National Health Study for a New Generation of U.S. Veterans
OMB 2900-0722
(VA Form 10-0523)

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 Enduring Freedom (OEF) and Operation Iraqi Freedom (OIF) Veterans and OEF/OIF-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 OEF and OIF Veterans has suggested significant health issues, especially mental health issues, among this new group of combat Veterans. Scientific literature and the media are reporting a variety of potential health issues among Veterans of conflicts in Afghanistan and Iraq. The conduct of a follow-up survey of a population-based sample of OEF/OIF Veterans and a comparable group of non-deployed Veterans will allow VA to collect longitudinal 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 50% of eligible OEF/OIF/OND (Operation New Dawn) Veterans had not utilized VA health care as of the end of FY 2010.

This will be the second effort to obtain a health survey from a fixed panel of participants as a part of a longitudinal study with a proposed ten year follow-up period. Data from the first effort is currently being analyzed and publications are forthcoming. Administration of additional surveys over time will help VA learn more about the health of recent Veterans, assist in planning and providing better health care for these Veterans, and will 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. All participants will have the option of answering the questionnaire online through use of a secure Web-based form that will be described in the introductory letter. A scannable paper questionnaire will be sent to each of the

Veterans selected for the study who do not access the online survey at the first invitation. All Veterans who receive a survey packet with the printed data collection form will be given another opportunity to complete the data collection online. According to the U.S. Department of Commerce, National Telecommunications and Information Administration, by October 2010, 71.1% of Americans used the Internet at home. Our experience with an online form during the initial data collection with this population was that almost 50% responded to the survey online (49.7% were submitted online, 43,9% were submitted as paper surveys, and 6.4% were obtained through a computer-assisted telephone interview, or CATI). The online survey will include an electronic consent as a prerequisite to completing the survey. This will allow for easy documentation of consent. 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.

To obtain additional survey responses, telephone interviews using a CATI software package will be attempted on non-respondents to the mail/online survey. Use of the CATI software is expected to reduce respondent burden through the use of automated skip patterns programmed into the software. A CATI will also be used to assess non-response bias and to obtain permission for medical records retrieval from approximately 2,000 Veterans who responded to the mail survey. VA understands that many Veterans will be in households that rely solely on cell phones, which may make completing telephone interviews more challenging for some portion of the study population. Some contact tracing methodologies may be able to identify cell phone numbers when they are available. The telephone interviews will predominantly be conducted with Veterans in households with landlines. This is one reason why VA is relying on mail/online surveys as the primary means of data collection.

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 study on a wide range of health concerns for OEF and OIF Veterans, which is generalizable to all OEF/OIF Veterans. At the end of FY2010, 50 percent of eligible OEF/OIF/OND Veterans had not utilized VA health care. VA needs to learn about the health status of those who do not use VA healthcare and attempt to ascertain why these Veterans do not use VA care despite the available benefit of five years of free healthcare.

For example, the 21-year Millennium Cohort Study does not focus on the specific health concerns of OEF/OIF Veterans. In addition, Post-Deployment Health Reassessments are conducted 90 to 180 days following return from deployment, whereas VA's longitudinal study will follow people for a longer period 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 provide valuable information on the 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 OEF/OIF and OEF/OIF-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 better 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 October 12, 2011, pages 63352-63353. 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 one employee on an Intergovernmental Personnel Act (IPA) agreement with VA, one faculty member of The George Washington University, an executive at a private survey research firm to obtain their views. The following professionals are consulted:

1. David Goldsmith, Ph.D.
   IPA Epidemiologist
   Epidemiology Program
   Office of Public Health
   Department of Veterans Affairs
   Washington, D.C. 20420
   Tel: (202)266-4695

2. Heather Young, Ph.D.

Associate Professor of Epidemiology and Biostatistics
Department of Epidemiology & Biostatistics
George Washington University
Ross Hall, Room 120A
2300 Eye Street, NW
Tel: (202) 994-6518

3. John Boyle, Ph.D.
abt SRBI
8403 Colesville Rd, Suite 820
Silver Spring, MD 20910
Tel: (301) 608-3883

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

As a part of the initial Office of Management and Budget (OMB) approval, VA was encouraged to test the effectiveness of a small monetary incentive to obtain higher response rates. In our pilot of this study, we evaluated the impact of a $5 incentive check on response rates. The pilot study sample included 3,000 Veterans (1,500 OEF/OIF Veterans and 1,500 OEF/OIF-era Veterans) who were randomly selected and assigned to one of three incentive groups: 1) a pre-paid group that received a $5 check with the survey packet; 2) a group that was promised postal delivery of a $5 check after returning the completed survey; and 3) a group that received no incentive check. There were increased response rates among both the pre-paid and promised incentive groups compared to the group that received no incentive, with the highest response rate among the pre-paid group. The response rates were 25.2% for the pre-paid group, 22.3% for the promised group, and 16.9% for the no incentive group. Based on the results of the pilot, we decided to mail a $10 check with each initial survey packet of the main study to maximize response rates. We also decided to give a $10 incentive for those that completed the CATI survey. Our findings about incentives can be found in the following publication:

Coughlin S, Aliaga P, Barth S, Eber S, Maillard J, Mahan C, Kang H, Schneiderman A, DeBakey S, Vanderwolf P, Williams M. The effectiveness of a monetary incentive on response rates in a survey of recent U.S. veterans. Survey Practice 2011.

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

a. VA informs 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 are 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 continue to 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 continue to 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, tobacco and alcohol use, sexually transmitted diseases, and pregnancy outcomes will 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 OEF/OIF 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 54, 55a, and 55b are 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 12 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) 10-0523	60,000	22,000	1 x 40 min.	14,667 hours
Medical records follow-up for respondents	2,000	600	1 x 5 min.	50 hours
Non-respondents telephone interview	38,000	1,500	1 x 30 min.	750 hours
Total Estimate				**15,467 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	$330,000
Medical records follow-up for respondents	$1.25	$750
Non-respondents telephone interview	$7.50	$11,250

The cost of all expected responses is $342,000.

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 the first phase of this study, we estimate the following costs:—

Phase I	
Task	Cost
Locate Study Participants	$150,000
Design, Print, and Manufacture Forms, Personalized Letters, Postcards and Envelopes	$330,000
Design and Deploy SQL Database	$100,000
Design and Maintain Web-based electronic survey	$165,000
Cost of Financial Incentive Payments	$400,000

Design and Deploy Contractor Data Interface	$5,000
Assemble, Address, and Mail Questionnaires and Postcards	$475,000
Data Entry of Completed Questionnaire	$75,000
Phase I Total	$1,700,000

Phase II	
Task	Cost
Prepare Veteran Contact Information	$3,000
Prepare CATI Questionnaire	$25,000
Design and Deploy Data Interface	$5,000
Conducting CATI interviews	$400,000
CATI incentive payments to participants	$15,000
Obtain medical records	$100,000
Incoming toll calls + monthly fee for toll line and telephone call staffing	$10,000
Phase II Total	$558,000

Study Management and Publications	
Task	Cost
Meetings and travel (Steering Committee)	$15,000
Prepare final report and peer review	$12,000
Final Total	$2,285,000

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

There are changes to the number of respondents expected based on our experience with the initial data collection. The initial estimation was much higher than results.

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 second 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 edited, designed, developed, and conducted. In Phase II (26 months), a telephone survey of non-respondent Veterans and medical records retrieval from respondents will take place. Researchers will attempt to contact all non-respondents to the mail and web survey. A sample of 2,000 Veterans who responded to the mail and web survey will be contacted to obtain copies of 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 additional small

incentives are needed to increase participation. See section below for description of planned statistical analyses. Results from the study will be submitted to scientific journals 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; prepare online and scanning data bases and programming, printing, and updating of mailing addresses.

    - Months 10-13: Complete initial mailing (notification letter), reminder letter, and up to six follow-up mailings (questionnaire package; postcard thank you/reminder; 2nd questionnaire package; postcard thank you/reminder; 3rd questionnaire package; postcard thank you/reminder).

    - Months 10-16: Scan in and edit questionnaire data from mail and merge with online survey data; perform quality assurance checks.

    - Months 17-19: Complete final databases from mail and online surveys.

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

    - Month 1-12: Finalize methods for CATI questionnaire survey; obtain telephone numbers.

    - Months 11-16: Select a sample of 2,000 respondents for validation of self-reported medical conditions and request permission for access to non-VA medical records.

    - Months 16-20: Identify all non-respondents to the mail survey and update their telephone numbers. Conduct telephone interviews with non-respondents to the mail and web survey who can be located and who give consent for CATI 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 does not request an exemption at this time.

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.