

information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*#1 Type of Information Collection Request: Revision of a Currently Approved Collection;*

*Title of Information Collection: OCR Pre-grant Data Request Package;*

*Form/OMB No.: OS-0990-0243;*

*Use: Recipients of HHS funds must review their policies/practices and submit documents to demonstrate compliance with the Civil Rights Requirements of Title VI of the Civil Rights Act of 1964, Section 504 of the Rehab Act of 1973 and the Age Discrimination Act 1975.*

*Frequency: Recordkeeping, Single time;*

*Affected Public: State, local, or tribal governments, business or other for profit;*

*Annual Number of Respondents: 4,000;*

*Total Annual Responses: 4,000;*

*Average Burden Per Response: 16 hours;*

*Total Annual Hours: 64,000;*

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access the HHS Web site address at <http://www.hhs.gov/oirm/infocollect/pending/> or e-mail your request, including your address, phone number, OMB number, and OS document identifier, to [naomi.cook@hhs.gov](mailto:naomi.cook@hhs.gov), or call the Reports Clearance Office on (202) 690-6162. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the OS Paperwork Clearance Officer designated at the following address: Department of Health and Human Services, Office of the Secretary, Assistant Secretary for Budget, Technology, and Finance, Office of Information and Resource Management, Attention: Naomi Cook (0990-0243), Room 531-H, 200 Independence Avenue, SW., Washington DC 20201.

**Robert E. Polson,**

*Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[60Day-04-24]

#### 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 on (404)498-1210.

*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 or other forms of information technology. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-E11, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

*Proposed Project: Evaluation of a Family History Tool for Health Promotion and Disease Prevention—New—Office of Genomics and Disease Prevention (OGDP), Centers for Disease Control and Prevention (CDC).*

#### Background

Although family history is a risk factor for most chronic diseases of public health significance, it is underutilized in the practice of preventive medicine and public health for assessing disease risk and influencing early detection and prevention strategies. It has been known for years that people that have close relatives with certain diseases like, heart disease, diabetes, and cancers, are more likely to develop those diseases themselves. Geneticists have long recognized the value of family history for discovering inherited disorders, usually the result of single gene

mutations. Although single gene disorders are typically associated with a large magnitude of risk, they account for a small proportion of individuals with a genetic risk for common, chronic diseases. Most of the genetic susceptibility to these disorders is the result of multiple genes interacting with multiple environmental factors. Family history is more than genetics; it reflects the consequences of inherited genetic susceptibilities, shared environment, shared cultures and common behaviors. All of these factors are important when estimating disease risk. In early 2002, the CDC Office of Genomics and Disease Prevention (OGDP) in collaboration with several CDC programs and NIH institutes began an initiative to develop a family history tool for identifying apparently healthy people who may be at increased risk for a number of common diseases. The major activities of this initiative have included: (1) Reviews of the literature for approximately 25 diseases; (2) assessments of family history tools currently in use or under development; (3) a meeting of experts to provide input into the process; (4) development of criteria for determining which diseases to include in the tool; (5) development of a framework for evaluating a family history tool and the development of a tool.

As a result of this initiative, a PC-based familial risk assessment tool was developed to be used as a public health strategy to improve health and prevent disease. The assessment tool is called, "Family Healthware." This tool will be used to collect information about the disease history of a person's first- and second-degree relatives (mother, father, children, siblings, grandparents, aunts, and uncles), use family history information to assess risk for common diseases of adulthood, and influence early detection and prevention strategies. The current version of the tool focuses on six diseases—heart disease, stroke, diabetes, and colorectal, breast, and ovarian cancer.

The proposed project is a study to evaluate the clinical utility of the "Family Healthware" tool by determining whether family history risk assessment, stratification, and personalized prevention messages have any impact on health behaviors, and use of medical services. In 2003, CDC awarded funding to three research centers to collaborate on a study set in primary care clinics to assess the clinical utility of the family history tool. The primary care clinics will be randomized into two groups. In group 1, patients attending the primary care clinics will be asked to complete the

family history tool and a questionnaire that includes an assessment of risk factors, preventive behaviors, use of medical services, and perception of risk. The patients will be provided with an assessment of their familial risk (average, above average, much above average) for each of the six diseases and information about preventive measures (e.g., diet, exercise, screening tests) that is tailored to their level of familial risk for each of the six diseases. After 6 months, the patients will be asked to complete a questionnaire that assess

their risk factors, use of medical services, interest in modifying health behaviors, and changes in risk perception. In group 2, patients will complete the questionnaire only (not the family history tool) and will be given standard public health messages about preventing the six diseases of interest (messages will not be tailored to risk level). After 6 months, the patients in group 2 will also complete the same post intervention questionnaire and will also complete the family history tool.

The purpose of having patients in group 2 complete the family history tool post intervention is so that the analysis can be stratified by familial risk level in both patient groups. The hypothesis to be tested in this study is that patients who are provided with personalized prevention messages based on an assessment of their family history of disease will be more motivated to make behavior changes and use preventive health services. There is no cost to respondents participating in this study.

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Group 1—healthy persons between the ages of 35 and 65 .....	3,750	12	45/60	5,625
Group 2—healthy persons between the ages of 35 and 65 .....	3,750	12	45/60	5,625
<b>Total</b> .....				<b>11,250</b>

<sup>1</sup> Pre-test and post-test.

Dated: January 26, 2004.

**Alvin Hall,**

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

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[60Day-04-25]

**Proposed Data Collections Submitted for Public Comment and Recommendations**

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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 or other forms of information technology. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-E11, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

*Proposed Project:* The National Centers for Autism and Developmental Disabilities Research and Epidemiology (CADDRE) Study—New—National Center for Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

The Children's Health Act of 2000 mandated CDC to establish autism surveillance and research programs to address the number, incidence, correlates, and causes of autism and related disabilities. Under the provisions of this act, CDC funded 5 CADDRE centers including the California Department of Health and Human Services, Colorado Department of Public Health and Environment, John Hopkins University, the University of

Pennsylvania, and the University of North Carolina at Chapel Hill. CDC National Center for Birth Defect and Developmental Disabilities will participate as the 6th site. The multi-site, collaborative study will be an epidemiological investigation of possible causes for the autism spectrum disorders.

Data collection methods will consist of the following: (1) Medical and educational record review of the child participant; (2) medical record review of the biological mother of the child participant; (3) a packet sent to the participants with self-administered questionnaires and a buccal swab kit; (4) a telephone interview focusing on pregnancy-related events and early life history (biological mother and/or primary caregiver interview); (5) a child development interview (for case participants only) administered over the telephone or in-person; (6) a developmental and physical exam of the child participant; (7) biological sampling of the child participant (blood and hair); and, (8) biological sampling of the biological parents of the child participant (blood only). OMB clearance is requested for the self administered questionnaires and buccal swab kit, the primary caregiver interview, and the child development interview. There is no cost to respondents.