

cases, it is possible to conceive situations in which senior or key personnel might not meet the definition of "investigator." Institutions are also responsible for obtaining financial disclosures from persons other than senior or key personnel who meet the definition of "investigator."

Q16: How should institutions with fewer than 50 employees complete the certification page for NSF proposals?

A16: Such institutions should annotate NSF Form 1207 or the addendum page (See Q&A1 above) to indicate that they have fewer than 50 employees and are therefore exempt from the Investigator Financial Disclosure Policy. These institutions are not exempt from the PHS regulations.

Q17: Salary, royalties and other payments that "are not expected to exceed \$10,000 over the next twelve month period" are excluded from the definition of "significant financial interest." How should an investigator estimate expected income over the next twelve months?

A17: The agencies have no preferred estimation method. Investigators must make their best reasonable estimates of expected income in determining whether salary, royalties or other payments constitute "significant financial interests." This issue is separate from an investigator's ongoing duty to update financial disclosures either annually or as new significant financial interests are obtained throughout the period of the award.

Q18: How can an institution determine that all required disclosures have been made before submitting a proposal to NSF or PHS?

A18: As part of the institution's routine proposal preparation procedures institutions should require investigators to ensure that they have made all required financial disclosures in accord with the regulations prior to the time the organizational representative makes the certification in an NSF or PHS proposal. NSF and PHS staff, auditors and others concerned with the proper implementation of these regulations would expect such an arrangement at any institution that certifies to the maintenance of an appropriate written, enforced policy on conflict of interest.

Q19: Must an investigator report to the institution a single share of stock?

A19: A single share of stock would have to be reported only if (i) it is valued at more than \$10,000 or represents more than a five percent ownership interest in the corporation; and (ii) it would reasonably appear that the value of the stock could be affected by the research for which funding is

sought or that the financial interest of the corporation would be so affected.

The rules define a significant financial interest as anything of monetary value including equity interests (e.g., stocks, stock options, or other ownership interests) but the definition excludes an equity interest that does not exceed \$10,000 in value and represents no more than a 5% ownership interest in any single entity. This means that, under the rules, an investigator would never have to report an equity interest of \$10,000 or less which represents 5% or less ownership interest in any single entity because that combination of value and ownership is excluded by definition from the term "significant financial interest." On the other hand, under the rules, an investigator would always have to report an equity interest exceeding \$10,000 or an ownership interest exceeding 5% in any single entity, regardless of value, if that equity interest or ownership interest was held in an entity whose financial interests would reasonably appear to be affected by the specified activities for which funding is sought.

Q20: When and how will the NSF and PHS rules be reviewed and revised?

A20: The agencies anticipate that after two or three years of experience with the rules, they will solicit public comments regarding whether changes are necessary or appropriate.

Dated: June 13, 1996.

Dr. Harold Varmus, M.D.,

Director, National Institutes of Health.

Lawrence Rudolph,

General Counsel, National Science Foundation.

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Centers for Disease Control and Prevention

[INFO-96-18]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer at (404) 639-7090.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques for other forms of information technology. Send comments to Wilma Johnson, CDC Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Projects

1. Survey of State-Based Diabetes Control Cooperative Agreement Programs—New—Diabetes mellitus and related complications are the seventh leading cause of death in the United States, and accounts for \$105 billion in direct medical costs and lost productivity each year. Approximately 14 million Americans have been diagnosed with diabetes, a leading cause of new blindness and end-stage renal failure in the United States and a major co-morbid factor in lower extremity amputation, cardiovascular disease and related death, and neonatal morbidity and mortality.

Through the support of the Centers for Disease Control and Prevention's (CDC) "State-Based Program to Reduce the Burden of Diabetes: A Health Systems Approach," public health departments in 42 states and four U.S. territorial affiliated jurisdictions have been charged with providing leadership in reducing the gap between what should be and what is the current standard of diabetes care.

CDC will collect information from diabetes State Program Coordinators regarding the four key areas of program implementation. They are (1) capacity building and infrastructure development, (2) surveillance and data collection, (3) health systems change, and (4) working with local programs.

The survey has three main objectives:

1. Document the progress made by Diabetes Control Programs in the four main areas of program implementation.
2. Assess the relationship between the level of infrastructure development, and a program's efforts to carry out surveillance activities, health systems change activities, and work with local programs. Information will help improve technical assistance (TA) and guidance offered to states by CDC.

3. Lay the groundwork for an evaluation instrument that can be used to collect data from Diabetes Control Programs at the end of the funding cycle in order to assess whether progress in program implementation and development is linked to reduced diabetes morbidity and mortality.

The data will result from self-administered mailed surveys sent to the Program Coordinator in each state. Most questions will be in the form of checklists although each of the four sections contain a number of open-ended questions for explanation of unique features of programs. It is

expected that the burden in time to each respondent will be about two (2) hours per Program Coordinator or Designee, resulting in a total burden of 92 hours. Results will also be made available to participants upon request. The total cost to respondents is estimated at \$1,840.

Respondents	No. of Respondents	No. of responses/respondent	Avg. burden response (in hrs.)	Total burden (in hrs.)
Diabetes program coordinators	46	1	2	92
Total				92

2. List of Ingredients Added to Tobacco in the Manufacture of Cigarette Products—(0920–0210)—Extension without change - Cigarette smoking is the leading preventable cause of premature death and disability in our nation. Each year more than 400,000 premature deaths occur as the result of cigarette smoking related diseases. The Centers for Disease Control and Prevention (CDC), Office on Smoking and Health has primary responsibility for the Department of Health and

Human Services' (HHS) smoking and health program. HHS's overall goal is to reduce death and disability resulting from cigarette smoking and other forms of tobacco use through programs of information, education and research.

The Comprehensive Smoking Education Act of 1984 (15 USC 1336 Pub.L. 98–474) requires each person who manufactures, packages, or imports cigarettes to provide the Secretary of HHS with a list of ingredients added to tobacco in the manufacture of cigarettes.

This legislation also authorizes HHS to undertake research, and to report to the Congress (as deemed appropriate), on the health effects of the ingredients.

In 1993, OMB reinstated approval for collection of ingredients information (0920–0210) after the expiration of the previous approval; this current approval expires on December 31, 1996. The total cost to the respondent is estimated at \$189,000.

Respondents	No. of respondents	No. of responses/respondent	Average burden/response (in hrs.)	Total burden (in hrs.)
Tobacco manufacturers	14	1	190	2,660

3. The Fourth National Health and Nutrition Examination Survey (NHANES IV) Pretests—New—The National Health and Nutrition Examination Survey (NHANES) has been conducted periodically since 1970 by the National Center for Health Statistics, CDC. NHANES IV is planned for 1998–2004 and two pretests are proposed to include 400 sample persons in each. They will receive an interview and a physical examination. The first pretest is needed to test the sampling process, data collection procedures, computer-assisted personal interviews (including translations into Spanish), examination protocols, and automated computer systems. The second pretest will test the revised survey questionnaires and examination procedures, quality control procedures and response rates. Participation in the

pretests and the full survey will be completely voluntary and confidential.

NHANES programs produce descriptive statistics which measure the health and nutrition status of the general population. Through the use of questionnaires, physical examinations, and laboratory tests, NHANES studies the relationship between diet, nutrition and health in a representative sample of the United States. NHANES monitors the prevalence of chronic conditions and risk factors related to health such as coronary heart disease, arthritis, osteoporosis, pulmonary and infectious diseases, diabetes, high blood pressure, high cholesterol, obesity, smoking, drug and alcohol use, environmental exposures, and diet. NHANES data are used to establish the norms for the general population against which health care providers can compare such patient characteristics as height, weight, and nutrient levels in the blood. Data from

future NHANES can be compared to those from previous NHANES to monitor changes in the health of the U.S. population. NHANES IV will also establish a national probability sample of genetic material for future genetic testing for susceptibility to disease.

Users of NHANES data include Congress; the World Health Organization; Federal agencies such as NIH, EPA, and USDA; private groups such as the American Heart Association; schools of public health; private businesses; individual practitioners; and administrators. NHANES data are used to establish, monitor, and evaluate recommended dietary allowances, food fortification policies, programs to limit environmental exposures, immunization guidelines and health education and disease prevention programs. The total cost to respondents for the two pretests is estimated at \$54,600.

Respondents	Number of respondents	Number of responses/respondent	Avg. burden/response (in hrs.)	Total burden (in hrs.)
Children	80	1	2.75	220

Respondents	Number of respondents	Number of responses/respondent	Avg. burden/response (in hrs.)	Total burden (in hrs.)
Adolescents and Adults	720	1	4.75	3420
Total				3640

4. The Second Longitudinal Study of Aging (LSOA II)—(0920-0219)—Revision—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. It will replicate portions of the first Longitudinal Study of Aging (LSOA), particularly the causes and consequences of changes in functional status. LSOA II is also 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.

Approximately 10,000 persons aged 70 and over were interviewed for the 1994 National Health Interview Survey's second Supplement on Aging (SOA II) between October of 1994 and March of 1996. LSOA II will reinterview the SOA II sample three times: in 1997, 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.

LSOA II will contain modules 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 the respondents is estimated at \$112,500.

Respondents	Number of respondents	Number of responses/respondent	Avg. burden/response (in hrs.)	Total burden (in hrs.)
Sample adult	10,000	1	.75	7,500
Total				7,500

Dated: June 27, 1996.

Wilma G. Johnson,

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

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[Announcement 658]

State Grants to Support the Evaluation of 5 A Day Nutrition Programs and Physical Activity Programs

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1996 funds for grants to support the evaluation of State and community nutrition and physical activity intervention programs.

This announcement addresses one required component and one optional component:

I. "5 A Day Evaluation" for supporting the evaluation of 5 A Day for Better Health nutrition intervention programs. Applicants must apply for the 5 A Day Evaluation component.

II. "Physical Activity Evaluation" for supporting the evaluation of a physical activity intervention. Application for the Physical Activity Evaluation component is optional.

The CDC is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000" a national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related specifically to the priority area of Nutrition with a secondary emphasis on Physical Activity and Fitness. (For ordering a copy of "Healthy People 2000" see the Section, "Where to Obtain Additional Information.")

Authority

This program is authorized under section 317(k)(2) [42 U.S.C. 247b(k)(2)]

of the Public Health Service Act, as amended.

Smoke-Free Workplace

CDC encourages all grant recipients to provide a smoke-free workplace and promote the nonuse of all tobacco products, and 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, and early childhood development services are provided to children.

Eligible Applicants

Eligible applicants are the official public health agencies of States or their bona fide agents. This includes the District of Columbia, American Samoa, the Commonwealth of Puerto Rico, the Virgin Islands, the Federated States of Micronesia, Guam, the Northern Mariana Islands, the Republic of the Marshall Islands, the Republic of Palau, and federally recognized Indian tribal governments, that have established,