

Justification A
Accelerated Aging among Vietnam-Era Veterans Survey
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.

The National Center for PTSD (NCPTSD) was recently allocated funds by Congress to be used for research to advance the prevention and treatment of PTSD. The original language of the legislation states the following: “The committee recognizes the importance of the VA National Center for PTSD in promoting better prevention, diagnoses, and treatment of PTSD.” In response to this, we have developed a study that aims to understand how and the degree to which warzone deployment is associated with increased morbidity and mortality, with particular attention to potential differences among white, black, and Hispanic Veterans, as well as male and female Veterans. To this end, we will consider multiple aspects of military service, deployment experiences, and current stressors of Vietnam-era Veterans in relation to current physical and mental health outcomes. This information will directly inform intervention efforts aimed at prevention or treatment of chronic disorders such as PTSD, depression, and substance/alcohol use disorders, as well as comorbid physical health conditions, particularly in underserved portions of our Veteran population. This type of information can inform system-wide interventions that can maximize Veterans’ likelihood of receiving timely and evidence-based healthcare, thereby preventing long-term health problems. As such, legal authority for this data collection is found under 38 U.S.C. 527, authorizing the collection of data that will allow for measurement and evaluation of the Department of Veterans Affairs Programs, the goal of which is improved healthcare 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.

The purpose of this study is to understand military and post-deployment factors that may be related to increased risk for accelerated aging (i.e., greater physical and mental morbidity and premature mortality), as well as how these effects might vary by race and gender. To implement this research, VHA and entities working on its’ behalf will conduct a mail and phone survey with an existing sample of approximately 10,000 Vietnam-era Veterans who participated in two prior studies. The first study included approximately 6,500 men recruited from the American Legion surveyed in 1984 and 1998. The second study included samples of (a) 2,500 women recruited from the Vietnam Women’s Memorial Project and (b) 1,230 black and Hispanic men recruited through the American Legion, both surveyed in 1998. The current data collection will involve measures assessing post-deployment exposures (e.g., life stressors, discrimination), important psychosocial factors (e.g., social support, personality factors), as well as a host of outcomes (e.g., mental and physical health, indicators of well-being, growth/resilience). Our response rate target for the mail survey is ~60%, which is consistent with other recent surveys in which Veteran samples are re-contacted, yielding approximately 4,560 survey completers (after accounting for deceased). Mail survey completers will be invited to participate in a telephone survey; we anticipate an 80% agreement rate, yielding about 3,650 telephone survey completers.

Specific aims are:

- Aim 1.** To examine changes in health and well-being as a function of deployment experience, gender, and race/ethnicity, and post-military risk and protective factors, as well as interactions among these characteristics.
- Aim 2.** To examine differences among survivors and decedents on baseline characteristics, changes in mental and physical health, and current outcomes.

Only de-identified data will be made available to approved VA researchers. Researchers from other Federal Agencies and academic partners may also request access to de-identified data.

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.

We considered three methodologies for surveying participants: mail survey, phone survey, and web-based survey. After comparing the relative advantages and disadvantages of these methods in terms of participants' convenience, privacy, data validity, logistics and cost, we chose a mail survey approach, which will be supplemented by a phone survey with a sub-set of the mail survey participants. Mail surveys were chosen as the primary data collection method, as they present a number of advantages as compared to other modalities. First, mail surveys can be completed at participants' leisure and so are more convenient. They also may offer greater privacy than phone interviews, which in some cases can be overheard. In addition, mail surveys reduce the potential for interviewer bias and may increase participants' comfort disclosing personal or sensitive information by providing an additional level of perceived anonymity. By following rigorous and recommended procedures (e.g., verified addresses, engaging packaging, repeat mailings), mail surveys can reach a greater proportion of the target audience than phone surveys, which encounter barriers related to unlisted numbers, decreased landline usage, answering machines, caller ID, and quick hang-ups. The main advantages to phone surveys, including lower demands for literacy and automated skip patterns, can be offset by using scales that have been validated with similar populations, carefully formatted instructions about which sections to complete and which to leave blank, and pre-testing the instrument before widespread use – all strategies we are using for the current project.

A mail survey also has several advantages over a web-based survey. First, mail surveys offer increased convenience for members of the target population who do not have easy access to the Internet. Further, it is easier to track who responds to a mail survey in order to ensure that our final sample is balanced on factors like gender. Whereas mail surveys can print an identification number or barcode on the survey, web-based surveys rely on participants accurately keying in an identification number. Web-based surveys may also raise Internet security concerns for some participants, reducing potential response rates. The main advantage of web-based surveys – automated skip patterns – can be addressed by using a well-designed mail survey, using the strategies described above.

To complement the mail survey, a separate phone data collection will be completed with the goal of conducting diagnostic assessments that could not easily be conducted by mail or web survey format (i.e., cognitive assessments, and clinical interviews). We will decrease phone-related barriers mentioned previously by inviting mail survey participants to provide permission and contact information for the phone survey.

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.

To date, there have been no large-scale longitudinal studies with these cohorts. Older male and especially minority and female Veterans represent important and understudied populations in general.

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

The collection of information involves individuals in their residences, not small businesses or other small entities.

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 critical to advance understanding as to how deployment experiences and post-military risk and protective factors may be related to accelerated aging (i.e., increased morbidity and mortality) among Veterans, as well as how these associations might differ based on race/ethnicity and gender. Additionally, this study was specifically funded by Congress, which stipulates that funds need to be obligated (i.e., used or under contract to be used with a vendor) by the end of September 2017. If the data collection is not done, not only will the scientific

integrity and value of the research would be significantly diminished, we will not be able to use the funds as intended and allocated by Congress.

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 July 3, 2018 (Volume 83, Number 31255, Pages 31255-31256). We 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- and 30-day Federal Register notices. The study team includes a group of experts in psychology (developmental, clinical, and social), epidemiology, longitudinal survey design and analysis, aging, gender differences, military and veteran populations, trauma, mental health, and risk and resilience. In addition, the study team has consulted with experts in these topics outside the agency during the study and survey design process.

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

Each participant will be sent a \$5 incentive with the survey mailing, with the primary goal of increasing the response rate. Studies have shown that sending an up-front incentive increases the likelihood of response by 61% and that sending a monetary incentive doubles the likelihood of response (Edwards, P., Roberts, I., Clarke, M., DiGuseppi, C., Pratap, S., Wentz, R., Kwan, I. & Cooper, R. [2007] Methods to increase response rates to postal questionnaires. *Cochrane Database of Systematic Reviews*, 4). Participants will receive an additional incentive if they complete the survey. For the phone survey, completers will receive an incentive once they have completed the interview.

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

Information supplied to respondents in the form of a pre-survey letter and informed consent fact sheet will be reviewed and approved by the Human Studies Committee (Institutional Review Board) of Columbia University to insure the protection of study participants.

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 (34VA11)" as set forth in the Compilation of Privacy Act Issuances via online GPO access at <http://www.gpoaccess.gov/privacyact/index.html>. Approved VA Researchers will be provided with de-identified datasets only.

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.

As addressed above in question A.2, one of the primary aims of this investigation is to examine the effects of exposure to deployment experiences (including combat and other potentially traumatic stressors) as well as post-military stressors on Veterans’ physical and mental health. Accordingly, respondents will be questioned about experiences of trauma (both within and outside of the military), mental health, and physical health. The investigative team has significant experience in the successful collection of information from victims of trauma, has a reputation for collecting such information in a compassionate manner and is sensitive to the possibility that participants may become distressed when recalling experiences of trauma. As addressed above in question A.10, all information provided to respondents, including the survey instruments (mail and phone), will be reviewed and approved by the Human Studies Committee of Columbia University (Institutional Review Board) prior to the initiation of data collection to insure the protection of study participants. The cover letter sent to participants with the survey instrument will explain the purpose of the survey and state that all analyses will be performed on aggregate-level data; no individual-level data will be reported. Additionally, participants will be provided several contact numbers in the event they have questions about this study or if they experience any discomfort while participating in the study. Specifically, participants will be provided a phone number for a member of the research study team. They will also be provided with a Veteran resource list and the Veteran Crisis Line number.

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:

Every effort has been made to minimize the data collection burden. The survey instrument was designed specifically to assess the critical constructs using the smallest number of reliable and valid items. Further, the survey instrument includes “skip-outs” so that respondents will not be required to respond to irrelevant questions. Data collection will involve a mailed survey, with a final target sample size of 4,560 participants and a phone survey, with a target sample of 3,650 participants. Pilot testing indicates that the survey instrument requires approximately 45 minutes to complete if a respondent answered all items (no skip-outs). The phone survey also takes about 45 minutes to complete. Using these values, we compute the estimated burden as follows:

VA Form 10-XXXXX	No. of respondents	x No. of responses	x No. of minutes	÷ by 60 =	Number of Hours
Mail Survey	4,560	1	45		3,420
Phone Interview	3,650	1	45		2,738

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 chart in 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.

Legally, respondents may not pay a person or business for assistance in completing the information collection and a person or business may not accept payment for assisting a respondent in completing the information collection. Therefore, there are no expected overhead costs for completing the information collection. VHA estimates the total cost to all respondents to be \$149,885.72 (6,158 burden hours x \$24.34 per hour).

May 2017 National Occupational Employment and Wage Estimates United States:

https://www.bls.gov/oes/current/oes_nat.htm

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).

- a. There is no capital, start-up, operation or maintenance costs.
- b. Cost estimates are not expected to vary widely. The only cost is that for the time of the respondent.
- c. 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.

All costs for this data collection are included in funds directed by Congress to the NCPTSD for appropriation to this survey (\$ 183,459 for the current fiscal year). Total costs will cover the expense of 1 mail data collection and 1 phone assessment, initially recruiting approximately 8, 210 participants with the estimated goal of 4,560 participants for the mail survey and 3,650 for the phone assessment. There are no additional costs to the government for this activity.

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.

Data will be tabulated and analyzed as follows. First, the data will be cleaned and checked for data entry errors, unusual variable distributions, potential errors due to skip patterns, the extent and patterns of missing data and outliers. For the items that are accompanied by multipoint Likert-type response formats (e.g., "strongly disagree"-to-"strongly agree"), the data will be checked by examining frequency distributions and calculating descriptive statistics. For dichotomous items, (e.g., "yes"/"no" responses), the probabilities of endorsement, or the proportion of respondents providing an affirmative response, will be reviewed. Next, we will construct scales using published scoring rubrics (when available) and compute Cronbach's alpha for internal consistency reliability, where appropriate.

After these initial steps in data checking, cleaning, and reduction, we will begin our analyses.

The final longitudinal dataset, which will include data from the prior assessments with these cohorts along with the current data collection, will be analyzed using traditional multivariate modeling techniques. Data will be analyzed

using a combination of regression-based methods, including hierarchical linear modeling (HLM; also called growth curve modeling, or multilevel or random coefficients regression), path analysis, and structural equation modeling. To address missing data, we will use a full information maximum likelihood (FIML) estimation procedure to achieve reduced standard errors and more precise parameter estimates. Potential confounders of study relationships will be considered, as appropriate. We will attend to both statistical significance and effect sizes for all analyses, which is consistent with APA Task Force recommendations.

The project's timeline calls for data collection to occur between September 2017 and September 2019. A complete final report will be submitted to the funding agency (approximately February 2020). Additionally, VA intends to publish this data in aggregate form. Dissemination of the study findings will include traditional academic mechanisms (e.g., articles published in peer-reviewed journals).

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. VA seeks an exemption that waives the displaying of the expiration date on this VA Form. The VA Form may be reproduced by the respondents and VA field facilities from the Internet and then stocked. If VA is 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.