

SUPPORTING STATEMENT - PART A

Prospective Studies of US Military Forces and Their Families: The Millennium Cohort Program – OMB # 0703-0064

Summary of Changes from Previously Approved Collection

- Title of the collection
- Revisions to the previously approved instruments including major revisions and the addition of sensitive items
- Adding a new instrument
 - Participant Feedback Survey
- Decrease in burden

Used a more accurate way to provide total and annual burden and labor costs

1. Need for the Information Collection

The Millennium Cohort Study (MCS) and the Millennium Cohort Family Study (Family Cohort Study; FCS) collectively make up the Millennium Cohort Program (MCP). The MCP is an Army and Defense Health Program research study conducted at the Naval Health Research Center (NHRC), San Diego, CA, with the primary objective to evaluate the impact of military service, including deployments and occupational exposures, on the long-term health of service members, Veterans, and family members. Information is collected to allow for the assessment of the impact of military deployments, combat, and other experiences. These longitudinal studies are authorized to collect data among participants to ascertain long-term health outcomes of military service members, Veterans, and family members.

The concept and design of the MCS was recommended in the 1998 Institute of Medicine (IOM) Report “The Gulf War Veterans: Measuring Health.” Under the subheading “Strategies to Protect the Health of Deployed US Forces,” IOM recommended that prospective investigations be planned to evaluate multi-dimensional factors relevant to health and health change so that these factors can be assessed over the lifetime of the service member.

Section 743 of the Strom Thurmond National Defense Authorization Act for FY1999 authorized the Secretary of Defense to “...establish a center devoted to a longitudinal study to evaluate data on the health conditions of members of the Armed Forces upon return from deployment on military operations for purposes of ensuring rapid identification of any trends in diseases, illnesses or injuries among such members as a result of such operation.”

Authority to request this information is granted under: 10 USC 136, Under Secretary of Defense for Personnel and Readiness, 10 USC 1782, Surveys of Military Families, 10 USC

2358, Research and Development Projects, Under Secretary of Defense Memorandum #: 99-028, 30 SEP 99 "Establishment of DoD Centers for Deployment Health" and Executive Order 9396, Numbering System for Federal Accounts Relating to Individual Persons.

The MCS was originally designed in response to the IOM recommendation and to Congress's authorization and funding as a prospective, 21-year-long, multi-panel and wave, cohort investigation. However, given that military experiences may contribute to health outcomes with long latencies along with the goal to evaluating the impacts of these experiences on the total life span of the service member, in 2013 the Office of the Assistant Secretary of Defense for Health Affairs authorized the extension of the MCS to 67 years. The study will now include future follow-ups beyond the original 21 years for up to 67 years until 2068. The signed memo from the OASD (HA) has been submitted as a part of this project.

The FCS, which focuses on family life and structure as well as the relationship between the service member and the spouse, was conceptualized and designed in response to concern for the potential effects of military deployment on service members, as well as their families, expressed by the Department of Defense (DoD), the Department of Veterans Affairs (VA), the American Psychology Association (APA), and the White House.

The main objectives of the MCP are (1) to develop a long-term profile of health change among current and former members of the Armed Forces, especially in relation to individual deployment experience, (2) to better define the nature of risk factors for the development of post-war illness among US military personnel, (3) to assess the impact of military service, including deployments, on the health and well-being of the family, and (4) to examine the relationships between the family members and the service member. These objectives will be accomplished by joining self-reported health status information collected from the study participants with electronic healthcare utilization, deployment, exposure, and demographic data available from other sources such as the Department of Defense (DoD), Department of Veterans Affairs (VA), federal or state agencies, or nongovernmental organizations for all participants. Self-reported information is collected using a baseline questionnaire and a series of follow-up questionnaires that are collected in 3-year intervals through at least 2068 for the MCS and 2031 for the FCS.

These findings will then provide strategic evidence that will help inform policy and guide interventions. This DoD capability is the first of its kind, using a large population-based cohort to assess the long-term impact of military service and deployment on the health of service members, their spouses, and co-resident children, and to evaluate the quality of the relationships between service members, spouses, and their children.

Due to the ongoing decline in survey response not just to this study but all DoD studies, the MCS has designed a participant feedback questionnaire that will help us gather crucial information about participant recruitment and study retention, such as reasons for non-response, correlates of non-response, motivations to participate, acceptability of study communication methods, and recommendations for improvement. Near the end of the

2023-2024 survey cycle, the Millennium Cohort Study will conduct the participant feedback survey among Panel 1-5 responders and non-responders. The survey will be bi-modal and was designed to assess a variety of factors including those that have motivated and/or discouraged Millennium Cohort participants to stay connected with the study. This data will be utilized in the design of the future surveys and survey operations to maximize retention and increase participation from previous non-responders. The survey was developed based on preliminary 2019-2021 MCS survey response data and the Hispanic Community Health Study Participant Feedback survey (OMB#: 0925-0584). The MCS Participant Feedback survey has been submitted as a part of this review.

2. Use of the Information

The MCS consists of five previously enrolled panels of current and former service members, who at the time of their voluntary enrollment into the study were listed on the Defense Manpower Data Center (DMDC) Active-Duty service rosters and were randomly selected from a large, representative military sample from all branches and components of service. A probability-based random sampling process is employed with oversampling for certain underrepresented sub-groups (e.g., female service members and married personnel) to ensure sufficient statistical power for addressing these sub-groups of the population reasonably well in a population-based setting.

All service members are encouraged to remain enrolled in the study after they leave military service and transition to Veteran status (i.e., become members of the public). At the time of this submission, 57% of the cohort has retired or separated from active military service.

The FCS currently consists of spouses of service members enrolled in the fourth and fifth panels of the MCS who voluntarily enrolled in the study.

Please see the table below for a detailed breakdown of each panel of the Millennium Cohort Study and the Family Study. All of the columns, with the exception of the last one, outline information for all participants, regardless of military status, while the last column only includes members of the public (i.e., spouses and former service members). The first column displays the panel and study. The second column displays the baseline enrollment period for all participants. The third column outlines the years of service restrictions for sample eligibility. The fourth column lists any specific sub-groups that were oversampled for within each panel. The fifth column displays the number of participants invited to enroll in each sample, while the sixth column lists the actual number enrolled in each panel. The final column identifies the number of former service members currently enrolled in each panel of the Millennium Cohort Study, and spouses in the Family Study.

Panel	Dates Enrolled	Years of Service at Enrollment	Oversampled Groups	Number Invited	Total Enrolled (% of contacted)	Total Members of the Public (% of participants)
1	Jul 2001- Jun 2003	All durations (cross-section of military population)	Females, National Guard/ Reserves, and prior deployers	213,949	77,047 (36%)	47,746 (62%)
2	Jun 2004- Feb 2006	1-2 years	Females and Marine Corps	122,410	31,110 (25%)	17,977 (58%)
3	Jun 2007- Dec 2008	1-3 years	Females and Marine Corps	153,649	43,439 (28%)	21,616 (50%)
4	June 2011- Apr 2013	2-5 years	Females and married	246,230	50,052(20%)	15,000 (30%)
5	Sept 2020- Aug 2021	1-5 years	Females and married	492,041	43,043(9%) *	0 (0%)
Panel	Dates Enrolled	Years of Service at Enrollment	Oversampled Groups	Number Invited	Total Enrolled (% of contacted)	Total Members of the Public (% of participants)
Family Panel 1	June 2011- July 2013	N/A	Males	22,417	9,872 (44%)	9,879 (100 %)
Family Panel 2	January 2021- August 2021	N/A	Males	194,000*	21,841(11%)*	21,841 (100%)*

*As of this writing, data collection is ongoing. Therefore, the enrolled numbers for Millennium Cohort Panel 5 and Family Cohort Panel 2 are not final.

The MCS will continue to collect data through both traditional paper surveys as well as an online version of the questionnaire. The upcoming FCS questionnaire will only be available online. All of the survey questions for both studies have been submitted as part of this submission.

Invitations, and requests for follow-up are initially sent through e-mail to encourage online survey submission and are followed by personalized US Postal Service mailed postcards, paper surveys, newsletters, and subsequent reminder postcards based on a modified Dillman approach. Copies of proposed communications with the respondents has been provided with this package for OMB's review.

The Dillman approach emphasizes providing explanations of how answering the survey will be useful. Emphasis in these communications is also placed on establishing the legitimacy of the survey by providing contact information and creating trust that the survey results will be useful when the survey is completed.

MCS participants who choose to fill out and submit a traditional paper survey are able to return it to the study team via a postage paid envelope that is included in the survey mailing. Completed MCS paper survey packets are returned to the study team for processing. Processing of the paper surveys includes: recording receipt of the survey, verifying that the survey was filled out by the intended participant, and ensuring that any consent forms, consent addendums, or HIPAA Authorizations were signed. Paper surveys are then scanned to create a high-quality digital copy, and data extraction is performed using survey-processing software.

All data will be maintained by the study team at the Deployment Health Research Department at the Naval Health Research Center for research purposes. All disclosures must have prior approval of the Naval Health Research Center Institutional Review Board and a Memorandum of Understanding (MOU) and/or Data Sharing agreement must be entered into to ensure the right and obligations of the signatories are clear. Access to data 1) is provided on need-to-know basis only; 2) must adhere to the rule of minimization in that only information necessary to accomplish the purpose for which the disclosure is being made is releasable; 3) must adhere to the privacy and security requirements applicable to protected health information and personally identifiable information under 45 C.F.R. Parts 160 and 164, HIPAA Security and Privacy Rule of 1996, and the Privacy Act of 1974 in accordance with the DoD guidance as applicable; and 4) follow strict guidelines established in the data sharing agreement. The current SORN allows for limited data sharing with the Department of Veterans Affairs and the Social Security Administration. To date, no MOU has been established to allow data to be used to make determinations regarding participants' access to medical care, treatment or services. DoD and VA policy makers and researchers will use findings from strategic analyses of collected survey data to develop prevention and treatment strategies that will maintain and improve the well-being of service members and their families.

3. Use of Information Technology

Given past online response rates across all panels, to both the MCS and the FCS surveys (89% and 12.6% respectively for the 2019-2021 survey cycle) and current trends with online questionnaires, we predict that over 90% of responders for the next survey cycle will complete an online survey.

The original designers of the MCS did not make 100% web-based participation an objective or a goal. Realizing the benefits of allowing web and paper-based submissions, and in an effort to reduce respondent burden, bi-modal submission continues to be offered to all MCS participants. However, due to the complexities of the evolving circumstances of

military spouses over time, such as change in marital status, the full FCS survey will only be available online.

The online surveys for both the MCS and the FCS are designed to adjust to tablet size and function within multiple mobile device operating systems. The surveys have clickable information icons to help answer participant questions and clarify survey items. Both online questionnaires have been optimized for readability and usability. The MCS and the FCS online surveys employ automatic skip patterns, which enable the responder to skip those sections of the online survey that do not pertain to them. Moreover, some additional smart features have been added to the Family survey, in which some text is auto-filled based on previously reported information from the participant, which helps to clarify survey items (e.g., prior survey completion date, spouse name, and randomly selected child name code).

The military maintains electronic records pertaining to inpatient and outpatient healthcare utilization, immunization, demographic and deployment status for all personnel. Through data use agreements, we are able to access these data for study participants and link this information to self-reported survey data, thus reducing the respondent burden of providing this information themselves.

4. Non-duplication

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

5. Burden on Small Businesses

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

6. Less Frequent Collection

Policy makers have called for longitudinal prospective investigations of deployment-related health effects based on the recommendation of the IOM and the US Congress. Scientific review of the MCS and FCS protocols has found that the frequency of data collection (i.e., every 3 years for 67 years for MCS and 21 years for FCS) will provide adequate prospective observation to permit meaningful statistical evaluation of long-term health changes among the study panels.

We followed the model of the Framingham Heart Study and other well-established longitudinal studies that have been successful using 2–4-year interval surveying methods. A three-year survey strategy was implemented due to the chronic nature of many of the surveyed endpoints, the logistical effort necessary for surveying nearly 280,000

participants in each cycle, and the addition of subsequent panels designed to reflect distinct temporal periods of military service.

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 (FRN) for the collection published on Friday, June 25, 2021. The 60-Day FRN citation is 86 FR 33695.

A 30-Day Federal Register Notice (FRN) for the collection published on Monday, August 23, 2021. The 30-Day FRN citation is 86 FR 47092.

Part B: CONSULTATION

A Strategic Board (SB) consisting of up to twelve civilian and military experts in epidemiology, preventive medicine, statistics, Veterans Affairs, family policy and research provides scientific and operational guidance for both studies on an on-going basis. This committee meets annually to review progress and recommend course corrections when needed. In addition, the research staff confers regularly with subject matter experts to optimize survey content, participant outreach, and research objectives. Furthermore, all project proposals must be submitted to for review and approval prior to initiation by the respective Scientific Review Committee (SRC) for each study. Both SRCs are comprised of military researchers, who meet quarterly to review newly submitted project proposals, and provide guidance to the project teams.

Other consultation and oversight of the MCS and the FCS includes regular reviews by the NHRC Institutional Review Board (IRB) and the Office of Budget and Management (OMB). See attached reports of approval.

9. Gifts or Payment

At the inception of the MCS, investigators and survey methodologists decided that: (1) the establishment of group identity among study participants would be critical to long-term (67-year) viability of the program and (2) incentives would be cost-effective if they prompted use of the secure internet site for response over mailed paper surveys (estimated cost savings is at least \$50/survey for internet response). The research team

subsequently designed and implemented an investigation into whether response rates differed by incentives offered prior to enrollment.

During the initial investigation, no differences in response rates were found between the groups who received different incentives, including those who did not receive an incentive. Following this research, the MCS team offered cost savings initiatives to motivate survey response via the internet. The NHRC IRB has reviewed changes to the original study protocol providing for the delivery of modest (under \$10) pre and/or post-incentives, such as challenge coins, hats, magnets, lunch bags and gift cards, to participants who fill out and submit the questionnaire over the secure internet site. The NHRC IRB continues to closely monitor use of incentives.

A second investigation into whether MCS response rates were affected by incentives offered prior to survey completion was conducted during the 2014-2016 survey cycle. For the 2014-2016 pre-incentive investigation, all participants with a current postal address were randomly assigned one of five pre-incentives: a two-dollar bill, a five-dollar gift card, a magnet, entry into a drawing for an iPad, or no pre-incentive. Pre-incentives were mailed in September 2014 along with an invitation to participate in the 2014-2016 survey. Additionally, since some participants did not get a pre-incentive by design or because of outdated contact information, the team sent challenge coins to all participants who completed the survey as another means of increasing retention and to keep contact with participants.

The number of participants in each group was determined a priori based on incentive availability, cost, and current literature. A total of 1,000 participants received entry into the iPad drawing. This number was chosen to ensure that the odds of winning one of the two available iPads were no greater than 1 in 500 and equates to approximately \$2 per person. The group that did not receive an incentive included 5,000 participants. This number was chosen because the literature and past experience suggested that this would be the least effective method to increase survey response. Resource availability dictated that 10,040 participants receive a gift card. The remaining participants were divided evenly between the cash and magnet groups, each with a final total of 78,203 participants. Literature indicated that cash would elicit the highest response rates, thus the study team ensured that this was one of the largest groups. The magnet was a nominal gift of equal value (\$2) and was also predicted to have a high success rate in inducing response. After the pre-incentives were mailed, we received 10,770 (6.2%) returned incentives due to outdated mailing addresses. These participants were removed from the analyses since we were unable to contact them via postal mail and therefore could not assess the pre-incentive effect on their response. Results from the 2014-2016 investigation determined that a \$2 bill and a \$5 gift card had higher response rates among participants who received them, compared to those who received no pre-incentive (Table 1). Participants given a \$2 bill or \$5 gift card had an approximately 27-28% higher odds of responding compared with those who were not given a pre-incentive. There was no observed difference in the odds of responding to the survey among participants who were entered into the iPad drawing or sent a magnet compared to those who did not receive a pre-incentive.

Table 1. Survey response rate and odds of response by pre-incentive type

	Survey Response*	
	% response	Odds Ratio (95% CI)
Total	32.4 [†]	
<i>Pre-Incentive Type</i>		
No pre-incentive	30.4	1.00 (ref)
\$2 bill	35.0	1.27 (1.18, 1.35)
Gift card	35.5	1.28 (1.18, 1.39)
Drawing/lottery	29.4	0.97 (0.83, 1.15)
Magnet	29.5	0.94 (0.88, 1.01)

*Logistic regression model adjusted for age, gender, race/ethnicity, marital status, education, service branch, military service status, service component, accession group, and foreign address. After adjustment, incentive type was statistically significantly associated with response (p -value < 0.001).

[†]Total includes all enrolled, living Millennium Cohort participants with a currently known postal mailing address.

In addition to the overall response rate, another area of specific interest was the effectiveness of pre-incentives in getting previous non-responders to re-engage in the study. These results indicated that the pre-incentives effective in the general study population (gift card and cash) were also the most effective among previous non-responders (Table 2). A total of 8.6% of last cycle's (2011-2013) non-responders who received a cash pre-incentive responded to the 2014 survey, and 8.3% responded after receiving the gift card, compared with 4.9% who did not obtain a pre-incentive. Participants given a \$2 bill or \$5 gift card had an approximately 82% or 77% greater odds of responding, respectively, compared with those who did not receive a pre-incentive.

Table 2. Survey response rate and odds of response by pre-incentive type among 2011 survey non-responders

	Survey Response*	
	% response	Odds Ratio (95% CI)
Total	6.8 [†]	
<i>Pre-Incentive</i>		
Letter	4.9	1.00 (ref)
Cash	8.6	1.82 (1.43, 2.33)
Gift card	8.3	1.77 (1.34, 2.33)
Lottery	3.8	0.77 (0.40, 1.48)
Magnet	5.1	1.03 (0.80, 1.32)

*Logistic regression model adjusted for age, gender, race/ethnicity, marital status, education, service branch, military service status, service component, accession group, and foreign address. After adjustment, incentive type was statistically significantly associated with response (p -value < 0.001).

[†]Total includes enrolled, living Millennium Cohort participants with a currently known postal mailing address, and did not complete a 2011 Millennium Cohort survey.

This investigation of pre-incentives not only indicated that pre-incentives were effective in boosting survey response rates, but also that certain types of pre-incentives were more successful than others, namely cash and gift cards. This information will help to maximize study retention and can be used to reduce costs. Based on these findings, the MCS and the FCS teams will invest in monetary pre-incentives in the upcoming survey cycle to continue to engage participants and to increase the survey response rate. We will be offering \$2 bill pre-incentives to all invited participants in both studies. Targeted pre-incentives may be utilized to improve response rates among specific sub-groups and/or historically low responding groups (e.g., Marine Corps personnel, male spouses, dual-military couples, etc.) All MCS responders who complete their survey online will be offered a \$5 gift card to Amazon, Starbucks, Walmart or Subway, while all FCS responders will be offered a \$10 gift card to either Amazon, Starbucks, Walmart or Subway.

The use of these cost savings initiatives by the MCP will be reviewed for approval by General Counsel before the launch of the next survey cycle. Once approved, we will submit the approval letter to OMB.

10. Confidentiality

The Privacy Act, as defined under Title 5, US Code 136, DoD Regulations, Executive Order 9396, and in DoD RCS#DD-HA(AR)2106 is printed before the first question of both the paper copy and the web version of the MCS and FCS questionnaires. The surveys will also include the SORN ID number, OMB control number, expiration date, and the Public Burden Statement. This document specifies the Authority supporting the request for information, the purpose for its collection, the routine uses to which it will be put, the scope of anonymity in the use of personal identifiers and the voluntary nature of participation.

A SORN is required. SORN NO6500-1, Millennium Cohort Study, can be found here: <https://dpcl.dod.mil/Privacy/SORNsIndex/DOD-wide-SORN-Article-View/Article/570396/n06500-1/>.

A PIA for the Millennium Cohort Program has been submitted to DHA for review and approval. A copy of the submitted document has been provided with this package for OMB's review. Once the PIA is approved, we will provide OMB with a copy.

Electronic records and original signed paper consent forms generated by the MCP are permanent and transferred to the nearest Federal Records Center (FRC) when 5 years old and then transferred to NARA when 20 years old. Temporary supporting records (to include paper records) are transferred to the nearest FRC when 5 years old and destroyed when 10 years old. Temporary non-record files (to include paper records or to include

paper copies of the surveys) will be destroyed when 5 years old or on completion or termination of project.

In December 2018 the MCS obtained a Certificate of Confidentiality from the Department of Human and Health Services, National Institute of Health that expires on September 30, 2068. The FCS obtained a Certificate of Confidentiality from the Department of Health and Human Services in August 2018, which expires December 31, 2023. Both certificates have been provided with this package.

11. Sensitive Questions

It is understood by the MCP Principal Investigators and program staff that all questions regarding health can be considered sensitive in nature. It is for this reason that assiduous attention is paid every day by all who are connected with the study to maintain the participant's privacy and confidentiality. For all sensitive item types listed, please refer to the table at the end of this section for the list and description of each individual item.

Personal Identifiers

SSN: As a security measure, all participants are asked to login to the secure online survey using their study assigned Subject Identification number and the last four digits of their Social Security Number or their DoD ID (only digits 6-10 are captured and used for verification). Additionally, participants are asked to provide the last four digits of their Social Security Number as an identity verification measure on the paper survey. The updated Social Security Number Justification Memo has been submitted for review and approval. Once the Social Security Number Justification Memo has been approved, we will submit a non-substantive change to OMB.

Sexual Orientation and Gender Identity

Since the enrollment of our first four panels of MCS participants, DODI 1304.26 ("Don't Ask, Don't Tell" [DADT]) was fully repealed in 2011 (https://archive.defense.gov/home/features/2010/0610_dadt/USD-PR-DADT_28Jan11.pdf). In 2021, an Executive Order was signed by President Biden, which ended a previously implemented transgender military ban (<https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/25/executive-order-on-enabling-all-qualified-americans-to-serve-their-country-in-uniform/>). Given these events, the number of participants who may be more willing to self-identify as a sexual or gender minority is unknown. This information cannot otherwise be obtained for our Cohort members, so it is essential to assess sexual orientation and gender identity on our surveys.

The sexual orientation question was first added to the MCS survey during the 2014-2016 survey data collection cycle. We included two questions to assess gender identity and one to assess sexual partner during the 2019-2021 survey cycle. We request approval

for the continued use of these three questions, plus an additional item on sexual orientation and gender identity to be included as part of the follow-up MCS and FCS questionnaires for the upcoming 2023-2025 data collection cycle. We propose a slight modification to the “other” response option for the sexual orientation and gender identity items. These slight modifications to the response option allow space for participants to feel included and aligns with current practices in other national epidemiological surveys.

Sexual Orientation: The proposed inclusion of an additional response option of “something else” for sexual orientation is adapted from the National Adult Tobacco Survey (NATS) sexual orientation responses options (i.e., lesbian or gay; straight, that is, not lesbian or gay; bisexual; *something else*; https://www.cdc.gov/tobacco/data_statistics/surveys/nats/pdfs/2013-2014-questionnaire-tag508.pdf). We propose to add this additional open-response category to be more inclusive of other sexual orientations that are not captured by the currently available response options (e.g., queer, pansexual, asexual, demisexual, same-gender loving, none of the above; Bates & Fischer, 2019). We also propose to continue to use the sexual partner item.

Our preliminary data from the 2019-2021 MCS survey cycle indicated that as of March 2021, of the n=33,048 Panel 5 participants who responded to the enrollment web survey, 85.76% (n=28,343) reporting being heterosexual or straight, 3.63% (n=1,200) reported being gay or lesbian, 7.19 % (n=2,376) reported being bisexual, and 3.42% (n=1,129) preferred not to answer. In addition, of the n=100,118 web survey responders for follow-up and new enrollment, 23.11% (n=23,137) responded having men only sexual partners, 64.46% (n=64,533) responded having women only sexual partners, 7.55% (n=7,556) responded to having sex with both men and women, and 2.79% (n=2,792) preferred not to answer.

Gender Identity: The two-step approach employed by the MCP surveys includes the assessment of sex assigned at birth along with one’s current gender was derived from recommended best practices for assessing gender identity in federal surveys (Bates & Fischer, 2019; NIH Sexual & Gender Minority Research Office, 2020). Our preliminary data from the 2019-2021 Millennium Cohort Study survey cycle indicated that as of March 2021, of the 100,499 participants who responded to the enrollment/follow-up web survey, 69.81% (n=69,586) identified as male, 29.38% (n=29,285) identified as female, and 0.2% (n=190) identified as “transgender”; yet 0.61% (n=613) reported “other or prefer not to answer”. These numbers differ slightly from the sex assigned at birth. Thus, we propose to slightly rephrase the “other” response option for gender identity, to be “not listed, please provide _____”, to be more inclusive of varying gender identity categories as listed in other current federal surveys (e.g., gender nonconforming, genderqueer, non-binary).

Harassment, Sexual Assault, Violence, and Sexual Health

Sexual Harassment and Assault: Service members and Veterans who experience sexual trauma during military service, including sexual harassment and sexual assault,

experience numerous adverse health and career outcomes. Little is known about factors that may moderate the association of sexual trauma with these various outcomes. Research findings will aid or strengthen the strategies used to improve mental and physical health outcomes as well as occupational outcomes of service members who have experienced recent sexual trauma.

Recent MCS findings from Millegan and colleagues (2015; 2016) found an association between sexual trauma (ie., harassment and assault) and poorer physical health for both men and women. Seelig et al (2017) found that among MCS participants reporting a history of prior alcohol problems at baseline, men and women reporting experiences of sexual assault had higher levels of unhealthy alcohol use relapse at a 3-year follow-up compared to those who did not experience sexual assault (men: 50% vs 43%; women 40% vs 37%). In adjusted models, however, this association only remained significant for women (Relative Risk [RR]: 1.73, 95% CI: 1.06, 2.83). Adler, LeardMann, Roenfeld, Jacobsen, and Forbes (2020) found that MCS service members and veterans who reported experiencing sexual assault in the last 3 years were more likely to screen positive for problematic anger compared to those with reported no recent sexual assault (32.5% vs 16.8%), however, once adjusted for other covariates such as PTSD, depression, and problem drinking, recent sexual assault was not independently associated with problematic anger (AOR=1.09; 95% CI 0.97, 1.23).

The MCS and FCS teams are well-positioned to inform DoD Sexual Assault Prevention and Response Office, DoD Office of Diversity, Equity and Inclusion, and DoD Psychological Health Center of Excellence policy development efforts with existing Knowledge Transfer Agreements (KTAs) with these organizations. In addition, the following written requirements exist that support this research and policy:

- DoD Sexual Assault Prevention and Response Research Agenda FY21-25, Executive Order: A Proclamation on National Sexual Assault Prevention and Awareness Month, March 2021,
- DoDI 1020.03 (Harassment prevention and response), DoDI 5505.1 (Investigation of sexual assault),
- DoDI 6495.02 (SAPR procedures), “Explain unique issues with sex offenders to include identifying, investigating, and documenting predatory behaviors.”,
- DoDI 6495.03 (Advocacy), and
- DoD Plan to Prevent & Respond to Sexual Assault of Military Men “Research on male victims of sexual assault is limited...research is a prerequisite to assess the need for and effectiveness of gender-specific approaches.”

Questions were previously included on the MCS and FCS survey addressing potential exposure to traumatic life events, in which participants are asked whether they have ever been (a) forced into sexual relations, i.e., been sexually assaulted, or (b) sexually harassed. Both questions came from the National Health Survey of Persian Gulf War Era Veterans (US Department of Veterans Affairs, Veterans Health Administration; OMB # 2900-0558 - Expiration Date 9/98) and have been reviewed by the DoD Sexual Assault Prevention and Response Office. For this body of research going forward, we propose to

ask a reduced set of questions from what was previously asked about recent sexual assault and harassment in the past 3 years.

Intimate Partner Violence (IPV): IPV threatens force readiness, health, and the well-being of the entire family system (service members, spouses, children) across multiple generations. There is virtually no research that has examined IPV in active-duty women, which is important for readiness and retention). Recent study findings using administrative data from the DoD Family Advocacy Program and the MCS indicate that among 54,667 active-duty personnel, DoD Family Advocacy Program records documented 501 participants (1%) with incidents of emotional or physical IPV in the data collection period. Results showed that general PTSD symptoms (e.g., anger/irritability, sleep disruption) and comorbid alcohol dependence were stronger predictors of IPV than trauma-specific PTSD symptomology (e.g., reexperiencing, hypervigilance) (Stander, Woodall, Richardson, Thomsen, Milner, McCarroll, Riggs, Cozza, 2021).

In addition to the following written requirements, this work extends a KTA with the DoD Psychological Health Center of Excellence that was established in 2021. Written requirements for this research include:

- DoDM 6400.01/6400.06: FAP Child Abuse and Domestic Abuse Incident Reporting System, August 11, 2016, DoD Instruction 6400.06 “Domestic Abuse Involving DoD Military Certain Affiliated Personnel”;
- Section 574 of Public Law 114-328 “DoD Report on Child Abuse and Neglect in the Military for FY2018” (April 2019);
- DoD Instruction 6490.04: Mental health evaluations of members of the military services;
- DoD Instruction 1010.10: Health Promotion and Disease Prevention: requires the Services to establish mechanisms to effectively analyze, measure, and report key performance indicators and metrics, as well as consolidated databases to track HR-sensitive themes such as suicide, sexual assault, and domestic violence;
- OUSD-P&R Strategic Plan FY 2018-2020: Trauma and PTSD are among the strongest risk factors for domestic violence. When a service member has PTSD, their domestic violence risk increases threefold; and
- Dr. Casey Taft, PI of the VA Center for PTSD, Testimony to the U.S. Senate Subcommittee on Personnel, Committee on Armed Service. Hearing on Domestic Violence and Child Abuse in the Military, March 8, 2018).

We propose to continue to use the 8-item Hit-Insult-Threaten-Scream (HITS) screener on the FCS survey and propose to introduce the HITS screener to the MCS survey for the next follow-up survey. The HITS screener asks about verbal, emotional and physical spousal abuse experienced and/or perpetrated by the participant. These questions were derived from the Hit-Insult-Threaten-Scream (HITS) violence screening tool utilized by VA. In the past OMB submission, these items have been selected and included in a manner coordinated with representatives from the DoD Office of Military Community and Family Policy and the DoD Family Advocacy Program.

Sexual Health: The annual incidence of sexual dysfunction among service men has more than doubled between 2004 and 2013, and research examining aspects of sexual dysfunction is extremely limited. Moreover, sexual dysfunction not only affects relationship quality, but can also have a significant negative impact on quality of life, overall health, well-being, and has been associated with increased suicide risk (Kolaja, Schuyler, Armenta, Orman, Stander, LeardMann, 2021). Our recent research from previous MCS surveys shows that among service women in the MCS, recent combat deployment and sexual assault were directly and indirectly, through PTSD, associated sexual health difficulties. Additionally, other factors (e.g., enlisted rank, childhood trauma, and disabling injury) were identified as risk factors for sexual health difficulties. (Kolaja, Schuyler, Armenta, Orman, Stander, LeardMann, 2021). Among service men in the MCS, numerous factors (e.g., older age, lower education, enlisted paygrade, disabling injury, BMI) were associated with sexual health problems. PTSD mediated the associations between stressors (combat deployment and sexual assault) and sexual health outcomes (Kolaja, Roenfeldt, Armenta, Schuyler, Orman, Stander, LeardMann, 2021). Both studies show that for men and women, military-related stressors negatively affected sexual health and comprehensive treatment options are warranted. We propose to continue asking participants these questions on sexual health and dysfunction, to continue to help the DoD and the VA understand service member sexual relationships and any effects they may have on mental and physical health.

Suicide Risk Items

Suicide and suicidal behaviors adversely impact readiness, survivability, and performance of individuals and units. Specific service-related experiences increase risk for suicide and suicidal behaviors. Certain types of transitions heighten risk for suicide and suicidal behaviors. The MCS and FCS have the unique capability of inform or improve prevention efforts and strategies by identifying differences between individuals with suicidal ideation, suicide attempts, and suicide deaths.

Our recent research showed that among 57,841 active-duty service members enrolled in the MCS who had deployed, high combat severity and certain specific combat experiences were associated with suicide attempts. However, these associations were mostly accounted for by mental disorders, especially PTSD (LeardMann et al., 2021). Findings suggest that service members who experienced high levels of combat or were exposed to certain types of combat experiences, involving unexpected events or those that challenge moral or ethical norms, may have an increased risk of a suicide attempt, either directly or indirectly through mental disorders (LeardMann et al., 2021). We also recently found that certain military occupations may be at greater risk for suicide. For example, recent MCS research showed that among Army officers (n=957), the prevalence of suicidal ideation among veterinarians (8.2%) was greater than those for physicians (3.9%) and dentists (3.7%). In adjusted models, veterinarians had elevated odds of suicidal ideation (odds ratio=1.91) compared with physicians and dentists, however this result was not statistically significant (95% confidence interval: 0.70, 5.17), possibly owing to the small sample size. In adjusted models, veterinarians had significantly higher odds of mental health problems, trouble sleeping, and lack of social support, compared with physicians and dentists. Further examination of Army policies and organizational structures related to

veterinarians may be warranted, along with the development of policies and interventions designed to improve mental health, sleep quality, and social support among military veterinarians (Rivera et al., 2021). The MCS study team briefed to the Army Veterinarian Corp and a new program was developed (VetFIT) specifically for Army veterinarians to try to mitigate some of these issues that emerged from this research.

There are several written requirements related to suicide and self-harm prevention in both active duty and veteran populations, such as:

- DoDI 6400.09: Integrated primary prevention of self-directed harm and prohibited abuse or harm (Sept 2020),
- DoD Suicide Prevention Research Strategy, FY2020-2030,
- DoDI 6490.16: Defense Suicide Prevention Program, Human Dimensions
- ICD v1.7, Health Promotion/Risk Reduction/Suicide Prevention,
- PREVENTS Executive Order (2019): President's Roadmap to Empower Veterans and End a National Tragedy of Suicide "...the Federal Government must advance our understanding of the underlying causal factors of veteran suicide...", and
- Executive Order on a National Roadmap to Empower Veterans and End Suicide, March 5, 2019.

The MCS and FCS studies have an active KTA and working relationship with Defense Suicide Prevention Office (DSPO), and are thus well positioned to inform DSPO guidelines and policy development efforts. In fact, the studies have consulted and received guidance from DSPO and leading subject matter experts in the selection of scales that address psychosocial and behavioral predictors of suicide risk. For example, it has been noted that the primary cause of suicide death is by firearm [60% of cases of active duty in 2019, (Defense Health Agency, 2021)], yet there is limited understanding if the risk factors for firearm suicide deaths differ from other suicide means.

The MCS proposes to include the following validated scales that assess psychosocial and behavioral factors that have been shown to correlate with suicide risk but also are clearly actionable, and therefore could possibly influence future policy efforts: Moral Injury (shame/guilt at actions and experiences), Suicide cognitions (e.g., perceived pain and unbearableness of life), non-suicidal self-injury, suicide exposure (e.g., knowing someone personally who has died by suicide), and suicide severity (e.g., Columbia suicide severity scale, which has been approved for DoD and VA screening purposes (see attached documentation from DSPO), and lastly the MCS and FCS propose to include the ninth item on the depressive symptomatology (PHQ-8) scale, which assesses suicide thoughts, and both studies plan to assess access to lethal means, (e.g., access to personal guns), with slight variations for the active duty population.

Deployment Exposures: Deployment-specific exposures are included to differentiate stressful exposures during deployment. Several questions, in the MCS follow-up survey and in the FCS surveys, "...being responsible for the death of a non-combatant," are recognized as potentially sensitive. Please note that these questions are a subset of the

Walter Reed Army Institute of Research (WRAIR) developed Mental Health Assessment Tool (MHAT), recommended by MHAT leaders (COL Charles Hoge and COL Carl Castro), and selected to specifically exclude incriminating queries (such as unnecessary use of force against non-combatants) and are important to continually assess these exposures. Therefore, we propose to continue to use these previously approved items, since deployments change over time and these exposures have been shown to be associated with numerous health outcomes in our previous research.

Physical Health and Health Behaviors:

Substance Use (non-active duty only): Military service members and their families transitioning to civilian life need to address a new set of challenges. In fact, 44% of recent service members reported having a difficult time with transitioning to civilian life. The DoD has very limited ability to understand the long-term impact of military life on families after service separation; reliance on VA data regarding a limited proportion of veterans leaves large knowledge gaps. Actual and perceived difficulties of service members to successfully transition to civilian life may negatively impact recruitment and retention efforts.

This research is based on DoDI 1332.35, Veterans Opportunity to Work (VOW) to Hire Heroes Act of 2011, Fiscal Year (FY) 1991 National Defense Authorization Act (NDAA), and MCTO's mission is to help foster a military culture that returns to America a career-ready veteran which strengthens the all-volunteer force. (www.dodtap.mil). In the Veteran-only sections of the MCS survey, we have included items that assess substance use/marijuana use, since in addition to the written requirements of stress during the transition period, there continues to be an increased prevalence of maladaptive coping through substance use, and more needs to be known for intervention.

Pregnancy: Although all active-duty service members have medical coverage, access to women-specific services may vary depending on duty location, deployment, or other factors. As women move into combat roles, there is a need to understand how this might impact their long-term health. Unplanned pregnancies, and limited access to gynecologic health services during deployment and field training affect both readiness and retention. There have also been recent policy changes to extend parental leave for military parents (<https://www.military.com/daily-news/2021/05/12/bill-would-expand-paid-parental-leave-all-new-military-parents.html>).

Identifying factors associated with outcomes that disproportionately impact women can facilitate increased awareness of these issues among leadership and lead to improved readiness and retention. In 2020, the NDAA 2020, Sec. 748 outlined the need for an annual review of Millennium Cohort Study findings on gynecological and perinatal health and other outcomes. As such, we have included additional questions in the Women-only module for the MCS and the FCS that assess pregnancy outcomes (e.g., single birth, elective, or therapeutic abortion); and for the MCS, we will assess risk behaviors (e.g., tobacco and alcohol use) immediately preceding and during pregnancy.

COVID-19: The Coronavirus Disease 2019 (COVID-19) pandemic discovered in Wuhan, China, saw its first case in the United States (US) on January 20, 2020 (Holshue et al 2020). Major life changes from COVID-19 public health measures during the pandemic include significant changes to daily routines, loss of income, difficulty obtaining essential needs, caring for family members, homeschooling children, and social isolation. Studies on previous pandemics are limited but have found these events to have adverse consequences on mental health along with the immediate effects of being infected with the disease (Chen et al, 2005; Menninger, 1919). There is, however, a substantial body of research on the adverse impact of life stressors on health and well-being (Scully, Tosi, Banning, 2000; Holmes & Rahe, 1967), as well as impact of social isolation on mental health outcomes and cardiovascular disease (Leigh-Hunt et al, 2017; Cacioppo, et al, 2006). Early research is showing the possibility of COVID-19 vaccine hesitancy among active duty personnel (<https://www.militarytimes.com/news/your-military/2021/05/17/covid-19-vaccine-hesitancy-higher-among-soldiers-black-service-members-study-shows/>). Military personnel and their families may experience additional stress from the COVID-19 pandemic as they are still expected to fulfill their duty in protecting US security and interests.

The MCS and FCS are uniquely positioned to examine health trends during the COVID-19 pandemic due to the concurrent collection of follow-up survey data since the fall of 2019. The survey cycle is scheduled to continue collecting participant responses through the middle of 2021; with the next planned follow-up assessment in 2023, making it one of the few studies capable of examining health trends before, during, and possibly after the COVID-19 pandemic. The COVID-19 pandemic is unprecedented during this time period, and the long-lasting physical and mental health effects are currently unknown. As such, including COVID diagnoses, complications, hospitalizations, and vaccination items on the MCS and FCS surveys will help us to determine whether exposure/illness due to COVID-19 impacts our service member and veteran participants. Examples of impact could be retention, long-term illness (physical and mental), and occupational outcomes.

Table 3. Millennium Cohort Study (MCS) and Family Cohort Study (FCS) Sensitive Questions

Study	Variable	Question	*Items that have been previously approved in our last submission to OMB are noted. **New items are noted
Personal Identifiers			
Both	SSN	What are the last four digits of your Social Security Number? (paper)	No change
Gender Identity and Sexual Orientation			
Both	Sex at birth	What sex were you assigned at birth, on your original birth certificate? (0) Male (1) Female	No change
Both	Sexual orientation	Do you consider yourself to be: (1) Heterosexual or straight (2) Gay or Lesbian	*Response option (5) is being added to the current follow-up MCS

		(3) Bisexual (4) Prefer not to answer *(5) Something else, please specify _____	survey item New item for FCS
Both	Sexual partner	Who have you EVER had sex with? 1 Men only 2 Women only 3 Both men and women 4 I have not had sex 5 Prefer not to answer	No change
Both	Current gender	How would you describe your current gender? (0) Male (1) Female (2) Transgender, male to female (3) Transgender, female to male (4) Prefer not to answer *(5) Not listed, please specify _____	*Response option (5) is modified from the current follow-up MCS survey to replace "Other" New for FCS
Harassment, Violence and Sexual Assault			
Both	Harassment	In the last 3 years , how often have you experienced... [Range 1-5, not at all (1), rarely (2), monthly (3), weekly (4), daily (5)] o Discrimination? (i.e., differential or unfair treatment based on your race, color, religion, sex, gender identity national origin, or sexual orientation) o Bullying? (i.e., acts of aggression with the intent of physically or psychologically harming a person) o Hazing? (i.e., acts that physically or psychologically injure or create a risk of injury in order to humiliate or "toughen up" people to fit into a group) o Sexual harassment? (i.e., repeated offensive comments or gestures of a sexual nature that may affect a person's job, pay, work performance, or career)	Approved for use on previous MCS Survey. This iteration we are reducing this battery of items from 17 to 4 items. We removed the stems from each harassment item of whether it occurred as part of your military duties, location of sexual harassment, and who was the perpetrator of sexual harassment
Both	Intimate Partner Violence	How often has this happened in the past 6 months? [Range 1-5, never(1) to frequently (5)]. a. You screamed or cursed at your partner (Examples: yelled at them, swore at them, etc.) b. Your partner screamed or cursed at you (Examples: yelled at you, swore at you, etc.) c. You insulted or talked down to your partner (Examples: called them names, belittled them, etc.) d. Your partner insulted or talked down to you (Examples: called you names, belittled you, etc.) e. You threatened your partner with harm (Examples: threatened to hit, throw something, or hurt them; intimidated them; punched a wall in front of them, etc.) f. Your partner threatened you with harm (Examples: threatened to hit, throw something, or hurt you, intimidated you; punched a wall in front of you, etc.) g. You physically hurt your partner (Examples: pushed, slapped, grabbed, punched, kicked, etc.)	New to MCS, previously on FCS Source: Portnoy et al 2018/ FCS Survey

		h. Your partner physically hurt you (Examples: pushed, slapped, grabbed, punched, kicked, etc.)	
Both	Sexual Assault (SA)	<p>In the past 3 years, how many times have you had unwanted experiences where a person(s) sexually touched you (e.g. intentional touching of genitalia, breasts or buttocks), made you sexually touch them, or attempted to or actually made you have sexual intercourse/oral or anal sex (including penetration with finger/object) without your consent?</p> <p>1 Never 2 Once 3 Twice 4 A few times 5 Many times</p> <p>In the past 3 years, did any of the unwanted sexual experiences occur during your military service, no matter who did it or where it happened (i.e., anytime since you joined the military)?</p> <p>1 No 2 Yes</p> <p>In the past 3 years, at the time that any of the unwanted sexual experiences occurred, was/were the offender(s)...? (<i>please mark all that apply</i>) (0, No, 1, Yes)</p> <p><input type="radio"/> Your spouse/significant other? <input type="radio"/> Other friend(s), relative(s), acquaintance(s) <input type="radio"/> Someone from work (e.g. co-worker, supervisor) <input type="radio"/> Unknown person(s)?</p>	<p>Items previously on MCS</p> <p>Modified frequency of SA, and whether SA occurred during military service to the past 3 years versus ever</p> <p>We reduced this from 63 to 6 items. Removed a total of 57 items:</p> <ul style="list-style-type: none"> • Ever experienced sexual assault (SA) • Age at first, most recent SA, first SA while serving. • Items related to SA reporting. • Items on perpetrator. • Items on SA location.
Both	Sexual Health	<p>During the last 4 weeks, how much have you been bothered by any of the following problems? [<i>Not bothered (1)</i> <i>Bothered a little (2)</i> <i>Bothered a lot (3)</i>]</p> <p><input type="radio"/> Pain or problems during sexual intercourse <input type="radio"/> Little or no sexual desire or pleasure during sex</p>	<p>No change from previous MCS surveys Each item is part of a larger validated scale (PHQ-risk scales).</p>
1. Suicide-Related Items			
MCS	Moral Injury	<p>Military service can entail doing or witnessing acts that may affect one's emotional well-being, relationships, and later quality of life. When considering your own feelings, beliefs, and behaviors related to things that you did/saw in the military, please indicate how much you personally agree or disagree with each statement. [Range 1-5, <i>Strongly Disagree, Disagree, Neutral, Agree, Strongly Agree</i>]</p> <p>a. I am ashamed of myself because of things that I did/saw during my military service. b. I am troubled because I violated my morals by failing to do something that I should have done during my military service. c. I feel guilt about things that happened during my military service that cannot be excused. d. The moral failures that I witnessed during my military service have left a bad taste in my mouth. e. Things I saw/did in the military have caused me at times to lose faith in the basic goodness of humanity.</p>	<p>New</p> <p>Source: Currier et al 2020</p>
Both	Deployment exposures	<p>In the last 3 years, how often have you experienced the following during deployment [<i>no, 1 time, more than 1 time, if yes, list most recent year of exposure</i>]</p> <p>a. Feeling that you were in great danger of being killed b. Being attacked or ambushed</p>	<p>No change from previous survey</p> <p>Source: WRAIR</p>

		<ul style="list-style-type: none"> c. Receiving small arms fire d. Clearing/searching homes or buildings e. Having an improvised explosive device (IED) or booby trap explode near you f. Being wounded or injured g. Seeing dead bodies or human remains h. Handling or uncovering human remains i. Knowing someone seriously injured or killed j. Seeing Americans who were seriously injured or killed k. Having a member of your unit be seriously injured l. or killed m. Being directly responsible for the death of an enemy n. combatant o. Being directly responsible for the death of a non-combatant p. Being exposed to smoke from burning trash and/or feces 	
Both	Depression symptoms (suicide thoughts)	<p>Over the last 2 weeks, how often have you been bothered by any of the following problems? <i>[range 1-4, not at all, several days, more than half the days, nearly every day]</i></p> <p>Thoughts that you would be better off dead or of hurting yourself in some way</p>	<p>Adding 9th item to the Phq-8, to enable assessment of the Phq-9</p> <p>Source: Kroenke et al (2001)</p>
MCS	Suicide cognitions	<p>The following statements are intended to assess your beliefs about your current problems. Please read each statement carefully and circle the number that best describes how you feel right now. <i>[Range 0-1, strongly disagree, disagree, neutral, agree, strongly agree]</i></p> <ul style="list-style-type: none"> a. It is unbearable when I get this upset. b. I can't imagine anyone being able to withstand this kind of pain. c. I don't deserve to live another moment. 	<p>New</p> <p>Source: Bryan et al (2017)</p>
MCS	Suicide exposure	<p>Over the course of your lifetime, has a close friend or family member die by suicide? Yes/No</p> <p>If yes, were any of these individuals, who died by suicide a service member or veteran? Yes/no</p>	<p>New</p> <p>Source Gutierrez, personal communication</p>
MCS	Suicide severity	<p>1. Have you ever wished you were dead or wished you could go to sleep and not wake up? No/Yes</p> <p>In the past month, have you ever wished you were dead or wished you could go to sleep and not wake up? No/Yes</p> <p>2. Have you ever actually had any thoughts of killing yourself? No/Yes</p> <p>In the past month, have you had these thoughts in the past month? No/Yes</p> <p>< If yes to 2, then answer below items....(a,b,c) all else, skip to 3>></p> <ul style="list-style-type: none"> a. Have you been thinking about how you might do this (e.g. "I thought about taking an overdose but I never made a specific plan as to when where or how I would actually do it....and I would never go through with it.")? No/Yes aa. In the past month, have you been thinking about how you might do this? No/Yes 	<p>New</p> <p>Source: Posner et al, DoD-DSPO approved.</p>

		<p>b. Have you ever had these thoughts and had some intention of acting on them? As opposed to “I have the thoughts but I definitely will not do anything about them.” No/Yes</p> <p>bb. In the past month, have you had these thoughts and had some intention of acting on them? No/Yes</p> <p>c. Have you ever started to work out or worked out the details of how to kill yourself? No/Yes</p> <p>cc. Did you ever intend to carry out this plan? No/Yes</p> <p>ccc. In the past month, have you had these thoughts and had some intention of acting on them? No/Yes</p> <p>3. Have you ever done anything, started to do anything, or prepared to do anything to end your life? No/Yes Examples: Collected pills, obtained a gun, gave away valuables, wrote a will or suicide note, took out pills but didn’t swallow any, held a gun but changed your mind or it was grabbed from your hand, went to the roof but didn’t jump; or actually took pills, tried to shoot yourself, cut yourself, tried to hang yourself, etc.</p> <p>a. Was this within the past three months?</p>	
MCS FCS- one item	Access to lethal means	<p>Active Duty/Reserve/National Guard question: Do you currently have a personal firearm(s) (e.g., not a military-issued firearm(s)) at your on-base residence? (Veteran only question: Are any firearms now kept in or around your home?)</p> <p><input type="radio"/> Yes</p> <p><input type="radio"/> No</p> <p><input type="radio"/> Don’t know/not sure</p> <p><input type="radio"/> Refuse to answer</p> <p>a. Active Duty/Reserve/National Guard question: Are any of these firearm(s) at your on-base residence now loaded? (Veteran only question: Are any of these firearms now loaded?)</p> <p><input type="radio"/> Yes</p> <p><input type="radio"/> No</p> <p><input type="radio"/> Don’t know/not sure</p> <p><input type="radio"/> Refuse to answer</p> <p>b. Are any of these firearm(s) at your on-base residence now unlocked? (Veteran version: Are any of these loaded firearms unlocked?)</p> <p><input type="radio"/> Yes</p> <p><input type="radio"/> No</p> <p><input type="radio"/> Don’t know/not sure</p> <p><input type="radio"/> Refuse to answer</p>	<p>New</p> <p>DSPO instructed</p> <p>Source: BRFSS/ Status of the Forces Active Duty 2020 Survey, VA working group</p>
MCS	Non- suicidal self injury	<p>Have you ever intentionally hurt yourself (e.g., cut or hit yourself) without any intention of killing yourself?</p> <p>0- No</p> <p>1- Yes</p>	<p>New</p> <p>Source: Status of the Forces Active Duty 2020 Survey</p>
Physical Health and Health Behaviors			
MCS	VA-only Substance	<p>In the past 12 months, how often have you used any drugs, including cocaine or crack, heroin, methamphetamine (crystal meth), hallucinogens, or ecstasy/MDMA? [range 0-5, Never, Less than monthly, Monthly,</p>	<p>New</p> <p>Veterans/Separated</p>

	Use	<p><i>Weekly, Daily or almost daily</i></p> <ul style="list-style-type: none"> <input type="radio"/> Cocaine, crack, or methamphetamine (crystal meth) <input type="radio"/> Heroin <input type="radio"/> Hallucinogens <input type="radio"/> Ecstasy/MDMA 	<p>individuals only</p> <p>Developed by VA work group</p>
MCS	Veteran/ Separated only Marijuana use	<p>In the past 12 months, how often have you used marijuana? <i>[range 0-5, Never, Less than monthly, Monthly, Weekly, Daily or almost daily]</i></p> <ul style="list-style-type: none"> <input type="radio"/> Marijuana 	<p>New</p> <p>Veterans/Separated individuals only</p> <p>Developed by VA work group.</p>
Both	Women- only Pregnancy outcome	<p>What was the outcome of your last pregnancy?</p> <ul style="list-style-type: none"> <input type="radio"/> Single live birth <input type="radio"/> Single stillbirth <input type="radio"/> Multiple birth <input type="radio"/> Miscarriage or spontaneous abortion (including chemical pregnancy) <input type="radio"/> Elective or therapeutic abortion <input type="radio"/> Tubal or ectopic pregnancy <input type="radio"/> Molar pregnancy 	<p>New</p> <p>Source: Sister Study and HCHS-SOL, Centers for Disease Control and Prevention.</p>
MCS	Risk behaviors during pregnancy	<p>These next questions ask about your behaviors before and during your last pregnancy.</p> <p><i>Did you smoke cigarettes?</i></p> <p>In the 3 months before your last pregnancy...</p> <ul style="list-style-type: none"> <input type="radio"/> No, not at all <input type="radio"/> Yes, some days <input type="radio"/> Yes, every day <p>During the last 3 months of your last pregnancy...</p> <ul style="list-style-type: none"> <input type="radio"/> No, not at all <input type="radio"/> Yes, some days <input type="radio"/> Yes, every day <p><i>How many alcohol drinks did you have in an average week?</i></p> <p>In the 3 months before your last pregnancy...</p> <ul style="list-style-type: none"> <input type="radio"/> I didn't drink then <input type="radio"/> Less than 1 drink a week <input type="radio"/> 1 to 3 drinks a week <input type="radio"/> 4 to 7 drinks a week <input type="radio"/> 8 to 13 drinks a week <input type="radio"/> 14 drinks or more a week <p>During the last 3 months of your last pregnancy</p> <ul style="list-style-type: none"> <input type="radio"/> I didn't drink then <input type="radio"/> Less than 1 drink a week <input type="radio"/> 1 to 3 drinks a week <input type="radio"/> 4 to 7 drinks a week <input type="radio"/> 8 to 13 drinks a week <input type="radio"/> 14 drinks or more a week 	<p>Pregnancy Risk Assessment Monitoring System (PRAMS) Questionnaire,</p>
Both	Covid-19 related items	<p>Has your doctor or other health professional ever told you that you have COVID-19 (Coronavirus disease 2019) or have you ever tested positive for SARS-CoV-2?</p> <ul style="list-style-type: none"> <input type="radio"/> No <input type="radio"/> Yes, once (or multiple times within a 14-day period) 	<p>New to both surveys</p> <p>Source: WRAIR</p>

		<p>o Yes, more than once where you were tested at least 14 days apart</p> <p>a. If yes, month/year of first diagnosis/positive test ___(mo) ___(year)</p> <p>Since the beginning of the COVID-19 pandemic, have you ever:</p> <p>a. Become seriously ill with COVID-19? Yes/no</p> <p>aa. If yes, month/year of when illness began ___(mo) ___(year)</p> <p>b. Been hospitalized with COVID-19? Yes/no</p> <p>bb. If yes, month/year of first hospitalization ___(mo) ___(year)</p> <p>c. Recovered from COVID-19? Yes/no covid_rec</p> <p>cc. If yes, month/year of recovery (no longer experiencing symptoms) ___(mo) ___(year)</p> <p>d. Experienced longer term health issues after you recovered from COVID-19? Yes/no</p> <p>Have you ever received a vaccine for COVID-19?</p> <p>o No</p> <p>o Yes, received all doses of vaccine in the series</p> <p>o Yes, but only received some of the vaccine doses in the series</p> <p>a. If yes, month/year of first dose of vaccination ___(mo) ___(year)</p>	
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* A copy of the References have been provided with this package for OMB's review.

12. Respondent Burden and its Labor Costs

Part A: ESTIMATION OF RESPONDENT BURDEN

1) Collection Instrument(s)

Millennium Cohort Study Follow-Up Survey

- a) Number of Respondents: 173,921
- b) Number of Responses Per Respondent: 1
- c) Number of Total Annual Responses: 173,921
- d) Response Time: .75 hours
- e) Respondent Burden Hours: 130,441 hours

Millennium Cohort Study Participant Feedback Survey

- a) Number of Respondents: 173,921
- b) Number of Responses Per Respondent: 1
- c) Number of Total Annual Responses: 173,921
- d) Response Time: 0.13 hours
- e) Respondent Burden Hours: 22,610 hours

Millennium Cohort Family Study Follow-Up Survey

- a) Number of Respondents: 14,768
- b) Number of Responses Per Respondent: 1

- c) Number of Total Annual Responses: 14,768
 - d) Response Time: .83 hours
 - e) Respondent Burden Hours: 12,257.44 hours
- 2) Total Submission Burden
- a) Total Number of Respondents: 188,689
 - b) Total Number of Annual Responses: 362,610
 - c) Total Respondent Burden Hours: 165,308.44 hours

Part B: LABOR COST OF RESPONDENT BURDEN

1) Collection Instrument(s)

Millennium Cohort Study Follow-Up Survey

- a) Number of Total Annual Responses: 43,480
- b) Response Time: .75 hours
- c) Respondent Hourly Wage: \$31.20
- d) Labor Burden per Response: \$23.40
- e) Total Labor Burden: \$1,017,432

Millennium Cohort Study Participant Feedback Survey

- a) Number of Total Annual Responses: 43,480
- b) Response Time: 0.13 hours
- c) Respondent Hourly Wage: \$31.20
- d) Labor Burden per Response: \$4.06
- e) Total Labor Burden: \$176,528.80

Millennium Cohort Family Study Follow-Up Survey

- a) Number of Total Annual Responses: 4,923
- b) Response Time: .83 hours
- c) Respondent Hourly Wage: \$27.07
- d) Labor Burden per Response: \$22.47
- e) Total Labor Burden: \$110,602.97

2) Overall Labor Burden

- a) Total Number of Annual Responses: 91,883
- b) Total Labor Burden: \$1,304,563.77

The civilian respondent hourly wage was estimated using the mean hourly wage for all occupations documented within the May 2020 National Occupational Employment and Wage Estimates provided by the United States Department of Labor, Bureau of Labor Statistics. The information can be found here:

http://www.bls.gov/oes/current/oes_nat.htm.

The Active-Duty service member respondent hourly wage was estimated using the mean hourly wage for all ranks documented within the January 2021 Monthly Basic Pay Table provided by Defense Finance and Accounting Service (DFAS). The information can be found here:

<https://www.dfas.mil/Portals/98/Documents/militarymembers/militarymembers/pay-tables/2021%20MilPay%20General.pdf>

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

Part A: LABOR COST TO THE FEDERAL GOVERNMENT

1) Collection Instrument(s)

Millennium Cohort Study Follow-Up Survey

- a) Number of Total Annual Responses: 43,480
- b) Processing Time per Response: 0.4 hours
- c) Hourly Wage of Worker(s) Processing Responses: \$25.79
- d) Cost to Process Each Response: \$10.32
- e) Total Cost to Process Responses: \$448,713.60

Millennium Cohort Study Participant Feedback Survey

- a) Number of Total Annual Responses: 43,480
- b) Processing Time per Response: 0.08 hours
- c) Hourly Wage of Worker(s) Processing Responses: \$25.79
- d) Cost to Process Each Response: \$2.06
- e) Total Cost to Process Responses: \$89,568.80

Millennium Cohort Family Study Follow-Up Survey

- a) Number of Total Annual Responses: 4,923
- b) Processing Time per Response: .25 hours
- c) Hourly Wage of Worker(s) Processing Responses: \$25.79
- d) Cost to Process Each Response: \$6.45
- e) Total Cost to Process Responses: \$31,738.89

2) Overall Labor Burden to the Federal Government

- a) Total Number of Annual Responses: 91,883
- b) Total Labor Burden: \$570,021.29

MCP surveys are completely processed by in-house contract staff. These staff members consist of Research Interns, Research Assistants and Study Coordinators. The hourly wage of workers was calculated by using the mean hourly wage for all staff members involved in the processing of annual responses which was provided by the contract company's fiscal officer.

Part B: OPERATIONAL AND MAINTENANCE COSTS

- 1) Cost Categories
 - a) Equipment: \$15,000
 - b) Printing: \$1,339,690
 - c) Postage: \$ 2,620,490
 - d) Software Purchases: \$0
 - e) Licensing Costs: \$0
 - f) Contract Staff Costs: \$892,245

- 2) Total Operational and Maintenance Cost: \$4,867,425

Part C: TOTAL COST TO THE FEDERAL GOVERNMENT

- 1) Total Labor Cost to the Federal Government: \$554,611.54

- 2) Total Operational and Maintenance Costs: \$4,867,425

- 3) Total Cost to the Federal Government: \$5,412,036.54

15. Reasons for Change in Burden

The calculated total respondent burden hours for the previously approved 2018-2021 data collection was 100,764 hours each year of the 3 year data collection for a total of 302,292 hours total over the 3 year period. The calculated total respondent burden hours for the 2021-2024 data collection is 165,308.44 hours total over the 3 year period. The change in burden results in an overall decrease of 136,983.56 burden hours.

The burden has decreased since the previous approval due to 1) attrition; 2) the lower than anticipated enrollment of the new MCFS panel; 3) the lower than anticipated enrollment of the new MCS panel that was approved by RCS; 4) and the continued decrease in participant response across all DoD surveys. For this submission the burden has been calculated for enrolled Active-Duty service members, separated/retired individuals, as well as the enrolled spouses of each group with a 30% loss to follow up rate.

16. Publication of Results

MCS researchers have published or have in press 124 peer-reviewed publications and the FCS has 23 peer-reviewed publications to date. A complete list of MCP publications to date has been submitted as a part of this submission.

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.