

SUPPORTING STATEMENT - PART A

Researcher Responsibilities – 0720-0042

1. Need for the Information Collection

Federal Government institutions wishing to conduct or support research on human subjects must first submit for approval to duly designated authorities an Assurance that they will comply with established guidelines in such research. Such Assurances are granted by Components of the Department of Defense (DoD) and by the Department of Health and Human Services (DHHS). DoD guidance requires principal and associate investigators individually and explicitly to acknowledge that they understand and accept responsibility for protecting the rights and welfare of human research subjects in accordance with: a) The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research; b) the DoD regulations for the protection of human subjects at Title 32 Code of Federal Regulations Part 219 (32 CFR 219), "Protection of Human Subjects" and DoD Instruction 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research"; c) the Assurance of the engaged institution; relevant institutional policies and procedures where appropriate; and other Federal, State, or local regulations where appropriate.

2. Use of the Information

This collection instrument is for use by the Component within the Office of the Under Secretary of Defense for Personnel and Readiness (USD(P&R)). Principal and associate investigators engaged in research involving human subjects supported or conducted under the purview of the USD(P&R) must read and sign the document attesting to their commitment to abide by the body of regulations designed to protect the wellbeing and privacy of human research subjects whether the research is clinical or behavioral/social. Respondents are informed of the purpose for the collection and how the information will be used by the Privacy Act Statement at the top of the document.

The document is provided through an electronic research management tool that is accessible via the internet. Principal and associate investigators will download the document, complete and sign it, and upload it back into the system. Institutions that do not use the electronic tool will distribute the document as an e-mail attachment. After completing and signing the document, the principal and associate investigators will scan the document and return it to the Component as a Portable Document Format (.pdf) attachment to an e-mail. The forms are stored on a secured drive as part of the research record.

3. Use of Information Technology

We anticipate 100% of responses will be collected electronically; however, if the investigators do not have access to the electronic research management tool or scanning equipment, they will be allowed to mail the document to the Component office.

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 collection does not involve small businesses or other small entities.

6. Less Frequent Collection

Individuals are requested to provide one response as a result of conducting human subject research under the purview of the USD(P&R). If they remain engaged in such research under USD(P&R) after three years, they will be asked to reaffirm their commitment to ethical human research by re-signing the form.

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 Friday, January 6, 2017. The 60-Day FRN citation is 82 FRN 1723. No comments were received during the 60-Day Comment Period.

A 30-Day Federal Register Notice for the collection published Thursday, May 4, 2017. The 30-Day FRN citation is 82 FRN 20866.

Part B: CONSULTATION

No additional consultation apart from soliciting public comments through the 60-Day Federal Register Noticed was conducted for this submission.

9. Gifts or Payment

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

10. Confidentiality

The collection contains no sensitive information. We ensure confidentiality to the fullest extent permitted by law.

The Privacy Act Statement (PAS) is located at the top of the collection instrument.

Systems of Record Notice (SORN) EDHA 18 located at:

<http://dpclid.defense.gov/Privacy/SORNsIndex/DOD-wide-SORN-Article-View/Article/570681/edha-18/>

The Privacy Impact Assessment (PIA) for the Electronic Institutional Review Board (e-IRB) system can be accessed using the link below:

<https://health.mil/Military-Health-Topics/Privacy-and-Civil-Liberties/Privacy-Impact-Assessments/MHS-PIA-List>

In accordance with the OUSD(P&R) Records Retention and Disposition Schedule, records must be deleted/destroyed 10 years after completion or termination of the research protocol.

11. Sensitive Questions

No questions considered sensitive are being asked in this collection.

12. Respondent Burden and its Labor Costs

(P): Repeat (using copy and paste) 1a-e for each collection instrument.

(P): If the same respondents are completing multiple instruments in a collection listed below, do not double count them in 12.a "Total Submission Burden" and 12.b. "Overall Labor Burden".

a. Estimation of Respondent Burden

1. Researcher Responsibilities Form

- a. Number of Respondents: 89
- b. Number of Responses Per Respondent: 1
- c. Number of Total Annual Responses: 89
- d. Response Time: 30 minutes
- e. Respondent Burden Hours: 45hours

2. Total Submission Burden (Summation or average based on collection)

- a. Total Number of Respondents: 89
- b. Total Number of Annual Responses: 89
- c. Total Respondent Burden Hours: 45 hours

b. Labor Cost of Respondent Burden

1. Researcher Responsibilities Form

- a. Number of Total Annual Responses: 89
- b. Response Time: 30 Minutes

- c. Respondent Hourly Wage: \$69.56
- d. Labor Burden per Response (*P: B multiplied by C*): \$34.78
- e. Total Labor Burden (*P: A multiplied by B multiplied by C*): \$3,130.20

2. Overall Labor Burden

- a. Total Number of Annual Responses (*P: add all "a's" in this section*): 89
- b. Total Labor Burden (*P: add all "e's" in this section*): \$3,130.20

The Respondent hourly wage was determined by using the Department of Labor Wage Website https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/16Tables/html/DCB_h.aspx

13. Respondent Costs Other Than Burden Hour Costs

There are no annualized costs to respondents other than the labor burden 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. Researcher Responsibilities Form

- a. Number of Total Annual Responses: 89
- b. Processing Time per Response: .08hours
- c. Hourly Wage of Worker(s) Processing Responses : \$69.56
- d. Cost to Process Each Response (*P: B multiplied by C*): \$5.56
- e. Total Cost to Process Responses (*P: A multiplied by B multiplied by C*): \$494.84

2. Overall Labor Burden to Federal Government

- a. Total Number of Annual Responses (*P: add all "a's" in this section*): 89
- b. Total Labor Burden (*P: add all "e's" in this section*): \$494.84

b. Operational and Maintenance Costs

- a. Equipment: \$0
- b. Printing: \$0
- c. Postage: \$0
- d. Software Purchases: \$0
- e. Licensing Costs: \$0
- f. Other: \$0
- g. Total: \$0
- 1. Total Operational and Maintenance Costs: \$0
- 2. Total Labor Cost to the Federal Government: \$494.84
- 3. Total Cost to the Federal Government \$494.84

15. Reasons for Change in Burden

This is a reinstatement of a collection that has expired. There has been no change in burden since the last approval.

16. Publication of Results

The results of this information collection will not be published.

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.