused on two priority cancers, female breast cancer and prostate cancer, which will build on and expand the work of two Patterns of Care (PoC) projects conducted collaboratively by CDC and selected state cancer registries. This program addresses the ''Healthy People 2010'' focus areas of Access to Quality Health Services and Cancer.

Measurable outcomes of the program will be in alignment with the following performance goals for the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP): (1) To improve the quality of state-based cancer registries, (2) to increase early detection of breast and cervical cancer by building nationwide programs in breast and cervical prevention, especially among high-risk, underserved women, and (3) to expand community-based breast and cervical cancer screening and diagnostic services to low income, medically underserved women. For women diagnosed with cancer or pre-cancer, ensure access to treatment services.

1. Research Objectives

Nature of Research Opportunity

The research priorities of the Centers for Disease Control and Prevention's (CDC) Cancer Surveillance Branch, within the Division of Cancer Prevention and Control, are to describe the burden of priority cancers and patterns of care among minority, rural, and other populations and to assess the quality of these data in NPCR funded cancer registries. This RFA builds on and extends the work of two patterns of care (PoC) projects conducted collaboratively by CDC and selected state cancer registries. It solicits applications in the form of cooperative agreements to utilize data from NPCR

funded cancer registries to perform enhanced surveillance and research regarding patterns of care in female breast and prostate cancers.

Recently published statistics from United States Cancer Statistics: 2001 Incidence and Mortality, a joint publication of CDC and the National Cancer Institute in collaboration with the North American Association of Central Cancer Registries, revealed that prostate cancer is the leading cancer diagnosed in men in the United States (U.S.) and breast cancer is the most common form of cancer diagnosed in U.S. women. Prostate and female breast cancers are the second leading cause of cancer death among men and women.

Background

In 1992, Congress established the NPCR by enacting the Cancer Registries Amendment Act (Public Law 102–515). This law, generally, authorizes the Centers for Disease Control and Prevention to provide funds to states and territories to: improve existing cancer registries; plan and implement registries where they do not exist; develop model legislation and regulations to enhance the viability of registry operations; set data standards for data completeness, timeliness, and quality; provide training for registry personnel; and help establish a computerized reporting and data-processing system.

The Institute of Medicine (IOM) reported in 1999 that some individuals with cancer were not receiving the care known to be the most effective for their cancer diagnoses. Subsequently in 2000, the IOM strongly recommended that information from existing data systems, specifically NPCR, be used to assess the quality of cancer care and variations in adherence to established standards of care in the United States. In addition, the 2000 IOM report also documented the need to assess the quality of data in NPCR funded registries for measuring variations in the delivery of cancer care.

In 2001, CDC responded to the IOM report by funding the Breast, Prostate, and Colon Data Quality and Patterns of Care study (PoC Part 1) involving eight NPCR funded cancer registries. This study was designed to assess the quality of data collected by population-based registries and to determine the proportion of patients diagnosed within a certain time period who received the established, stage-specific standard of care. The eight NPCR funded cancer registries also participated in Phase II of the international CONCORD study, which sought to measure and explain differences in cancer survival between Europe, Canada, and the United States. Additionally, CDC funded three NPCR cancer registries for a second PoC study, Ovarian Cancer Treatment Patterns and Outcomes (PoC Part 3), which was designed to describe the first course of treatment for ovarian cancer and to assess the effects of physician specialty on the quality of staging and treatment data.

Scientific Knowledge To Be Achieved Through This Funding Opportunity

The research to be supported by this RFA will focus on improving the completeness, timeliness, quality, and use of recent first course of treatment and stage data and on describing patterns of care for two priority cancers, female breast cancer and prostate cancer. Additional research on the patterns of care for patients diagnosed with these two cancers, and continued assessment of the quality and completeness of relevant data collected by population-based cancer registries, has the potential to influence adherence to established standards of cancer care. A long term goal of conducting such studies is to further develop the capacity of NPCR funded registries to engage in advanced cancer surveillance activities that will contribute to improving aspects of cancer care.

Experimental Approach and Research Objectives

Using a standardized protocol for data collection by the participating NPCR funded registries, enhanced surveillance and research will be conducted targeting female breast cancer and prostate cancer. The four broad research objectives of this RFA are to:

(1) Determine the proportion of patients who received the recognized standard of care for stages I through III female breast cancer.

(2) Describe the treatment patterns for all stages of prostate cancer.

(3) Determine the tumor, patient, provider, and health system characteristics that are associated with different cancer treatments for female breast and prostate cancers.

(4) Assess the completeness and quality of the stage and first course of treatment data that are collected by cancer registries for female breast and prostate cancers.

These four research objectives will focus on the two most recent diagnosis years available, as determined by the Steering Committee and defined in the study protocol.

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

II. Award Information

1. Mechanism(s) of Support

This funding opportunity will use the CDC (U58) cooperative agreement award mechanism. The award recipient 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 Requirements*, ''Cooperative Agreement Terms and Conditions of Award''.

This funding opportunity uses the just-in-time budget concepts. It 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.*

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

2. Funds Available

The NCCDPHP intends to commit approximately $2 million in FY 2005 to fund up to six new competitive cooperative agreements in response to this RFA. An applicant may request a project period of up to three years and a maximum budget for total costs of $333,000 per year. Approximately $6 million will be available for the entire three years.

The earliest anticipated start date is August 31, 2005, with three performance periods between September 2005 and September 2008.

Although the financial plans of the NCCDPHP provide support for this program, awards pursuant to this funding opportunity are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications. Continuation of awards will be conditioned on 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
- 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 Marianna 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 and populations necessary to conduct the research activities of the RFA.

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

The following criteria will be used to determine an applicant's eligibility:

1.a. NPCR funded cancer registries, or their designated agent, meeting United States Cancer Statistics (USCS) publication criteria for either diagnosis year 2000 or 2001. Publication criteria are demonstrated through case ascertainment of ≥90% with ≤5% of cases being ascertained by death certificate only, ≤5% of cases missing race, ≤3% of cases missing sex and age, and ≥97% of cases passing a set of single-field and inter-field computerized edits. Funding will be contingent on registry data meeting USCS publication criteria for diagnosis year 2002.

1.b. NPCR funded cancer registries that have a minimum of 2,000 female breast cancer cases (stages I through III) and 2,000 prostate cancer cases (all stages) over the two year period, as demonstrated in Appendix E of the 2000 and 2001 publications of USCS.

2. Public or private institutions that can demonstrate an effective and well-defined working relationship between the institution and the NPCR funded cancer registry in that state. Evidence must be provided in the form of a Letter of Support from the NPCR funded registry describing the strong working relationship and assuring access to data for the period of the study.

Investigators may submit only one application under this funding announcement. If your application is incomplete or non-responsive to the special eligibility 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 the submission requirements. Applicants that request a funding amount greater than the award ceiling 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 *PHS 398 Application Form* 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: May 27, 2005.

Application Receipt Date: June 38, 2005.

Peer Review Date: Week of July 25, 2005.

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 deadlines. 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 prospective applicants send a Letter of Intent (LOI). 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 or PA)
- 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 e-mailed by May 27, 2005, to: Office of Extramural Research, NCCDPHP, Centers for Disease Control and Prevention, 4770 Buford Highway, NE., Mailstop K–92, Atlanta, GA 30341. Telephone: 770/488–8390. Fax: 770/488–8046. E-mail: *OER@cdc.gov.*

3.B. Sending an Application

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–CDC–RFA DP–05–071, 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., Centers for Disease Control and Prevention, Office of Extramural Research, NCCDPHP, 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

The general instructions in the PHS 398 should be followed; however, applications must also include the following:

1. A work plan describing activities to meet the project goals and objectives and demonstrating the capability to abstract the required number of cases.
2. A personnel plan describing the team members' roles in carrying out the objectives of the project, including the planned percent of effort for team members.
3. A timeline that adequately demonstrates appropriate distribution of project activities over the three year study period.
4. Letters of support from collaborating partners that provide evidence of an active collaboration and commitment to work as full partners.

This announcement 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 United States 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 RFA will be evaluated for scientific and technical merit by an external peer review group convened by the NCCDPHP in accordance with the review criteria stated below.

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

- Undergo a selection process in which only those applications deemed to have the highest scientific merit, generally the top half of 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 of 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?

Does the work plan describe activities that meet the project goals and objectives and demonstrate the capability to abstract the required number of cases? Does the personnel plan describe the team members' roles in carrying out the objectives of the project? Are the PI's and other team members' percent effort adequate for the conduct of the study? Is a timeline provided that demonstrates appropriate distribution of project activities over the three-year study period? Does the applicant provide evidence of the capacity to engage in advanced cancer surveillance activities that will ultimately contribute to improving aspects of cancer care?

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?

Does the project have the potential to provide insights about patterns of care in diverse racial, ethnic, geographic, socio-economic, and other special populations?

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)?

Does the project team have expertise in cancer surveillance research or provide evidence of recent preparation that would enhance its successful involvement in such a project?

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?

2. A. Additional Review Criteria

Collaboration. Does the applicant provide evidence of an active collaboration and commitment to work as full partners? Do current or past cancer surveillance projects involve successful collaborations between the researchers and the partnering public or private institutions?

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.

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 the application is completed, the Principal Investigator will receive a written critique called a Summary Statement. Those applications under consideration for funding will receive a call or email from the Grants Management Specialist (GMS) of the Procurements and Grants Office (PGO) with 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 officer identified in the application.

Selection of the application for award is not an authorization to begin performance. Any cost incurred before receipt of the NoA is 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 Web site 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 at each research site will have the primary responsibility to lead the efforts of the research team to:

1. Participate effectively within the research collaborative group, composed of investigators from each of the research sites and CDC investigators, to develop the specific research questions to be addressed in the project (Section I Research Objectives, 1–4) and the resulting standard research protocol, including the study design, design of the instruments, development of study methods and procedures, collection, analysis and interpretation of data, and methods for dissemination of results.

2. Assist in the development of a research protocol for the Institutional Review Board (IRB) review by all cooperating institutions participating in the research project. The CDC IRB will review and approve the protocol initially, and on at least an annual basis, until the research project is completed.

3. Collaborate with other study investigators and follow common protocols and manuals of operation developed by the Steering Committee.

4. Obtain an annual, updated local institutional IRB approval.

5. Assure and maintain the confidentiality of all study data.

6. Participate actively in CDC site visits designed to support and enhance research progress and performance.

7. Participate in the analyses of aggregated study data and state-specific data.

8. Develop and produce technical reports or manuscripts for peer-reviewed publications.

9. Serve as a member of the Steering Committee that will provide scientific oversight for the study.

10. Participate in national, regional, and local communication of study development, implementation, and findings to public, professional, and governmental organizations and agencies, through written, oral, and electronic means.

11. Communicate state-specific findings to the public, cancer registry, and medical and cancer control communities through presentations and publications.

Awardees 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 and applicable federal laws and regulations.

2. A.2. NCCDPHP Responsibilities

A NCCDPHP Project Scientist and PoC multidisciplinary team will have substantial programmatic involvement that is above and beyond the normal stewardship role in awards, as described below:

1. Participate in the development of the study by providing scientific consultation and technical assistance in the development of the research questions, study design and protocol, the development of sampling procedures, the design of the instruments, development of study methods and procedures, including collection, analysis, and interpretation of data, resolution of data quality issues, and dissemination of results.

2. Facilitate communication among recipients for the development of a common protocol, quality control, interim data monitoring, data analysis, interpretation of findings, reporting, and coordination of activities, through written, oral, and electronic means.

3. Support the recipients' activities by collaborating and providing ongoing scientific and public health consultation and assistance in the development of activities related to the cooperative agreement, including conducting site visits to recipient institutions.

4. Facilitate movement of the initial research protocol through the CDC Institutional Review Board (IRB), including keeping the CDC IRB abreast of protocol amendments, and facilitating annual reviews.

5. Participate in joint data analyses and interpretation and the presentation and publication of findings.

6. Collaborate in producing technical reports and manuscripts for peer-reviewed publications, as appropriate.

7. Facilitate distribution and dissemination of research findings.

8. Assure and maintain the confidentiality of all study data.

Additionally, an agency program official or the 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 following are areas of joint responsibility between the award recipients and the NCCDPHP project team:

1. Participation in the development of a Steering Committee that will provide scientific oversight for the study. The Steering Committee, the main governing board of the study, will be composed of the Principal Investigator from each research site and a NCCDPHP Project Scientist serving as consultant. The role of chairperson will be rotated among the Principal Investigators of the research sites. The Principal Investigators must have proven evidence of leadership ability and be able to make an adequate time commitment to the cooperative agreement.

The Steering Committee, in collaboration with NCCDPHP project scientists, 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 a common research design, protocols and manuals of operations, facilitating the conduct and monitoring of studies, developing policies relating to access to patient data, and reporting study results. The Steering Committee must approve the protocol, changes to protocols, and manuals of operation. The Principal Investigator of each research site will be responsible for the execution of the protocol and will provide progress reports to the Steering Committee. The Steering Committee will establish guidelines for presentations at scientific meetings and for writing and publishing manuscripts on the findings of the study.

2. Identify ways to collaborate with cancer care providers and others to use

research findings to improve care to patients.

3. Establish agreements for sharing data.

Each full member will have one vote. Grantee members of the Steering Committee will be required to accept and implement policies approved by the Steering Committee.

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.

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, PhD, M.S.P.H., Centers for Disease Control and Prevention, Office of Extramural Research, NCCDPHP, 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, Centers for Disease Control and Prevention, Office of Extramural Research, NCCDPHP, 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

Lucy Picciolo, Procurements and Grants Office, Centers for Disease Control and Prevention, Koger Office Park, Colgate Building, Mailstop E–14, Atlanta, GA 30341–5539. Telephone: 770/488–2683. E-mail: *lip6@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) Web site 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–9 Paperwork Reduction Act Requirements

Under the Paperwork Reduction Act, projects that involve the collection of information from ten 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. 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–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]

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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;