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

PERSONNEL AND READINESS

DEC 13 2022

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 (NDAA) 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 interim 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 period of January 31, 2021 to October 15, 2021. During this period, USUHS conducted or sponsored 44 projects that met the criteria for application of the NDAA Survey Exemption.

This interim report demonstrates an estimated 3,924 days saved in time and an estimated $58,998 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 Rob Portman
Ranking Member

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

PERSONNEL AND READINESS

DEC 13 2022

The Honorable Carolyn B. Maloney
Chairwoman
Committee on Oversight and Reform
U.S. House of Representatives
Washington, DC 20515

Dear Madam Chairwoman:

The Department's response to section 716 of the William M. (Mac) Thornberry National Defense Authorization Act (NDAA) 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.

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cc:
The Honorable James R. Comer
Ranking Member

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

PERSONNEL AND READINESS

DEC 13 2022

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

Dear Mr. Chairman:

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Gilbert R. Cisneros, Jr.

Enclosure:
As stated

cc:
The Honorable James M. Inhofe
Ranking Member

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

PERSONNEL AND READINESS

DEC 13 2022

The Honorable Adam Smith
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

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Sincerely,

Gilbert R. Cisneros, Jr.

Enclosure:
As stated

cc:
The Honorable Mike D. Rogers
Ranking Member

Interim Report to the Committees on Armed Services of the Senate and the House of Representatives, the Committee on Oversight and Reform of the House of Representatives, and the Committee on Homeland Security and Governmental Affairs of the Senate

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

December 2022

The estimated cost of this report or study for the Department of Defense is approximately $9,890 in Fiscal Years 2021 - 2022. This includes $10 in expenses and $9,880 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 interim report is in response to the requirement in 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 "NDAA Survey Exemption") for the Uniformed Services University of the Health Sciences (USUHS) to submit an interim report on preliminary findings with respect to:

- The estimated time saved by the USUHS (if applicable) by reason of the temporary exemption from certain PRA requirements;
- 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;
- The estimated cost savings by USUHS that can be attributed to such exemption; and
- 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 the NDAA for FY 2021was 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. Additionally, by January 1, 2023, DoD must provide a final report updating any information provided in the interim report and provide "any recommendations with respect to policy or legislative actions regarding the exemption." This interim report describes the impact of the exemption for the initial 8.5 months, from January 31, 2021 to October 15, 2021.

Executive Summary

Section 716 provides 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 are conducted or sponsored by USUHS and funded by the Defense Health Program (DHP). This temporary reprieve carries 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).[1]

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 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), must 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 are issued a Report Control Symbol license. 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 applies to collections of information covered by the PRA that consist of voluntary collection of information in DHP-funded research and program evaluations that are conducted or sponsored by USUHS. It does 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).

[1] Section 1320.3(c)(3) of title 5, Code of Federal Regulations (CFR), 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."

The temporary exemption in section 716 applies to "research" and "program evaluations." These terms are 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 defines 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 to not contribute to generalizable knowledge.

This report describes the impact the exemption had upon the conduct of research and program evaluation at USUHS for the 8.5 month period from January 31, 2021 to October 15, 2021. 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.] DoDM 8910.01, Volume 2, Encl. 3, para. 7.

During this period, USUHS conducted or sponsored 12 human research studies and program evaluations involving voluntary participation of populations considered "general public" that met the PRA definition of an "information collection" and would likely have required a multi-staged DoD review and OMB clearance.

The section 716 exemption resulted in an estimate of 3,924 days saved in the time it would likely have taken to receive an OMB approval to conduct activities that involved an information collection subject to the PRA. 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.

The estimated USUHS cost savings was calculated on the basis of Principal Investigator (PI) additional time involved in preparation of materials for submission and response to queries including revision of study materials. The estimated cost savings to USUHS during this 8.5 month period is $58,998.

Finally, 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 received information on the purpose of the collections and time required to participate in them), USUHS contends there was no additional respondent burden imposed as a result of the temporary exemption. It is likely all these projects would have eventually been approved by the DoD and by OMB after lengthier, iterative reviews.

Background

1. 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 four of USUHS's 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 collaborate with other leading experts at USUHS's centers and institutes on projects 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.

2. 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 the OMB executes the requirements for approval of Federal information collections from the general public. The 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 DoDM 8910.01, Volumes 1 and 2. In addition, DoDI 1100.13 establishes policy concerning information collections specifically involving the use of surveys. Within DoD, OIM determines

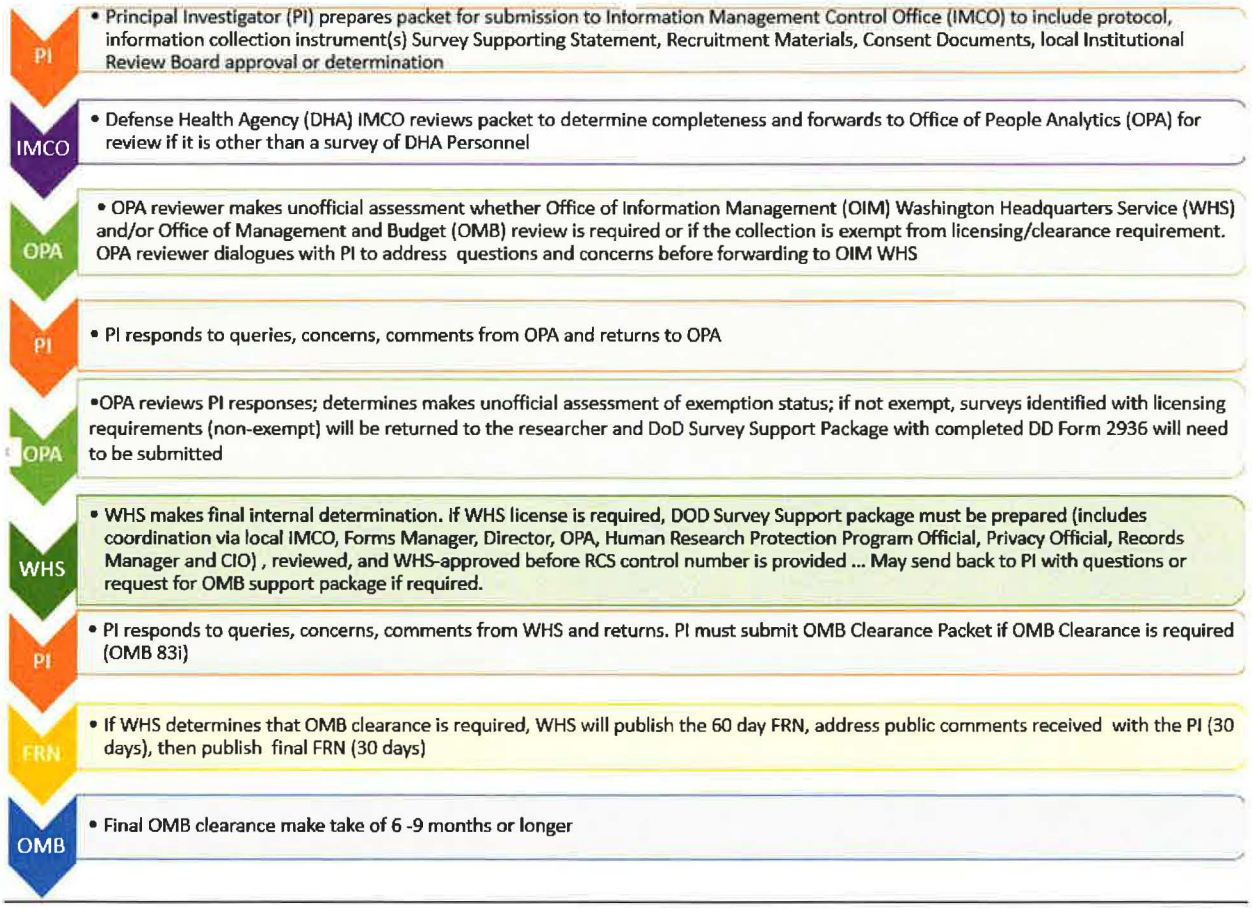
whether a study or program evaluation is exempt from DoD and/or OMB clearance requirements.

3. **References** (see Appendix A)

4. **Definitions** (see Appendix B)

5. **DoD Survey Review Requirements**

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 may be iterative and prolonged in that clarification/additional information and/or revisions may be sought from the investigator at multiple points in the process, which can lead to extensive delays. If an information collection will require 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.

6. 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 40 percent (50 out of 128 protocols) of the USUHS research and program evaluation activities approved between January 31, 2021 and October 15, 2021.

As parts of 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. Most of the subjects enrolled in USUHS studies are either active duty Service members (ADSMs), DoD healthcare beneficiaries, or USUHS faculty. 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 our 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 or program evaluation protocols to the USUHS HRPPO for either IRB review or a determination by a designated Exemptions Determination Official (EDO) that IRB review is not required. Therefore, every protocol that meets the criteria for applicability of

the section 716 exemption must also receive either IRB approval or an EDO determination that the protocol is considered either exempt human subjects research and therefore exempt from IRB review or is a program evaluation, which means that it does not meet the regulatory definition of "research" in accordance with 32 CFR § 219.102(*l*). For those protocols that meet the criteria of the section 716 exemption, the PI is made aware by the inclusion of following language in the IRB approval or EDO determination memorandum (memo):

> "Information Collections – This study meets the applicability of the NDAA FY21, Sec 716, which provides an 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 are conducted or sponsored by the Uniformed Services University of the Health Sciences; and funded through the Defense Health Program (DHP)."

7. Interpretation of the Waiver at USUHS

USUHS interprets 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 does not apply to research conducted or sponsored by USUHS that is funded from other sources, such as NIH or DHS.

8. 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 or after January 31, 2021 that involved "collections of information" under the PRA.

The 716 Report Process

1. The 716 Report

Section 716 requires USUHS to provide the following findings:

A. The estimated time saved by USUHS (if applicable) by reason of the temporary exemption from certain PRA requirements;

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;

C. The estimated cost savings by USUHS that can be attributed to such exemption; and

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

2. 716 Methodology

A. The estimated time saved by USUHS (if applicable) by reason of the temporary exemption from certain PRA requirements:

Method: USUHS employed the use of estimated planning factors based on historical data and published timelines for information collection approval by the DoD and the OMB to determine time saved and cost avoided by application of the NDAA Survey Exemption. The breakout of the estimated time saved is depicted in Table 1 below.

Table 1. Estimated Number of Days Saved by Interval in Times to Approval for USU Studies

Activity	Estimated Number of Days to Completion
PI and study team to prepare submission packet	4
HRPPO Review	3
PI to respond to each level of DoD reviewers questions and obtain all required DoD office concurrences	6
IMCO Review	14
OPA Review	15
OIM WHS Review	15
Federal Register Notices, responses and OMB review/approval	270
Total	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: Studies and program evaluations that were DHP-funded, USUHS-conducted or sponsored and involved voluntary participation during the 8.5 month period of January 31, 2021 to October 15, 2021, 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 avoided by application of the NDAA Survey Review 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 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.

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 academic ranks and hourly salary are:

1) Professor ($130.97/hour)

2) Associate Professor ($98.72/hour)

3) Assistant Professor ($81.53/hour)

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

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

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

Findings

1. The estimated time saved by the USUHS, if applicable, by reason of the temporary exemption from certain PRA requirements is depicted in the table below:

   Table 2. Minimum Estimated Time in Days to Approval saved by USUHS as a result 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	10	327	3,270
Program Evaluation	2	327	654
Total	12		3,924

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. See Appendix D for a line listing of research studies and program evaluations that have been initiated, are ongoing, or have been completed during the reporting period of January 31, 2021 to October 15, 2021.

3. The estimated cost savings by USUHS that can be attributed to this exemption for the period January 31, 2021 to October 15, 2021, is $58,998.

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

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 as a result 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.

Conclusion

USUHS investigators take pride in conducting research that can translate to benefits for the Warfighter and the military community. Delays in USUHS research activities delays the development of knowledge that improves care for our military and education of military healthcare providers.

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 are intended in part to minimize the burden on the public and which are applied to collections of information from 10 or more persons adds several months to the approval process for valuable medical research studies and program evaluations that need timely execution.

This congressional NDAA Survey Exemption is allowing 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 in order to identify needs for improvement in an efficient and effective fashion that respects the rights and welfare of the respondents and imposes no additional burdens. The survey exemption data we have presented here provide the foundation for the argument that the exemption benefits the Warfighter in reducing unnecessary research time and costs. Although the amount of cost savings is only $58,998, the figure that more accurately reflects the positive impact of the exemption is the 3,924 days saved. The days, and the significant number of hours that make up those days, can really make the difference between whether a study is conducted in a timely manner or conducted at all.

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

DoDI 8910.01, "Information Collection and Reporting," May 19, 2014

DoDM 8910.01, Volume 1, "DoD Information Collections Manual: Procedures for DoD Internal Information Collections," June 30, 2014

DoDM 8910.01, Volume 2, "DoD Information Collections Manual: Procedures for DoD Public Information Collections," June 30, 2014

Part 219 of title 32, CFR, "Protection of Human Subjects"

Chapter 35 of title 44, U.S. Code, (also known as the "Paperwork Reduction Act")

Part 1320 of title 5, CFR, "Controlling Paperwork Burdens on the Public"

Office of People Analytics Survey Supporting Statement, July 2014 *current edition*

Office of Management and Budget Supporting Statement, current edition

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

Sections 3506-3508 of title 44, U.S. Code, "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
ADSM	active duty Service member
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
EDO	Exemptions Determination Official
FY	Fiscal Year
HRPPO	Human Research Protections Program Office
IMCO	Information Collection Management Office
IRB	Institutional Review Board
NDAA	National Defense Authorization Act
NIH	National Institutes of Health
OMB	Office of Management and Budget
OIM	Office of Information Management
OPA	Office of People Analytics
PI	Principal Investigator
PRA	Paperwork Reduction Act of 1995
U.S.C.	United States Code
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 for FY 2021 Survey Exemption

	Title of Study or Program Evaluation	Type of Activity	Target Population	Number of Subjects	Type of Data Collection
1	Telephone-Based Interviews with Service Members Undergoing Military Life Transitions Following Medical and Physical Evaluation Boards (Mil-iTransition Part 1)	Research	ADSM + Fed and Non-Fed Civilian	500	interview, questionnaire
2	Adjustment disorders in the US military: Addressing Gaps in Knowledge and Practice	Research	ADSM + Fed and Non-Fed Civilian	425	interview, questionnaire, focus group, survey
3	Cross-Sectional Assessment of Resident and Faculty Physicians Regarding Systems-Based Practice	Research	ADSM + Fed and Non-Fed Civilian	550	survey
4	Executive Functioning in Amazon Mechanical Turk (EFMTurk)	Research	ADSM + Fed and Non-Fed Civilian	5000	Anonymous survey, questionnaires
5	How Historically Underrepresented and Marginalized Dental Faculty Thrive and Exercise Agency at Predominantly White Public Institutions: A Qualitative Interview Study	Research	ADSM + Fed and Non-Fed Civilian	20	interviews
6	Unravelling Dental Faculty Development: Creating a Competency Framework and EPAs for Military Dental Educators	Research	ADSM + Fed and Non-Fed Civilian	450	interview
7	Quality Improvement Project to Improve Faculty Development, Representation, and Inclusion via Sponsorship	Research	ADSM + Fed and Non-Fed Civilian	1000	questionnaires
8	Military Nutrition Environment Evaluations	Research	ADSM + Fed and Non-Fed Civilian	200	questionnaires
	Title of	**Type of Activity**			

	Study or Program Evaluation		Target Population	Number of Subjects	Type of Data Collection
9	Military-Civilian National Disaster Medical System Interoperability Study (MCNIS)	Program Evaluation	ADSM + Fed and Non-Fed Civilian	115	questionnaire
10	Military Separation Evaluation	Research	ADSM + Fed and Non-Fed Civilian	500	questionnaire
11	Outside COVID vaccination tracking	Program Evaluation	ADSM + Fed and Non-Fed Civilian	400	questionnaire
12	Military-Civilian National Disaster Medical System Interoperability Study (MCNIS) - Focus Groups	Research	ADSM + Fed and Non-Fed Civilian	90	questionnaires, focus groups