JUSTIFICATION A

TITLE: Using Peer Mentors to Support PACT Team Efforts to Improve Diabetes – PACT Demo Lab VISN 4
Investigator: Judith Long, MD

OMB FORM 2900-XXXX

A. JUSTIFICATION

1. Explain the circumstances that make the collection of information necessary. Identify legal or administrative requirements that necessitate the collection of information.

This project is being conducted under the auspices of the VISN 4 Demonstration Lab, which was funded by Patient Care Services to assess the Patient Aligned Care Team (PACT) model of care for Veterans. There is considerable interest in and urgency to implement the PACT model – reflecting both a desire to improve health care for Veterans and to sustain the VA's leadership in health care quality. CEPACT aims to contribute to these goals by evaluating the effects of the VA PACT initiative and by test new, innovative strategies for patient care that can be spread if proven effective.

This study tests a peer mentor strategy for primary care patients with poorly controlled Type 2 Diabetes Mellitus (DM). DM self-care activities which are essential for attaining and maintaining DM control for the most part take place outside of clinical encounters. While clinically based programs are important in supporting patient efforts, they often do not provide patients with sufficient support and reinforcement to help them become more engaged and successful in self-care. Disease-specific social support has been shown to improve DM self-management behaviors and may be particularly beneficial when the support come from a peer with the same chronic condition.

Legal authority for this data collection is found under 38 USC, Part I, Chapter 5, Section 527 that authorizes the collection of data that will allow measurement and evaluation of the Department of Veterans Affairs Programs, the goal of which is improved health care for veterans.

2. Indicate how, by whom, and for what purposes the information is to be used; indicate actual use the agency has made of the information received from current collection.

We plan to enroll up to 600 patients from clinics in VISN 4. 240 of these patients will serve as peer mentors during the course of the study. This information will be used by the Principal Investigator, Judith Long, and her research team to evaluate the effectiveness of peer mentoring in improving glucose control relative to usual care for patients receiving primary care at VA facilities.

The results of the study may be published; however, steps will be taken to keep patient information private to the extent permitted by law at all stages of the research process. Data collection began in September of 2012 and is currently underway. There has been no analysis of the current data and thus there has been no actual use of this information to date. This work has been partially funded by the VISN 4 Demonstration Lab, which in and of itself is funded by Patient Care Services (to assess the Patient Aligned Care Team (PACT) model of care for Veterans).This work is also being funded by VA HSR&D and from initiation was deemed research and received all the same regulatory oversight as any VA research. The aims of this study are multiple.

Our primary aims for the entire study are to:

1. Test the effectiveness of a peer mentor model in a mixed race population of poorly controlled diabetic veterans.

H1: Compared to usual care, veterans in the peer mentor arms will have improved glucose control regardless of race or ethnicity at 6 and 12 months.

2. Test the effectiveness of a self-sustaining peer-mentoring program that trains former peer mentees to be peer mentors to support health-related behavior change.
   H2: Compared to usual care, veterans who receive peer mentoring from former mentees will have improved glucose control as measured by glycosylated hemoglobin (HbA1c), blood pressure, LDL levels, DM quality of life, and depression scores.
3. Assess the effects of becoming a mentor on those who were originally mentees.
   H3: Compared to past mentees who are not randomized to becoming a mentor, past mentees randomized to becoming a mentor will have better glucose control, blood pressure, LDL levels, DM quality of life, and depression scores.
4. Conduct a rigorous qualitative evaluation examining in-depth the mentor-mentee relationship, the transition to becoming a mentor, qualities of a successful mentor, and factors relevant to broader program implementation.

Secondary Aims:

4. In those randomized to being a mentee, explore mentor characteristics associated with improved HbA1c. Predictors to be evaluated include past mentoring dose of the current mentor, the mentor's past change in HbA1c, the mentor's starting HbA1c, current mentoring dose provided by the mentor, mentee's evaluation of the mentor, and mentor's depression score at baseline.
5. Work with the Camden Community Based Outpatient Clinic (CBOC) to implement a PACT based peer mentor program for diabetics to better understand facilitators and barriers to program implementation.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g. permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also describe any consideration of using information technology to reduce burden.

Data collection will take place via in person interviews during clinic visits to accommodate varied literacy skills and visual ability among the study population and by telephone between clinic visits to reduce travel burden on the patient. The in-person interview consists of a structured survey instrument and open ended questions. Data will be collected verbally and via electronic questionnaires by project staff every 6 months for up to 24 months. The end date for concluding this project 3/31/2018.

Qualitative interviews will be conducted during the in-person study visits and recorded digitally for subsequent transcription. Use of digital recorders reduces respondent burden when compared with methods of data collection that require written responses or access to and ability to navigate the Web. The burden of travel to and from study visits will be minimized by scheduling visits at a time most convenient to participants. Improved information technology will not decrease the burden on the public.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item 2 above.

The VISN 4 PACT Demonstration Laboratory has funded this research study based on its potential to address the health care needs of veterans with poorly controlled Diabetes Mellitus. All research and intervention assessments were selected to address both clinical and theoretical questions of interest and are therefore not duplicative of any other assessments routinely administered to this population.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

No small businesses or entities will be involved in this study.

6. Describe the consequences to Federal program or policy activities if the collection is not conducted or is conducted less frequently as well as any technical or legal obstacles to reducing burden.

By not collecting this information, the VA would not be responsive to the needs of the patient. The VA is making a significant investment in improving its primary care model through the Patient Aligned Care Team (PACT) initiative. This project is a clinical innovation study funded through the VISN 4 PACT Demonstration Lab. Not conducting or conducting data collection less frequently will result in a lack of information on the effectiveness of interventions designed to improve primary care for veterans. As a consequence, the VA would not be able to make evidence based decisions about further improvements to primary care and diabetes management.

7. Explain any special circumstances that would cause an information collection to be conducted more often than quarterly or require respondents to prepare written responses to a collection of information in fewer than 30 days after receipt of it; submit more than an original and two copies of any document; retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years; in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study and require the use of a statistical data classification that has not been reviewed and approved by OMB.

There are two such special circumstances:
1) This project requires brief monthly telephone call with the patients serving as peer mentors. They will be asked two data collection questions during this call:

1. Did you talk to [your mentee] this month? Yes/No
    1a. If No: Why not?
    1b. If Yes: How many times did you talk to them?

This information is critical as it ascertains fidelity to the peer mentor model and the "dose" of mentoring each mentee receives. It also serves as confirmation of their time spent mentoring, which is eligible for payment.

2) We also will administer the hypoglycemic symptoms questions to patients at a two-month interval (month one and month three) once during the study. In a previous study, the Data Safety Monitoring Board recommended these clinical data be collected at months one and three. The data collection schedule for this study follows this recommendation.

8. a. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the sponsor's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the sponsor in responses to these comments. Specifically address comments received on cost and hour burden.

The notice of Proposed Information Collection Activity was published in the Federal Register on December 12, 2014 (Volume 79, Page 72249). We received no comments in response to this notice.

b. Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, clarity of instructions and recordkeeping, disclosure or reporting format, and on the data elements to be recorded, disclosed or reported. Explain any circumstances which preclude consultation every three years with representatives of those from whom information is to be obtained.

Outside consultation is conducted with the public through the 60- and 30-day Federal Register notices.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

There are approximately three clinic visits for each patient over the course of the study. During the clinic visits, patients will spend approximately 45 minutes being interviewed and will provide a blood sample to test glucose levels. Patients will be compensated $50 for each visit to compensate for the unusual amount of burden to the patient associated with data collection, including the biological sample. (3 in person visits x 600 people = 1800 visits x $50/visit = $90,000). Patients will not be compensated for the brief phone calls occurring between visits.

Patients selected to complete qualitative interviews will be compensated $40 per interview. 90 patients will complete up to 3 interviews at their person visits (3 interviews x 90 people = 270 interviews x $40 = $10,800). : Compensation is offered to support study subjects' compliance over an extended period of time and ensure complete data collection, as well compensate for the burden of a significant amount of time required for the data collection points.

Mentors will be compensated an additional $20 per month for routine mentor activities for a period of 6 months. (240 mentors x 6 months x $20 = $28,800) Mentors will receive a brief monthly phone call (see item 7 above) to assess their eligibility for this payment. Compensation is offered to support mentors' compliance over an extended period of time and ensure complete data collection.

10. Describe any assurance of privacy to the extent permitted by law provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

Information on these forms will become part of a system of records which complies with the Privacy Act of 1974. This system is identified as "Veteran, Patient, Employee and Volunteer Research and Development Project Records-VA (34VA11)" as set forth in the Compilation of Privacy Act Issuances via online GPO access at *http://www.gpoaccess.gov/privacyact/index.html*

11. Provide additional justification for any questions of a sensitive nature (Information that, with a reasonable degree of medical certainty, is likely to have a serious adverse effect on an individual's mental or physical health if revealed to him or her), such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private; include specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

There are no questions of a sensitive nature.

12. Estimate of the hour burden of the collection of information:

a. The number of respondents, frequency of responses, annual hour burden, and explanation for each form is reported as follows:

VA Form 10-10138	No. of respondents	x No. of responses	x No. of minutes	÷ by 60=	Number of Hours
Baseline survey	**600**	**1**	**45**		**450**
10-10138a 6 mo survey	**600**	**1**	**30**		**300**

Qualitative interview	**270**	**3**	**15**		**202.5**
12 mo survey 10-10138b	**600**	**1**	**30**		**300**
18 mo survey	**160**	**1**	**30**		**80**
Hypoglycemic symptoms	**600**	**2** (months 1 and 3)	**2**		**40**
Monthly peer mentor questions	**240**	**5**	**5**		**100**
					1472.5

b. If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens in Item 13 of OMB 83-I.

See chart in subparagraph 12a above.

c. Provide estimates of annual cost to respondents for the hour burdens for collections of information. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included in Item 14.

Cost estimates are minimal (5 minutes per month in paperwork x $24/hr = $2.00per month x 6 months = $12.00 annual cost) and not expected to vary widely. The only cost is for the mentor to track how many times they have spoken with the mentee each month. This information will be collected via a monthly phone call with study personnel. Mentors are compensated $20 per month to cover this minimal recordkeeping burden as well as their time spent speaking with the mentee each month. Compensation is offered to support mentors' compliance over an extended period of time and ensure complete data collection

13. Provide an estimate of the total annual cost burden to respondents or record keepers resulting from the collection of information. (Do not include the cost of any hour burden shown in Items 12 and 14).

$1800 for 240 peer mentors. Cost estimates are minimal (5 minutes per month in paperwork x $24/hr = $2.00 per month x 6 months = $12.00 annual cost) and not expected to vary widely. The only cost is for the mentor to track how many times they have spoken with the mentee each month. This information will be collected via a monthly phone call with study personnel. Mentors are compensated $20 per month to cover this minimal recordkeeping burden as well as their time spent speaking with the mentee each month. Compensation is offered to support mentors' compliance over an extended period of time and ensure complete data collection

14. Provide estimates of annual cost to the Federal Government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operation expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies also may aggregate cost estimates from Items 12, 13, and 14 in a single table.

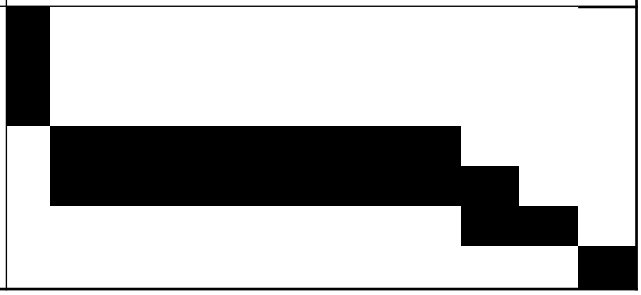
All costs for this data collection are included in grant funds already approved by VHA Patient Care Services for the PACT Demonstration Laboratory. There are no additional costs to the government for this activity. Grant funding is $822,214 for FY2014-FY2018 for this project.

15. Explain the reason for any burden hour changes or adjustments reported in items 13 or 14 of the OMB form 83-1.

This is a new collection and all burden hours are considered a program increase.

16. For collections of information whose results will be published, outline plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

VA intends to publish this data in aggregate form. Dissemination of the study findings will include traditional academic mechanisms (e.g., articles published in peer-reviewed journals) and presentations to VA Patient Care Services, Primary Care, and other relevant stakeholders.

Event	**Study Month** 6 12 18 24 30 36 42 48 54 60 66
IRB approval	
Hire/train staff	
Obtain Equipment	
Patient recruitment	
Active data collection	
Data cleaning and analysis	
Dissemination of findings	

17. If seeking approval to omit the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

VA does not seek to omit the expiration date.

18. Explain each exception to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submissions," of OMB 83-I.

There are no exceptions.