3. The Second Longitudinal Study of Aging (LSOA II)—(0920–0219)—Revision—National Center for Health Statistics (NCHS) The Second Longitudinal Study of Aging is a second-generation, longitudinal survey of a nationally representative sample of civilian, non-institutionalized persons 70 years of age and older. Participation is voluntary, and individually identified data are confidential. The LSOA II replicates portions of the first Longitudinal Study of Aging (LSOA), particularly the causes and consequences of changes in functional status. In addition, the LSOA II is designed to monitor the impact of changes in Medicare, Medicaid, and managed care on the health status of the elderly and their patterns of health care utilization. Both LSOAs are joint projects of the National Center for Health Statistics (NCHS) and the National Institute on Aging (NIA).

The Supplement on Aging (SOA), part of the 1984 National Health Interview Survey (NHIS), established a baseline on 7,527 persons who were then aged 70 and older. The first LSOA reinterviewed them in 1986, 1988 and 1990. Data from the SOA and LSOA have been widely used for research and policy analysis relevant to the older population.

In 1994, 9,447 persons aged 70 and over were interviewed as part of the National Health Interview Survey's Second Supplement on Aging (SOA II) between October of 1994 and March of 1996. The first LSOA II re-interview wave was conducted between May 1997 and March 1998. The LSOA II will re-interview the SOA II sample two additional times: in 1999 and 2001. As in the first LSOA, these reinterviews will be conducted using computer assisted telephone interviewing (CATI). Beyond that, LSOA II will use methodological and conceptual developments of the past decade.

The LSOA II contains substantive topics on scientifically important and policy-relevant domains, including: (1) Assistance with activities of daily living, (2) chronic conditions and impairments, (3) family structure, relationships, and living arrangements, (4) health opinions and behaviors, (5) use of health, personal care and social services, (6) use of assistive devices and technologies, (7) health insurance, (8) housing and long-term care, (9) social activity, (10) employment history, (11) transportation, and (12) cognition. This new data will result in publication of new national health statistics on the elderly and the release of public use micro data files. The total cost to respondents is estimated at $106,275.

Respondents	Number of respondents	Number of responses/respondent	Avg. burden per response (in hrs.)	Total burden (in hrs.)
Sample adult	9,447	1	.75	7,085
Total				7,085

Dated: July 23, 1998.

Charles W. Gollmar,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–20576 Filed 7–31–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 98100]

Grants for Minority Health Statistics Dissertation Research; Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 98 funds for a dissertation research grants program for the Minority Health Statistics Grants Program of the National Center for Health Statistics (NCHS), CDC. This program addresses the ''Healthy People 2000'' priority area(s), Surveillance and Data Systems. The Minority Health Statistics Grants Program was established to award grants for (1) the conduct of special surveys or studies on the health of racial and ethnic populations or subpopulations; (2) analysis of data on ethnic and racial populations and subpopulations; and (3) research on improving methods for developing statistics on ethnic and racial populations and subpopulations. Grants for Minority Health Statistics Dissertations advance these purposes by supporting research and by improving the quality of minority health statistics dissertation research projects. These grants will enable doctoral students to undertake significant data gathering, analytic, and methodological research projects. The students will also gain invaluable training and research experience that will be beneficial to future careers in minority health research. The use of data from the National Center for Health Statistics is encouraged. More information about NCHS data systems may be obtained via the Internet at http://www.cdc.gov/nchswww/.

B. Eligible Applicants

Eligible applicants may be public or private nonprofit institutions that will administer the grant on behalf of the proposed Principal Investigator (doctoral candidate). Examples of public and private nonprofit organizations include universities, colleges, research institutions, hospitals, and 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.

The proposed Principal Investigator must be a registered doctoral candidate in resident or nonresident status. All requirements for the doctoral degree other than the dissertation must be completed by the time of the award.

Students seeking a doctorate in any relevant research discipline are eligible.

A student enrolled in a doctoral program in a research discipline which requires a dissertation based on original research may apply through their institution for support to complete the research and dissertation. The dissertation must examine and/or develop some aspect of statistical research on racial and ethnic populations or subpopulations. It should focus on one or more of the following research program areas: community-based research, methods and theory development, health promotion and data standards development, and data analysis and dissemination.

Prior to submission of the application, the dissertation proposal must be approved by the dissertation faculty committee and certified by the faculty advisor. This information must be verified in a letter of certification from the thesis chairperson and submitted with the grant application.

Applications from doctoral students who are women, members of minority groups, persons with disability, students of Historically Black Colleges and Universities, Hispanic Serving Institutions, and other predominately minority and minority serving institutions are encouraged.

An applicant institution may be either the degree-granting institution or another non-profit institution with which the proposed Principal Investigator is professionally affiliated. In determining which institution is more appropriate, the Principal Investigator must consider the extent to which the resources of the designated institution are capable of supporting the proposed research effort.

The proposed investigator who receives support for dissertation research under a grant may not at the same time receive support under a predoctoral training grant or fellowship awarded by any other agency, or component, of the U.S. Department of Health and Human Services.

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 $250,000 is available in FY 98 to fund approximately 10 awards. It is expected that the average award will be $20,000 ranging from $15,000 to $30,000. It is expected that the awards will begin on or about September 30, 1998. The awards will be made for a 12-month budget period within a project period of up to 2 years. Funding estimates are subject to change.

Funding support may only be requested for the amount of time necessary to complete the dissertation within the authorized project period.

Use of Funds

Responsibility for the planning, direction, and execution of the proposed project will be solely that of the proposed Principal Investigator (the doctoral candidate).

The total direct costs must not exceed $30,000 for the entire project period. An application that exceeds this amount will be returned to the applicant. No supplemental funds will be awarded.

Allowable costs include: the investigator's salary and direct project expenses such as travel, data processing, and supplies. Fees for maintaining matriculation or other fees imposed on those preparing dissertations are allowable costs, provided the fees are required of all students of similar standing, regardless of the source of funding. Applicants are expected to work full time on the project. Any level of effort that is less than full time must be fully justified.

Indirect costs under this grant program are limited to eight percent of direct costs, excluding tuition and related fees and expenditures for equipment. Indirect costs will be awarded at the actual indirect cost rate for the institution, if the rate is less than eight percent.

D. Program Requirements

The dissertation constitutes the final report of the grant. The dissertation must be officially accepted by the faculty committee or university official responsible for the candidate's dissertation and must be signed by the responsible officials. Three copies of the dissertation shall be submitted to the CDC.

E. Application Content

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. The narrative should be no more than 25 pages, double-spaced, printed on one side, with one inch margins, and unreduced font. Applications will be eligible for support only during the review cycle for which they are submitted. No application can be submitted more than once even in revised form.

Applicants must follow the instructions in the research grant application PHS Form 398 in preparing the application with the following information/changes:

1. The graduate student should be identified as the Principal Investigator.

2. A questionnaire may be included as an appendix if it is essential to evaluate the proposal. A list of literature cited is required and may be included in the appendix. No other material should be provided in an appendix.

3. A letter from the faculty committee or the university official directly responsible for supervising the dissertation research must be submitted with the grant application. The letter must certify that (a) the committee has approved the formal proposal for the dissertation, (b) the grant application represents the dissertation proposal, and (c) the applicant will complete all requirements for the doctoral degree except the dissertation by the anticipated date of the grant award.

4. The application must identify all members of the faculty committee by listing the names on Form BB. A brief biographical sketch for each should be provided as explained in Form 398, page FF.

5. Applicants should give special attention to the sections of the application dealing with human subjects, protection and gender and minority representation by addressing the applicability and method of compliance.

6. The project description in the application must describe the scientific significance of the work, including its relationship to other current research, and the design of the project in sufficient detail to permit evaluation. It should also present and interpret progress to date if the research is already underway.

7. A detailed budget must be provided identifying the items for which funds are requested and their estimated costs. A budget justification explaining the necessity of these expenses for the research should also be included.

8. Statements of ''Current and Pending Support'' for both the student and the dissertation advisor must be identified on Form GG.

F. Submission and Deadline

Letter of Intent (LOI)

The LOI should identify program announcement number 98100, and the name of the principal investigator. The letter of intent does not influence review or funding decisions, but it will enable CDC to plan the review more efficiently. The LOI should be submitted on or before August 17, 1998, to: David Elswick, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 98100, Centers for Disease Control and Prevention (CDC), Room 321, 255 East Paces Ferry Road, NE., M/S E13, Atlanta, Georgia 30305–2209.

Application

Submit the original and five copies of PHS–398 (OMB Number 0925–0001) (adhere to the instructions on the Errata Instruction Sheet for PHS 398). Forms are in the application kit. On or before August 31, 1998, submit the application to: David Elswick, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 98100, Centers for Disease Control and Prevention (CDC), Room 300, 255 East Paces Ferry Road, NE., M/S E13, Atlanta, Georgia 30305–2209.

If your application does not arrive in time for submission to the independent

review group, it will not be considered unless you can provide proof that you mailed it on or before the deadline (i.e., receipt from U.S. Postal Service or a commercial carrier; private metered postmarks are not acceptable).

G. Evaluation Criteria

Proposals are judged on the basis of their scientific merit, the theoretical importance of the research question and the appropriateness of the proposed data and methodology to be used in addressing the question.

Each application will be evaluated individually against the following criteria by an independent review group appointed by CDC.

1. Significance and originality of the research.
2. Knowledge of research relevant to the topic.
3. Appropriateness of methods and data, including a description and justification of the analytic techniques that will be employed and a discussion of the methodological problems that might be encountered.
4. Availability and adequacy of data.
5. Organization of the project.
6. Adequacy of facilities and resources. Human subjects involvement and protection (when appropriate).
7. Representation of women and minorities (when appropriate).
8. Appropriateness of the budget.

In evaluating applications and making recommendations reviewers assess the applicant's potential for making significant contributions to the field of minority health statistics research.

Three factors influence the final funding decisions on applications for support of dissertations: (1) Reviewers' evaluation of the application; (2) the potential of the applicant to contribute to the field; and (3) the general needs of the field.

H. Other Requirements

Technical Reporting Requirements

Provide CDC with original plus two copies of:

1. Annual progress reports;
2. Financial status report, no more than 90 days after the end of the budget period; and
3. Final financial status and performance reports, no more than 90 days after the end of the project period.

Send all reports to David Elswick, Grants Management Specialist, using the address information listed under Section J of this program announcement entitled ''Where to Obtain Additional Information.''

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

AR98–1 Human Subjects Requirements
AR98–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research
AR98–4 HIV/AIDS Confidentiality Provisions
AR98–9 Paperwork Reduction Act Requirements
AR98–10 Smoke-Free Workplace Requirements
AR98–11 Healthy People 2000
AR98–12 Lobbying Restrictions
AR98–13 Prohibition on Use of CDC Funds for Certain Gun Control Activities
AR98–14 Accounting System Requirements
AR98–15 Proof of Non-Profit Status

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 306(m) of the Public Health Service Act (42 U.S.C. 242k(m)), as amended. The Catalog of Federal Domestic Assistance number is 93.283.

J. Where To Obtain Additional Information

To receive additional written information call 1–888-GRANTS4. You will be asked to leave your name, address, and phone number and will need to refer to Announcement 98100. You will receive a complete program description, information on application procedures, and application forms. CDC will not send application kits by facsimile or express mail.

Please refer to announcement number 98100 when requesting information and submitting an application.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained by contacting: David Elswick, Grants Management Specialist, Grants Management Branch, Procurement and Grants Office, Announcement 98100, Centers for Disease Control and Prevention (CDC), Room 300, 255 East Paces Ferry Road, NE., M/S E–13, Atlanta, GA 30305–2209, telephone (404)842–6521.

See also the CDC home page on the Internet: *http://www.cdc.gov*

For program technical assistance, contact: Audrey L. Burwell, M.S., Minority Health Statistics Grants Program Director, National Center for Health Statistics, CDC, 6525 Belcrest Road, Room 1100, Hyattsville, MD 20782, Telephone: (301) 436–7062, extension 127, Email: AZB2@CDC.GOV.

Website: www.cdc.gov/nchswww/about/grants/grants1.htm.

Dated: July 28, 1998.

John L. Williams,

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

[FR Doc. 98–20575 Filed 7–31–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96E–0314]

Determination of Regulatory Review Period for Purposes of Patent Extension; GEMZAR®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for GEMZAR® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6620.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical