SUPPORTING STATEMENT A

FOR PAPERWORK REDUCTION ACT SUBMISSIONS

FOR

COMMUNITY EVALUATION OF

THE NATIONAL DIABETES EDUCATION PROGRAM'S

DIABETES HEALTHSENSE WEBSITE

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National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

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SUPPORTING STATEMENT

A. 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) review and approve a new data collection effort. This collection is for NIDDK to evaluate the process and outcomes of community use of Diabetes HealthSense, a website compendium of resources that has been developed as part of the NIDDK/NIH's 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. NDEP's goal is to reduce the burden of diabetes and prediabetes in the United States, and its territories, by facilitating the adoption of proven strategies to prevent or delay the onset of diabetes and its complications. NDEP audiences include the public, people at risk for diabetes,

people with diabetes and their families, with special emphasis on racial/ethnic populations; health care professionals, community health workers, community and health care focused organizations; and payers and purchasers of health care. The NDEP objectives are:

(1) Increase awareness and knowledge of the seriousness of diabetes, its risk factors, and effective strategies for preventing type 2 diabetes and complications associated with diabetes

(2) Increase the number of people who live well with diabetes and effectively manage their disease to prevent or delay complications and improve quality of life

(3) Decrease the number of Americans with undiagnosed diabetes

(4) Among people at risk for type 2 diabetes, increase the number who make and sustain effective lifestyle changes to prevent diabetes

(5) Facilitate efforts to improve diabetes-related health care and education, as well as systems for delivering care

(6) Reduce health disparities in populations disproportionately burdened by diabetes

(7) Facilitate the incorporation of evidence-based research findings into health care practices

According to the Centers for Disease Control and Prevention (CDC), diabetes affects nearly 26 million people in the United States – more than eight percent of the population.[1] Further, an additional 79 million American adults have prediabetes, a condition in which blood glucose (blood sugar) levels are higher than normal but not to the level indicating diabetes. Complications of diabetes include heart disease, stroke, hypertension, kidney failure, nervous system disease, lower-limb amputations, and blindness. It is the 7th leading cause of death in the

US. Many others can be considered at-risk for diabetes because of modifiable risk factors such as obesity, physical inactivity, smoking, and high blood pressure.

Diabetes can be managed and type 2 diabetes can be prevented or delayed in part by making lifestyle changes, such as improving diet, exercising, losing excess weight, and managing blood glucose levels.[2] However, many people with diabetes report low adherence to recommendations for diet, exercise, medication taking, and glucose testing.[3] Diabetes self-management is critical to positive outcomes, and self-management efforts need to be supported by ongoing education.[4]

NDEP's Diabetes HealthSense resource can be a first step to help people at risk of and people with diabetes (PAR/PWD) make important lifestyle changes.[5] Diabetes HealthSense is a searchable web-based compendium of psychosocial and behavioral resources that support people with diabetes, people at risk for the disease, and those who care for them. It offers research articles for health care professionals interested in finding out more about the science of behavior change and associated psychosocial issues.

The resource was originally launched in 2008 as the Support for Behavior Change Resource, which focused on providing information to raise awareness of how to make and sustain changes. NDEP developed Diabetes HealthSense as the program moved from raising awareness about diabetes to helping people address the "how to" challenges associated with making and sustaining lifestyle changes. Usability testing on the initial tool was conducted in 2010, and an expanded and upgraded version was released as Diabetes HealthSense in 2011.The new version, which also includes a series of behavior change videos, can be found here: http://ndep.nih.gov/resources/diabetes-healthsense/index.aspx.

Research on health information-seeking by people with diabetes suggests that many are passive recipients of information. That is, they are not actively seeking information themselves but they might be exposed by a story in the news or by picking up a brochure in their physician's office.[4,6] Those who more actively seek information report finding information that was either too general for their needs or that conflicted with other information. Many identified their healthcare professionals as one of their most important information sources and indicated they relied on their providers to help them understand information about diabetes and its management.[4,6]

However, many health professionals report limited training, knowledge, and confidence to help patients manage diabetes.[7,8] Only half of the providers surveyed in one study reported receiving postgraduate training on dietary management of diabetes and fewer than one-third reported receiving training related to diabetes self-management support and education for patients with diabetes, effective communication and motivation strategies to support behavior change, or managing the psychological aspects of diabetes.[8] Further, more than half of those surveyed reported that they would be interested in attending training programs to help them learn more about how to help people with diabetes.

Because people with diabetes rely on health professionals and allied professionals to help them understand information about diabetes, this study will use community educators to provide information about Diabetes HealthSense to study participants. To ensure educators' knowledge, confidence, and skills related to teaching PAR/PWD about Diabetes HealthSense, they will participate in a Diabetes HealthSense educator training session, and they will be provided with a supplementary PowerPoint presentation with embedded video and accompanying talking points to help them assist PAR/PWD gain optimal value from the website.

The primary objectives of this evaluation include: 1) Assessing educators' experience and satisfaction with the Diabetes HealthSense website; 2) Assessing the extent to which, through participation in the Diabetes HealthSense educator training session, educators can increase their knowledge, confidence, and ability to promote and use NDEP resources; and, 3) Assessing the extent to which the website with guided exploration can help people at risk of diabetes and people with diabetes prevent or manage diabetes.

The evaluation of the Diabetes HealthSense website is needed to understand whether this resource has a positive effect on educators and participants and to inform NDEP's future decisions about the website, including whether to make changes to it and whether to invest additional resources to support, promote, or expand the site. Additionally, evaluation of this resource will help NDEP test if this type of tool and approach of providing access to aggregated resources should be expanded and serve as a model for other NDEP initiatives.

A.2. <u>Purpose and Use of the Information</u>

The data collected from this evaluation will provide NDEP with information about 1) how NDEP partners (community educators) use an NDEP-created resource in their communities; 2) how participation in the Diabetes HealthSense educator training session and use of NDEP resources has an impact on educators' knowledge, self-efficacy, and ability to promote and implement NDEP resources with PAR/PWD and other educators; and, 3) how the Diabetes HealthSense resource has an impact on knowledge, self-efficacy, and behaviors of PAR/PWD. Such data will help inform NDEP's future decisions about the Diabetes HealthSense website, including whether to make changes to the website and whether to invest additional resources to

support, promote, or expand the resource. There is no current data collection related to Diabetes HealthSense.

NDEP proposes to conduct an evaluation using 15 community sites. Sites will be recruited to participate in the study and will be randomly assigned to serve as either intervention (n=5) or comparison (n=10) sites. NDEP partners (community educators) at each intervention site will be asked to participate in two interviews, one at the beginning of the project (Educator Pretest Interview) and one at the end (Educator Posttest Interview). In addition, the community educator at each site will receive the Diabetes HealthSense educator training session and then implement two Diabetes HealthSense Educational Programs to provide a guided exploration of the resource to 10 groups of approximately 15 to 20 participants each. Participants will be selected to participate if they have been told by a physician or health care provider that they have diabetes or prediabetes or if they are at risk for diabetes based on their Diabetes Risk Test score; and if they are age 35 or older; able to communicate in English; and use and have access to the Internet. Sites will implement all programs in English. Educators will be asked to complete recruitment guides during the participant recruitment process to ensure they are recruiting participants who meet the inclusion criteria. Data collection methods for the participants will include online surveys and phone interviews. After loss to follow-up, we expect a total of 150 intervention participants (PAR and PWD) to complete the following survey tools: Participant Pretest Survey, Participant Posttest Survey, and Participant Exit Satisfaction Survey. One participant from each intervention group will be randomly selected to participate in a follow-up telephone interview scheduled within 2 weeks from posttest data collection. The participants in the comparison group will complete the pretest and the posttest over the same time period as the intervention group (posttest about 4 weeks after pretest). These participants, however, will not

participate in a guided exploration nor have any other resources provided to them beyond usual care by the community site.

See Attachment 2 for summary information about this project including a more detailed listing of the project's research questions.

All data collected will be used by NDEP to examine the usefulness of the Diabetes HealthSense website. The study will provide important outcome data about the program's impact on the primary audiences of community partners as well as PAR/PWD. This data will examine use over time as well as impacts on knowledge, self-efficacy, emotional distress, and behaviors. This study will help inform decisions about further support and promotion of this program. Without this study, NDEP will not know if the program is having its desired effect.

A.3. Use of Improved Information Technology and Burden Reduction

Pretest and posttest data from all intervention and comparison participants as well as data from the Participant Exit Satisfaction Survey will be collected via web-based surveys. Participants will access the surveys through a hyperlink, respond to survey questions, and submit the responses electronically. Benefits of web-based surveys include reduced implementation costs, simplified questionnaire formatting, improved data quality, elimination of data entry, reduced processing costs, and faster data collection.[9] In addition, submission of electronic data reduces the burden on respondents in that their data is submitted at the click of a button.

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

No previous studies have collected information about satisfaction with or outcomes resulting from use of Diabetes HealthSense, such as changes in knowledge, self-efficacy,

emotional distress, and/or behaviors among people with diabetes or those at risk. In addition, no data have been collected from community educators about their satisfaction with Diabetes HealthSense or NDEP's instructional tool for local implementation, or outcomes resulting from use, such as changes in their knowledge about NDEP resources or how to help people prevent or manage diabetes, their skills to help community members use resources such as Diabetes HealthSense, or their self-efficacy around implementing Diabetes HealthSense or helping community members use it or similar tools.

A number of national surveys collect data on some diabetes-related knowledge, attitudes, and behaviors, including the National Health Interview Survey and NDEP's public survey (OMB No. 0925-0552). However, these sources do not assess effectiveness, outcome of, and satisfaction with Diabetes HealthSense specifically. This information collection request was created because none of the above data sources provide the necessary information to evaluate Diabetes HealthSense.

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

No small businesses will be involved in this study.

A.6. Consequences of Collecting the Information Less Frequently

This is a one-time study that will begin and end during a 31-month project period. There are no legal obstacles to reduce the burden. All partners will be asked to participate in pretest and posttest interviews. These interviews will provide valuable information about the extent to which the trainers are implementing the educational intervention as intended as well as on their general use of the materials. These educators will also be asked to complete participant recruitment guides to ensure that all participants fit program inclusion criteria. For the project,

participants will be asked to complete an online pretest questionnaire prior to participation in the Diabetes HealthSense educational intervention and an online posttest questionnaire 4 weeks after the Diabetes HealthSense educational intervention. In addition, comparison group participants will also be asked to complete online pretest/posttest questionnaires. This pretest/posttest intervention group/comparison group methodology is important for measuring the program impacts.

In addition to the pretest/posttest questionnaires, intervention participants will be asked to complete online participant exit surveys at the end of the education intervention. One participant from each intervention group will also be randomly selected to participate in a follow-up interview within 6 weeks of the educational program (within 2 weeks of the posttest data collection). The information provided by these assessments as well as the partner pretest and posttest interviews will reveal the extent to which the educational program and the website are understandable, usable, educational, and able to help participants make lifestyle changes to prevent or manage diabetes. This information will provide guidance to modify and enhance the program as needed for potential future implementation. Without this data collection, there will be no way to gauge educator and participant satisfaction and experience with the educational intervention or website and its resources.

These data collection efforts will also be used to gauge fidelity. If there is failure to implement the intervention with fidelity, there is the potential to conclude erroneously that the results of the evaluation can be attributed to the intervention model, rather than extraneous or historical factors. Similarly, if the educational intervention is not implemented with fidelity, data suggesting that the intervention did not have the desired outcomes also must be questioned. Studying fidelity of implementation can explain why innovations succeed and fail and can allow

for the identification of changes made to a program during implementation as they might affect outcomes.[10] Understanding how fidelity moderates the outcomes of the intervention can be crucial to guiding revisions to interventions for future implementation.

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

This study requires less than quarterly data collection. As part of the project, Diabetes HealthSense educators will be asked to complete a participant recruitment guide for each group of participants they recruit. Participants will be asked to complete a pretest survey before the education program and a posttest survey four weeks following the educational program. In addition, participants will be asked to complete a satisfaction exit survey directly following the educational program. This information is crucial to help inform NDEP's future decisions about Diabetes HealthSense, including whether to make changes to the website and whether to invest additional resources to support, promote, or expand the resource and future implementation of the program.

There are no other special circumstances applicable to this project. This request complies with the regulation.

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

A 60- Day Federal Register Notice was published on August 5, 2013 (Vol. 78, No.150) on pages 47326-47327. There was one public comment. The comment conveyed broad discontent with the government's use of money and the department's involvement in diabetes

prevention. An acknowledgement of receipt and a statement of appreciation was sent in response to this comment. See Attachment 2.

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

Evidence exists that incentives make a difference in response rates. For example, meta-analytic results indicated that while both monetary and non-monetary rewards increased response rates (the average increase in response rates was 19.1% for monetary rewards and 7.9% for non-monetary rewards) monetary incentives increased response rates more so than non-monetary incentives or gifts.[11,12] More specifically, this research found that prepaid incentives yield significantly higher response rates than those promised and response rates increase with increasing amounts of money. Thus, providing an incentive to respondents to participate in a survey has been shown to be an effective method of increasing response rates.

To encourage participation and to increase response rates, participants in the comparison group will receive a cash acknowledgement of time and trouble (a total of $40 distributed after the pretest). This will be used to help ensure completion of both surveys by all comparison group participants, which is critical for ensuring an adequate comparison group.

In addition to the potential benefit of participating in the intervention, a small acknowledgement of time and trouble in the form of $25 will be given to each intervention group participant after completing the posttest questionnaire. The $25 will be used to help ensure adequate participation in all phases of the evaluation, which is critical to determining the impact of the program.

A.10. Assurance of Confidentiality Provided to Respondents

All respondents will be assured that their data will be kept private 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. Minors are not included in the study. Prior to any data collection, participants will be informed of the following: the purpose and use of the data collection, NIDDK sponsorship, and that their participation is voluntary at all times. Further, they will be told that their names will not be linked to any data, that results will be presented in aggregate, and that all electronic data will be protected by the use of passwords only accessible by the principal investigator and project manager. They will have the opportunity to ask questions about the study. Identifying information will be kept separate from data. When data is no longer needed it will be destroyed.

A.11. Justification for Sensitive Questions

To ensure the similarity of participants in the intervention group and the comparison group, questions are asked about race/ethnicity, income, and perceived health status. Information will be collected directly from respondents, who will be assured that this information is voluntary and will be treated as private to the extent provided by law. Questions on race/ethnicity are in compliance with OMB Directive No. 15. 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 records containing permanent identifiers that can be used for retrieval.

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

The maximum hour burden for all respondents to complete all instruments is estimated to be 328. Table A. 12-1 below presents the overall project hour burden.

A. 12-1 -- Estimates of Hour Burden by Anticipated Data Collection Methods

Form Name	Type of Respondent	Estimated Number of Respondents	Estimated Number of Responses per Respondent	Average Time per Response (in hours)	Estimated Total Annual Burden Hours
Participant Pretest	Adult intervention participants	200	1	20/60	67
Participant Posttest	Adult intervention participants	150	1	20/60	50
Participant Exit Satisfaction Survey	Adult intervention participants	200	1	10/60	33
Participant Follow-up Interview	Adult intervention participants	10	1	1	10
Participant Pretest	Adult comparison group participants	250	1	20/60	83
Participant Posttest	Adult comparison group participants	150	1	20/60	50
Community Educator Pre Interview	Community educators	5	1	1	5
Community Educator Post Interview	Community educators	5	1	1	5
Intervention Participant	Community educators	5	2	15/60	3

Recruitment Guide					
Comparison Participant Recruitment Guide	Community educators	10	1	15/60	3
				TOTAL	309

As presented in Table A. 12-2 below, the total annual burden cost for the evaluation is estimated to be $7,002.80. The hourly wage estimates for all surveys were based on the 2012 Department of Labor, Bureau of Labor Statistics median weekly earnings for men 16 years and over who are full-time wage and salary workers. The following table shows how the total annual burden cost was calculated for the adult respondents.

A. 12-2 -- Estimated Cost to Respondents

Form Name	Type of Respondent	Total Burden (in hours)	Hourly Wage Rate	Total Respondent Costs
Participant Pretest	Adult intervention participants	67	$21.35	$1,430.45
Participant Posttest	Adult intervention participants	50	$21.35	$1,067.50
Participant Exit Satisfaction Survey	Adult intervention participants	33	$21.35	$704.55
Participant Follow-up Interview	Adult intervention participants	10	$21.35	$213.50
Participant Pretest	Adult comparison group participants	83	$21.35	$1,772.05

Participant Posttest	Adult comparison group participants	50	$21.35	$1,067.50
Community Educator Pre Interview	Community educators	5	$21.35	$106.75
Community Educator Post Interview	Community educators	5	$21.35	$106.75
Intervention Participant Recruitment Guide	Community educators	3	$21.35	$64.05
Comparison Participant Recruitment Guide	Community educators	3	$21.35	$64.05
			TOTAL	$6597.15

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

There are no maintenance or capital costs to respondents.

A.14. Annualized Cost to the Federal Government

The approximate annual cost to the government for this study is $215,000. This is calculated from the costs outlined in the table below for the 31-month project period, dividing the total by 31 months and multiplying by 12.

$$\frac{\$554{,}000 \text{ total costs}}{\text{31-month project period}} \times 12 \text{ months} = \$215{,}000 \text{ per year}$$

The costs outlined below include costs for research design, developing instruments, development of the Office of Management and Budget information collection package, Institutional Review Board approval to assure human subjects are protected, pretesting, implementing the intervention, data collection and management, data analyses, and reporting and presenting the findings to the NDEP senior management after the analyses are completed. The

IRB approval process will be conducted through an external IRB organization, which charges a $4,000 fee that is included in the planning and development line item below.

A. 14-1 -- Estimates of Costs to the Federal Government

Evaluation Task	Estimated Cost
Planning and development (research design, developing instruments, development of the OMB ICR, IRB approval, and pretesting)	$202,000
Implementation (implementing the intervention, data collection and management)	$273,000
Data analysis and reporting	$79,000
TOTAL	$554,000

A.15. Explanation for Program Changes or Adjustments

This is a new data collection. All hours will be considered a program increase.

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

The results of this data collection will be tabulated and summarized in a final report that will be submitted to NDEP. This report will discuss the findings of each research question and is intended as an internal document. To ensure broad distribution of the findings, NDEP plans to publish the results of this study in a peer-reviewed journal and on its webpage, and to present these findings in meetings with federal decision-makers and at professional conferences.

Descriptive analyses (frequencies, percentages, means) will be conducted for all items. Scales will be created for each domain (knowledge, self-efficacy, beliefs, distress, and behaviors)

by summing the items within that domain. Factor analysis and internal consistency reliability using Cronbach's alpha will be conducted to determine whether the scales measure a unidimensional construct and have acceptable reliability (Cronbach's alpha>=.7). Chi-square tests of significance will be used to determine whether the intervention and comparison groups differ significantly on baseline characteristics that might influence results. Because of the proposed design in which participants are nested within sites that either participated in the intervention or not, linear mixed models will be used to analyze differences between the intervention participants and the comparison group participants on their pre and post questionnaire responses.

Thematic analysis will be used to summarize all qualitative information.

More detailed analysis plans are presented in Attachment 2. The tables in Attachment 2 demonstrate the link between each research question, the evaluation forms, specific form questions, and analysis plans.

The duration of the activities will span 31 months. The timetable for key activities is outlined in Table A. 16-1 below.

A. 16-1 Project Time Schedule

Activity	Time Schedule
Site Training	1 to 3 months following OMB approval
Data Collection	4 to 9 months following OMB approval
Data Analysis	10 to 13 months following OMB approval
Report Writing	14 to 15 months following OMB approval

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

No approval to eliminate the expiration date of OMB approval 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

There are no exceptions to the certification statement. This data collection has been designed in accordance with the requirements specified in Item 19 of the OMB 83-1