Supporting Statement A

for OMB Clearance Request

National Kidney Disease Education Program
National Institute of Diabetes and Digestive and Kidney Diseases

"Evaluation of a Kidney Disease Education Program with Promotores in the Hispanic Community"
(NIDDK, NIH)

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A. Justification

A.1. Circumstances Making the Collection of Information Necessary

The 42 US Code 285c provides the authority to the National Institute of Diabetes and Digestive and Kidney Diseases to conduct and support research, training, health information dissemination, and other programs with respect to diabetes mellitus and endocrine and metabolic diseases, digestive diseases and nutritional disorders, and kidney, urologic, and hematologic diseases. This collection by the National Kidney Disease Education Program (NKDEP), a program of the NIDDK, will evaluate a kidney disease education and awareness program disseminated through promotores in the Hispanic community and help to meet its mission to improve the understanding, detection, and management of kidney disease.

A.2. Purpose and Use of the Information

The NKDEP is expanding its community outreach efforts to target Hispanic Americans. A growing number of Hispanics are diagnosed with chronic kidney disease (CKD) each year. Since 2000, the number of Hispanics with kidney failure has increased by more than 70 percent.[1] Additionally, compared to non-Hispanics, Hispanics are almost 1.5 times more likely to be diagnosed with kidney failure.[2] Diabetes is the leading cause of kidney failure, causing more than 40% of cases.[3] To reach this high-risk population, NKDEP is developing a kidney disease education program, which includes a flip chart and a training manual, to be used in collaboration with existing, diabetes-focused "promotores de salud" (promotores) programs in the Hispanic community. Promotores are community health workers who live and work in the Hispanic community and are a trusted source of information.

This collection of information is necessary for NKDEP to assess program effectiveness and make any needed improvements to program materials, training, and delivery before national dissemination. In

[1] U.S. Renal Data System, USRDS 2010 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2010.
[2] U.S. Renal Data System, USRDS 2010 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2012.
[3] Ibid.

addition, the data collection will assess the methodology and instruments that are planned to evaluate the program when disseminated nationally. The descriptions of the national evaluation in this document are the planned activities and will need to be re-evaluated after the pilot study is completed. At that time, NKDEP will submit the national evaluation to OMB for approval as a revision request.

Using quantitative and qualitative instruments, the information collected during a pilot study of a total of 100 clients and their promotores in Hispanic communities in New York City and Los Angeles will inform NKDEP on whether the materials and the intervention will be effective in educating the Hispanic community about the behavior changes needed to identify and manage chronic kidney disease.
The pilot study also will evaluate the effectiveness of the training for promotores on how to use the NKDEP materials with clients, and the promotores' ability to administer the pre-test and post-test surveys for purposes of a national evaluation.

For the pilot study, five promotores in each community will be selected and trained to use the materials (flipchart and manual) with their clients. To evaluate the training, the promotores will complete quantitative pre-test and post-test surveys before and after the training to assess their knowledge about CKD (Attachment 1). Part of the training will include role-play presentations by the promotores to their peers. Researchers will observe and assess the role-playing sessions using an observation checklist. After the training, the promotores will participate in an in-depth interview (Attachment 2) to assess perceived quality of the training, perceived quality of the materials and resources, perceived strengths and weaknesses of the training, and materials and opportunities for improvements.

After the training, the promotores will conduct the pilot educational intervention using the draft materials in a session with their existing clients with diabetes. One group of clients will serve as the experimental group and one as the control group, with 50 people in each group. Using a staggered time series design, both groups will receive the educational intervention but at different times. Clients in each group will complete a quantitative pre-test survey at the same time. (Attachment 3). The clients in the experimental

group will receive the intervention immediately after the pre-test and complete a post-test (Attachment 3) one month after the educational intervention. While the experimental group is receiving the educational intervention, the control group will not be engaged. The clients in the control group will complete the post-test twice (Attachment 3) at two different time periods. The first time the control group takes the post-test will be at the same time as the experimental group to control for societal influences. The control group will then receive the educational intervention and take the same post-test a second time one month after the intervention. Researchers will observe the sessions as well as administration of the pre-test/post-test surveys using an observation checklist. In addition, after completing the intervention and the post-test in the experimental group or the second post-test in the control group, ten clients will be selected through a convenience sample to participate in an in-depth interview (Attachment 4) to assess perceived quality of the education they received, perceived quality of the promotor's counseling and information provided, perceived strengths and weaknesses of the program, and opportunities for improvements. NKDEP will use the information for planning (revising and finalizing the draft flipchart and training guide) and for evaluation (assessing the promotores' and clients' change in knowledge and awareness and reported behavior and health status). Results of the information collection will enable NKDEP to identify weaknesses or areas of the overall training program that are ineffective. NKDEP will be able to determine if the training and materials are achieving the desired results, if the clients understand and receive the information in the way it was intended, and if the promotores are appropriately using the materials with clients. Without this information, NKDEP risks the possibility of inefficiently and ineffectively implementing its program with untested materials when disseminated nationally.

In addition, if the pre-test and post-test client surveys are understandable and can be successfully administered by the promotores, NKDEP plans to embed them into the training manual that will be disseminated nationally and conduct national-level evaluation of clients' change in knowledge, awareness, reported behavior change and health status. To do this, NKDEP plans to recruit 20

promotores over two years who are trained during the national implementation to administer the program and the pre-test and post-test surveys with 400 clients total.

A.3. Use of Information Technology and Burden Reduction

Because promotores do not typically use information technology, NKDEP will not use it in these evaluations to ensure the most accurate responses are collected and to minimize the burden on both the clients and promotores from altering their usual methods.

During the pilot, the pre-test and post-test surveys assessing knowledge and awareness and reported behavior and health status change will be administered in person for both promotores and clients. The promotores will complete on their own the pre-test before the training and the post-test immediately following the training. Literacy is assumed in the promotores group because of their position, but a researcher will be present to monitor and answer questions.

The client pre-test and post-tests will be administered in person in small groups where the promotores will read the questions aloud in Spanish. Clients will record individual responses on their own on paper, with assistance from the promotores, if needed. Reading the questions and being available to provide assistance, if needed, addresses any literacy concerns in the client groups. There will be researchers present to monitor the administration and help with additional clarification.

The promotores in-depth interviews will be completed in person by the researcher immediately after the training. The client in-depth interviews will be completed in person by the researcher immediately after the promotor finishes the intervention session.

Further, the surveys and interview guides are designed so that only the minimum information necessary for the purposes of the project is collected.

For the national evaluation, NKDEP plans to have the promotores administer the client pre-test and post-test surveys using the same approach as during the pilot evaluation, collecting only the minimum information necessary for the purposes of the project.

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

NKDEP has taken steps to ensure that the proposed data collection does not duplicate ongoing efforts and that no existing data sets would address the proposed study questions. Furthermore, there are no similar data available as these resources are newly developed, and this is the first time they will be tested. Based on a literature review, there are no existing studies or research that adequately addresses the questions this collection seeks to answer. Based on an environmental scan, no existing diabetes education materials were found that focus specifically on kidney disease for the Hispanic audience.

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

Information collection does not impact small business or other small entities.

A.6. Consequences of Not Collecting the Information or Collecting Less Frequently

A one-time collection is being requested. If it is not collected, NKDEP would not be able to test the materials on more than nine people, limiting the cultural diversity within the Hispanic population included and limiting our ability to assess the quality of the promotores' training and the materials. In addition, NKDEP would not be able to assess the change in knowledge and awareness and reported change in behavior and health status when the program is implemented nationally.

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

No special circumstances or special permission is requested to conduct the information collection in a manner considered unfavorable by the OMB. The proposed project fully complies with all guidelines of 5 CFR 1320.5

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

The 60-day Federal Register Notice was published on July 19, 2013, Volume 78, pages 43214-43215. One comment was received. The comment stated that since the program addresses Hispanics only, it focuses on political spending and not health spending. The commenter was sent an acknowledgement of receipt of the comment and that the agency will take the comment into consideration.

The NKDEP consulted with several individuals outside the agency regarding the proposed information collection. The following individuals were consulted on conceptualization of the project:

Mona Rowe, MCP

Sarah Glavin, PhD

Jamelle E. Banks, MPH

Office of Science Policy and Evaluation, National Institute of Child Health and Human Development

Wilma T. Robinson, PhD

Formerly with the DHHS Office of the Assistant Secretary for Planning and Evaluation

The following individual was consulted on the methodology of the project:

Julie Wright Nunes, MD

University of Michigan Health System Department of Medicine

The following individuals were consulted on the methodology and instruments:

Moshe Engelberg, MPH, PhD

John Elder, MPH, PhD

Teresa Sanchez, MA

Research Works

Anna Zawislanski, MPH

Raquel Garcia Pertusa

Ogilvy Washington

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

The promotores and clients will receive a gift card for their efforts in providing the data for and helping to administer this collection. Payment compensates clients for travel time and expense to go to the clinic to take the post-tests; both locations for data collection are in large urban areas that involve cost for public transportation and additional time to travel to the clinic location. It also provides incentive for their time that is necessary to encourage participation; promotores and clients are populations that are harder to reach and are in lower-income households, earning close to minimum wage. In addition, promotores require additional time to administer the post-test surveys to their clients. Payment for each method is estimated as follows:

- Promotores = $70 total for completing the pre-test and post-test as part of the training (5 minutes per test); for administering the two surveys (pre-test/post-test) in experimental group or for administering the three surveys (pre-test/post-test/second post-test) in control group (15 minutes each test for up to ten clients), and for participating in the qualitative interview (5 minutes) and observed session
- Clients = $40 total for completing the pre-test and post-test (a total of two tests; 10 minutes each test) or completing the pre-test, post-test, and second post-test surveys (a total of three tests; 10 minutes each test); and for participating in the qualitative interview (5 minutes)

A.10. Assurance of Confidentiality Provided to Respondents

In order to recruit promotores for the training and pre- and post-tests, their names and contact information may be obtained by ResearchWorks/Ogilvy from the promotores programs in the two cities. However, no personally identifiable information will be collected during the tests, and names, phone numbers, and addresses will not be stored with the data collected. The selected promotores will identify a list of interested clients who have diabetes. ResearchWorks will help the promotores assign clients to experimental and control groups, and will contact clients by phone to schedule second post-test surveys.

Client names and phone numbers will be shared with ResearchWorks for scheduling purposes, and not stored with the data collected.

Collected data will be stored on password-protected computers. Stored data will be de-identified by assigning numbers to each client and promotor. Hard copies of the collected data will be stored in a locked file cabinet and in an office with a locked door; the key will be stored in a separate locked file cabinet in the contractor's office. The data received by NKDEP will only include de-identified data. Additionally, all respondents will sign informed consent forms and/or provide verbal consent. They will be assured that the information they provide will be treated in a secure manner and will be used only for the purpose of this study. They will be told about the purpose and procedures of the study, be notified of any risks or benefits, assured of the data confidentiality, who to contact if they have questions about the research, that their participation is voluntary and that they can withdraw or refuse to answer questions at any time (Attachment 5).

This data collection and project will require IRB approval **(pending local IRB Approval through the San Diego State University by ResearchWorks)**.

Privacy Impact Assessment Information

This project is subject to the Privacy Act (Attachment 6).

A.11. Justification for Sensitive Questions

No sensitive questions are to be asked during any of the surveys or qualitative interviews after promotores or client observation sessions.

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

Table A.12.A details the annualized number of respondents, the average response burden per interview, and the total response burden for the surveys and interviews for the pilot evaluation. For the pilot study, the contractor anticipates that the pre-test and post-test surveys, administered by pencil and paper to

promotores, will take approximately 5 minutes each for the promotores to complete. The clients' pretest and post-test surveys will take approximately 10 minutes each for clients to complete; an additional 5 minutes is added to each survey for the promotores' time to administer the survey and share the results with the contractor or NKDEP (15 minutes total for each test). A researcher will fill out an observation checklist on the promotores to assess the promotores' presentations during training and for the client sessions. The in-depth interviews administered after an observed promotores training or client session will take approximately 5 minutes each, but could take less depending upon the level of detail in the feedback. NKDEP plans for 10 promotores to complete the pre-test and post-test surveys and in-depth interviews after being observed during the training session; 50 clients in the experimental and control groups (for a total of 100) to participate in the pre-test and post-test surveys; 50 clients from the control group to participate in the second post-test; and 10 clients to participate in the in-depth interviews after the observed client session.

For the national evaluation, NKDEP plans to collect data from 400 clients using the client pre-test and post-test surveys (Attachment 3), involving administration by 20 promotores. The same level of burden as the pilot is assumed for clients to take the pre-test and post-test surveys (10 minutes each) and promotores to administer the surveys and share the results (15 minutes each).

Table A.12.A. Estimate Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Response Burden (hours)	Total Burden Hours
Pilot study collection					
Promotores	Promotores training pre-test, post-test, and qualitative in-depth interview post client session (Attachment 1 and 2)	12	1	5/60	1
Promotores	Administer client pre-test, post-test, and second post-tests for experimental and control groups (Attachment 3)	20	17	15/60	85
Client Group	Client pre-test, post-test, second post-test for experimental and control groups (Attachment 3)	85	1	10/60	14
Client Group	Client qualitative in-depth	4	1	10/60	1

(partial)	interview post-client session (Attachment 4)				
Total		121			101

Table A.12.B Estimate Annualized Hourly Cost

Type of Respondent	Form Name	No. of Respondents	Total Burden Hours	Hourly Wage Cost	Respondent Cost
Pilot study collection					
Promotores	Promotores training pre-test, post-test, and qualitative in-depth interview post client session (Attachment 1 and 2)	12	1	18.02 (1)	18.00
Promotores	Administer client pre-test, post-test, and second post-tests for experimental and control groups (Attachment 3)	20	85	18.02	1532.00
Client Group	Client pre-test, post-test, second post-test for experimental and control groups (Attachment 3)	85	14	13.38 (2)	188.00
Client Group (partial)	Client qualitative in-depth interview post-client session (Attachment 4)	4	1	13.38	14.00
Total		121	101		1752.00

(1) http://www.bls.gov/oes/current/oes211094.htm Occupational Employment and Wages, May 2012

21-1094 Community Health Workers

(2) http://www.bls.gov/cps/cpsrace2010.pdf Table 14 (p.41) Labor Force Characteristics by Race and Ethnicity August 2011. BLS Report 1032

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

Respondents will not incur capital, start-up, operational, or maintenance costs as a result of participation in this information collection. Respondents should be able to answer all questions without referring to their records and do not need any type of special equipment or processes to complete this information collection.

A.14. Annualized Cost to the Federal Government

The annualized cost to the Federal government for the pilot study is $30,000 through a subcontract with ResearchWorks. The pilot study will be completed in approximately one year; a national study is planned

for two years after completion of the pilot. Cost estimates cover the development, implementation, data collection and analysis of the survey and trainings planned for the pilot study, including:

- Development of the methodology and instruments (Attachments 1-5)
- Data and analysis reporting
- Creation of final written summary reports

A.15. Explanation for Program Changes or Adjustments

The proposed evaluation is a new project; program changes or adjustments are not needed for this information collection.

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

A.16.A. Tabulation and Analysis Plan

Pre-test and post-test survey data of the same subjects will be analyzed in a variety of ways. The following will be used: 1) paired t-tests (to assess the continuous data, e.g., pre-test and post-test of the percent correct on the knowledge test), 2) non-parametric tests of association (for the binary data, e.g., talked to health provider vs. whether they answered a specific question right or wrong), and 3) point-biserial correlations (for comparisons of binary and continuous, e.g., level of health engagement vs. stayed in the group/dropped out of the group). Analysis of covariance will be used to examine the differences in groups from pre-test to post-test survey, controlling for gender and age. Linear regressions will be used for continuous data and logistic regressions will be used for binary outcomes to 'predict' outcomes such as who benefited from the classes most.

For the pilot study, the primary analysis will be the comparison of the control and experimental groups. For the national study, the analysis will focus on predictors of high pre-test scores and on improvement from pre-test to post-test.

A.16.B. Publications

The results of the analysis will be reported in a Final Report, including a brief executive summary written in clear language. The report for the pilot study will include study implementation, methods used, major results, final tools, and recommendations for next steps for national dissemination of the materials and quantitative instruments. The report for the national study will include study implementation, methods used, and major results. The research findings/final reports may be adapted into an article for submission to a peer reviewed journal. This will be determined/discussed at a later date.

Table A.16-1. Time Schedule

Activity	**Time schedule**
Pilot Study	
• Recruitment of promotores	1 month after OMB approval
• Promotores training and data collection	2-3 months after OMB approval
• Recruitment of clients	2-4 months after OMB approval
• Client Experimental and Control Group pre-test and experimental in-depth interview	4-5 months after OMB approval
• Client Experimental and Control Group post-test and control in-depth interview	4-5 months after OMB approval
• Client Control Group second post-test	5-6 months after OMB approval
• Data cleaning and analysis	7-12 months after OMB approval
• Final pilot report writing	7-12 months after OMB approval
National Study	
• Recruitment of promotores	13-30 months after OMB approval
• Promotores training	14-31 months after OMB approval
• Recruitment of clients	14-32 months after OMB approval
• Client pre-test	14-33 months after OMB approval
• Client post-test	15- 34 months after OMB approval
• Data cleaning and analysis	35-36 months after OMB approval
• Final national report writing	35-36 months after OMB approval

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

NKDEP intends to display the OMB approval expiration date in the upper right hand corner of the surveys and interview guides. The information collection control number also will be displayed.

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

NKDEP intends to meet all certification requirements and is, therefore, not seeking exception to any part of the Certification for Paperwork Reduction Act Submission.