

**NATIONAL DIABETES EDUCATION PROGRAM
SURVEY OF THE PUBLIC**

**REQUEST FOR OMB REVIEW
AND SUPPORTING STATEMENT**

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LIST OF ATTACHMENTS

- Attachment A Survey of the Public's Knowledge, Attitudes and Practices
 Questionnaire**
- Attachment B Evaluation Work Group**
- Attachment C 2006 Work Group Report**

JUSTIFICATION

A.1. Circumstances Making the Collection of Information Necessary

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), requests that the Office of Management and Budget (OMB) approve, under the *Paperwork Reduction Act of 1995*, clearance for NIDDK to conduct a survey of the public to support program planning activities of the National Diabetes Education Program (NDEP).

The National Diabetes Research and Education Act, Public Law 93-354, amended the Public Health Service Act to provide greater and more effective efforts in research and public education with regard to diabetes. Current authorization for NIDDK's research and information dissemination activities is contained in 42 USC 285c. The Act authorizes the establishment of the Diabetes Mellitus Interagency Coordinating Committee to coordinate the activities of National Institutes of Health (NIH) and other agencies related to diabetes and its complications. The Diabetes Mellitus Interagency Coordinating Committee launched the National Diabetes Education Program (NDEP) in 1997, in response to scientific evidence that improved management of diabetes can significantly reduce morbidity and mortality related to the disease.

NDEP is a partnership of the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) and more than 200 public and private

organizations. Its long-term goals are to improve the treatment and health outcomes of people with diabetes, to promote early diagnosis, and, ultimately, to prevent the onset of diabetes. The program audiences include the public, people at risk for diabetes, people with diabetes and their families, with special emphasis on racial/ethnic populations; health care providers; payers and purchasers of health care and health care system policy makers. The NDEP objectives are:

- to increase awareness of the seriousness of diabetes, its risk factors, and strategies for preventing diabetes and its complications among at risk groups;
- to improve understanding about diabetes and its control and to promote better self-management behaviors among people with diabetes;
- to improve health care providers' understanding of diabetes and its control and to promote an integrated approach to care;
- to promote health care policies that improve the quality of and access to diabetes care; and
- to reduce disparities in health and racial and ethnic populations disproportionately affected by diabetes.

An integral part of the NDEP strategic plan is evaluation. The evaluation documents the extent to which the NDEP program has been implemented and how successful it has been in meeting the program objectives.

In March 2006, NDEP launched a national probability telephone survey (OMB No. 0925-0552) on the public's knowledge, attitudes and practices related to diabetes. This survey is being repeated in 2008. The surveys are designed to collect information on key target audiences of NDEP – people with diabetes and their families, people with pre-diabetes, people at risk for developing diabetes and the public. To improve estimates of minorities, a stratified sample design was used that oversamples African American and Hispanic households. These surveys are funded by the NIH One Percent Evaluation Set-Aside Program administered by the Office of Evaluation, Office of Portfolio Analysis and Strategic Initiatives (OPASI) within the Office of the Director (OD).

The Department of Health and Human Services (DHHS) is authorized, under the Public Health Service (PHS) Act, to allocate up to one percent of appropriations for PHS programs for the evaluation of their effectiveness. In addition to assessing the effectiveness of federal health programs, the purpose of the One Percent Evaluation Set-Aside is to identify ways to improve their implementation and effectiveness. The One Percent Evaluation Set-Aside provides a critical funding mechanism by which NIH and other public health service agencies can evaluate program performance.

Approval is requested for an extension to the data collection currently approved by OMB (OMB No. 0925-0552/ Exp.11/30.2008). Procedures for this data collection are described in Section B. The survey questionnaire is included in Attachment A. The total number of burden hours will not exceed 575.

A.2. Purpose and Use of the Information

The purpose of this clearance request is to further collect data that support the program planning activities of the National Diabetes Education Program. The lead agency for implementation and evaluation of NDEP is the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). As noted earlier, the NIDDK is specifically mandated to “conduct and support research, training, health information dissemination, and other programs with respect to diabetes” To that end, the National Diabetes Education Program conducts diabetes awareness and education activities, develops and disseminates education tools and resources, and promotes initiatives to improve the quality of and access to diabetes care.

Designated as an integral part of the National Diabetes Education Program’s strategic plan, an evaluation plan has been outlined by the NDEP evaluation work group and consultants. It is a comprehensive strategy for process and impact evaluation. The process evaluation monitors program implementation, demonstrates progress toward achievement of objectives, and identifies areas in need of mid-course correction or

continuation. Some elements of the process evaluation are accomplished by the following:

- Television, radio and print public service advertising placements are tracked and the reach and frequency of TV messages, for example, are reported as the number of plays (frequency) and estimated number of listeners (reach).
- Results of press releases are tracked by a clipping service and the number of news stories and the number of publications that pick up the story and their circulation (reach) are reported.
- Publications ordered from the National Diabetes Information Clearinghouse and public inquiries to CDCs Division of Diabetes Translation are tracked as well as web statistics.

The NDEP evaluation plan relies primarily on secondary data from a variety of national sources such as National Health and Nutrition Examination Survey (NHANES OMB No. 0920-0237/ Exp. 3/31/2007), the National Health Interview Survey (NHIS OMB No. 0920-0214/ Exp. 12/31/2007), the Behavioral Risk Factor Surveillance System (BRFSS). Also, data will be drawn from sources such as the American Diabetes Association Physician Study, the National Committee for Quality Assurance's Diabetes Physician Recognition Program and HEDIS® measures, and relevant professional associations. However, the NDEP evaluation work group determined that there is additional information needed for future program planning and outreach efforts for which there appear to be no existing data source.

The data collected in this study will supplement available secondary data to inform a progress report on NDEP and help shape NDEP's future initiatives.

A.3. Use of Information Technology and Burden Reduction

The survey will be conducted using Computer Assisted Telephone Interview, or CATI. This technology has several advantages over the traditional pen and paper method. First, data are available sooner because data entry and most manual editing and data cleaning steps are eliminated. Data cleaning is more efficient because potential interviewer errors,

such as missed questions or inappropriate skips, are practically eliminated. Also, any discrepancies between responses may be automatically identified for probing during the course of the interview. The overall result is a lower response burden for participants.

A.4. Efforts to Identify Duplication and Use of Similar Information

After conducting a thorough assessment of available data sources, the evaluation work group determined that primary data need to be collected to effectively assess outreach efforts of the National Diabetes Education Program. As the program evolves, the work group will continue to review existing literature and databases and work with outside consultants to search for compatible secondary data sources. The evaluation currently relies on a variety of data sources including the National Health and Nutrition Examination Survey (NHANES OMB No. 0920-0237), the National Health Interview Survey (NHIS OMB No. 0920-0214), the Behavioral Risk Factor Surveillance System (BRFSS), and American HealthStyles Survey. Also, wherever appropriate, the NIDDK work with survey designers to “piggy-back” questions onto other national surveys. For example, when the National Center for Health Statistics invited agencies to submit research proposals for questionnaire material, laboratory assessments, and examination components to the NHANES survey for 2005-2006, NIDDK responded with their intent to continue to fund the NHANES questionnaire administered to persons with diabetes, which queries individuals about diagnosis of diabetes, age of diagnosis, glyceemic treatment, and diagnosis of retinopathy.

A.5. Impact on Small Businesses or Other Small Entities

This data collection effort is not expected to have any impact on small businesses or other small entities.

A.6. Consequences of Collecting the Information Less Frequently

Respondents will only be contacted once.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances relating to the guidelines of 5 CFR 1320.5 and the project fully complies.

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

A 60- Day Federal Register Notice was published on September 8, 2008 on pages 52052-52053. There were no public comments.

NDEP Evaluation Work Group members are listed in Attachment B..

A.9. Explanation of Any Payment or Gift to Respondents

There are no payments to respondents anticipated.

A.10. Assurance of Confidentiality Provided to Respondents

This study provides assurance of confidentiality to respondents, as required by the Privacy Act of 1974 (P.L. 93-579), section 301 (g) of the Public Health Service Act, as amended, and P.L. 93-218, as amended. Prior to any data collection, individuals will be advised of the following: the nature of the activity; the purpose and use of the data collection, NIDDK sponsorship, and the fact that participation is voluntary at all times. Since responses are voluntary, respondents will be assured that there will be no penalties if they decide not to respond, either to the information collection as a whole or to any particular questions.

As a further guarantee of confidentiality, all presentation of data in reports will be in aggregate form, with no links to individuals being preserved. Reports will only be used by project staff for research purposes and for development of specific communication messages and educational materials.

A.11. Justification for Sensitive Questions

To reach NDEP target audiences, questions regarding race/ethnicity, income and /or health status are necessary. Individual respondents will be informed that this information is important to discovering whether NDEP is reaching the people for whom the educational messages are intended. Information will be collected directly from respondents, who will be assured that this information is voluntary and will be treated as confidential to the extent provided by law. Questions on race/ethnicity are in compliance with OMB Directive No. 15.

Some surveys may include questions regarding how one perceives his/her own risk for diabetes and its complications. This information is needed to gain a better understanding of the target audience so that messages, strategies and materials designed will be appropriate and sensitive. Questions of this nature require sensitivity in how they are worded and approached. As noted in section A.10., participants have already been informed upfront about the nature of their participation.

Raw data from data collections that include sensitive information are not retained once the data has been extracted and aggregated; nor does the information become part of record containing permanent identifiers that can be used for retrieval.

A.12. Estimates of Hour Burden Including Annualized Hourly Costs

A.12 - 1 ESTIMATES OF HOUR BURDEN				
Type of Respondents	Number of Respondents	Frequency of Response	Average Time per Response	Total Hour Burden
Screening interview with ineligible persons	1659	1	.03	50
Eligible respondents	2100	1	.25	525
Totals	3759			575

A.12 - 2 COST TO RESPONDENTS				
Type of Respondents	Number of Respondents	Frequency of Response	Hourly Wage Rate	Respondent Cost
Public including patients and their family members	2100	1	\$20.00	\$10,500
Total				\$10,500.00

A.13. Estimate of Other Total Annual Cost Burden to Respondents or Recordkeepers

There will be no capital, operating, or maintenance costs to the respondents.

A.14. Annualized Cost to the Federal Government

The approximate annual cost to the government for this study is \$250,000. This cost is based on costs for research design, pretesting, development of the Office of Management and Budget clearance package, programming for data collection, data analyses and reporting and presenting the findings to the NDEP Steering Committee and Operations Committee annually.

This survey is funded by the 1-percent evaluation set-aside legislative authority, which is provided for in Section 241 of the Public Health Service (PHS) Act.

A.15. Explanation for Program Changes or Adjustments

This is an extension to a data collection currently approved by OMB. The survey is increasing the eligibility of participants to 35 years and older. In order to compare the results from the previous survey of adults ages 45 and older, it is necessary to increase the sample size to have adequate numbers of adults ages 45 and older.

A.16. Plans for Tabulation and Publication and Project Time Schedule

This survey will be conducted by Social & Scientific Systems (SSS), NIDDK’s contractor supporting the evaluation activities of the National Diabetes Education Program. SSS will be responsible for working with the NDEP Evaluation Work Group and data collection, analysis and report writing.

A.16 -1 Survey Time Schedule	
Activity	Time Schedule
Questionnaire and sampling plan development and approval	OMB approval
Begin CATI interviews	1-2 months after OMB approval
Completed field work	5-7 months after OMB approval
Analyses	7-9 months after OMB approval
Report on survey results and presentation together with other Impact measures of the NDEP to the Executive and Steering Committee	12 months after OMB approval

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

No exemption is requested. The OMB control number and expiration date will be displayed in the upper right hand corner of all data collection instruments.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

This data collection has been designed in accordance with the requirements specified in Item 19 of the OMB 83-I. No exceptions to certification are required.