

SUPPORTING STATEMENT A

Million Veteran Program (MVP) COVID-19 Survey

OMB Control Number 2900-NEW

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 Million Veteran Program (MVP) is a national, voluntary, medical research program. MVP establishes an ongoing partnership with Veteran participants who give their informed consent to authorize access to electronic health record data, provide biospecimens for further analysis in conjunction with their health status, and provide self-reported data through methods such as personal logs and surveys.

In response to the COVID-19 pandemic, all MVP participants will be invited to complete the MVP COVID-19 Survey. The survey collects demographics, COVID-19 symptoms and treatment, comorbidity, healthcare utilization, well-being, and psychosocial outcomes. MVP participants can complete the survey up to 4 times. MVP is uniquely positioned to analyze survey data in conjunction with biospecimens and assist with identification of potential biomarkers, as well as allow researchers to analyze the incidence and outcomes of COVID-19 using genomic data.

Data is collected per Code of Federal Regulations Title 38, Part 16, and the MVP research protocol approved by the VA Central Institutional Review Board. In addition, 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.

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 respondents are MVP study participants who have given informed consent and HIPAA authorization to share data with researchers, including self-reported data collected via surveys.

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.

This data collection is available by both mail and internet (social media, etc.) to reach the broadest Veteran audience. Improved information technology will not decrease the burden on the public.

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.

This collection of data is specific for the MVP and does not duplicate any other studies.

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

Because this is a survey of individuals, no small businesses or other small entities are 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 the patient and to the legal requirement to release of information if information were collected less frequently.

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 XXXXX (Volume XX, Number XX, Page XXXXX). 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.

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

No payment or gift is provided to respondents.

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.

If filed in research records: Information on these forms will become part of a system of records that 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.

There are some questions of a sensitive nature, however no individually identifying information is collected in the survey or will be released as part of the analysis of the survey results.

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:

Category of Respondent	No. of Respondents	X No. of responses	X No. of minutes	Divided by 60 =	Number of hours	
MVP participants	1,000,000	Up to 4	25 minutes			1,666,667
Totals	1,000,000					1,666,667

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.

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.

VA cannot make assumptions about the population of respondents because of the variability of factors such as the educational background and wage potential of respondents. Therefore, VBA used general wage data to estimate the respondents’ costs associated with completing the information collection.

The Bureau of Labor Statistics (BLS) gathers information on full-time wage and salary workers. In accordance with the latest available BLS Occupational Wage Code Median Hourly (May 2019), the mean hourly wage is \$25.72 based on the BLS wage code – “00-0000 All Occupations.” This information was taken from the following website: https://www.bls.gov/oes/current/oes_nat.htm.

Legally, respondents may not pay a person or business for assistance in completing the information collection. Therefore, there are no expected overhead costs for completing the information collection. VBA estimates the total cost to all respondents to be \$42,866,675.20 (1,666,667. burden hours x \$25.72 per hour).

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 are 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 beyond that which is considered usual and customary.

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.

FEDERAL COST: The estimated annual cost to the Federal government is \$2,832,172.

	Projected	Cost/unit	Total
1st invite full survey	29,959	\$3.17	\$94,970
1st invite 1-page invitation to go online	339,019	\$0.87	\$294,947
1st invite emailed invitation	360,647	\$0.00	\$0
Survey requested by Veterans	39,679	\$2.27	\$90,071
2 nd invite full survey	647,000	\$2.27	\$1,468,690
Survey Scans	290,623	\$3.04	\$883,494
Total Costs			\$2,832,172
Assumes a response rate of 40%			

15. Explain the reason for any burden hour changes or adjustments reported in items 13 or 14.

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.

VA does not intend to publish this data.

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 will include the expiration date on all forms.

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.