Follow-Up Study of a National Cohort of Gulf War and Gulf Era Veterans

VA Form 10-0488
VA Form 10-0488a Consent Form for Release of Medical Records
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.

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 data collection will help the VA assess the health of Veterans who served during the 1990-1991 Gulf War 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.

The *VA National Health Survey of Gulf War Era Veterans and Their Families* previously approved under OMB 2900-0558 and the *Longitudinal Health Study of Gulf War Era Veterans*, previously approved under OMB 2900-0637, have identified a constellation of symptoms and medical/psychological conditions associated with Gulf War combat deployment and service. VA research studies showed that Veterans of the 1990-1991 Gulf War were potentially exposed to a variety of environmental factors potentially linked to chronic conditions including Chronic Fatigue Syndrome and unexplained multi-symptom illnesses. The planned study will involve surviving members of a panel of 15,000 Gulf War Veterans and 15,000 Gulf Era Veterans; 1,135 were deceased as of February 9, 2012. By conducting a follow-up study of Gulf War Veterans and non-deployed Veterans who served during the same era, VA will be able to improve our understanding of the long-term consequences of military deployment. This research, which will occur a year after the 20th anniversary of the first Gulf War, is essential for the VA to plan and provide better health care for these Veterans and to develop an improved understanding of the natural history of chronic conditions such as Chronic Fatigue Syndrome and unexplained multi-symptom illnesses.

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 paper and Web-based forms will be used in this survey. In Phase I, a scannable, structured health questionnaire will be sent to each of the 28,865 Veterans selected for the study. Of these Veterans, the estimated response rate is 50-60% Phase I (plus an additional 10 percentage points following Phase II CATI interviews). All participants, including those who have received a paper questionnaire, will also have the option of participating through use of a Web-based questionnaire. A comparison of survey data collection using the Web in concert with a postal mailed questionnaire demonstrated more complete data and marked cost savings. The online survey will include

electronic informed 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 pages are inadvertently skipped in a paper survey response. Furthermore, electronic skip patterns will automatically skip irrelevant or non-applicable questions, which will reduce the respondent's burden in terms of time. The Web site will be equipped with a firewall and will be password-protected to ensure participant confidentiality. In Phase II, the projected 700 out of 1,000 Veterans who responded to the mail or online survey will be contacted for medical records retrieval. The records will be retrieved by mailing a letter to the selected Veterans who report a visit or hospitalization for a health condition or illness. The letters will be accompanied by a consent form 10-0488a for release of medical records, which was developed for this study and reviewed and approved by the IRB. Also in Phase II, members of the panel who did not respond to the invitations to participate in the survey by submitting a web-based survey or completing a paper questionnaire will be contacted by telephone to better understand reasons for nonresponse and to invite them to participate in a CATI telephone interview. The addition of CATI telephone interviews is likely to increase the response rate by an additional 10 percentage points for an overall estimated response rate of about 60-70%.

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.

VHA is not aware of any other large-scale, longitudinal, population-based studies on a wide range of health concerns for U.S. Veterans of the first Gulf War, which provide data that are generalizable to all U.S. Gulf War Veterans. VA needs to know why Gulf War Veterans have not used VA care, and the types of chronic health conditions and problems among both users and non-users. Other surveys of Veterans (for example, the Health Surveillance of a New Generation of Veterans, OMB 2900-0722 conducted by VA and the Millennium Cohort Study conducted by the Department of Defense, OMB Approval Number 0720-0029, http://www.millenniumcohort.org/), have focused on recent Veterans who served in Operations Iraqi Freedom and Enduring Freedom, rather than Veterans of the first Gulf War. The planned follow up study will examine changes in health status over time, by comparison of results. with those of previous VA surveys of the same sample conducted under 2900-0637.

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.

VA would not be responsive to the needs of Veterans of the first Gulf War if information were collected less frequently. The planned follow-up study is a necessary part of VA's efforts to address the health concerns and problems of Gulf War Veterans. When combined with findings from earlier survey's conducted for 2900-0558 and 2900-0637, the information obtained from this survey will provide a comprehensive understanding of the experiences and health concerns of Gulf War Veterans over the 20 year period since the war. This study reaches out to a large national sample of participants, examines Veterans' chronic health problems and concerns more than 20 years after deployment, and addresses the concerns of both VA users and non-users. The findings obtained from this study will help VA to better understand the current health concerns of Gulf War Veterans as well as chronic health concerns that persist long after deployment or which occur only after an extended period of time has elapsed.

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 7, 2010 (Volume 75, Number 172, Pages 54445-54446). VHA received the following comments in response to the Federal Register Notice.

Public Comments Received, VA-2010-VACO-0001-0126:

Name: William Joel Meggs
Address: Brody School of Medicine at East Carolina University

The Environmental Epidemiology Service (EES), Office of Public Health and Environmental Hazards, offers the following responses to the public comments offered by Dr. William Joel Meggs of Brody School of Medicine at East Carolina University regarding the planned "Follow-Up Study of a National Cohort of Gulf War and Gulf War Era Veterans." Dr. Meggs is a member of the Research Advisory Committee on Gulf War Veterans' Illnesses. The Committee as a whole also provided comments which are dealt with in a separate response. The public comments were provided as part of the Office of Management and Budget (OMB) 30 day public comment period, in response to an announcement of the proposed study published by the Department of Veterans Affairs (VA) in the *Federal Register*.

First comment from Dr. Meggs: ***"Medical history should contain all diagnosed medical conditions."***

VA response: The EES is grateful to Dr. Meggs for taking the time to provide comments. We agree with this recommendation and plan to add an "other" category to question 8c. and 8d.

Second comment: ***"Surgical history should include all surgeries."***

VA response: Questions are included in the questionnaire about clinic or doctor visits in the past 12 months (questions 5a. and 5b.) and hospitalizations in the past 12 months (questions 6a. and 6b.). It is not practical to ask the respondents to report information about all surgeries following the Gulf War since some respondents may have been hospitalized or treated in outpatient clinics numerous times over the 20-year time period. Recall bias is a further consideration. However, self-reported information about hospitalizations will now be available from three time periods (1995-1997, 2003-2005, and 2011-2012) and additional review of VA medical records databases, which include surgical procedures, is ongoing.

Third comment: ***"Section 38 asks about alternative treatments. Veterans should rate whether or***

not the treatments helped. There should be an "other" section for veterans to report treatments not listed. The question 38g asks about high dose megavitamin therapies. Also ask about regular dose supplements-fish oil, antioxidants, etc."

VA response. Surviving members of the panel of 30,000 Gulf War and Gulf Era Veterans who will be contacted as part of the planned survey were initially contacted as part of EES longitudinal studies in 1995-1997 (the National Health Survey of Persian Gulf Era Veterans), and many were resurveyed 10 years later in 2003-2005 (the Longitudinal Health Study of Persian Gulf War Era Veterans). The survey data collected in 2003-2005 did include questions about medications, treatments, nutritional supplements, or other therapies the respondents may have taken and whether the treatments or supplements helped their unexplained illness symptoms. Those data are currently being analyzed under a separate IRB-approved protocol. In the current survey, we chose to include somewhat different questions which have previously been used in a national survey of more recent Veterans from Operation Enduring Freedom and Operation Iraqi Freedom.

Fourth comment: ***"There should be a section to list any conventional therapies and whether or not they were helpful."***

VA response: As noted above, EES investigators collected such data as part of the 2003-2005 survey. Those data will be analyzed and submitted for publication in a peer-reviewed journal.

Fifth comment: ***"Since many ill Gulf War veterans report intolerances to foods, alcohol, chemical fumes, there should be questions about exposures that make symptoms worse. In section 38, a question should ask about avoidance of fumes or other substances and special diets as alternative therapies."***

VA response: We appreciate Dr. Meggs suggestions and think his idea is worthwhile to consider. However, in any given survey questionnaire, there is a limit to the total number of questions that can be accommodated and difficult decisions have to be made about which questions to include and where to pare down sections of the questionnaire. Response rates tend to be lower when potential respondents are asked to complete an overly lengthy questionnaire and there are also cost and formatting constraints that limit the total number of questionnaire pages.

Sixth comment: ***"The symptom survey should ask about skin conditions, recurrent sinusitis, sinus infections, and upper respiratory symptoms…"***

VA response: Question 8a, item 5 asks about dermatitis or any other skin trouble. Question 22 items o. and p. ask about problems with coughing and fever or chills. We can insert a question about recurrent sinus infections or sinusitis as Dr. Meggs recommended.

Seventh comment*: "Questions should ask about abnormal sensitivity to bright lights, loud noises, odors, and being touched."*

VA response: As noted in the response to Comment 5, the 2003-2005 survey included items that addressed the impact of various treatments, diet, and chemical smells on symptoms.

Eighth comment: ***"Finally, before the survey is finalized, it should be broadly reviewed by stakeholders and those with expertise including advocacy groups for Gulf War Illness victims, the VA Research Advisory Committee, the VA Office of Research, and researchers in the field."***

VA response: The scientific protocol and draft questionnaire were reviewed by the Research and Development Committee at the VA Medical Center in Washington, DC. A number of outside experts have also commented on the draft questionnaire. The scientific protocol states that the procedures for data collection will be pilot tested. Pilot testing of the questionnaire will provide opportunities for

feedback from Veterans who served in the 1991 Gulf War or during the Gulf Era. The VA Medical Center IRB, which reviewed the scientific protocol and draft questionnaire includes Veterans.

From: Adrian Atizado
Disabled American Veterans (DAV):

Comment: ***I (Atizado) find the limited information provided under the Abstract (below) lacking relevant information that does little to encourage and to a great extent precludes meaningful public participation. It is virtually impossible to comment on (1) Whether the proposed collection of information is necessary for the proper performance of VHA's functions, including whether the information will have practical utility; (2) the accuracy of VHA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.***

… Additional information would be welcomed such as a copy of VA Forms 10-0488 and 10-0488a and a summary of and/or source of information for the Follow-Up Study of a National Cohort of Gulf War and Gulf Era Veterans.

VA Response: Atizado was provided a copy of VA Form 10-0488 and 10-0488a.

Storm/Desert Shield Veteran Richard Sartorao.
Telephone call to VA Clearance Liaison:

Comment: ***Will I (Sartorao) have to initiate contact for the study or will VA review the Veterans health information/records?***

As the VHA OMB liaison, Cynthia Harvey-Pryor placed a return phone call to the Veteran. She read the following statement that was provided as a response from the program office of the principle investigator:

VA Response: The health survey questionnaire gathers information on topics that pertain to current health concerns of veterans of the particular conflict. As such, the health information cannot be expected to be found in claims folders of veterans nor in administrative records. The sampling of veterans is designed in a scientific manner to represent the population of the particular conflict. Thus, volunteers are not encouraged; use of their information would be likely to introduce selection bias.

If Mr. Sartorao is selected in the scientific sampling procedure, he will be contacted initially by mail and requested to complete the survey questionnaire (about a 30-40 minute task). He will have the option to decline to participate, without that affecting any VA benefits to which he is entitled.

Clare Mahan, VHA Health Statistician

Additional suggestions and discussion was submitted by the Gulf War Advisory Committee. VA's response is provided under the supplementary supporting statement category in ROCIS.

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. The scientists and professionals that are consulted include:

Jerrome Yesavage, MD
Professor of Psychiatry
Stanford University School of Medicine, and
Associate Chief of Staff for Mental Health
VA Medical Center
3801 Miranda Avenue
Palo Alto, CA 94304
Tel. (650) 852-3287

Han Kang, DrPH (Retired)
c/o Environmental Epidemiology Service (135)
Department of Veterans Affairs
810 Vermont Avenue, NW
Washington, DC 20420
Tel. (202) 266-4559

Paul Levine, M.D.
Professor of Epidemiology and Biostatistics
George Washington University
Ross Hall Room 121
2300 I Street, NW
Washington, DC 20037
Tel. (202) 994-4582

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

VHA will offer a small incentive in the mailed survey package to increase participation. Prior studies indicate that offering a financial incentive of five dollars ($5-10) or more can be effective in increasing survey response rates. The VA conducted a randomized trial of a five dollar incentive as part of a recent survey of 3,000 Veterans who served in Operations Iraqi Freedom and Enduring Freedom (OMB Number 2900-0722, Health Surveillance for a New Generation of Veterans); the modest incentive boosted the response rate from 21.1% to 29.8%; the trial involving 3,000 Veterans was carried out over a relatively short time period and did not make use of an advance letter to maximize response rates.

10. Describe any assurances of privacy, to the extent permitted by law, provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

VHA will inform 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 completed. They will also be told that no individual findings will be presented; only aggregate results will be published or presented at scientific meetings.

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 health care utilization, and to locate

medical records. Personal identifiers will not 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.

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.

Information on these forms 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 and sexually transmitted diseases 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 Gulf War and other Veterans need. Answers to some questions may also help researchers determine a relationship between war-time service and health outcomes. Three questions are identical or slightly altered versions of questions that can be found in the optional sexual behavior module of the Behavioral Risk Factor Surveillance System. 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. The question about voluntary HIV testing is an important question to address among U.S. Veterans who should be tested for HIV on a regular basis.

Only persons who consent to participation in the research will be asked these questions. They will be told 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.

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 10-0488	**Estimated No. of respondents***	**x No. of minutes**	**÷ by 60**	**Burden Hours**
Respondents to survey (mail, online, CATI)	18,762	30	9,381	
Medical Records Consent Form 10-0488a	700	10	117	
			9,498	

*****Of the original panel of 30,000 Veterans, 1135 were deceased as of February 9, 2012.

b. 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 $142,470 ($15 per hour x 9,498 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).

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 Health Surveillance of a New Generation of Veterans, 2900-0722 (which focuses on Veterans who served in Operations Iraqi Freedom and Enduring Freedom rather than Veterans who served in the first Gulf War), the planned follow up study of Gulf War Veterans is projected to cost $1,231,000.

Phase I (cost to Implementation of Survey)	**Cost**
Locate Study Participants	$20,000
Design, Print, and Manufacture Forms, Personalized Letters, and Envelopes	$600,000
Design and Implement SQL Database	$35,000
Design and Maintain Web-based electronic survey	$100,000
Design and Implement Contractor Data Interface	$5,000
Assemble, Address, and Mail Questionnaires, and Letters add to admin staff	$250,000
Cost of $10 financial incentive	$200,000
Incoming Toll Free Calls Plus Monthly Fee for Toll Free Line and Staffing	$3,000
Data Entry of Completed Questionnaires	$50,000
Phase I Total	$1,263,000

Phase II Task (administrative)	**Cost**
Prepare Veteran Contact Information	$5000
Incoming Toll Free Calls Plus Monthly Fee for Toll Free Line and Staffing	$3,000
CATI telephone interviews	$500,000

(Pre-paid Postage/copying) Medical Records	$150,000
Scanning and Abstraction of Medical Records	$50,000
Data Analysis	$100,000
Prepare Final Report and Technical Review	$25,000
Phase II Total	$848,000
Grand Total for Phases I and II	$1,231,000

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.

As data are entered, preliminary analyses will be conducted to identify and correct any systematic errors in data collection. A $10 incentive will be provided to increase participation. Additional information about the statistical analysis plan is provided below. The results of 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.

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

VHA is not seeking approval to omit the expiration date for OMB approval

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.