for Injury Prevention and Control, 4770 Buford Highway, NE, Mailstop K–60, Atlanta, GA 30341, Telephone:, (770) 488–4277 (Denise Johnson), (770) 488–4266 (Joyce McCurdy), E-mail addresses: dxj@cdc.gov (Denise Johnson), Jmm6@cdc.gov (Joyce McCurdy).

Dated: April 28, 1999.

John L. Williams,

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

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BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 99117]

Prevention Research Using Genetic Information To Prevent Disease and Improve Health; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC), Office of Genetics and Disease Prevention, in cooperation with the Office of Prevention Research, Office of the Director, announces the availability of fiscal year (FY) 1999 funds for a cooperative agreement program for Prevention Research Using Genetic Information to Prevent Disease and Improve Health.

This program addresses the ''Healthy People 2000'' priority areas of Maternal and Infant Health, Heart Disease and Stroke, Cancer, and Diabetes and Chronic Disabling Conditions.

The purpose of this program is to strengthen science for public health action, collaborate with healthcare partners for prevention, and promote healthy living at every stage of life and is consistent with the implementation of an agency-wide strategic plan for genetics and public health.

The program will provide funding for conducting population-based research to:

1. Assess how risk for disease and disability in well-defined populations is influenced by the interaction of human genetic variation with modifiable risk factors.

2. Ensure that genetic tests and services are incorporated in population-based interventions that promote health and prevent disease and disability.

B. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private nonprofit organizations, State and local governments or their bona fide agents, and federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations.

Note: Pub. L. 104–65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan or any other form.

C. Availability of Funds

Approximately $700,000 is available in FY 1999 to fund two awards. It is expected that the average award will be $350,000 to begin on or about September 30, 1999 for a 12-month budget period within a project period of up to 3 years. Funding estimates may vary and are subject to change.

The maximum funding level for any award for year one will not exceed $400,000 (including both direct and indirect costs). Applications that exceed the funding cap of $400,000 will be excluded from the competition and returned to the applicant. Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

Use of Funds

Cooperative agreement funds will not be made available to support the provision of direct care, facility or capital outlay. Eligible applicants may enter into contracts, including consortia agreements (as set forth in the PHS Grants Policy Statement, dated April 1, 1994), as necessary to meet the requirements of the program and strengthen the overall application.

D. Programmatic Interests

Immediate programmatic interest is focused on research in two categories:

1. Epidemiologic research that assesses the interaction of modifiable risk factors (e.g., diet, chemical exposures, infections, lifestyle) with known genetic disease risk factors in well-defined populations, and demonstrates how this information can help target disease prevention efforts.

2. Prevention effectiveness research that demonstrates in well defined populations the effectiveness and safety of using genetic information to prevent disease, disability and death by identifying persons at risk and carrying out appropriate interventions.

For examples of research questions meeting these general criteria, see Addendum II (included in application kit).

Proposals for research in either category must address at least one of the five following disease groups, which represent some of the leading causes of mortality, morbidity, and disability in the United States, and which have identifiable genetic and environmental risk factors:

1. Cardiovascular disease.
2. Cancer.
3. Arthritis.
4. Diabetes.
5. Pediatric pulmonary disease (asthma, cystic fibrosis).

Proposals addressing genetic traits (e.g., hemochromatosis) that contribute to development of more than one of these diseases (e.g., cancer, diabetes, and arthritis) will also be considered.

Research studies proposed for either category must be community- or population-based, i.e, based on systematic samples of a population or on population-based registries. Proposals should seek to establish or strengthen collaborative efforts among public, private, and academic partners (e.g., state health departments, health maintenance organizations, and schools of public health) that can be sustained for subsequent research and program development. Proposals should also emphasize the potential applications of the research outcomes in guiding disease prevention program activities. An important component of such efforts is a commitment to training in the use of genetic information for public health and for developing community-based capacity for prevention program development.

E. Cooperative Activities

The recipient will be responsible for conducting the activities under 1., below, and CDC will be responsible for conducting activities under 2., below:

1. Recipient Activities

a. Develop a comprehensive protocol and plan for implementing either epidemiologic or prevention effectiveness research.

b. Establish procedures to maintain the rights and confidentiality of all study participants including the identification of applicable laws.

c. Disseminate results of research studies through paper and electronic publications and presentations.

d. Serve as a resource for professional and public information and education in use of genetic information for public health.

e. Develop collaboration among public, private, and academic partners

that can be sustained for subsequent research and program development (e.g., state health departments, health maintenance organizations, schools of public health)

f. Participate in meetings with CDC and other investigators and relevant public health officials.

2. CDC Activities

a. Provide up-to-date scientific information.

b. Provide liaison among grantees and collaborating CDC Centers.

c. Provide technical guidance in the development of study protocols, consent forms, and data collection forms.

d. Coordinate research activities among sites, when appropriate.

e. Convene meetings among collaborators to discuss preliminary findings and improve research outcomes.

F. Application Content

1. A description of all the project staff regardless of their funding source. The description should include title, qualifications, experience, percentage of time each will devote to the project, as well as that portion of the salary to be paid by the cooperative agreement.

2. A table of contents showing the page location of relevant application contents.

3. A detailed budget for year one of the cooperative agreement.

4. Budget projections for subsequent years.

5. A biographical sketch for the Principal Investigator/Program Director and for all key personnel.

6. A description of the involvement of other entities that will relate to the proposed project, if applicable, including public, private, and academic partners. The description should include evidence of support and a clear statement of roles.

7. A description of the performance sites and capabilities.

8. A description of those activities conducted by the applicant related to, but not supported by the cooperative agreement.

9. A plan that justifies the research needs and describes the scientific basis for the research, the expected outcome, and the relevance of the findings to the Purpose of the Announcement.

10. Specific, measurable, and time-framed objectives.

11. A detailed plan describing the methods by which the objectives will be achieved.

12. A comprehensive evaluation plan.

An applicant organization has the option of having specific salary and fringe benefit amounts for individuals omitted from the copies of the application which are made available to outside review groups. To execute this option: on the original and five copies of the application (See Submission and Deadline), the applicant must use asterisks to indicate the individuals for whom salaries and fringe benefits are not shown; the subtotals must still be shown. In addition, the applicant must submit an additional copy of page four of Form PHS–398, completed in full, with the asterisks replaced by the salaries and fringe benefits. This budget page will be reserved for internal staff use only.

G. Submission and Deadline

Submit the original and five copies of PHS–398 (OMB Number 0925–0001) (adhere to the instructions the Errata Instruction sheet for PHS 398). Forms are in the application Kit. On or before June 30, 1999, submit the application to:

Mattie Jackson, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement #99117, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, Georgia 30341–4146.

Deadline: Applications shall be considered as meeting the deadline if they are either:

1. Received at the above address on or before the deadline date; or

2. Sent on or before the deadline date and received in time for submission to review committee. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

Late Applications: Applications which do not meet the criteria in (a) or (b) above are considered late applications, will not be considered, and will be returned to the applicant.

H. Evaluation Criteria

Applications will be subjected to a preliminary evaluation (triage) by the Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: Prevention Research Using Genetic Information to Prevent Disease and Improve Health, Program Announcement #99117, to determine if the application is of sufficient technical and scientific merit to warrant further review. CDC will withdraw from further consideration applications judged to be noncompetitive and promptly notify the principal investigator/program director and the official signing the applicant organization. Those applications judged to be competitive will be further evaluated by a dual review process.

The primary review of all proposals will include:

1. The specific aims of the research project, i.e., the broad long-term objectives and the intended outcome of the specific research proposal in relation to the targeted areas described (see Programmatic Interests.)

2. The background of the proposal, i.e., the basis for the present proposal, the critical evaluation of existing knowledge, and the specific identification of the knowledge gaps in the use of genetic information in public health, which the proposal intends to address.

3. The significance and originality from a scientific or technical standpoint of the specific aims of the proposed research.

4. The adequacy of the proposed research design, approaches, and methodology to carry out the research, including quality assurance procedures, plan for data management, and statistical analysis plan.

5. The extent to which the research findings will lead to identifying and targeting modifiable risk factors that interact with genetic factors in causing disease, or will demonstrate the prevention effectiveness of using genetic information to prevent disease.

6. The extent to which the evaluation plan will allow the measurement of progress toward the achievement of the stated objectives.

7. A principal investigator who has conducted, evaluated, and published genetics research in peer-reviewed journals, and has specific authority and responsibility to carry out the proposed project.

8. Qualifications and demonstrated experience on the applicant's project team in conducting relevant public health genetics studies and the appropriateness of personnel to accomplish the proposed activities.

9. Effective and well-defined working relationships within the performing organization and with other interested, public, private, and academic partners (as evidenced by letters detailing the nature and the extent of the involvement).

10. Adequacy of existing and proposed facilities and resources and the ability to carry out a research project on the use of genetics information in prevention research related to the specified disease groups (see Programmatic Interests).

11. Gender and Minority Issues—The extent of plans to adequately include both sexes and minorities and their subgroups (as appropriate with the

scientific goals of the project), and to ensure the recruitment and retention of human subjects.

12. Human Subjects—The quality of procedures for the protection of human subjects, and plans for documenting all procedures for compliance with applicable published regulations.

The secondary review will be conducted by a panel of Senior Federal Officials based on the ranked proposals to assure maximal impact and balance of proposed research. The factors to be considered will include:

1. The results of the primary review including the proposal's priority score as the primary factor in the selection process.

2. The match between the proposal and the program announcement and programmatic interests.

3. The relevance and balance of proposed research relative to CDC programs and priorities.

4. The significance of the proposed activities in relation to the priorities and objectives stated in ''Health People 2000''.

5. Geographic balance and budgetary considerations.

I. Other Requirements

Technical Reporting Requirements

Provide CDC with an original plus two copies of

1. Annual progress reports,

2. Financial status report, no more that 90 days after the end of the budget period, and

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

Send all reports to the Grants Management Specialist listed in Section K ''Where to Obtain Additional Information'.

The following additional requirements are applicable to this program. For a complete description of each, see Addendum I in the application package.

AR–1—Human Subjects Requirements
AR–2—Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR–3—Public Health System Reporting Requirements
AR–10—Smoke-Free Workplace Requirements
AR–11—Healthy People 2000
AR–12—Lobbying Restrictions

J. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under sections 301 and 317 [42U.S.C.241 and 247b] of the Public Health Service Act, as amended. The catalog of Federal Domestic Assistance number is 93.283.

K. Where To Obtain Additional Information

This and other CDC announcements may be downloaded through the CDC homepage on the Internet at http://www.cdc.gov. Please refer to Program Announcement Number 99117 when requesting information. To receive additional written information and to request an application kit, call 1–888-GRANTS4 (1–888–472–6874). You will be asked to leave your name and address and will be instructed to identify the Announcement number of interest. If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from:

Mattie Jackson, Grant Management Specialist, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, Georgia 30341–4146, Telephone: (770) 488–2718, Internet address: mij3@cdc.gov

For program technical assistance contact: Marta Gwinn, M.D., M.P.H., Office of Genetics and Disease Prevention, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, NE, Mailstop K–28, Atlanta, Georgia 30341–3724, telephone (770) 488–3235, Internet address: mlg1@cdc.gov

Dated: April 28, 1999.

John L. Williams,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Grants for Radiation Studies and Research

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Grants for Radiation Studies and Research, in response to Program Announcement 99020.

Times and Dates: 8 a.m.—9 a.m., May 19, 1999 (Open); 9 a.m.—6 p.m., May 19, 1999 (Closed); 8 a.m.—5 p.m., May 20, 1999 (Closed).

Place: Centers for Disease Control and Prevention, Chamblee Campus, Building 101, (Room 1301B on May 19; Room 3002 on May 20), 4770 Buford Highway, NE, Atlanta, GA.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Pub. L. 92–463.

Matters to be Discussed: The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement 99020.

Contact Person For More Information: C.M. Wood, CDC, NCEH, Chamblee Campus, Building 101, 4770 Buford Highway, NE, Atlanta, GA., phone 770/488–7642.

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 the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: April 28, 1999.

Carolyn J. Russell,

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

[FR Doc. 99–11096 Filed 5–3–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Assessment of Preclinical Reproductive Toxicity Data; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to discuss an approach for the integrative assessment of preclinical reproductive toxicity findings and other information for pharmaceuticals. The purpose of the meeting is to provide information on the agency's approach, using several pharmaceutical data sets, and to invite members of the public to provide comments on the utility of the approach. The agency intends to consider feedback from the meeting in the development of guidance for integrative assessments of pharmaceutical reproductive risk.

DATES: The public meeting will be held on June 24, 1999, from 9 a.m. to 4 p.m.