VISN 6 PILOT STUDY

OPERATION ENDURING FREEDOM/OPERATION IRAQI FREEDOM VETERANS HEALTH AND NEEDS ASSESSMENT OMB FORM 2900-XXXX VA FORM 10-21091

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 Department of Veterans Affairs (VA) Mid-Atlantic Region's Mental Illness Research, Education and Clinical Center (MIRECC) was funded by Veterans Health Administration (VHA) as a translational research center for post deployment mental health in FY 2005. The work of the MIRECC Clinical component is focused on identifying, refining and disseminating best practices for assisting returning war zone veterans and their families who are facing general readjustment issues and often clinical problems such as Post Traumatic Stress Disorder (PTSD) and Traumatic Brain Injury (TBI). Over 1.6 million Americans have been deployed at least once to Afghanistan (Operation Enduring Freedom-OEF) or Iraq (Operation Iraqi Freedom-OIF). Over 37% of OEF/OIF veterans eligible for VA services have enrolled, and additional funds have been appropriated by Congress to fund VA health care as mental health and multidisciplinary treatment teams have expanded to meet the needs of these newest veterans. However, the needs, concerns and health care preferences for VA services among this group of veterans have largely been inferred from medical records, without direct input from veterans. The proposed regional needs assessment survey will provide this important direct input, will help guide Veterans Integrated Service Network (VISN) VISN 6 program development and will pilot the survey instrument for a future national effort. 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. This needs assessment will also support compliance with the Department of Veterans Affairs Memorandum September 11, 2007 from the Deputy Under Secretary for Health for Operations and Management (10N), regarding “Access for Mental Health and the Use of Mental Health supplemental facilities funding” by addressing key issues such as preferred services, hours of operations and need for expansion or renovation of mental health treatment programs.

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 will be used to improve the quality and relevance of care offered as well as access to care through the removal of identified barriers to care and the development of care pathways as indicated by veterans' responses. Stakeholders with whom the information will be shared include VHA national and regional health care leadership, VA and Department of Defense (DoD) and State health care providers across veterans' continuum of care, health care quality improvement personnel, state of North Carolina National Guard and Reserves leadership and Family Assistance Programs, regional DoD Military Treatment Facilities, and researchers interested in Health Services or Clinical Interventions. Survey results will help optimize the use of new funding for VA program development. The methods proposed for this anonymous survey will help evaluate strategies for engaging this group of new veterans.

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.

The collection of information will be exclusively by written survey. Although alternate means of data collection were considered, our analysis indicates variable access to high speed internet could serve as a barrier to completing the survey electronically. Instead, we have chosen to ask survey respondents about their survey methods preferences to guide our future efforts. The survey itself is formatted for ease of self administration and will be printed in three colors. The survey is in electronically scan-able format for CS Optical Scan 4. The survey cover letter contains elements of informed consent, assurance of the anonymity of responses and contact information for both VA investigators and the survey research contract organization, Schulman, Ronca & Bucuvalas Inc. (SRBI).

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.

Our work has included analysis of the VHA Survey of Healthcare Experiences of Patients (SHEP), which is focused on patient satisfaction with the veterans' last outpatient clinical visit or hospitalization. The health behavior questions added to the SHEP in recent years have been useful in identifying perceived receipt of prevention efforts like influenza vaccination and advice to stop smoking, but many problems of high relevance to OEF/OIF veterans are not assessed by this measure, like PTSD and blast exposure. These issues are particularly important to the veteran population in VISN 6 which includes North Carolina, the 4th most military-personnel dense state in the nation. Further, no other survey has combined succinct, validated screening measures with assessment of barriers to care and patient preferences for delivery of both information and related health care. Finally, we propose to survey not just VA users, but a random sample of ALL VA-eligible OEF/OIF veterans in our region, in order to determine community perceptions and experiences with VA, as these are potentially our future "customers".

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

Data will be collected from individual VA-eligible veterans and surveys will be sent to their homes, so there will be no impact on small businesses.

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 survey is not conducted, the consequences include: (1) missed opportunities to inform VA healthcare decision-making and program development for this important new veteran patient group for which Congress has appropriated additional funding; (2) pilot data will not be available to inform future national research, including Health Services Research and Clinical Interventions that could be tailored to veterans' identified needs and preferences; (3) veterans will not have the opportunity to provide direct input as to their concerns and preferences for health information, VA and other health care; (4) without the secondary analysis of response rates (some will receive an advance letter to let them know the survey is coming), the effectiveness of this added step to engage the veteran will not be known, and (5) the VA will not have the perspective of the non-enrolled but VA-eligible veteran who may seek services in the

future, based upon the growing number of returning war zone veterans turning to the VA for health care. Further, MIRECC funds have been appropriated for this project and a contract and Business Associate Agreement (BAA) has been secured.

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 no such special circumstances.

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 September 11, 2008, Page 52901-52902. There were no comments received 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.

Within VAMC Durham and VISN 6 MIRECC channels, the proposed study has been approved by the VAMC Durham Institutional Review Board (IRB) and Research & Development (R&D) committees and a waiver of informed consent has been granted. The survey has subsequently been completed by several VA employees who are also Global War on Terror (GWOT) veterans to solicit their views, suggestions, and time estimates for completion (respondent burden). Some questions were changed based upon their feedback, and the overall review of the instrument and its cover letter were rated very positively by these representatives of the target population.

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

No payment or gift will be provided to respondents.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

We comply with the provisions of the Privacy Act of 1974 (5 U.S.C. 522A). Respondents are not requested to provide their name, social security number or any other distinguishing information which would personally identify them. Their survey responses are completely confidential and cannot be linked

to any individual. Although this strategy precludes calculating response bias, we have chosen to optimize the response rate by assuring full anonymity. We have obtained IRB approval for a waiver of informed consent so there will be no signed documents associated with participation.

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.

Questions about combat trauma, symptoms of PTSD, depression, alcohol use and TBI are of a sensitive nature. These questions are carefully worded within standardized measures that will allow us to estimate the prevalence of health and mental health risks in the VISN 6 catchment area. Because we are including eligible veterans who are not necessarily enrolled in VA, we will be able to estimate health risks among veterans not yet coming to VA. Because we will also be providing the investigators' contact information (psychologists), mental health support will be easily accessible should help be desired related to the survey questions or an unrelated issue.

12. Estimate of the hour burden of the collection of information: Total Burden=1000 hours

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

VA Form 10-21091	No. of respondents 3,000	x No. of responses one time--20 minutes max	/ by 60 60,000	Number of Hours 1,000

The initial random sample to be extracted includes 8,500 OEF/OIF veterans who will receive a survey and cover letter. An estimated 33% response rate based on prior OEF/OIF work done by the research contractors will yield 2,805 returns, rounded up to 3,000 for cost estimates. We estimate a 15-20 minute respondent burden for completion of the formatted eight-page survey booklet. Using the higher estimate, 3,000 respondents x 20 minutes yields a one time burden of 1,000 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.

We do not require any additional recordkeeping. The cost to the respondents for completing these forms is $15,000. ($15 per hour x 1,000 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 are no annual 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 cost of the single administration of this project to the Federal Government is listed in our contract and includes:

ESTIMATED TOTAL COST: $48,471.00

STAFF	Hourly Wage	Total Hours	Cost
Partner-in-charge	$128.29	40	$5,131.76
Senior Analyst/Moderator	$68.41	80	$5,472.46
Research Associate	$26.73	120	$3,207.69
Secretary	$22.99	200	$4,598.93
TOTAL STAFF COST			$18,410.84

OTHER DIRECT COST	Cost Per Item	Quantity	Actual Cost
NCOA address update	$65.00	1	$65.00
Printing			$8,100.00
Labels	$0.09	8500	$765.00
Envelopes - out	$0.25	8500	$2,125.00
Envelopes - return	$0.23	8500	$1,955.00
Cover letter	$0.09	8500	$765.00
Postage - out	$1.31	8500	$11,135.00
Postage - return	$1.10	3000	$3,300.00
Advance letter	$0.74	2500	$1,850.00
TOTAL OTHER DIRECT COST			$30,059.99
TOTAL COSTS			$48,470.83

15. Explain the reason for any burden hour changes since the last submission.

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 plan to create a report based upon tabulated responses and the de-identified data set to be obtained from our research contractors (SRBI) for circulation within the MIRECC and VISN 6 to inform health care decision-making. Standardized instruments will be scored according to recommended procedures for each screening and assessment measure within the survey, many of which are also associated with performance measures in VA clinical settings. The sample size will provide adequate cell sizes for comparisons of groups based upon age groups and VA enrollment status (VA healthcare service users vs. non-users). As for the timeline, when approved by OMB, the surveys will be printed within 6 weeks. The surveys will be mailed with a cover letter and a postage prepaid envelope for return of the completed survey. Two weeks after the initial mailing, a follow up letter will be mailed to thank the participant for returning the completed survey and to prompt a return of the survey if they have not yet done so. Data collection will end within four weeks of the final mailing, and then surveys will be scanned for data entry. Data will be cleaned and converted into a Statistical Package for the Social Sciences (SPSS) data file. Results will be presented to stakeholders (state/DoD/VA) in the form of presentations and other reports. Once approved, this pilot needs assessment project will be expedited to assure completion within five months of approval. Local IRB approvals have already been obtained. The survey research contract has been obtained. Dr. Han Kang and the Office of Environmental Epidemiology have been informed about this study, as his office will extract the sample from the Defense Manpower Data Center (DMDC) roster through a Data Use Agreement.

Results from this pilot study will be used to tailor a larger national needs assessment project in collaboration with VA Health Services Research and Development Service (HSR&D).

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

There is no reason to omit the display of an 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 requested.