Health Surveillance for a New Generation of U.S. Veterans

A. JUSTIFICATION

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

Legal authority for this data collection is found under Title 38, USC, Part V, Chapter 73, Subchapter I, Section 7303, which allows the Veterans Health Administration to carry out research in connection with the provision of medical care and treatment to veterans, and to stress research into illnesses and injuries, particularly related to service. This data collection will help the Department of Veterans Affairs (VA) assess the health of Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF) veterans and OIF/OEF-era veterans, and to plan and provide better health care for these 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.

A number of health studies, including the VA National Health Survey of Gulf War Era Veterans and Their Families (n=30,000), and the Longitudinal Health Study of Gulf War Era Veterans (n=30,000), have identified a constellation of symptoms and medical/psychological conditions associated with combat deployment and service. A periodic monitoring of the VA health care usage of returning OIF and OEF veterans has suggested significant health issues, especially mental health issues, among this new group of combat veterans. The survey of a population based sample of OIF/OEF veterans and a comparable group of non-deployed veterans will allow VA to collect information on their current health status and concerns, exposures of concern in the theater, health care preferences, and health behaviors and attitudes. More importantly, the proposed survey will help VA to gain knowledge on the veterans who have not used VA health care since they returned from the current conflict. Approximately 2/3 of OIF/OEF veterans have not used VA health care, despite intensive outreach efforts. Information from the survey will assist VA in planning and providing better health care for these veterans and to improve VA's understanding of the long-term consequences of military deployment.

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.

A combination of mail and online surveys and telephone interviewing will be used as the survey methods. In Phase I, a scannable, structured health questionnaire will be sent to each of the 60,000 veterans selected for the study. All participants, including those who

have received a paper questionnaire, will also have the option of answering the questionnaire online. Almost 75% of U.S. households were connected to the Internet in 2004 and the percentage may be higher when the survey is implemented in 2008. A comparison of survey data collection using the Web (n=42,127) in concert with a postal mailed questionnaire (n=34,833) demonstrated more complete data and marked cost savings at a minimal risk of enrolling a non-representative group. The online survey will include electronic consent as part of the Web site log-on process. This will allow for easy documentation of consent and mitigate the need for subsequent participant contact, as is necessary when a consent form is missing from a paper survey response. Furthermore electronic skip patterns will automatically skip irrelevant or non-applicable questions, which will reduce the respondent's burden hours. The Web site will be built with a firewall and will be password-protected to ensure patient confidentiality.

In Phase II, to obtain additional survey responses, to assess non-response bias, and to obtain permission for medical records retrieval, telephone interviews using a computer-assisted telephone interviewing (CATI) software package will be attempted on 2,000 non-respondents to the mail survey. VA understands that many veterans will be in households that rely solely on cell phones, which will make telephone interviews impossible for some portion of VA's population. The telephone interviews will be limited to veterans in households with landlines. This is one reason why VA is relying on mail survey/online survey as the primary means of data collection. VA may be able to use telephone data available from VA records; however, the group that uses VA healthcare may not necessarily be representative of all veterans. On the questionnaires, veterans will be asked whether they use only cell phones, use only landlines, or use both so VA can weigh the telephone responses appropriately.

In addition, 1,000 veterans who responded to the mail survey will be contacted for medical records retrieval.

Use of both the Web-based questionnaire and the CATI software are expected to reduce public burden by built-in skip patterns in the software.

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.

VA is not aware of any other large-scale, longitudinal, population-based studies on a wide range of health concerns for OIF and OEF veterans, which is generalizable to all OIF/OEF veterans. Almost two-thirds of recent combat veterans have not used VA healthcare since they were separated from active duty. VA needs to know why they did not use VA care despite the two years of free healthcare eligibility, and the type of health concerns and problems among the non-users.

For example, the 21-year Millennium Cohort Study does not focus on the specific health concerns of OIF/OEF veterans. In addition, the Post-Deployment Health Reassessments are conducted 90 to 180 days following return from deployment, whereas VA's

longitudinal study will follow people for longer periods of time. Other surveys conducted of military personnel or veterans (such as the 2005 Department of Defense Survey of Health Related Behavior among Military Personnel) focus on particular areas of interest, such as risky behavior or satisfaction with VA services. VA's longitudinal survey will be able to track changes in health status over time and also provide valuable information on effects of combat deployment on health.

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 will be 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.

This study is unique and necessary because it will provide a comprehensive understanding of the experiences and health care needs OIF/OEF and OIF/OEF-era veterans. This study reaches out to a vast number and geographic range of participants; captures veterans' health experiences over a significantly long time frame; has a broad scope of inquiry; and explores the needs of both VA and non-VA users. It will provide a considerable amount of invaluable information on the health issues of concern to returning veterans, including post-traumatic stress disorder, traumatic brain injury, attitudes about and use of VA healthcare services, environmental exposures in theater, and suicidal ideation. The findings obtained from this study will help VA to best understand recent veterans, so that it can effectively allocate health care resources and maximize the quality of care it offers. If this research is not conducted or if data collection is conducted less frequently, the VA will lack this valuable information.

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 March 17, 2008 (Volume 73, Number 52, Page 14307). 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 three faculty members of The George Washington University and a private survey research firm to obtain their views. The professionals that are consulted include:

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2. Samuel J. Simmens, Ph.D.
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3. Heather Young, Ph.D.
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4. John Boyle, Ph.D.
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9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

If response rates are lower than desired, VA may consider offering a small incentive or enhancement to the mail package to increase participation. Possible options include:

a. Mailing a five dollar check as an incentive for potential participants who do not respond to the first mailing. According to Dillman (John Wiley &Sons, Inc. 2007), financial incentives can increase response rates significantly. Regulations may require mailing a check rather than sending cash. Dillman reports that offering a check has been proven as effective as offering an equivalent cash incentive for amounts of five dollars or more.

b. Mailing a material incentive such as a book of stamps or a pedometer that includes the study name, logo, and phone number. According to Dillman, material incentives also improve response rates. However, financial incentives have proven to be more effective in improving response rates, so VA will consider that option first.

c. Delivering the second follow-up survey via Fed Ex. Researchers found this effective in improving the response rate when conducting the 2005 Longitudinal Health Study of Persian Gulf War Veterans. They mailed random samples of survey packages by three methods: FedEx, United States Postal Service (USPS) certified mail, and USPS regular mail. Response rates were significantly superior ($p<0.05$) for the sample delivered by FedEx compared to the other two methods. In addition, this is a cost-effective way to get the attention of veterans. The cost to the government per FedEx package is much less expensive than the cost to the consumer for the same FedEx package.

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

a. VA plans to tell respondents that their answers will be kept confidential and that their personal identifiers will be stripped from electronic data sets after necessary data set linkages have been done. Respondents also will be told that no individual findings will be presented; only group analyses will be published or presented at meetings.
b. Confidentiality of all records pertaining to individuals in the study will be carefully protected. Names of individuals will be used solely for purposes of locating persons, to determine their military service status, for interviewing them,

for monitoring VA and DOD healthcare utilization, and to locate medical records. Personal identifiers will not be retained on any data record used for analysis, nor will they be included in any publication or other presentation of results. Records with personal identifiers will be under the control of VA officials or their agents.

c. The records will be maintained in VA offices or those of contractors. Access to VA working space and records storage areas will be restricted to VA employees or authorized agents on a "need to know" basis. The file areas are locked after normal business hours. Strict control measures will be enforced to ensure that disclosure is limited to a "need to know" basis.
d. Information on the form 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 (34VA12)" 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.

Some of the data to be collected for the study is considered private and sensitive. Questions that address issues such as personal health problems, military sexual trauma, substance abuse, sexually transmitted diseases, and pregnancy outcomes may be asked. These sensitive questions will be asked because the answers to them may help the VA plan for and provide the mental and physical health services that OIF/OEF and other veterans need. Answers to some questions may also help researchers determine a relationship between service in Iraq or Afghanistan and health outcomes. Questions 57, 58, and 59 are identical or slightly altered versions of questions that can be found within the optional sexual behavior module of the Behavioral Risk Factor Surveillance System (BRFSS). This national survey, begun in 1984 by the Centers for Disease Control and Prevention, is a state-based system of health surveys that collects information on health risks and preventive health practices. Each year, more than 350,000 adults are interviewed by telephone. Question 56 has been asked in the core HIV/AIDS portion of the BRFSS for well over a decade. It has been approved and used for many years to determine the prevalence of voluntary HIV testing in the U.S. This is an important question to address among U.S. veterans who, if they are engaging in high risk sexual behavior, should be tested for HIV on a regular basis.

Only individuals who consent to participation in the research will be asked these questions. They will be told that they can choose not to answer any questions or stop participation for any reason. The purpose of the survey will be explained in the informed consent procedures (either written or oral).

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:

	Total possible	Number of respondents expected	Frequency of responses	Annual hour burden
Respondents to survey (mail, online)	60,000	36,000	1	40 minutes/person 24,000 hours total
Medical records follow-up for respondents	1,000	700	1	5 minutes/person 58.3 hours total
Non-respondents telephone interview	2,000	1,600	1	30 minutes/person 800 hours total
Total contacted (mail, online, telephone)	63,000	38,300	1	24,858 hours total

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 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.

The total cost to each individual respondent varies:

	Individual cost ($15/hour)	Group cost
Respondents to survey (mail, online)	$15.00	$540,000
Medical records follow-up for respondents	$1.25	$875
Non-respondents telephone interview	$7.50	$12,000

The cost of all expected responses is $552,875.

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).

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.

Based upon VA's Environmental Epidemiology Service Longitudinal Health Study of Gulf War Veterans and allowing for inflation, this similar health study of 60,000 veterans returning from OIF and OEF is projected to cost $1,221,000. The earlier study initially involved data collection for 30,000 veterans via mail and telephone, with medical record validation.—

Phase I	
Task	Cost
Locate Study Participants	$28,000
Design, Print, and Manufacture Forms, Personalized Letters, Postcards and Envelopes	$250,000
Design and Deploy SQL Database	$36,000
Design and Maintain Web-based electronic survey	$50,000
Design and Deploy Contractor Data Interface	$2,000
Assemble, Address, and Mail Questionnaires and Postcards	$328,000
Data Entry of Completed Questionnaire	$70,000
Phase I Total	$764,000

Phase II	
Task	Cost
Prepare Veteran Contact Information	$3,000
Prepare CATI Questionnaire	$14,000
Design and Deploy Data Interface	$3,000
Conducting CATI interviews	$300,000
Obtain medical records	$100,000
Incoming toll calls + monthly fee for toll line and telephone call staffing	$10,000
Phase II Total	$430,000

Study Management and Publications	
Task	Cost
Meetings and travel (Steering Committee)	$15,000
Prepare final report and peer review	$12,000
Final Total	$1,221,000

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.

The basic study design is a longitudinal study, with this study being the first wave of data collection. Additional cycles of data collection will be proposed in the future. During Phase I (19 months), a mail and Web-based survey of 60,000 veterans will be designed, developed, and conducted. In Phase II (26 months), a telephone survey of non-respondent veterans and medical records retrieval will take place. Through the telephone survey, researchers will attempt to contact 2,000 non-respondents to the mail survey and 1,000 veterans who responded to the mail survey, and obtain copies of certain medical records.

As data are entered, preliminary analyses will be conducted to identify and correct any systematic errors in data collection. Participation rates will be monitored to determine whether small incentives are needed to increase participation. See section below for description of planned statistical analyses. The results of the study will be submitted to a scientific journal for publication to ensure wide dissemination of the findings. As appropriate, publications and presentations aimed at VA health care providers and veterans will be prepared.

1. Phase I (Postal Survey) – 19 months

    - Months 1-9: Finalize lists of eligible veterans; determine vital status; finalize data collection instruments (mail survey, online survey, telephone questionnaire); submit IRB and OMB documents for review; finalize informed consent documents; obtain approval from IRB and OMB; select contractor; conduct OpScan programming, printing, and updating of mailing addresses.

- Months 10-13: Complete initial mailing (notification letter) and four follow-up mailings (questionnaire package; postcard reminder; 2nd questionnaire package; 3rd questionnaire package).

- Months 10-16: Scan in and edit questionnaire data from mail and online surveys; quality assurance checks.

- Months 17-18: Complete final databases from mail and online surveys.

- Months 16-19: Send notification letters to veterans who screen positive for health conditions but do not report receiving current treatment (letters encouraging them to seek care and how to get access to VA care).

2. Phase II (Telephone survey and validation of self-reported data) – 26 months, including overlap with Phase I

- Month 1-12: Finalize methods for Computer Assisted Telephone Interview (CATI) questionnaire survey; obtain telephone numbers.

- Months 11-16: Select a sample of 1,000 respondents for validation of self-reported medical conditions and request permission for access to non-VA medical records.

- Months 16-20: Identify a sample of 2,000 non-respondents to the mail survey and update their telephone numbers. Conduct telephone interviews with non-respondents to the mail survey who can be located and who give consent for participation.

- Months 20-26: Review medical records (VA and non-VA), review, abstract and code relevant medical data.

3. Phase III (passive surveillance, preparation of analysis file, data analysis, report writing)

- Months 12-30: Obtain causes of death from the National Death Index, National Center for Health Statistics, inpatient & outpatient data from VA and DOD, VA's disability compensation data, and edit data and conduct data analysis.

- Months 25-36: Draft report on results of surveys for peer-review.

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 an exemption that waives the display of the expiration date. Given sufficient funding, the study will be repeated at least two more times over a period of ten years. The same questionnaire and materials will be used throughout the study period. The process of updating the expiration date periodically would be time consuming and costly (increased printing costs, for example).

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.

B. Employing Statistical Methods

This collection of information does not employ statistical methods.