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

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

1. Provide a numerical estimate of the potential respondent universe and describe any sampling or other respondent selection method to be used. Data on the number of entities (e.g., households or persons) in the universe and the corresponding sample are to be provided in tabular format for the universe as a whole and for each strata. Indicate expected response rates. If this has been conducted previously include actual response rates achieved.

Phase I will include a mail/Web survey of 30,000 Gulf War and Gulf Era Veterans conducted during a 16 month period that will include an advance letter and three mailing waves. In Phase II, medical records will be retrieved for 1,000 Veterans in order to validate selected health conditions.

Except for the initial number of Veterans to be contacted, these numbers are estimates. The final numbers will be determined by the response rate and the number of surveys returned undeliverable during each of the mailing waves in Phase I.

	To Be Contacted	Expected Response (Number)	Expected Response (Percent)
VA Form 10-0488 Mail/Web Survey	30,000	18,000	60
VA Form 10-0488a Medical Records Consent	1,000	700	70

2. Describe the procedures for the collection of information, including:

• Statistical methodology for stratification and sample selection

The potential participants in this study (15,000 Gulf War Veterans and 15,000 Gulf Era Veterans) were identified prior to a survey conducted in 1995-1997. The populations from which the samples were drawn were identified by the DoD. The DoD Defense Manpower Data Center in Monterey, California provided military and demographic information for 693,826 US troops who were deployed in the Persian Gulf area during the first Gulf War. The Defense Manpower Data Center also identified 800,680 individuals who were in the military between September 1990 and May 1991 but did not serve in the Persian gulf theaters of operation.

A stratified random sampling method was used to ensure that each subgroup was adequately represented. The populations were stratified by gender and unit component (active duty, reserve, National Guard). Women and those who served in the reserve/National Guard were over-sampled, so that one-fifth of the sample are women, one-quarter were National Guard members, and one-third were reservists.

Power calculations indicated that the samples of 15,000 Gulf War Veterans and 15,000 Gulf Era Veterans are likely to be adequate.

The samples of 15,000 Gulf War and 15,000 Gulf Era Veterans will be prepared for processing through an interagency agreement with the National Institute for Occupational Safety and Health (NIOSH) for the Taxpayer Retrieval System, which enables us to obtain taxpayers' last known addresses. For those who are missing IRS mailing addresses, credit bureau databases will be searched for alternative mailing addresses.

The Social Security Administration, under the terms of an agreement, periodically sends VA a computer file of deceased individuals for whom the deaths were reported to SSA (Death Master File). We will search this data source and those who are recorded as deceased will be deleted from the sample.

• Estimation procedure

Unadjusted risk ratios will be calculated directly from the data. The Mantel-Haenszel method and logistic regression analysis will be used to compute adjusted relative risk estimates with 95% confidence intervals. Relative risk estimates will be adjusted for age, gender, branch of service (Army, Navy, Air Force, Marines), unit component (active duty, reserve, National Guard), and other variables.

• Degree of accuracy needed

Statistical power for a study of a given sample size depends on the prevalence of specific conditions among the controls and the relative risk of the specific conditions which are considered important to detect. The below table describes the sample size required for each group and the statistical power of the study under various conditions. Assuming, for example, that a condition is present among 5% of Gulf Era Veterans and 7.5% of Gulf War Veterans [relative risk (RR) = 1.5], to establish that this difference is true with 80% power and 5% statistical significance would require a sample of 1,469 Veterans in each of the two groups. Detection of differences in rarer conditions would require larger sample sizes.

Sample Size Required for Each Group

RR	P=0.01		P=0.05		P=0.10	
	90%	80%	90%	80%	90%	80%
1.2			10,910	8,149	5,137	3,837
1.5	10,364	7,741	1,966	1,469	916	685
2.0	3,100	2,316	581	434	266	199
2.5	1,602	1,197	296	221	133	99
3.0	1,027	767	187	140	82	62

Alpha = 0.05, two-sided test.
RR = smallest detectable relative risk.
P = prevalence rate of disease among the controls.
90% and 80% statistical power.

• Unusual problems requiring specialized sampling procedures

Women Veterans were over-sampled to ensure that there are adequate numbers (20 percent of the study sample).

• Any use of less frequent than annual data collection to reduce burden

Members of this cohort of Veterans who served in the first Gulf War are surveyed every 5 to 10 years to reduce respondent burden.

3. Describe methods to maximize response rate and to deal with issues of non-response. The accuracy and reliability of information collected must be shown to be adequate for intended uses. For collections based on sampling, a special justification must be provided for any collection that will not yield "reliable" data that can be generalized to the universe studied.

The Dillman method, which incorporates four contacts by first class mail with an additional contact by telephone, was a preferred method for achieving satisfactory response rates until the proliferation of cell phone usage. We plan to adopt a modified Dillman method, for this mixed-mode postal and Web-based survey, which includes an advance letter and three waves of mailings. Post card reminders/thank you cards will be mailed after each of the 3 mailings. To maximize response rates, the advance letter will be signed by a respected VA official. In addition, information about the launch of the survey will be distributed via a VA media release, social networking sites (Facebook, Twitter), and Veteran Service Organizations.

A $5 incentive will be provided to increase response rates. Prior studies indicate that offering a financial incentive of five dollars or more can be effective in increasing survey response rates.

All Veterans eligible to participate in this study, including those who receive a paper questionnaire, will have the option of completing the survey via the internet using a Web-based data collection form, which is likely to maximize response rates and reduce participant burden.

4. Describe any tests of procedures or methods to be undertaken. Testing is encouraged as an effective means of refining collections to minimize burden and improve utility. Tests must be approved if they call for answers to identical questions of 10 or more individuals.

We will be carrying out a pilot test of the procedures for the mail and Web-based survey data collection among a sample of 9 Veterans. If OMB grants us permission under this request, we will also conduct a larger pilot study involving 500 Gulf War Veterans. The completion of a larger pilot study with 500 potential participants, would help VA to ensure that the contractor is ready to initiate and monitor the data collection procedures before the launch of the main survey. In addition, we will be comparing self-reports versus medical records for 1,000 Veterans as a validation test.

5. Provide the name and telephone number of individuals consulted on statistical aspects of the design and the name of the agency unit, contractor(s), grantee(s), or other person(s) who will actually collect and/or analyze the information for the agency.

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Data Collection Support Contractor:

To be selected