

SUPPORTING STATEMENT - PART A

(Health Status Evaluation of an Infantry Battalion Following Deployment in Support of Operation Iraqi Freedom (2004-2005) – 0702-XXXX)

1. Need for the Information Collection

From October, 2004 through September, 2005, the 1st Battalion, 24th Infantry (1-24 IN) was assigned to and deployed with the 1st Brigade, 25th Infantry Division "Lightning" Stryker Brigade Combat Team (SBCT) in support of Operation Iraqi Freedom, serving in the vicinity of Mosul, Iraq. A previously conducted "Deployment and Environmental Health Surveillance Investigation" by the U.S. Army Public Health Center (APHC) in December of 2014 was unable to discern etiologic elements connecting the multitude of conditions and symptoms reported by these military members during the deployment(s) timeframe. A copy of this report has been included with the submission package to OMB. It is theorized that environmental exposures may have increased the risk of developing certain conditions has not been definitively identified. Furthermore, the report focused on summarizing the health status of a small subset of 1-24 IN service members; however, a comprehensive comparative health status evaluation seeking to include all former members of the 1-24 IN who served in Iraq has never been conducted.

The purpose of this initiative is to identify the frequency of post-deployment medical encounters for cancers, respiratory diseases, circulatory system diseases, and mental health disorders among soldiers and veterans that deployed to Iraq with the 1-24 IN in 2004-2005. The investigation is being conducted at the request of the Chief of Staff of the Army, Gen. Milley, who tasked APHC with investigating the health status of former members of the above identified group. This tasking was itself motivated by members of the 1-24 IN who have voiced concern regarding the high numbers of soldiers (among their ranks) who have been diagnosed with lymphoma, leukemia, bile duct cancer, prostate cancer, Crohn's Disease, sleep apnea, asthma, depression, liver disorders, among others conditions and symptoms. This investigation will focus on cancer incidence (though a broad set of non-cancer diagnoses will also be evaluated), in an attempt to quantify the concerns raised among members of the 1-24 IN.

The authority for this information collection originates from Executive Order 12196, Occupational Safety and Health Programs for Federal Employees. Executive Order (EO) 12196, among other requirements, compels heads of Agencies to a) assure responses to employee reports of hazardous conditions, and b) operate an occupational safety and health management information system, to include the maintenance of such records as the Secretary may require. Army Regulation (AR) 40-5, Preventive Medicine (see enclosure), implements EO 12196 for the US Army, defining preventive medicine responsibilities to include programs covering all Army personnel to include the Active Army, the Army National Guard, and the Army Reserve. Specifically, AR 40-5 directs USACHPPM (now APHC) to a) provide worldwide support of Army preventive medicine activities through,

supportive services, program development, and investigations, b) provide support for comprehensive health surveillance for the Army and DOD, and develop, and c) maintain data analysis and archiving for worldwide military health surveillance activities.

2. Use of the Information

The overall goal of this investigation is to characterize the burden of disease among former members of the 1-24 IN following their deployment to Iraq in 2004-2005. This population consists predominately of Veterans who have separated from military service. In order to characterize the post-deployment health status of the 1-24 IN, the investigation includes the following objectives:

1. Identify the set of self-reported health conditions affecting the 1-24 IN subsequent to their 2004-2005 deployment to Iraq;
2. Compare the frequency of post-deployment self-reported health conditions between those in the 1-24 IN who remain in service and those who have separated or retired from the Army and are Department of Veterans Affairs (VA) beneficiaries;
3. Compare the frequency of self-reported health conditions between former members of the 1-24 IN and a similar exposure group consisting of non-deployed personnel in the 1 SBCT to subsets of Millennium Cohort Study participants. APHC will obtain rosters of the formerly deployed personnel to be compared in this investigation, except for Millennium Cohort Study participants who will be identified by the Naval Health Research Center. Health status for these individuals, other 1 SBCT personnel, and comparison SBCT personnel will be ascertained in two ways:
 - a. By mining outpatient and inpatient diagnosis and discharge codes (International Classification of Diseases, 9th Revision, ICD-9 CM codes) contained in the Defense Medical Surveillance System maintained by the Armed Forces Health Surveillance Branch and the VA Health Data Repository maintained by the VA Office of Public Health. Meeting this objective will require a single pull of pre-existing health care encounter data records from DoD and VA health databases.
 - b. By inviting former members of the 1 SBCT to complete a health survey designed to be directly comparable to surveys completed by participants in the Millennium Cohort Study. Meeting this objective will require a single information collection effort (i.e., a one-time survey of former Army personnel. Meeting the objective will additionally entail leveraging of a pre-existing Millennium Cohort Study database of MCS study participants' survey response data.

As described in Section 3, the initial invitation to participate in the Post-deployment Health Survey will be sent by email, if available, or U.S. Postal Service (mail), and telephonically should a response not be received after use of the prior two methods. Contact information for potential survey respondents will be obtained from internal Army records. It is anticipated that 80% of respondents will complete the survey on-line utilizing Verint Public Health survey software, a secure APHC survey website (See screenshots of online survey instrument, enclosed). The initial splash screen of the survey website (URL:) displays a privacy statement and agency disclosure notice. After clicking the splash page “OK” button, the survey landing page displays the survey approval authority, survey control number, and expiration date. This information is followed by survey information presented on multiple pages. Before accessing the survey itself, the respondent will be presented with a voluntary consent statement, which reads, “By clicking “Next” you are consenting to participate in the survey described above. You are also indicating that you understand that your consent is completely voluntary, and that your consent is based solely on the information provided above.” The survey follows, presented on multiple pages (See screenshots of online survey, enclosed).

Recognizing that some survey participants may have limited access to electronic media (20%), a hardcopy survey will be made available for completion, which will be returned to APHC via certified mail in an envelope with postage provided to the participant by APHC. Alternatively, the survey may be delivered telephonically, if necessary. The information preceding the online survey, including the privacy statement and agency disclosure notice, survey control information, and informed consent verbiage will be included in the written survey (see paper version of the survey, enclosed). For surveys completed telephonically, the interviewer will read the information contained in the online and paper based survey packages, prior to delivering the survey itself (i.e. the privacy statement and agency disclosure notice, survey control information, and informed consent verbiage.)

Responses to paper-based surveys and surveys delivered telephonically will be entered into the online Verint survey application by APHC staff. After a quality control check by a second data entry personnel, paper-based surveys will be destroyed using a government-approved cross-cut paper shredder.

The Post-deployment Health Survey dataset exported from Verint will be saved and stored on the APHC secure S: drive in a directory accessible only by APHC project staff. Read and write access to the primary and derivative analytic datasets will be restricted by Common Access Card (CAC) to the APHC project personnel and for whom S: drive access has been granted.

3. Use of Information Technology

The initial invitation to participate in the survey will be sent by email (if available), U.S. Postal Service (mail), and telephonically should a response not noted via the prior two methods. The survey itself will be completed on-line utilizing an approved enterprise web

survey software. Approximately 80% of respondents will complete the survey in this electronic fashion. Recognizing that an estimated 20% of survey participants may have limited access to electronic media, a hardcopy survey and/or survey delivered telephonically will be made available (with the results being transcribed into the above mentioned computer application).

4. Non-duplication

The information obtained through this collection is unique and is not already available for use or adaptation from another cleared source.

5. Burden on Small Businesses

This information collection does not impose a significant economic impact on a substantial number of small businesses or entities.

6. Less Frequent Collection

This section is not applicable because this clearance request is for single data collection cycle.

7. Paperwork Reduction Act Guidelines

This collection of information does not require collection to be conducted in a manner inconsistent with the guidelines delineated in 5 CFR 1320.5(d)(2).

8. Consultation and Public Comments

Part A: PUBLIC NOTICE

A 60-Day Federal Register Notice for the collection published on Tuesday, March 13, 2018. The 60-Day FRN citation is 83 FRN 10841.

No comments were received during the 60-Day Comment Period.

A 30-Day Federal Register Notice for the collection published on Wednesday, May 30, 2018. The 30-Day FRN citation is 83 FRN 24749.

Part B: CONSULTATION

In addition to soliciting public comments through the 60-Day Federal Register Notice, the Army intends to seek out consultation from relevant authorities before the next OMB reinstatement.

9. Gifts or Payment

No payments or gifts are being offered to respondents as an incentive to participate in the collection.

10. Confidentiality

A Privacy Act Statement is not required for this collection because we are not requesting individuals to furnish personal information for a system of records.

A System of Record Notice (SORN) is not required for this collection because records are not retrievable by PII.

A Privacy Impact Assessment (PIA) is not required for this collection because PII is not being collected electronically.

Within one month of their receipt by APHC, paper copies of completed surveys will be transcribed into Verint, and then destroyed using a cross-cut shredder. Electronic data files derived from the completed surveys will be stored on APHC's secure servers indefinitely.

11. Sensitive Questions

The questionnaire contains questions on a broad range of health topics, including medical conditions, health behaviors, and exposures that may have affected the interviewees' health. There is a risk of possible discomfort from answering questions which participants consider to be of a sensitive nature. Interviewees' may skip any question that makes them feel uncomfortable. Participation is completely voluntary and can be discontinued at any time.

12. Respondent Burden and its Labor Costs

a. Estimation of Respondent Burden

1. Post-deployment Health Survey
 - a. Number of Respondents: 3,500
 - b. Number of Responses Per Respondent: 1
 - c. Number of Total Annual Responses: 1
 - d. Response Time: 1 hour
 - e. Respondent Burden Hours: 3,500 hours

- 2. Total Submission Burden
 - a. Total Number of Respondents: 3,500
 - b. Total Number of Annual Responses: 3,500
 - c. Total Respondent Burden Hours: 3,500 hours

b. Labor Cost of Respondent Burden

- 1. Post-deployment Health Survey
 - a. Number of Total Annual Responses: 3,500
 - b. Response Time: 1 hour
 - c. Respondent Hourly Wage: \$23.86
 - d. Labor Burden per Response: \$23.86
 - e. Total Labor Burden: \$83,510

The respondent hourly wage was determined by using the Bureau of Labor Statistics Website; Mean Hourly Wage, All Occupations, \$23.86.
(https://www.bls.gov/oes/current/oes_nat.htm; 03 November 2017).

2. Overall Labor Burden

- a. Total Number of Annual Responses: 3,500
- b. Total Labor Burden: \$83,510

13. Respondent Costs Other Than Burden Hour Costs

There is the assumption that participants have a permanent home address of record and have and/or have access to email/internet or a telephonic device. Thus there should be no additional annualized costs to respondents other than the labor costs addressed in Section 12 of this document to complete this collection.

14. Cost to the Federal Government

a. Labor Cost to the Federal Government

- 1. Post-deployment Health Survey
 - a. Number of Total Annual Responses: 3,500
 - b. Processing Time per Response: 3 hours
 - c. Hourly Wage of Worker(s) Processing Responses: \$32.88
 - d. Cost to Process Each Response: \$98.64
 - e. Total Cost to Process Responses: \$345,240

2. Overall Labor Burden to Federal Government

- a. Total Number of Annual Responses: 3,500
- b. Total Labor Burden: \$345,240

The hourly wage of worker(s) processing responses was determined by using the U.S. Office of Personnel Management (OPM) Website; Hourly Wage, Grade 10-Step 5, for the locality pay area of Washington-Baltimore-Arlington, DC-MD-VA-WV-PA (where U.S. Army Public Health Center, Aberdeen Proving Ground, Maryland is located), \$32.88. (https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2017/DCB_h.pdf; 03 November 2017).

b. Operational and Maintenance Costs

- a. Equipment: \$0
- b. Printing: \$0
- c. Postage: \$3,000
- d. Software Purchases: \$0
- e. Licensing Costs: \$0
- f. Other: \$500 (paper); \$500 (envelopes)
- g. Total: \$4,000

- 1. Total Operational and Maintenance Costs: \$4,000
- 2. Total Labor Cost to the Federal Government: \$345,240
- 3. Total Cost to the Federal Government: \$349,240

15. Reasons for Change in Burden

This is a new collection with a new associated burden.

16. Publication of Results

The deliverables of this initiative will include an APHC information paper, a technical report, and summary presentations of the evaluation and its findings, including a presentation and brief to the Chief of Staff of the Army and the Surgeon General. Per the Chief of Staff of the Army's tasker, this initiative will be conducted rapidly, with initial results provided in an information paper summarizing the progress of the investigation.

A full report of the findings of this investigation will be written within 18 months of approval of this project by the APHC Public Health Review Board and other parties, as appropriate.

17. Non-Display of OMB Expiration Date

We are not seeking approval to omit the display of the expiration date of the OMB approval on the collection instrument.

18. Exceptions to "Certification for Paperwork Reduction Submissions"

We are not requesting any exemptions to the provisions stated in 5 CFR 1320.9.