Using Peer Support Efforts to Mentors to PACT Team Improve Diabetes – PACT Demo Lab VISN 4 VA Form 10-10138

The Paperwork Reduction Act of 1995: This information is collected in accordance with section 3507 of the Paperwork Reduction Act of 1995. Accordingly, we may not conduct or sponsor and you are not required to respond to, a collection of information unless it displays a valid OMB number. We anticipate that the time expended by all individuals who complete this survey will average 2-45 minutes. This includes the time it will take to follow instructions, gather the necessary facts and respond to questions asked. Customer satisfaction is used to gauge customer perceptions of VA services as well as customer expectations and desires. The results of this telephone/mail survey will lead to improvements in the quality of service delivery by helping to by evaluating the effects of the VA PACT initiative and by testing new, innovative strategies for patient care that can be spread if proven effective. Participation in this survey is voluntary and failure to respond will have no impact on benefits to which you may be entitled.

OMB No. 2900-XXXX
Estimated Burden: 1473 hours
Expiration Date: 03/31/2018

VA Department of Veterans Affairs	**VA RESEARCH CONSENT FORM**

Subject Name: _____ Date: _____

Subject's First Letter of Last Name and Last 4 of the Social Security #: _____

Title of Study: Using Peer Mentors to Support PACT Team Efforts to Improve Diabetes Control (CEPACT)- Stage 1

Principal Investigator: _____Judith A. Long, MD_____VAMC: Philadelphia (642)

Version date and version number: 06 4/2/2015

STAGE 1
PRINCIPLE INVESTIGATOR'S NAME: JUDITH A. LONG, MD
COMPLETE ADDRESS: 3900 WOODLAND AVENUE PHILADELPHIA, PA 19104

NAME OF STUDY SPONSOR: CEPACT

WHY AM I BEING ASKED TO VOLUNTEER?
You are being asked to voluntarily participate in a research study because you have poorly controlled diabetes and you speak English. **Your participation is voluntary which means you can choose whether or not you want to take part. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The study doctor and/or a member of the research team will talk to you about the research study, and they will give you this consent form to read. You are encouraged to discuss this study and form with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team about this form. If you decide to participate, you will be asked to sign this form and you will receive a signed copy.**

WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?
The purpose of this research study is to determine if peer counseling can help improve glucose control in diabetics.

HOW LONG WILL I BE IN THE STUDY? HOW MANY PEOPLE WILL BE IN THE STUDY?
You will be involved with this study for an 18-24 month period**. You will have** 3-4 **visits at the Philadelphia VA Medical Center (PVAMC). We plan to enroll around** 600 **Veterans from PVAMC.**

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A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S Law. This Web site will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Web site at any time.

WHAT AM I BEING ASKED TO DO?

First, you will be asked to complete a baseline survey that should take about 25 minutes. We will then measure your blood pressure and weight. After that you will get your blood drawn. At the end of this first visit you will be given $50 for your time.

Second, you will need to give us a working phone number. We will call you to let you know your starting glucose control or HbA1c level. Also, we will call at 1 and 3 months to ask you about how you are doing and if you had low blood sugar during the month.

Third, you will be asked to return to the VA at 6 and 12 months to talk to us about being in the study as well as get your blood drawn again. Your medical health record will be under electronic review for an additional 6 months after your last visit. At the end of each in-person visit you will again be given $50 for your time. We will give you vouchers that you can redeem for cash at the Philadelphia VA Medical Center.

Once you complete the consent procedure you will be assigned by chance to either get usual care or a peer mentor.

For Usual Care:

- You will complete the assessments described above at baseline, 6 months and 12 months. You will be notified of your starting HbA1c and the American Diabetes Association (ADA) and VA recommended goals for your glucose levels. You will be called at one month and three months to check in and assess for hypoglycemic events. No additional interventions will be provided.

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For Peer Mentoring:

- You will complete the assessments described above at baseline, 6 months, 12 months and 18 months. You will be notified of your starting HbA1c and the American Diabetes Association (ADA) and VA recommended goals for your glucose levels. You will be called at one month and three monthsto check in and assess for hypoglycemic events.
- In addition, you will be matched within the next 1-3 weeks with a peer mentor who will start calling you. We will introduce you by phone to a person who also has diabetes and who also was once in poor control. You will be expected to talk with the mentor at least once a week for 6 months. You must be willing to provide a working phone number and any other applicable personal information for your mentor. If you and your mentor want to meet in person that is fine, but not necessary.
- Finally, after 6 months you will randomly assigned to either become a mentor for someone who is in poor control or to not become a mentor. If you are assigned to become a mentor, you must be willing to provide a working phone number and any other applicable personal information to communicate with your mentee. At your six month visit we will train you how to be a mentor. This should take about 20-30 minutes. We will then introduce you to a mentee over the phone. We will call you monthly to ask you how many times you talked to the veteran you are trying to help and if you have any questions or concerns about being a mentor. At the seven months and nine months, we will call you to assess for hypoglycemic events. If you talk to your mentee 4 or more times each month you will receive $20 for that month.
- You may also be asked to complete a 20 minute voice-recorded, qualitative interview at 6 months and 12 months to evaluate your overall experience while participating in the study. You will be asked to sign a consent form authorizing the use of your voice. The information gathered from these qualitative interviews will inform the design of sustainable health interventions. The interview will be transcribed by Alpha Transcription and coded by VA study staff members, working out of the University of Pennsylvania. You will be given an additional $40 for your time upon the completion of each interview.

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All study procedures will be done at the Philadelphia VA Medical Center.

WHAT ARE THE POSSIBLE RISKS OR DISCOMFORTS?

There are few risks associated with this study. You will lose time. Also, we will be collecting identifiable data from you as part of this study. There is the potential risk that this data may be lost or stolen. We will try to keep your information safe. It will be kept in the Philadelphia VA Medical Center in locked cabinets, behind locked doors. Computerized data will be maintained in password protected files on Philadelphia VA Medical Center servers behind a firewall. We employ all the standard security used for all VA clinical data.

WHAT ARE THE POSSIBLE BENEFITS OF THE STUDY?

You may not benefit from participating in this research study. If during the study you are successful at lowering HbA1c and you are able to maintain this new level after the study you may avoid getting some common complications of diabetes. In addition, this study will contribute to our general knowledge about treatment of patients with diabetes.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT PARTICIPATE?

One of the choices is not to participate in this research study. Participation is voluntary and you do not have to participate if you do not want to. This study will not affect the care you receive at any VA Medical Center. Participation is voluntary. There will be no consequences to you if you choose not to enroll in this study. In addition, you may withdraw from the study at any time without any consequences to you for withdrawing.

WILL I HAVE TO PAY FOR ANYTHING IF I PARTICIPATE IN THIS STUDY?

You will not have to pay for any research procedures or tests that result from participating in this study.

WHO CAN SEE OR USE MY INFORMATION? HOW WILL MY PERSONAL INFORMATION BE PROTECTED?

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Information that will be used: During the course of this study, we will collect personal information such as your name, social security number, age, and contact information so that we can stay in touch with you. We will be drawing blood and will notify you of the test results. We will measure your blood pressure and weight, have you complete 3 surveys and we may ask you to complete two qualitative interviews that will be voice recorded and stored electronically. We will also be monitoring your medical health record for an additional 6 months after your last visit.

Your name and social security number will be used only as necessary within the Philadelphia VA Medical Center. But other private information may be disclosed to the study sponsor. The VA is paying for this study. If you have an accident or reaction during the course of the study, your entire medical record may be used and disclosed as clinically necessary.

Internal monitors from the PVAMC Institutional Review Board (IRB), a research oversight committee, may inspect study records for quality assurance.

This informed consent document will be added to your medical record.

The results of this study may be published; however, you will not be identified by name or other personal identifiers. Further, your medical records will not be revealed unless required or authorized by law.

This information will be kept in the Philadelphia VA Medical Center Annex in locked cabinets, behind locked doors on the 2nd floor in room 17. Files that are actively in use will be stored in locked cabinets behind locked doors on the 2nd floor of the Philadelphia VA Medical Center Annex in Suite 200. Computerized data will be in password protected files on Philadelphia VA Medical Center servers behind a firewall. We will employ all the standard security used for all VA clinical data.

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The required records, including the investigator's research records, must be retained until disposition instructions are approved by the National Archives and Records Administration and are published in VHA's Records Control Schedule (RCS 10-1).

SPECIAL CIRCUMSTANCES

None

WHAT SHOULD I DO IF I HAVE BEEN INJURED OR EXPERIENCE A MEDICAL PROBLEM?

In the event that you sustain injury or illness as a result of your participation in this VA approved research study, conducted under the supervision of one or more VA employees, all medical treatment (emergent as well as medical treatment beyond necessary emergent care) will be provided by the VA.

It is important that you tell your study doctor, Dr. Judith Long, if you feel that you have been injured because of taking part in this study. You can tell the study doctor in person or call her **at 215-823-5800 x7147 during the day and at 215-823-5800 ext 0 to have her or the on-call doctor paged after hours.**.

WHEN IS THE STUDY OVER? CAN I LEAVE THE STUDY BEFORE IT ENDS?

- **You understand that you do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled. If you withdraw, you may be asked to return for a final study visit in order to assure your safety. You should withdraw in writing in order to withdraw your permission for us to continue to use the protected health information we have already collected about you. Even if you withdraw, we can continue to use information about you that has been collected up to that point. No information will be collected after you formally withdrawal in writing at the address listed on the first page of this consent.**

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- **This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time without your consent because:**
  - **The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.**
  - **You have not followed study instructions.**
  - **The Sponsor or the study Principal Investigator has decided to stop the study.**

There are no consequences if you decide to withdraw.

You can withdraw from the study at any time. If you wish to discontinue our use of information already collected, please indicate your decision to withdraw in writing to the address listed on the first page.

- **WHAT ARE MY RIGHTS AS A RESEARCH SUBJECT?**

You have read or have had read to you all of the above. Dr. Judith Long and/or research coordinator has explained the study to you and answered all of your questions. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you.

You understand that you do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled.

The results of this study may be published; however, you will not be identified by name or other personal identifiers. Further, your medical records will not be revealed unless required or authorized by law.

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In case there are medical problems, research related injuries or questions, you have been told you can call Dr. Judith Long at 215-823-5800 x7147 **during the day** and at 215-823-5800 ext 0 to have her or the on-call doctor paged **after hours**.

In the event that you sustain injury or illness as a result of your participation in this VA approved research study, conducted under the supervision of one or more VA employees, all medical treatment (emergent as well as medical treatment beyond necessary emergent care) will be provided by the VA.

If you would like to discuss problems, complaints, concerns, or questions with someone who is not directly associated with your participation in this study or you have any questions regarding your rights as a research subjects; if you feel you have been injured, or you want to check the validity of the study and its personnel within the VA, you may contact the Research Compliance Officer at 215-823-7847 or the Patient Representative at 215-823-5803 from 8:00 AM to 4:30 PM Monday through Friday.

If you have concerns or complaints about the research study, you may contact the research staff involved with this study at *215-823-5800 x7929.*

As a Veteran, we value your input into how research is conducted at the Philadelphia VA Medical Center. If you would like to offer suggestions and opinions, or if you would like to participate in future discussions of research in Philadelphia, please call the Research and Development (R&D) Administrative Officer at (215) 823-6023 or R&D Associate Chief of Staff at (215) 823-4021.

There will be no cost to you for your participation in this study. However if you are receiving medical care and services from the VA that are not part of this study, and you are a veteran described in federal regulations as a "category 7" veteran, you may be

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required to make co-payments for the care and services that are not required as part of this research study.

You understand that in the event of injury resulting from the research procedures, eligible veterans will be entitled to medical care and treatment for any sustained injury. Compensation may also be payable under 38 USC 1151 or in some circumstances, under the Federal Tort Claims Act.

I voluntarily consent to participate in this study. I confirm that I have read this consent and authorization document, or it has been read to me and that it explains what this research project is about and how and why it is being done. I will receive a signed consent form of this document upon my signature.

_____ _____

Subject's Signature (required) **Date (by Subject)**

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_____	_____
Print Subject's Name (required)	**Subject's Full Social Security #**

_____	_____
Signature of Person Obtaining Consent (required)	**Date (by Person Obtaining Consent)**

_____
Print Person Obtaining Consent's Name (required)