

Supporting Statement

Operation UNITED ASSISTANCE

EBOLA VIRUS DISEASE [EVD] REDEPLOYMENT ASSESSMENT AND MEDICAL CLEARANCE AND EXPOSURE RISK EVALUATION OF DoD MILITARY, CIVILIAN, AND CONTRACT PERSONNEL DEPLOYING TO EBOLA OUTBREAK COUNTRIES

SUPPORTING STATEMENT – PART A

A. JUSTIFICATION

1. Need for the Information Collection

Ebola virus disease (EVD), formerly known as Ebola haemorrhagic fever, is a severe, often fatal illness in humans. The virus is transmitted to people from wild animals and spreads in the human population through human-to-human transmission. The average EVD case fatality rate is around 50%. Case fatality rates have varied from 25% to 90% in past outbreaks. The ongoing Ebola epidemic is the largest in history, affecting multiple countries in West Africa (ref. <http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/distribution-map.html#areas>). Recently, Ebola was imported to the US from Liberia and has been associated with locally acquired cases in healthcare workers as reported in the United States: (<http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/united-states-imported-case.html>). CDC and partners are taking precautions to prevent the further spread of Ebola within the United States. CDC is working with other U.S. government agencies, the World Health Organization (WHO), and other domestic and international partners and has activated its Emergency Operations Center to help coordinate technical assistance and control activities with partners. CDC has also deployed teams of public health experts to West Africa and will continue to send experts to the affected countries.

The Department of Defense (DoD) is currently supporting Ebola efforts in West Africa under Operation United Assistance (OUA). As part of this overseas humanitarian assistance/disaster relief (OHADR) mission, several thousand personnel, including Service members, civilians, and contractors will be deploying to the area where they will face the very real risk of exposure to EVD. The “Ebola Virus Disease Redeployment Risk Assessment and Medical Clearance Form” is designed to collect information from individuals at the time of redeployment from West Africa is critical to DoD’s efforts to ensure that Ebola exposure risk is evaluated, proper prevention and quarantine efforts are implemented, appropriate medical care is provided, and the spread of Ebola beyond West Africa is minimized.

This proposed information collection activity is supported by several DoD regulations, Federal laws, and a new Executive Order, including:

- 10 U.S.C. § 136(b) which assigns the responsibilities of the DoD Under Secretary of Defense for Personnel and Readiness (USD(P&R)), and includes maintenance of health and readiness of DoD personnel in those responsibilities.
- DoDD 5124.02, which assigns the responsibilities of the (USD(P&R)), including support of health and medical affairs, and assurance of readiness of personnel.
- DoDD 6490.02E, “Comprehensive Health Surveillance” and DoDI 6490.03, “Deployment Health” (DoDI 6490.03), which form the basis for all pre- and post-deployment surveillance, as well as in-theater surveillance.
- Section 361 of the Public Health Service Act (42 U.S. Code § 264)
- 42 Code of Federal Regulations Parts 70 and 71
- Executive Order: Ordering the Selected Reserve and Certain Individual Ready Reserve Members of the Armed Forces to Active Duty (<http://www.whitehouse.gov/the-press-office/2014/10/16/executive-order-ordering-selected-reserve-and-certain-individual-ready-r>)

2. Use of the Information

This information will be used by DoD medical and public health officials to: (1) ensure Ebola exposure risk is evaluated, (2) proper prevention and quarantine efforts are implemented, (3) appropriate medical care is provided, (4) medical surveillance programs are robust, and (4) the spread of Ebola beyond West Africa is minimized.

3. Use of Information Technology

To enable to rapid transmission of the data collected to medical and public health authorities, DoD is currently assessing whether any current field deployable information systems can be used for this data collection. Technical approaches being considered include the use of DoD theater medical information systems, fillable pdfs, or scantron-type systems which would be supported by information technology in the field. Given the infrastructure shortfalls and the lack of DoD information systems in West Africa, the fallback position until the technology solution is available will be to have the respondents complete the questionnaires by hand with their data subsequently being entered into by the DoD Medical/Public Health community personnel.

4. Non-duplication

No information is already available which can be used, or modified for use, for the purposes of this collection. This information collection will be sensitive to rapidly changing health risks in an area with an epidemic of a deadly disease.

5. Burden on Small Business

All respondents are individuals, and none are small businesses.

6. Less Frequent Collection

Less frequent collection of the requested information would pose an enormous health risk to the respondents as well as the U.S. public, by increasing the risk of spread of Ebola Virus Disease between DoD personnel, and from DoD personnel to their family members, and close contacts upon return from deployment. The entire purpose of the information collection – medical surveillance – would be defeated by less frequent collection.

7. Paperwork Reduction Act Guidelines

The following special circumstances exist that require the collection to be conducted in a manner inconsistent with the guidelines delineated in 5 CFR 1320.5(d)(2):

(a) Respondents are likely to be required to report more frequently than quarterly using the *Ebola Virus Disease Exposure Risk Evaluation Form* because this form will be used for recording possible new exposure events, physical signs, or symptoms. Because they will be potentially at risk for Ebola Virus Disease (EVD), they will need to be continually monitored for changes in their status to ensure their well-being as well as that of their coworkers and military members in close proximity.

(b) Both forms used for EVD surveillance will need to be completed by respondents promptly, in fewer than 30 days. Often the forms will need to be completed upon receipt, depending on the urgency of the situation, and the perceived health risk to the respondent as well as potential contacts in West Africa, as well as to those encountered upon return to the U.S.

8. Consultation and Public Comments

a. The Department of Defense is requesting emergency processing of this request under 5 CFR § 1320.13, and requests waiver of the notice requirement under 5 CFR § 1320.13(d). We need to obtain approval of this information collection no later than October 23, 2014.

b. Notice of this information collection has not been published in the Federal Register because of the emergent nature of the health crisis in West Africa, and the immediate deployment of DoD military and civilian personnel, as well as contractor personnel. The information collection is required immediately, prior to expiration of the time period required for notice and comment. This is essential to the mission of the Agency to ensure the health of deploying personnel, as well as those members of the public that they may have contact with upon their return to the U.S. To comply with the normal procedures and timelines of OMB would risk harm to those members of the public deploying to West Africa, as well as the population remaining in the U.S due to the heightened risk of spread of the disease without careful health surveillance upon return from deployment.

c. The Department of Defense has consulted with the Centers for Disease Control and Prevention, the Department of State, the Agency for International Development, and several Defense Agencies regarding disease control efforts and health surveillance in response to the public health emergency in West Africa. DoD has also specifically discussed these new information collections with representatives of the various Military Services, representing deploying military members, who have participated in the development of the content of the forms. Other personnel, including DoD civilian and contractor personnel are already required by DoD regulations (DoDI 6490.03) and, in the case of contractors, by their contracts, to fulfill all health and medical surveillance requirements related to their specific deployment, based on the geographic location, and health hazards. No members of the general public or government personnel unaffiliated with this DoD deployment to West Africa will be asked to complete this information collection.

9. Gifts or Payment

There will be no gifts or payments provided to respondents.

10. Confidentiality

The Privacy Act System of Records Notice (SORN) ID number is A0040-5a DASG DoD “Defense Medical Surveillance System”. (August 19, 2009, 74 FR 41877)

The information collected using the “Ebola Virus Disease Redeployment Risk Assessment and Medical Clearance Form” will be subject to the Privacy Act and the Health Insurance Portability and Accountability Act (HIPAA). As such, they will be protected by Federal laws and regulations on confidentiality of health records, as well as DoD regulations, including DoDD 5400.11, DoD 5400.11-R, DoD 6025.18-R, and DoD 8580.02-R.

11. Sensitive Questions

Sensitive information will be collected on the “Ebola Virus Disease Redeployment Risk Assessment and Medical Clearance Form,” including personal health information and the social security number, because this data will comprise part of the individual’s medical record and is required for health surveillance as well as Ebola prevention measures, including illness investigations and contact tracing.

12. Respondent Burden, and its Labor Costs

a. Estimation of Respondent Burden

Due to the urgency of this request, an estimate of the respondent burden is approximately 1,200. Based on our experience with our pre- and post-deployment health assessment forms (DD Forms 2795, 2796, and 2900), we estimate the respondent burden for each form at 12 minutes. It may take longer if the medical provider reviewing the form determines additional medical assessment is required due to potential exposure to Ebola.

The table below provides information on the estimated time to complete the data collection forms. We assess approximately 1,200 contractors (*two forms per contractor). Respondents on average spend 12 minutes per form. The total respondent burden is estimated at 480 hours (1,200 respondents * 2 forms* 12 minutes each/60).

A	B	C	D	E	F	G
Estimated Number of Respondents	Average Burden per Respondent per Form (Minutes)	Total Annual Burden per Form (Minutes)	Number of Responses per Respondent	Total Respondent Burden (Minutes)	Total Burden per Respondent (Minutes)	Total Respondent Burden (Hours)
		(A*B)		(C*D)	(B*D)	(E/60)
DD Form 2290 N = 1200	12	14400	1	14400	12	240
DD Form 2291 N = 1200	12	14400	1	14400	12	240
*Each respondent is required to complete 2 forms.						480

b. Labor Cost of Respondent Burden

The estimated labor cost of Respondent Burden is based on the average of the 2014 Government Service Salary Schedule, GS-9, Step 7.

Total annual burden hours * estimated hourly salary of respondents annualized cost to respondents

Estimated annual salary per contractor = \$62,573 (\$30.08/hour)

480 burden hours * \$30.08 = \$14,438

= \$12.03 per respondent (\$14,438/ 1,200)

13. Respondent Costs Other Than Burden Hour Costs

No costs are anticipated for the respondent, since they will be using resources provided by DoD to complete the forms.

14. Cost to the Federal Government

As the situation requiring the implementation of these data collection requirements is unprecedented in history, annualized costs to the Federal Government in collecting and

processing the information collected is a crude estimate at best. Given an initial estimate of 12 minutes for each respondent to complete the forms, 15 minutes for a licensed medical provider to review the forms, and other associated costs, the following table provides our best estimate on costs to the Federal Government given the uncertainties surrounding the number of deployers to West Africa in support of OUA:

Element	Estimated Cost
Equipment in the field	\$ 20,000.00
Overhead	\$ -
Postage	\$ -
Contracting out for services	\$ -
Indirect cost for respondent completion of forms	\$ 100,000.00
Indirect cost for provider review of forms	\$ 100,000.00
Total Estimated Cost to Federal Government	\$ 220,000.00
Number of forms to be completed	4,000
Time to complete forms (hours)	0.50
Cost / hour for respondent completion of forms	\$ 50.00
Time to review forms (hours)	0.25
Cost / hour for licensed provider to review forms	\$ 100.00

NOTE: The estimate of the number of “Ebola Virus Disease Exposure Risk Evaluation Forms” to be completed is based on the belief that far less than half of the DoD’s deploying force will be possibly exposed to EVD while some individuals, by virtue of their duties, may have more than one possible exposure. If EVD is effectively controlled, there should be no further need to continue to collect this information beyond OUA, resulting in no future annualized costs.

15. Reasons for Change in Burden

Not applicable. This is a new and urgent data collection.

16. Publication of Results

At present time, there are no plans for using this data for statistical purposes.

17. Non-Display of OMB Expiration Date

Due to the unprecedented nature of this emerging public health risk, we are uncertain how long the DoD will be supporting OUA. As such, we are requesting an expiration date be omitted from this data collection instrument.

18. Exceptions to "Certification for Paperwork Reduction Submissions"

There are no provisions of Item 19.a of OMB Form 83-I to which DoD cannot certify.