JUSTIFICATION TEMPLATE

Interconnected Factors That influence Health, Experiences and Needs (IF-THEN) Study
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.

The purpose of the study, which is funded by the PACT Demonstration Lab Coordinating Center, is to conduct a survey of Veterans to capture novel predictors of hospital admission and identify clusters of complex patients based on survey- and claims-based covariates. This study provides the first empirical application of the Cycle of Complexity conceptual model that the study team developed and recently published, which postulates that patient complexity represents more than having multiple chronic conditions. It is critical to evaluate whether complexity defined on the basis of survey-based and claims-based covariates is more predictive than diagnosis of multiple chronic conditions based on claims data alone.

The proposed patient survey is designed to measure a broad range of self-reported patient factors that increase Veterans' risk for being admitted to hospital, including life stressors, perceived locus of control, grit, resilience, functional status, social support and loneliness, sleep problems, symptoms, food insecurity, and patient activation. This survey will help us understand, for the first time, the extent to which self-reported factors can markedly improve prediction of patient risk for hospital admission, which may help the PACT Demonstration Lab Coordinating Center Intelligence improve its risk prediction models. This project may also identify patient-reported outcomes (PROs) that can be effectively integrated into routine VA clinical practice, as the VA begins to explore inclusion of PROs into the VA electronic health record. We are requesting approval to conduct this survey to a nationally representative sample of 10,000 patients who obtain primary care in VA because there are no extant VA surveys that capture the range of patient factors that we propose to collect, which are not available in VA administrative databases. If we did not capture these patient factors, our risk prediction analysis might be incorrect or biased.

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 (See Appendix A. [encl OABI Letter]).

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.

Information from this patient survey mailing will be utilized by the Durham VA HSR&D Principal Investigator (Dr. Maciejewski) and co-investigators under the auspices of the PACT Demonstration Lab Coordinating Center (PACT DLCC) to determine self-reported risk factors that improve prediction of hospital admission and identify clusters of complex patients based on survey- and claims-based covariates. The survey responses will be merged with VA claims data to evaluate demographic and comorbidity differences between survey respondents and non-respondents, which will be reported to PACT DLCC leadership. Then, the study team will develop a risk prediction model for the outcome of hospital admission to understand if inclusion of survey-based predictors can improve the predictive power of the model, with results reported to PACT DLCC leadership. Finally, the study team will conduct cluster analysis to determine if there are clinically coherent subgroups that can be identified among survey respondents, which will also be reported to PACT DLCC leadership.

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.

Improved information technology such as electronic submission of responses will not decrease the burden on the public. We wish to collect information from all interested Veterans in our sample, so limiting the response method to electronic means would exclude those patients without internet access.

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.

Prior to submitting this report, we evaluated several existing VA survey efforts but there is no extant prototype for this type of information on self-reported characteristics that increase Veterans' risk for being admitted to hospital, including life stressors, perceived locus of control, grit, resilience, functional status, social support and loneliness, sleep problems, symptoms, food insecurity, and patient activation.

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

Since these are applications for individual benefits, 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 data are not collected, the VA would not be maximally responsive to the needs of the patients at greatest medical risk. Further, failure to collect the proposed survey data would represent a breach of the Memorandum of Understanding that we have established with the PACT Demonstration Lab Coordinating Center.

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.

The proposed patient survey will only be conducted once, so there are no such special circumstances associated with this survey.

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: 1/26/2017 Vol. 82, No. 8563 / Pages 8563-8364. One comment was received.

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.

After consulting with the PACT Demonstration Lab Coordinating Center to confirm that they did not know of available data that captures the key patient-reported factors that we seek to obtain, we conducted extensive literature research. No existing prototype for this type of information was found in government and public agencies. 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.

Consistent with mail survey methodology that attempts to maximum response rates, we will be including a sheet of 4 Forever stamps worth approximately $2 in the initial survey mailing. There will be no other payment or gifts 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.

We will comply with the provisions of 38 U.S. C5701 and the Privacy Act of 1974. All reasonable efforts will be made to protect participants against the risk of loss of privacy and confidentiality and to minimize this risk. In our recruitment letter, we assure patients that their survey responses will not be stored in their medical records or disclosed to their physician(s). Only those involved in survey data collection and analysis will have access to survey data linked to individual medical outcomes. Study data will be kept in accordance with the Department of Veterans Affairs Record Control Schedule 10-1 (RCS 10-1).

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-XXXXX	No. of respondents	x No. of responses	x No. of minutes	÷ by 60 =	Number of Hours
Application/Survey	5000	1 = 5000	30 = 150,000		2500

It is estimated that the mailed patient survey will take 30 minutes for respondents to respond to the survey. A total not to exceed 10,000 surveys will be mailed out with an expected 50% to be returned (5,000). The number of respondents = 5,000 x 30 minutes to respond to survey = 150,000 burden minutes, divided by 60 minutes = 2500 hours.

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. VHA estimates the total cost to all respondents to be $35,475 (2,500 burden hours x $14.19 per hour).

May 2015 National Occupational Employment and Wage Estimates United States:
http://www.bls.gov/oes/current/oes_nat.htm

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. A total of $140,000 in costs will be required for a non-VA survey vendor to develop the survey template and data entry form for the proposed patient survey and to conduct the mailed survey and complete data entry on returned surveys. These costs are covered by funds provided by the PACT Demonstration Lab Coordinating Center.
b. Cost estimates are not expected to vary widely. The only cost is that for the time of the respondent.
c. There is minimal 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.

These annual costs for operation expenses and salary expenses are covered by funds provided by the PACT Demonstration Lab Coordinating Center.

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.

We intend to publish the results of this patient survey, consistent with the aims of the funded study and our Memorandum of Understanding with the PACT Demonstration Lab Coordinating Center. All results will be reported in aggregate form, so no patients will be individually identifiable. If OMB approval is obtained by December 2016, we intend to have a non-VA survey vendor under contract with the VA HSR&D project team to begin collection of the mailed patient survey by February 2017. We expect the vendor to complete data collection by June 2017. We will conduct data cleaning and analysis in July-September 2017. We intend to submit a manuscript reporting aggregate survey data in September-December 2017.

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 seeks to minimize the cost to itself of collecting, processing and using the information by not displaying the expiration date. VA seeks an exemption that waives the displaying of the expiration date on this VA Form. If VA is required to display an expiration date, it would result in unnecessary waste of existing stock of the forms.

Inclusion of the expiration date would place an unnecessary burden on the respondent (since they would find it necessary to obtain a newer version, while VA would have accepted the old one).

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.