

**Supporting Statement B
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)**

September 12, 2013

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B. Collections of Information Employing Statistical Methods

B.1. Respondent Universe and Sampling Methods

Promotores Recruitment

To select and recruit promotores for the pilot study in New York, NY, NKDEP will work with the New York-Presbyterian Hospital, Community Health Education and Outreach Program. In addition, to select and recruit promotores for the pilot study in Los Angeles, CA, NKDEP will work with Vision y Compromiso Promotores and Community Health Workers Network. Five promotores per city will be selected to participate in the study via a convenience sample. Promotores will be selected based on having previous experience with diabetes education. These promotores will then be invited to participate, provide informed consent, and offered an incentive to participate in the study.

To recruit 20 promotores for the national evaluation, NKDEP plans to work with promotores' organizations in two new geographic locations and continue working with the organizations listed above.

Client Recruitment

For both the pilot study and national evaluation, clients will be recruited through their promotores. Both ResearchWorks and NKDEP will not have access to the promotores database of clients.

The promotores will select client participants based on the criteria of being Spanish-speaking, having diabetes, and attending diabetes education classes. For the pilot study, each promotora will select 15 potential participants from her client list who will have interest and ability to participate in and complete the study. The intent is to recruit 10 participants per promotor/a who will be assigned to the experimental or control group based on ability to schedule attendance for the group sessions. The promotor/a will contact the clients by phone to invite them to participate in the study, and ResearchWorks will work with the promotor/a on scheduling to ensure fidelity to the research design. The clients will then be invited to participate, provide informed consent, and offered an incentive to participate in the study.

ResearchWorks will contact the clients in the experimental group by phone to schedule the second post-test.

For the national evaluation, NKDEP plans for the 20 promotores to identify a total of 400 clients to participate over two years. The promotores will determine which clients qualify to participate and conduct the recruitment.

B.2. Procedures for the Collection of Information

Describe the procedures for the collection of information including:

- **Statistical method for stratification and sample selection:** There will be no stratification because this is a convenience sample of promotores and clients.
- **Estimation procedure:** Not applicable; there will be no estimation procedure for the same reasons as there will be no stratification.
- **Degree of accuracy needed for the purpose described in the justification:** Not applicable.
- **Unusual problems requiring specialized sampling procedures:** Not applicable.
- **Any use of periodic (less frequent than annual) data collection cycles to reduce burden:** Not applicable.

B.3. Methods to Maximize Response Rates and Deal with Nonresponse

To maximize response rates, we will utilize methods that are based on ResearchWorks' more than 25 years of experience conducting similar types of studies, particularly those with the target populations in this environment (Community Health Workers/Promotores, Spanish-speaking clients, etc.). Additionally, the response rates on studies conducted by ResearchWorks are in the 90 percent range in primarily Spanish-speaking populations. ResearchWorks will use bilingual, bicultural surveyors who use role-play to prepare for the environment and the cultural expectations of promotores' organizations and dynamics. NKDEP has well-established relationships with the two organizations that will be contacted, which may enhance recruitment for the promotores.

For the client recruitment, NKDEP will send reminders to the promotores to ask their clients to participate. To maximize the response and retention rate of client subjects, we propose to recruit 10 clients from each promoter/a, based on his/her best judgment on who from their client list has diabetes and the ability to come onsite for research and intervention activities. We will over recruit by 10% to account for attrition. To maximize response rates, NDKEP also will offer incentives to participate in the surveys and interviews. 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.

For the experimental group, the pre-test and in-depth interview will be conducted the same day as the educational intervention. For the control group, the in-depth interview will be conducted the same day as the first post-test and the educational intervention. The incentives for the interviews will be distributed immediately following the interview. The incentives for the surveys will be distributed after the post-test is completed in the experimental group, and after the second post-test survey for the control group. Promotores and clients will receive a cash or gift card incentive for their involvement and participation in the data collection.

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)

Statistical analyses will treat clients who are lost to follow-up as “treatment failures” (i.e., they will be assigned the same values as at baseline). Non-responses within a survey will be coded as “missing data.”

B.4. Testing Procedures

The design of this study and the research instruments themselves are based on more than 25 years experience of the key expert, Dr. John Elder (Attachment 7 Biographical Sketch for list of relevant peer-reviewed publications using similar methods and instruments). Similar instruments on different health topics have been pretested and fielded with promotores and their clients alike in Spanish on dozens of research projects funded by NIH and others. These instruments will be pretested while the Federal Register Notice is posted and submit any revised instruments with the final OMB package.

B.5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Dr. John Elder designed the data collection and will be analyzing the data. He will help oversee the data collection along with ResearchWorks’ staff, using Research Associates who have been trained by Dr. Elder or ResearchWorks in administering Spanish instruments.

- Moshe Engelberg, M.P.H, Ph.D.
- John Elder, M.P.H., Ph.D.
- Teresa Sanchez, M.A.

ResearchWorks

- Elizabeth C. Wright, Ph.D.

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