Survey of Chronic Gastrointestinal Illness in Persian Gulf Veterans
(Irritable Bowel Syndrome-Diarrhea)

VA Form 10-21092a,b,c
OMB 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.

Approximately 700,000 United States military personnel were deployed in the first Persian Gulf (PG) War. Several months after their return, up to 25% of Veterans had persistent gastrointestinal symptoms (i.e., loose stools, excessive gas and abdominal pain) typical of diarrhea-predominant irritable bowel syndrome (IBS), which they suspected to be related to their military service in the Gulf. The cause and treatment of IBS-diarrhea has not been studied well in PG Veterans. The George E. Wahlen VA Medical Center Salt Lake City, UT is conducting a study to evaluate the burden of chronic gastrointestinal illnesses in PG Veterans and to determine if IBS-diarrhea is caused by the presence of excessive bacteria in the intestines and whether eradication of these bacteria reduces symptoms of chronic diarrhea in PG Veterans.

Legal authority for this data collection is found under 38 USC, Part I, Chapter 5, Section 527 "Veterans Benefits" 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.

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.

Objective #1: Estimate the burden of disease due to chronic gastrointestinal illness in PG veterans. Following OMB approval, the Department of Defense (DoD) will provide a list of PG Veterans residing in Utah. These Veterans will be asked to participate in a validated survey. The survey consists of three sections: 1) Modified Bowel Disease Questionnaire (BDQ), 2) Irritable Bowel Syndrome Quality of Life scale (IBS-QOL), and 3) the Brief Symptom Inventory (BSI-18).

The information obtained from this survey conducted by George E. Wahlen V.A. Medical Center will inform us about the burden of chronic gastrointestinal illness in PG Veterans. This information will also be used in the following two objectives of the study.

Objective #2 : Evaluate whether small bowel bacterial overgrowth (SBBO) is associated with chronic diarrhea in PG Veterans. In this part of the study, participants (a subset of Veterans who have and do not have IBS- information obtained from the survey (Objective #1)) will receive informed consent for further medical tests (unless have had these tests in last 6 months). These tests include: Blood samples for routine blood tests, a stool sample to check for infection, breath tests to check for presence of bacteria, and a colonoscopy and biopsy to compare IBS-diarrhea veterans to non-IBS-diarrhea Veterans.

Objective #3: Determine whether eradication of SBBO reduces symptoms of chronic diarrhea in PG Veterans. These participants will include only Veterans who have IBS with diarrhea. The diagnosis of IBS-diarrhea will be based on the information obtained from the survey (Objective #1) and Objective

#2. This part of the study will compare rifaximin (an antibiotic) 550 mg orally two times per day for 14 days to a placebo in 140 patients with diarrhea-predominant IBS.

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 process will be initiated by sending an introductory letter to all PG Veterans in Utah. Within 5 to 7 days of the letter, the survey will be mailed to the Veteran. Completion of the survey will be taken as the Veteran's consent to participate in the survey. All PG Veterans will be initially sent the paper copy of the survey. However, if they wish, information will be collected by telephone or electronic/internet fill-able, printable form. All paper copies of the surveys will be electronically scanned and electronically stored.

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.

No study in the past has evaluated the burden of gastrointestinal illnesses in PG Veterans. The role of small bowel bacterial overgrowth in causing chronic GI symptoms in PG Veterans has also not been evaluated.

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

The information collected by this survey is for the benefit of Veterans. No small businesses or other small entities will be impacted.

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.

The Department of Veterans Affairs could respond best to the needs of Veterans with GI symptoms (especially IBS) if they know the burden of these disorders and allow research to advance its diagnosis and treatment. The Department of Veterans Affairs would not be responsive to the needs of the Veterans if information were collected less frequently. The proposed rate of data collection provides the most current information on study outcomes.

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 in this study.

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 May 11, 2009, pages 21853-21854. VA received no comments 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-day and 30-day Federal Register notices.

This study grant was independently reviewed by three reviewers and finally approved by the Department of Veterans Affairs. The survey contents and methods described were approved as outlined above.

This study has been approved by the University and the George E. Wahlen VA Medical Center Institutional Review Board, Salt Lake City, UT.

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

Study participants are compensated $20 for the initial survey and each study visit that they complete.

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

***The following confidentiality statement will be added to all consent form and all efforts will be made that Veterans understand the confidential nature of data collection*:**

"All information gathered during this study will be treated confidentially. Individuals will be identified only by initials and numbers. Any information about you which leaves the hospital will have your name and address removed so that you cannot be recognized from it. Only those who work with this study will be allowed access to your information. Your identity will not be disclosed in any publication.

The information gathered from this study will be stored in locked secure cabinets in the Division of Gastroenterology, George E. Wahlen V.A. Medical Center and the University of Utah Hospital. The computerized data is saved on password-protected computers, also in secured Gastroenterology research offices. The principal investigator, co-investigator, and study coordinator will have access to this data. Your study data will be kept as confidential as possible under local, state and federal laws. By signing this informed consent form, you authorize such access".

If filed in the medical record: Assurances of confidentiality are contained in 38 U.S.C. 5701 and 7332. Respondents are informed that the information collected will become part of the Consolidated Health Record that complies with the Privacy Act of 1974. These forms are part of the system of records identified as 24VA19 "Patient Medical Record – VA" as set forth in the Compilation of Privacy Act Issuances via online GPO access at *http://www.gpoaccess.gov/privacyact/index.html*.

If filed in research records: 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 such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private; include specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

There are no questions of a sensitive nature.

12. Estimate of the hour burden of the collection of information:

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

VA Forms	**Number of Respondents X**	**Frequency of Responses X**	**Time (minutes) ÷ 60 =**	**Total Annual Hour Burden**
Consent (Cases) 10-21092a	165	1	15	41
Consent (Control) 10-21092b	189	1	10	31
Veterans Survey 10-21092c	4000	1	**45**	**3000**
Total	4000	1	**53**	**3072**

The survey consists of 4 sections: 1) Background Questions; 2) Modified Bowel Disease Questionnaire (BDQ); 3) IBS-QOL; 4) Brief Symptom Inventory (BSI-18). The total time involved to complete the survey will take approximately 30-45 minutes (5 to complete Background Questions, 20 to complete bowel disease questionnaire, 14 minutes for IBS quality of life questionnaire and 6 minutes for BSI-18 questionnaire).

The survey will be performed only once. The information gained from the initial survey will be used for subsequent study objectives after obtaining informed consent.

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.

Form 10-21092A is a patient information Research and Consent Form (Cases). The burden hour is 4 minutes. Form 10-21092B is a patient information Research and Consent Form (Controls) with a burden of 4 minutes. Form 10-21092C is the survey instrument, which has a burden of 45 minutes.

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.

There is no annual cost to respondents of the survey.

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 cost to respondents of the survey. The estimated cost for recordkeeping is $120,000 ($40,000 per year).

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.

This study has two program assistants who distribute, collect, and process the survey. Assistant #1 is a GS 4 with an hourly salary of $12.72. Assistant #2 is a part-time (20hr per week) GS 4 with an hourly salary of $12.72. At least half of their paid time is spent processing the survey. Therefore, the cost to processing the survey is $12.72 (full-time salary) + $6.36 (part-time salary) x 3000 = $57,240 ÷ 2 = $28,620. The annual cost to the Federal Government is $53,260.00.

Survey Design/Printing		$10, 000
Postage for Response 1 letter	4000 (frequency) x $0.42 =	$1680
Postage for Response 2 letter	4000 (frequency) x $0.42 =	$1680
Postage for survey	4000 (frequency) x $1.34 =	$5360
Postage for participants' return of survey	4000 (frequency) x $1.34 =	$5360
Printing Costs for Letters	8000 (frequency) x $.07 =	$560

Support Staff	GS 4 (see Item 12c)	$28, 620
TOTAL ANNUAL COST		**$53, 260**

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

This is a new collection.

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.

All surveys will be electronically scanned weekly. The information collected will be stored in excel spreadsheet. This is a 3-year project. Time schedule for the publication of results will be determined at the completion of the study.

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

VA seeks to minimize the cost to itself of collecting, processing and using the information by not displaying the expiration date. We seek an exemption that waives the displaying of the expiration date on this VA Form. If we are required to display an expiration date, it would result in unnecessary waste of existing stock of the forms. Inclusion of the expiration date would place an unnecessary burden on the respondent (since they would find it necessary to obtain a newer version, while VA would have accepted the old one).

18. Explain each exception to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submissions," of OMB 83-I.

There are no exceptions.