TO CONDUCT THE POINT-OF-CARE RESEARCH QUESTIONNAIRE
OMB FORM 2900-XXXX
VA Form 10-10069

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 funded by the VA office of research and development (ORD) in order to develop and implement a new research protocol in the VA. The information from the project is related to the December 21, 2010 VA Strategic Plan Refresh 2011 – 2015 which sets forth 16 major transformation initiatives that "serve as a platform to transform the VA into a 21st century organization that is people-centric, results driven, and forward looking. Success in each of every one of the major initiatives is ambitious, balance, relentlessly client-focused, and requires collaboration from parts of the Department." Initiative #16 addresses Point-of-Care Research.

#16 Perform Research and Development to Enhance the Long-term Health and Well-being of Veterans

Health care today is both an art and a science. Much innovation is needed to consistently deliver the right care, at the right place, at the right time. Embedding research within a large-scale, integrated health care system with a longitudinal electronic health record creates a national laboratory for the discovery of health care innovations. Because clinical care and research occur together under one roof, VA brings scientific discovery from the patient's bedside to the laboratory and back, making this program one of VA's most effective tools for improving the care of Veterans. VA will play a leading role in the advancement of clinical medical knowledge, particularly in those health issues associated with military service, by excelling in research and development of evidence-based clinical care and delivery system improvements to enhance the long-term health and well-being of Veterans.

Additionally, Charlene Weir, PhD of the Salt Lake City VA Salt Lake Informatics, Decision Enhancement, and Surveillance Center applied for and received an investigator-initiated VA Clinical Science Research and Development (CSR&D) Award 1I01CX000691-01. The purpose of the grant is to evaluate patient and provider attitudes and willingness to participate in Point-of-Care Research (POC-R). Although clinical trials are the medical standard for evidence-based practice, their expense difficulties recruiting providers and patients, and concerns about applicability for general practice make such trials of less than ideal practical significance. Observation studies are highly practical but are problematic methodologically as the lack of randomization results in limitations of possible conclusions.

Point-of-care research (POC-R) is an intermediary approach to bridge the gap between clinical trials and observation studies. POC-R is being considered as a serious alternative by the larger health science community in NIH and across the nation. The POC-R technique permits potential subject identification, criteria for enrollment, and follow-up via electronic medical records eliminating the need for resources to support dedicated clinical trial staff thereby reducing randomized trial costs significantly. The POC-R provides a potential mechanism for improving the breadth and significance of clinical research programs in VA. To maximize the utility of POC-R and to facilitate effective implementation throughout the VA, it is important to understand the concerns patients might have regarding POC-R policies.

The objectives of this study are twofold: 1) Identify the barriers and facilitators to adoption of a Point-of-care research innovative program by assessing the perceptions and attitudes of patients; and 2) Produce guidelines for VHA regarding implementation of POC-R. We will use a questionnaire.

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.

The information collected through the veteran patient questionnaire will be used by the overarching scientific community and by the VA ORD program office.

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.

Recruitment strategies are limited due to the delay in beginning the project. All participants will be recruited via email, mail, and phone calls (please see supplementary attached IRB protocol). If they don't respond in 2 weeks, a copy of the questionnaire plus a reminder will be mailed according to the procedure outline in Section B Question 4 of this document. The questionnaire will take about 15 minutes. Promoting technology we will use the social media site Facebook to recruit participants.

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 information being collected is currently not available in any form. The questions being asked are about a new kind of research protocol.

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

No small businesses or other small entities are impacted by the information collection.

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.

If the collection of the information is not conducted the VA would not have the information required to implement the program, VA Strategic Plan Refresh 2011 – 2015 #16.

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 questionnaire 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 no such special circumstances.

8a. 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 February 7, 2013 (Volume 78, Number 26, Page 9108-9109). We received no comments in response to this notice.

8b. 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 has been made with representatives from the Boston VA Medical Center who piloted the Point-of-Care Research method and faculty at the University of Utah. Once the questionnaire is implemented no additional consultation will be necessary.

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

No payment or gift is provided to respondents.

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.

The University of Utah and VA Institutional Review Board, that has the salutatory authority to cover research projects for Human Subject Review, extensively reviewed this proposal. We have complied with their rules for confidentiality and privacy in that review. These include the security measures described in the attached IRB protocol for data collection and storage. Our institution has adopted those rules for privacy and confidentiality (including data security procedures). Our VA Privacy Officer reviews every IRB application as part of our local scientific review. In addition, we all have undergone extensive required training in that regard. The language “kept secret” was designed to meet a 6th grade reading level and was approved by our research office as being appropriate.

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 10-10069	No. of respondents	x No. of responses	Equals	x No. of minutes	Equals	÷ by 60=	Number of Hours
Point-of-Care Research	600	1	600	15	9000		150

Questionnaire							

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.

This request covers only one form.

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.

VA does not require any additional recordkeeping. The cost to the respondents for completing these forms is $13,800. ($23 per hour x 600 burden hours).

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

a. There is no capital, start-up, operation or maintenance costs.
b. Cost estimates are not expected to vary widely. The only cost is that for the time of the respondent.
c. There is no anticipated recordkeeping burden.

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.

The original funding for the project was $425,000 for a one-year study that included focus groups for providers and patients as well as a national survey for both of those groups.

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.

Because the outcomes of this study will be useful to the larger clinical research community the study results will be published, as well as reporting the POC-R implementation guidelines to the VA Clinical Science Research & Development Office. Analytical techniques for collection analysis are outlined in Section B of this document.

A literature review is currently being done as the basis for article publications. As the results are tabulated and analyzed articles will be prepared for the health care research community. Potential journals for publications are: Journal of Health Service Research and Policy, Clinical Trials, Journal of the American Medical Informatics Association, Journal of the American Medical Association, BMC Medical Research Methodology, Journal of Applied Psychology, American Journal of Evaluation, etc.

Our original time frame was for one year. The delay in this component of the project was due to delays in achieving OMB approval. If we receive OMB approval, we will begin data collection within a few weeks and expect to finish data collection within 3 months. Data analysis will take another month.

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 approval 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 from the topics in the Certification for the Paperwork Reduction Act Submissions and the Point-of-Care Research Questionnaire data collection complies with 5 CFR 1320.9.