



PERSONNEL AND  
READINESS

UNDER SECRETARY OF DEFENSE  
4000 DEFENSE PENTAGON  
WASHINGTON, D.C. 20301-4000

APR 26 2023

The Honorable Gary C. Peters  
Chairman  
Committee on Homeland Security and  
Governmental Affairs  
United States Senate  
Washington, DC 20510

Dear Mr. Chairman:

The Department's response to section 716 of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021 (Public Law 116-283), "Temporary Exemption for Uniformed Services University of the Health Sciences from Certain Paperwork Reduction Act Requirements," is enclosed.

This report describes the impact that this exemption has had upon the conduct of research and program evaluation at the Uniformed Services University of the Health Sciences (USUHS) for the 24-month period of January 31, 2021 to January 30, 2023. During this period, USUHS conducted or sponsored 78 projects that met the criteria for application of the temporary exemption.

This report demonstrates an estimated 25,506 days saved in time and an estimated \$318,198 in cost savings with no additional respondent burden, by removing the Department of Defense (DoD) exemption determination, DoD survey license approval, or Office of Management and Budget (OMB) approval to conduct activities that involved an information collection. These days are inclusive of additional time for application preparation, coordination of multi-level DoD office review, publication of Federal Register Notices, revisions to data collection instruments, and OMB review and approval.

Thank you for your continued strong support for the health and well-being of our Service members, veterans, and their families. I am sending similar letters to the other appropriate congressional committees.

Sincerely,

Gilbert R. Cisneros, Jr.

Enclosure:  
As stated

cc:  
The Honorable Rand Paul  
Ranking Member



**UNDER SECRETARY OF DEFENSE**  
4000 DEFENSE PENTAGON  
WASHINGTON, D.C. 20301-4000

PERSONNEL AND  
READINESS

**APR 26 2023**

The Honorable James R. Comer  
Chairman  
Committee on Oversight and Accountability  
U.S. House of Representatives  
Washington, DC 20515

Dear Mr. Chairman:

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Gilbert R. Cisneros, Jr.

Enclosure:  
As stated

cc:  
The Honorable Jamie Raskin  
Ranking Member



**UNDER SECRETARY OF DEFENSE**  
4000 DEFENSE PENTAGON  
WASHINGTON, D.C. 20301-4000

**PERSONNEL AND  
READINESS**

**APR 26 2023**

The Honorable Jack Reed  
Chairman  
Committee on Armed Services  
United States Senate  
Washington, DC 20510

Dear Mr. Chairman:

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Enclosure:  
As stated

cc:  
The Honorable Roger F. Wicker  
Ranking Member



**UNDER SECRETARY OF DEFENSE**  
4000 DEFENSE PENTAGON  
WASHINGTON, D.C. 20301-4000

PERSONNEL AND  
READINESS

**APR 26 2023**

The Honorable Mike D. Rogers  
Chairman  
Committee on Armed Services  
U.S. House of Representatives  
Washington, DC 20515

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Gilbert R. Cisneros, Jr.

Enclosure:  
As stated

cc:  
The Honorable Adam Smith  
Ranking Member

# Report to Congress



## Temporary Exemption for Uniformed Services University of the Health Sciences from Certain Paperwork Reduction Act Requirements

**April 2023**

The estimated cost of this report or study for the Department of Defense is approximately \$7,380 in Fiscal Years 2021 - 2023. This includes \$10 in expenses and \$7,370 in DoD labor.

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## Introduction

The former Director and Deputy Director of the National Institutes of Health (NIH), Drs. Francis Collins and Kathy Hudson (2017), noted the following after Congress granted the NIH a waiver from the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. § 3501 et seq.):

Minimizing needless paperwork and bureaucracy is an admirable goal. However, as applied to biomedical research, the law requires multiple levels of government review and public comment on any set of questions that NIH researchers propose to ask of 10 or more persons in a scientific study supported by contracts, the Intramural Research Program, and many cooperative agreements. This process rarely results in substantive changes, but it delays the start of research for 9 months, on average — dissuading investigators, especially trainees, from undertaking important studies. Through the Cures Act, lawmakers have now liberated science from this red tape by eliminating Paperwork Reduction Act requirements for NIH research — a step that will help speed the initiation of research and the generation of new knowledge. (*New England Journal of Medicine*)

This report is in response to section 716 of the William M. (Mac) Thornberry National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2021 (Public Law 116–283), “Temporary Exemption for Uniformed Services University of the Health Sciences from Certain Paperwork Reduction Act Requirements” (herein referred to as the “temporary exemption”) for the Uniformed Services University of the Health Sciences (USUHS) to submit an updated report containing:

1. The estimated time saved by the USUHS (if applicable) by reason of the temporary exemption from certain PRA requirements;
2. The research within the scope of such exemption that has been initiated, is ongoing, or has been completed during the period in which the exemption is in effect;
3. The estimated cost savings by USUHS that can be attributed to such exemption; and
4. The additional burdens upon the research subjects of USUHS that are attributable to such exemption.

The exemption period commenced on January 31, 2021, which was 30 days from January 1, 2021, the date that the NDAA for FY 2021 was enacted via override of the President’s veto. Section 716 required the Department of Defense (DoD) to submit an interim report on its preliminary findings. USUHS submitted an interim report for the period February 1, 2021 to October 15, 2021. Additionally, by January 1, 2023, DoD was required to provide a final report updating any information provided in the interim report. This updated Final Report describes the impact of the exemption for the 24 months, from January 31, 2021 to January 30, 2023.

## Executive Summary

Section 716 provided a temporary, 2-year exemption from the requirements of 44 U.S.C. §§ 3506(c), 3507, and 3508 for the voluntary collection of information during the conduct of research and program evaluations that were conducted or sponsored by USUHS and funded by the Defense Health Program (DHP). This temporary reprieve carried with it reporting requirements at the 1-year and 2-year marks.

The PRA applies to collection of information from 10 or more members of the public using “identical questions” or, alternatively, collections from Federal agencies, instrumentalities, or employees (including Service members) “to be used for general statistical purposes.” 44 U.S.C. § 3502(3)(A).<sup>1</sup>

The requirements in 44 U.S.C. §§ 3506(c), 3507, and 3508 were enacted pursuant to the PRA. Department of Defense Instruction (DoDI) 8910.01, “Information Collection and Reporting,” and Department of Defense Manual (DoDM) 8910.01, Volume 1, “DoD Information Collections Manual: Procedures for DoD Internal Information Collections,” and Volume 2, “DoD Information Collections Manual: Procedures for DoD Public Information Collections,” serve in part to implement the requirements of the PRA and establish the rules and procedures for DoD and Office of the Secretary of Defense Components to collect information internally from DoD populations, from multiple DoD Components, or from the general public. In addition, DoDI 1100.13, “DoD Surveys,” establishes DoD policy concerning collections of information specifically involving the use of surveys.

DoD internal information collection proposals, which are beyond the scope of the PRA unless the results “are to be used for general statistical purposes,” in accordance with 44 U.S.C. § 3502(3)(A), until recently, had to be reviewed and approved, pursuant to DoD policy, by the Office of Information Management (OIM) within Washington Headquarters Services (WHS), Executive Services Directorate, Directives Division. If not determined to be exempt from the requirement for a license, such internal collections were issued a Report Control Symbol (RCS) license.<sup>2</sup> If the DoD information collection involves a collection of information from the general public from 10 or more persons or one in which the results “are to be used for general statistical purposes,” in accordance with 44 U.S.C. § 3502(3)(A), then the project is likely covered by the PRA and must also be reviewed by OIM, which makes a determination about PRA applicability and coordinates with the Office of Management and Budget (OMB) for review and approval.

The temporary exemption of section 716 only applied to collections of information covered by the PRA that consisted of voluntary collection of information in DHP-funded research and

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<sup>1</sup> Section 1320.3(c)(3) of title 5, Code of Federal Regulations, elaborates upon the latter portion of the statute’s definition of a “collection of information” to include “questions posed to agencies, instrumentalities, or employees of the United States, if the results are to be used for general statistical purposes, that is, if the results are to be used for statistical compilations of general public interest, including compilations showing the status or implementation of Federal activities and programs.”

<sup>2</sup> DoDI 8910.01, “DoD Implementation of the Paperwork Reduction Act,” December 5, 2022, recently eliminated the RCS licensing requirement for internal information collections that are not surveys. The RCS requirement remains in effect for surveys until December 4, 2023. DoDI 1100.13 remains in effect as DoD’s policy for the conduct of surveys.



program evaluations that were conducted or sponsored by USUHS. It did not apply to research or program evaluations conducted or sponsored by USUHS and funded from other sources, such as the NIH or Department of Homeland Security (DHS).

The temporary exemption in section 716 applied to “research” and “program evaluations.” These terms were not defined in the NDAA. In application of the exemption, USUHS employed the definition of research found in 32 CFR § 219.102, which is a “systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” USUHS defined program evaluation as a systematic method for collecting, analyzing, and using information to answer questions about projects, policies, and programs, particularly about their effectiveness and efficiency. Program evaluations are typically considered as not contributing to generalizable knowledge.

In general, military personnel are considered “members of the public” if the collection of information is addressed to them in their personal capacity as private citizens, but are not considered members of the public if they are responding to questions concerning their duty status to determine the effectiveness of Federal programs. Retirees and military dependents are generally considered members of the public [unless surveyed in accordance with 10 U.S.C. § 1782. Enclosure 3, Paragraph 7 of DoDM 8910.01, Volume 2.

This report describes the impact the exemption had upon the conduct of research and program evaluation at USUHS for the 24-month period from January 31, 2021 to January 30, 2023. The Key findings were:

1. During this period, USUHS initiated, conducted, or completed 78 human research studies and program evaluations that met the PRA definition of an “information collection” and would likely have required a multi-staged DoD review and OMB clearance.
2. Of greatest impact was the finding that application of the section 716 exemption resulted in a cumulative estimate of 25,506 days saved in the time it would likely have taken to coordinate the review processes necessary to receive an OMB approval to conduct activities that involved an information collection that would otherwise been subject to the PRA. These days include the estimated additional time the Principal Investigators (PIs) would have needed to spend in application preparation, coordination of multi-level DoD office reviews and responses to questions, publication of Federal Register Notices, revisions to data collection instruments, and OMB review and approval.
3. The estimated cost savings to USUHS during this 24 month period is \$318,198. The estimated USUHS cost savings were calculated based on PI additional time involved in preparation of materials for submission and response to queries, including revision of study materials.
4. USUHS affirms that there was no additional respondent burden imposed because of the temporary exemption, given that it is likely that all these projects would have eventually been approved by the DoD and by OMB after lengthier, iterative reviews.

## **Background**

### **USUHS**

The mission of USUHS is to educate, train, and comprehensively prepare uniformed services health professionals, scientists, and leaders to support the Military and Public Health Systems, the National Security and National Defense Strategies of the United States, and the readiness of our Uniformed Services, to include providing operational support to units around the world. The University's research program covers a wide range of topics important to both the military and public health. Research and scholarship is one of USUHS's three Mission Domains. USUHS's research priorities include basic, translational and applied research, clinical research, systems and operations research, population health, health services and health policy research, radiobiology and related fields research, and research in support of military readiness and operations. USUHS is home to many different research centers and institutes that help advance the University's research, education, and public service missions. Faculty members and students initiate biomedical, psychosocial, and behavioral studies and program evaluations in collaboration with other leading experts at USUHS's centers and institutes to push critical boundaries across many different biomedical science disciplines.

The University consists of the F. Edward Hébert School of Medicine, a medical school, which includes a full health sciences graduate education program; the Daniel K. Inouye Graduate School of Nursing; the Postgraduate Dental College; and the College of Allied Health Sciences. USUHS is authorized to grant appropriate advanced academic degrees and to establish postdoctoral, postgraduate/undergraduate programs, and technological institutes and institutes related to treatment and research in the health sciences. USUHS develops and supports academic and training programs designed to educate and train both health care providers and biomedical researchers. The ability to plan, conduct and complete faculty and student investigator-initiated research and program evaluation is central to accomplishing USUHS's academic and research missions.

### **The PRA and its Implementation in the DoD**

The PRA is a law governing certain collections of information by Federal agencies. This law requires Federal agencies to obtain OMB approval before requesting certain information from 10 or more members of the public using identical questions or certain internal agency collections that are to be used for general statistical purposes. "Information collections" include, among other things, forms, interviews, and reporting and recordkeeping requirements. One of the PRA's key purposes is to minimize the paperwork burden on members of the public resulting from collections of information by the Federal Government. The PRA is codified at subchapter I of chapter 35 of title 44, U.S.C.

Section 3506 of title 44, U.S. Code, details the Federal agency responsibilities for PRA implementation. Sections 3507 and 3508 of title 44, U.S. Code, describe how OMB executes the requirements for approval of Federal information collections from the general public. DoD establishes and reissues policies and assigns responsibilities for the collection of information and the control of the paperwork burden consistent with the PRA via DoDI 8910.01 and Volumes 1 and 2 of DoDM 8910.01. In addition, DoDI 1100.13 establishes policy concerning information

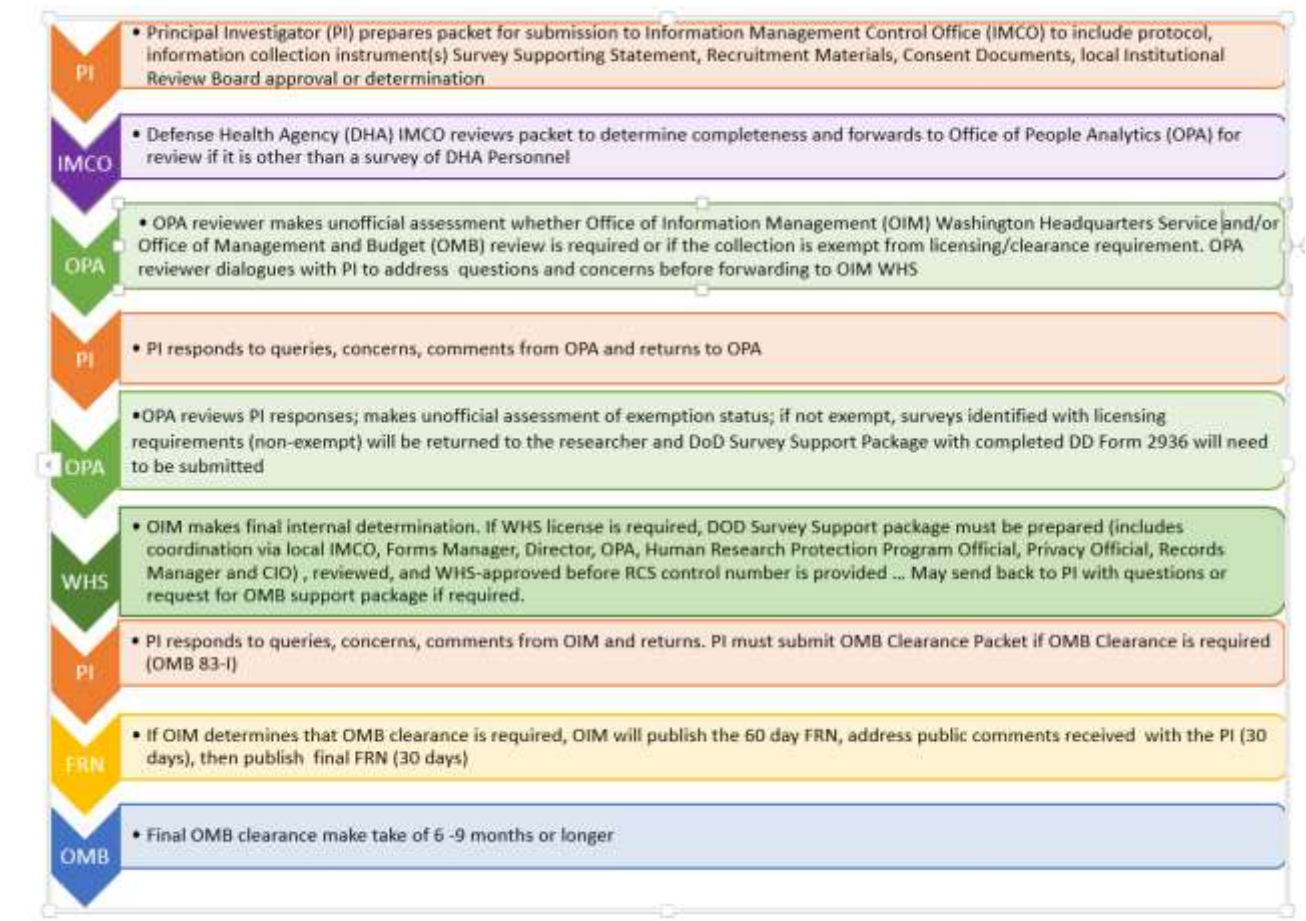
collections specifically involving the use of surveys. Within DoD, OIM determines whether a study or program evaluation is exempt from DoD and/or OMB clearance requirements.

**References** (see Appendix A)

**Definitions** (see Appendix B)

**DoD Survey Review Requirements**

Prior to the temporary exemption of section 716, the sequential reviews typically employed by USUHS to obtain DoD approval of research studies or program evaluations that meet the definition of an “information collection,” whether involving members of the public or an internal DoD population, are depicted in the figure below.



The review process was often iterative and prolonged in that clarification/additional information and/or revisions may be sought from the investigator by process reviewers at multiple stages in the process, which can lead to extensive delays. If an information collection requires OMB approval/clearance, additional supporting documents and signature coordination must be prepared and submitted to the Information Collection Management Office (IMCO) through the multiple DoD levels of review.

## **Survey Research and Program Evaluation at USUHS**

The use of surveys, questionnaires, interviews, and focus groups are common methods of data collection employed in human research and program evaluation. Human subject research involves a systematic investigation designed to develop or contribute to generalizable knowledge that obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or obtains, uses, studies, analyzes, or generates identifiable private information, personally identifiable information, or identifiable biospecimens. In contrast, program evaluations typically involve the systematic investigation of a specific program, organization, or process that involves participation of individuals engaged in that program, organization, or process. Activities involving program evaluation are usually focused on the program and not the individual supplying information. Surveys, questionnaires, interviews and focus groups were used to collect data in 28 percent (106 out of 376 protocols) of the USUHS research and program evaluation activities approved in the 24 months between January 31, 2021 and January 30, 2023.

Originating within a DoD institution, USUHS research and program evaluation are designed to be relevant to the DoD community and the Warfighter. USUHS investigators acknowledge the privilege to conduct research that can be directly translated to further developing, protecting, and assisting the military community. Delays in USUHS research activities also delay the development of knowledge that improves care to our military and education of military healthcare providers.

Research and program evaluation activities that use survey-style methodology must be conducted with the voluntary participation of human subjects. Research that requires regulatory review and approval by an Institutional Review Board (IRB) also requires regulatory-compliant, voluntary, and documented informed consent, unless otherwise waived by the IRB. Research and program evaluation activities that do not require approval of the IRB nonetheless must inform subjects or participants about the reason for the information collection, what is involved, and obtain the potential respondents' express or implied consent. At USUHS, human research studies and program evaluation projects are, at a minimum, reviewed by the human research protection analysts in the Human Research Protections Program Office (HRPPO).

Survey-style methodology is an often-employed research method for student-conducted research. As a part of the USUHS accreditation requirements as a university with a medical school, graduate health science school, graduate nursing school, and post-graduate dental college, research is a mission domain of the institution.

In accordance with DoDI 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and-Supported Research," all DoD institutions must have policies and procedures to ensure that applicable regulatory requirements for human subjects research are met and approvals are in place prior to conducting research. This requirement is met at USUHS by the submission of research and program evaluation protocols to the USUHS HRPPO for either IRB review or a determination by a designated Exemptions Determination Official that IRB review is not required.

## **Interpretation of the Waiver at USUHS**

USUHS interpreted section 716 as exempting USUHS from those requirements in DoDM 8910.01 and DoDI 8910.01 that implement the provisions of 44 U.S.C. §§ 3506(c), 3507, and 3508 in connection with USUHS-conducted or sponsored DHP-funded research and program evaluation that involves voluntary participation. The exemption did not apply to research conducted or sponsored by USUHS that was solely funded from other sources, such as NIH or DHS.

## **Application of the Waiver at USUHS**

All USUHS projects that involve the collection of data from humans are required to be reviewed by the USUHS HRPPO to determine the applicability of Federal and DoD regulatory requirements for review and approval. The USUHS HRPPO personnel applied the section 716 exemption to USUHS-conducted or sponsored, DHP-funded research and program evaluations initiated on from the period January 31, 2021 to January 30, 2023 that involved “collections of information” under the PRA.

## **The 716 Report Process**

### **The 716 Report**

Section 716 requires USUHS to update the findings previously reported in the Interim Report:

1. The estimated time saved by the USUHS (if applicable) by reason of the temporary exemption from certain PRA requirements;
2. The research within the scope of such exemption that has been initiated, is ongoing, or has been completed during the period in which the exemption is in effect;
3. The estimated cost savings by USUHS that can be attributed to such exemption; and
4. The additional burdens upon the research subjects of USUHS that are attributable to such exemption.

### **716 Methodology**

- A. The estimated time saved by USUHS by reason of the temporary exemption from certain PRA requirements:

Method: USUHS employed the use of estimated planning factors based on actual USU historical data and the DoD and OMB published timelines for information collection approval by the OMB to determine time saved and cost avoided by application of the temporary exemption. The breakout of the estimated time saved is depicted in Table 1 on the next page.

Table 1. Estimated Number of Days Saved in Times to Approval per Research Study or Program Evaluation

Activity	Estimated Number of Days to Completion
<b>PI and study team to prepare submission packet</b>	4
<b>HRPPO Review</b>	3
<b>PI to respond to each level of DoD reviewers questions and obtain all required DoD office concurrences</b>	6
<b>IMCO Review</b>	14
<b>Office of People Analytics Review</b>	15
<b>OIM WHS Review</b>	15
<b>Federal Register Notices, responses, and OMB review/approval</b>	270
<b>Total</b>	327

- B. The research and program evaluation within the scope of such exemption that has been initiated, is ongoing, or has been completed during the period in which the exemption is in effect:

Method: All studies and program evaluations (initiated, ongoing, or completed) that were DHP-funded, USUHS-conducted or sponsored and involved voluntary participation during the 24 month period of January 31, 2021, to January 30, 2023, were identified based upon whether OMB review and approval would likely have been required (Appendix D).

- C. The estimated cost savings by USUHS that can be attributed to such exemption:

Method: The cost to USUHS saved by application of the temporary exemption was estimated first by calculating the number of hours a PI would likely have taken to prepare the additional materials required for submission. The estimated number of 40 hours, which we utilized for the cost savings estimate, was conservative and included initial preparation, time to respond to questions, coordinate required serial office representatives' concurrences and to revise materials as requested or required. Then PIs were categorized based on actual or comparable academic faculty rank and an average salary per hour, noting student studies were required to involve a faculty member. The

average hourly salaries based on academic rank for the first period of January 31, 2021, to October 15, 2022 were:

- 1) Professor (\$130.97/hour);
- 2) Associate Professor (\$98.72/hour); and
- 3) Assistant Professor (\$81.53/hour).

The average hourly salaries based on academic rank for the second period of October 15, 2022 to January 30, 2023 were:

- 1) Professor (\$140.00/hour);
- 2) Associate Professor (\$118/hour); and
- 3) Assistant Professor (\$72/hour).

The cost savings to USUHS were calculated based on average hourly salary for the PI (as categorized above) and the number of hours in direct submission preparation likely for the research study or program evaluation.

D. The additional burdens upon the research subjects of USUHS that are attributable to such exemption:

The additional burdens upon the research subjects were those of duty time required to be spent in mandatory completion of the information collections.

## Findings

A. The estimated time saved by the USUHS by reason of the temporary exemption from certain PRA requirements is **25,506 days**, as depicted in the table below:

Table 2. Minimum Estimated Time in Days to Approval saved by USUHS because of the NDAA Survey Exemption

Type of Project	Number of Projects	Estimated Additional Approval Time (days) to Receive OMB Clearance	Total Estimated Additional Approval Time (days) Likely Required x Number of Projects
Research Study	68	327	22,236 days
Program Evaluation	10	327	3,270 days
Total	78	327	25,506 Days

- B. The research within the scope of such exemption that has been initiated, is ongoing, or has been completed during the period in which the exemption is in effect. There have been **78** research or program evaluation projects initiated, ongoing, or completed during the reporting period of January 31, 2021 to January 30, 2023. See Appendix D for a line listing of research studies and program evaluations.
- C. The estimated cost savings by USUHS that can be attributed to this exemption for the period January 31, 2021 to January 30, 2023, is **\$318,198**.
- D. The additional burdens upon the research subjects of USUHS that are attributable to such exemption: **none**. Given that all participation in these research studies and program evaluations was completely voluntary and was only conducted with the consent of the participants who had been given information on the purpose of the information collection and time required to participate, USUHS contends that there was **no additional respondent burden** imposed because of the temporary exemption. It is likely that all these projects would have eventually been approved by the DoD and by OMB – but only after undergoing the review procedures otherwise required by the PRA and/or DoD policy.

## **Additional Information**

In December 2010, the Administrator of OMB published a memorandum for the heads of the executive departments and agencies and independent regulatory agencies titled “Facilitating Scientific Research by Streamlining the Paperwork Reduction Process.” In that memorandum the Administrator established that PRA requirements did not extend to federally funded investigator-initiated research conducted by non-federal personnel because these grantee-conducted information collections had not been specifically requested by the Federal agency. This interpretation, however, was not applied to Federal investigator-initiated scientific research involving collections of information from 10 or more members of the general public.

The inapplicability of the PRA to investigator-initiated scientific research has already been legislated for two of the three largest federal agencies conducting biomedical, psychosocial, and behavioral research (The National Institutes of Health in 2016 and the Veterans’ Health Administration in 2022), leaving only the DoD remaining. Most recently, section 181 of the “Joseph Maxwell Cleland and Robert Joseph Dole Memorial Veterans Benefits and Health Care Improvement Act of 2022,” enacted via Public Law 117–328, the Consolidated Appropriations Act, 2023, amended 38 U.S.C. § 7330D and rendered the PRA inapplicable to “to the voluntary collection of information during the conduct of research by the Veterans Health Administration, including the Office of Research and Development, or individuals or entities affiliated with the Veterans Health Administration.”

The PRA does not apply to Government-owned and contractor-operated (GOCO) laboratories<sup>3</sup> but does apply to Government-owned and Government-operated (GOGO) laboratories. Therefore, GOCOs can conduct biomedical research involving information collection in a far more efficient manner than GOGOs.

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<sup>3</sup>The definition of “agency” under 5 CFR § 1320.3(a)(4) excludes Government-owned contractor-operated facilities, including laboratories engaged in national defense research and production activities.



## Conclusion

USUHS investigators conduct research that can translate to benefits for the Warfighter, the military community, and the public. USUHS students work with faculty investigators to conduct research that fulfills their academic requirements. Delays in the approvals of USUHS research and program evaluation activities not only delay the development of knowledge that improves care for our military and education of military healthcare providers but also compromises students' abilities to complete advanced degree requirements.

Conducting research is integral to running a health science academy. It is required for maintaining accreditation, allows USUHS to recruit the best faculty members to teach and mentor our students, and leverages our expertise to find solutions for DoD beneficiaries. At USUHS, faculty, staff, and students need to conduct human research and program evaluations that employ information collection methods that are subject to the broadly applied requirements for multi-level DoD and OMB review and approval. Addressing PRA requirements, which were originally intended in part to minimize burden, adds several months to the approval process for valuable medical research studies and program evaluations that need timely execution.

The congressional temporary exemption granted to USUHS allowed student researchers to complete studies needed to graduate on time, medical researchers to conduct important studies relevant to the health of Warfighters and their families, and educational and medical programs to be evaluated to identify needs for improvement. All these activities that have been initiated, are ongoing, or have been completed have done so in an efficient and effective fashion that respects the rights and welfare of the respondents and imposes no additional burdens on them. As an educational institution, a large part of the burden of this additional time for approvals falls on students, given their limited time at USUHS to conduct and complete research activities that are integral to their degree completion.

The Survey Exemption data presented in this summary provides the foundation for the finding that the exemption of USUHS investigator-initiated biomedical, psychosocial, and behavioral research and program evaluation benefits the Warfighter in reducing unnecessary research time and costs. Although the amount of cost savings adds up to only \$318,198, the figure that more accurately reflects the positive impact of the exemption is the 25,506 days saved. The days, and the significant number of hours that make up those days, can determine whether a study is conducted in a timely manner, within budget, or even conducted at all.

USUHS's research helps to save lives. Timely completion of this mission serves not only the educational needs of the students, but also contributes to new findings for the Warfighter, and ultimately supports national security and enables USUHS students to learn to care for those in harm's way.

## Appendix A

### References

DoDI 3216.02, “Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and -Supported Research.” April 15, 2020

DoDI 1100.13, “DoD Surveys,” January 15, 2015, as amended

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DoDM 8910.01, Volume 1, “DoD Information Collections Manual: Procedures for DoD Internal Information Collections,” June 30, 2014, as amended

DoDM 8910.01, Volume 2, “DoD Information Collections Manual: Procedures for DoD Public Information Collections,” June 30, 2014, as amended

Code of Federal Regulations, part 219 of title 32, “Protection of Human Subjects”

United States Code, chapter 35, subchapter I, of title 44, (also known as the “Paperwork Reduction Act”)

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Hudson, K.L. & Collins, F.S The 21st Century Cures Act — A View from the NIH, NEJM 376;2 January 12, 2017

Joseph Maxwell Cleland and Robert Joseph Dole Memorial Veterans Benefits Improvement Act, Sec. 181. Inapplicability of Paperwork Reduction Act. December 2022, enacted via Public Law 117-328, the Consolidated Appropriations Act, 2023, amended 38 U.S.C. § 7330D.

United States Code, sections 3506-3508 of title 44, “Public Printing and Documents”

## Appendix B

### Definitions

5 CFR § 1320.3(h) defines “information” as follows: “Information means any statement or estimate of fact or opinion, regardless of form or format, whether in numerical, graphic, or narrative form, and whether oral or maintained on paper, electronic or other media.”

44 U.S.C. § 3502(3) defines “collection of information” as follows:

(3) the term “collection of information”—

(A) means the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public, of facts or opinions by or for an agency, regardless of form or format, calling for either—

(i) answers to identical questions posed to, or identical reporting or recordkeeping requirements imposed on, ten or more persons, other than agencies, instrumentalities, or employees of the United States; or(ii) answers to questions posed to agencies, instrumentalities, or employees of the United States which are to be used for general statistical purposes; and

(B) shall not include a collection of information described under section 3518(c)(1);

## Appendix C

### Acronyms

Acronym	Term
CFR	Code of Federal Regulations
DHP	Defense Health Program
DHS	Department of Homeland Security
DoD	Department of Defense
DoDI	Department of Defense Instruction
DoDM	Department of Defense Manual
FY	Fiscal Year
HRPPO	Human Research Protections Program Office
IMCO	Information Collection Management Office
IRB	Institutional Review Board
MHS	Military Health System
NDAA	National Defense Authorization Act
NIH	National Institutes of Health
OIM	Office of Information Management
OMB	Office of Management and Budget
PI	Principal Investigator
PRA	Paperwork Reduction Act of 1995
RCS	Report Control Symbol
USC	United States Code
USU	Uniformed Services University
USUHS	Uniformed Services University of the Health Sciences
WHS	Washington Headquarters Service

## Appendix D

Listing of USUHS Human Research Studies and Program Evaluations  
Impacted by the NDAA 2021 Survey Exemption

Title	Research or Program Evaluation	Number of Subjects	Methods
Telephone-Based Interviews with Service Members Undergoing Military Life Transitions Following Medical and Physical Evaluation Boards (Mil-iTransition Part 1)	Research	500	Interview, Questionnaire
Adjustment Disorders in the US military: Addressing Gaps in Knowledge and Practice	Research	425	Interview, Questionnaire, Focus Group, Survey
Cross-Sectional Assessment of Resident and Faculty Physicians Regarding Systems-Based Practice	Research	550	Survey
Executive Functioning in Amazon Mechanical Turk (EFMTurk)	Research	5000	Survey, Questionnaires
How Historically Underrepresented and Marginalized Dental Faculty Thrive and Exercise Agency at Predominantly White Public Institutions: A Qualitative Interview Study	Research	20	Interviews
Unravelling Dental Faculty Development: Creating a Competency Framework and EPAs for Military Dental Educators	Research	450	Interview
Quality Improvement Project to Improve Faculty Development,	Research	1000	Questionnaires

Title	Research or Program Evaluation	Number of Subjects	Methods
<b>Representation, and Inclusion via Sponsorship</b>			
<b>Military Nutrition Environment Evaluations</b>	Research	200	Questionnaires
<b>Military-Civilian National Disaster Medical System Interoperability Study (MCNIS) (Phase I)</b>	Program Evaluation	115	Questionnaire
<b>Military-Civilian National Disaster Medical System Interoperability Study (MCNIS)</b>	Program Evaluation	90	Focus Groups
<b>Military Separation Evaluation</b>	Research	500	Questionnaire
<b>Outside COVID Vaccination Tracking</b>	Program Evaluation	400	Questionnaire
<b>Endodontic Competence of the New General Dentist: Updating Our Needs Assessment for the 21st Century</b>	Research	19	Interview
<b>Advancing Evidence-Based Practice in the Military: A Descriptive Analysis</b>	Research	150	Questionnaires
<b>Building Multisectoral Health Security Alliances through Military-Focused Partnerships: An African Partner Outbreak Response Alliance (APORA) Evaluation Supporting DoD Global Health Security Across Diverse Sectors</b>	Program Evaluation	4-8 nations (not subjects)	Interviews, Focus Groups
<b>The Perceptions of Military Spouses regarding their Resiliency</b>	Research	10	Interview
<b>The Experiences of Physicians Caring for</b>	Research	20	Interview

Title	Research or Program Evaluation	Number of Subjects	Methods
<b>Patients after a Mass Shooting</b>			
<b>The CARE-SALTOS Integrated (CSI) Study: Characterizing Potential Chronic Brain Health Effects of Concussion and Repetitive Head Impact Exposures – Explosive Ordnance Disposal (EOD) Cohort</b>	Research	2000	Questionnaire survey
<b>An examination of the relationship between physical activity, mental health, and cognition</b>	Research	300	Online Survey
<b>What's at Stake? Exploring Use of the American Academy of Periodontology In-Service Examination.</b>	Research	30	interview
<b>"Diversity" work and identity in academic medical institutions</b>	Research	40	Interviews
<b>Evaluation and optimization of a portable light delivery system for increased alertness and performance</b>	Research	20	surveys
<b>Development and testing of an online immersive interactive learning experience to augment suicide prevention training workshops for behavioral health providers</b>	Research	160	Questionnaires
<b>Improving Family Readiness Through Primary Care Behavioral Health</b>	Research	240	Questionnaires/Surveys

Title	Research or Program Evaluation	Number of Subjects	Methods
<b>IMPACT - Integrated Military Partnership and Civilian Trauma Systems: Phase II Mixed Methods Study</b>	Research	300	Questionnaires/Surveys
<b>An Integrated Biopsychological Model of Post-Deployment Respiratory Distress</b>	Research	340	Survey
<b>Better Together: A Relationship Enrichment Program Targeting Transdiagnostic Interpersonal Emotion Regulation among Military Couples</b>	Research	100	Questionnaires/Interview
<b>Injury Insight Study</b>	Research	50	Surveys
<b>COVID-19 VLOG (Virtual Learning in Obstetrics &amp; Gynecology): Clerkship Students' Attitudes and Perceptions on Distance Learning</b>	Program Evaluation (Curriculum evaluation)	132	Survey
<b>Active Duty &amp; Veterans' Holistic Musculoskeletal Management and Enhancement (ADVET-HOMME)</b>	Research	150	Surveys
<b>Factors Impacting Choice of Programs in TRICARE</b>	Research	20	Surveys/Interviews
<b>Exploration of Parenting Challenges of Military-Connected Fathers with Young Children during Military Deployment</b>	Research	120	Interviews
<b>PrEP Resource: An App-Based Platform for Improving PrEP Prescribing Habits</b>	Program Evaluation	12	Surveys



<b>Title</b>	<b>Research or Program Evaluation</b>	<b>Number of Subjects</b>	<b>Methods</b>
<b>Deceleration and Disenrollment in USU Students</b>	Research	20	Interviews
<b>LEOPARD: Longitudinal Endpoint Optimization to Provide Assessments of Relevant Drugs</b>	Research	1000	Surveys
<b>Arthroscopic Skills Degradation After Prolonged Absence</b>	Research	48	Surveys/Questionnaires
<b>Military Spouses' Perceptions of Suicide within the Military Spouse Community</b>	Research	196	Surveys
<b>Exercise Collapse Associated with Sickle Cell Trait</b>	Research	30	Questionnaire
<b>Health Professionals Supporting Trainees' Professional Acts of Resistance</b>	Research	25	Survey
<b>Evaluation of the USINDOPACOM Military-Civilian Health Security Summit</b>	Program Evaluation	150	Survey
<b>Education Value Units</b>	Research	20	Interview
<b>Physicians Use of Social Media to Disseminate Health Information</b>	Research	24	Interview
<b>Assessing the Potential for Burnout among Occupational Therapy, Physical Therapy, and Physical Medicine and Rehabilitation Providers in the Military Health System</b>	Research	300	Survey
<b>Picking Apart PEC: How Do We Characterize the Structure, Programmatic</b>	Research	24	Interview

Title	Research or Program Evaluation	Number of Subjects	Methods
Improvement, and Outcomes?			
Landscapes of Practice – Maintaining Competency in Multiple Specialties of Medicine	Research	30	Interview
Evaluation of Department of Defense Antimicrobial Stewardship Programs: Structure and Outcomes	Research	47	Survey
Experiences of Lesbian, Gay, Bisexual, Transgender and Queer (LGBTQ) Families in the military	Research	17	Interviews
Addressing Military Health Providers Burnout, to Improve Readiness and Retention	Research	778	Survey/Interview
Assessing the Health and Trauma System of the Ukraine Multi-Domain Medical Battlefield: Perspectives of Returned Volunteers	Research	25	Interview
Osteopathic Recognition Grant Proposal: A Concurrent Mixed Methods Approach	Research	450	Survey/Interview
Filling the Gaps in Military Health System Response to COVID-19	Research	30	Interviews
Military Experiences with WIC Enrollment - Assessment and Evaluation	Research	350	Survey
A Qualitative Study of Asian Faculty Experiences of Leadership in Medical Education	Research	30	Interviews

Title	Research or Program Evaluation	Number of Subjects	Methods
<b>Leadership in Medical Education</b>	Research	55	Interview
<b>Evaluation of Outcomes from the African Peacekeeping Rapid Response Partnership (APRRP)</b>	Program Evaluation	40	Questionnaire
<b>An Examination of Cultural Beliefs and Rituals on Symptomatology</b>	Research	525	Surveys
<b>An Examination of The Role of Moral Injury in Military Participants</b>	Research	500	Surveys
<b>Educational Technology: A National Faculty Needs Assessment</b>	Research	2000	Surveys
<b>Understanding Medical Academic Leaders' Perceptions of the Value Of a Certificate In Health Professions Education</b>	Research	30	Interviews
<b>Continuing Professional Development Experiences of Minoritized Physicians</b>	Research	30	Interviews
<b>Revaluation of Disaster Core Competencies: A Decade Later</b>	Research	520	Survey/Interview
<b>Addressing Persistent Racial Disparities in MHS Maternal and Pediatric Healthcare: A Causal Network Analysis</b>	Research	40	Interviews
<b>Stress Response and Adaptive Coping Strategies among USUHS Graduate Students</b>	Research	432	Surveys/Interviews
<b>Leadership Success Study</b>	Research	20	Survey/Interview
<b>Evaluation of Mosquito Surveillance Equipment and Resources: Is the</b>	Research	100	Survey

Title	Research or Program Evaluation	Number of Subjects	Methods
military doing enough for Force Health Protection?			
Kiosk as Recruitment Tool for Behavioral Health Studies	Program Evaluation	300	Surveys
Military physician maintenance of competencies	Research	45	Interviews
A Mixed Methods Study to Examine Attitudes Toward Suicide Among Military Leaders	Research	480	Surveys/Interviews
Prevention of Adverse Sexual Health Outcomes: A Case Study of Strategy Execution in the U.S. Military	Research	29	Interviews
How Do Online Female Faculty Cope with Student Evaluations of Teaching? - An Interpretive Phenomenological Study	Research	35	Interviews
The Experiences of Ukrainian Military Medical Personnel Participating In Operation Gunpowder	Research	52	Interviews
Resilience and Stress in Homeland Security Employees (RSHSE): A Health Surveillance Project	Program Evaluation	1600	Survey/Interview
Evaluation of Gender Disparity in Tactical Combat Casualty Care	Research	24	Survey
Assessing Mid-Career Female Physician Burnout in the Military Health System: How to find joy in practice after the COVID-19 Pandemic	Research	30	Interviews

Title	Research or Program Evaluation	Number of Subjects	Methods
Perceptions of an Acceptance-Based Weight-Management Treatment among Military populations	Research	700	Survey
Trauma-Informed Advising	Program Evaluation	50	Questionnaire
Developing an optimal curriculum for research education in post-graduate dental residency programs	Research	18	Interviews
Exploring Health Professions Education Admissions Practices	Research	150	Survey