

SUPPORTING STATEMENT - PART A

(Prospective Studies of US Military Forces: The Millennium Cohort Study– OMB # 0703-0064)

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 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 for this collection is granted under 10 U.S.C. 136, 1782 and 2358, and Under Secretary of Defense Memorandum #: 99-028, 30 SEP 99 "Establishment of DoD Centers for Deployment Health".

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 electronic healthcare utilization, deployment, exposure, and demographic data available from other Department of Defense (DoD) sources for all participants, with self-reported health status information collected from the study 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.

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.

2. Use of the Information

The MCS consists 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, married personnel, special operators) to ensure sufficient statistical power for addressing these sub-groups of the population reasonably well in a population-based setting.

The MCS currently consists of four previously enrolled panels of Active Duty Service members, Reserve and National Guard, and Veterans; a fifth panel of Active Duty Service members will be enrolled during the upcoming survey cycle. The target population for this new panel will be 425,000 Service members on Active Duty rosters, with 1-4 years of military service. This panel will be oversampled for female and married personnel. The baseline MCS survey will only be completed by Active Duty service members, who are not considered members of the public by OMB standards, and are therefore not included in burden calculations.

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, 48% of the cohort has retired or separated from active military service and are therefore included in the MCS respondent calculations referred to for this submission. Only those MSC participants that are no longer Active Duty military have been included in the MCS burden calculations presented below. The burden to the Active Duty participants will be calculated during the study's RCS approval process.

The FCS currently consists of spouses of Service members (i.e. members of the public) enrolled in the fourth panel of the MCS who voluntarily enrolled in the study. Spouses of Service members within the target population for the fifth panel of the MCS will be enrolled into a second panel of the FCS.

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	TBD	1-4 years	Females and Married	425,000*	85,000(20%)*	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	9,879 (44%)	9,879 (100 %)
Family Panel 2	TBD	N/A	TBD	212,500*	85,000(40%)*	85,000 (100%)*

The MCS will continue to collect data through both traditional paper surveys as well as an online version of the questionnaire. The full version of 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 any communication 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.

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. Documents listing the MCS and FCS participant contacts have been submitted as a part of this submission.

Data collection for the upcoming survey cycle for both the MCS and the FCS will begin approximately one month after receiving OMB approval, and will proceed for 18-24 months.

Completed MCS paper survey packets are returned to the study team for processing via USPS. Processing of the paper surveys includes: recording receipt of the survey, verifying that the survey was filled out by the intended participant, and for newly enrolled participants, ensuring that the consent form was 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) 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; and 3) must 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, but we are in the process of updating our SORN because we have not and do not intend to use the data for any purposes aside from those which are research-related. Once the SORN is updated, we will submit a non-substantive change to OMB. The primary objective of this research project is to create a data repository to study the impact of military service on Service members and their families. 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 to both the MCS and the FCS surveys and current trends with online questionnaires, we predict that 87% 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. Based on early response rates, an abbreviated paper survey may be offered toward the end of the survey cycle for late responders.

The online surveys for both the MCS and the FCS were 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.

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 200,000 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 for the collection published on Wednesday, February 14, 2018. The 60-Day FRN citation is 83 FRN 6535.

One comment was received during the 60-Day Comment Period. However, our Agency did not respond as the comment was deemed unrelated to the collection's subject matter.

Part B: CONSULTATION

A Strategic Board (SB) consisting of twelve civilian and military experts in epidemiology, preventive medicine, statistics, and veterans affairs provides strategic scientific planning advisement on 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.

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 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 off of 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. All Millennium Cohort responders will be offered a \$5 gift card to Amazon, Starbucks, Walmart or Subway, while all Family Study responders will be offered a \$10 gift card to either Amazon or Starbucks.

The use of these cost savings initiatives by the MCP was reviewed and approved by General Counsel on February 5, 2018. The approval letter was submitted as part of this package

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.

The updated SORN for both studies was published on the Defense Privacy and Civil Liberties Division (DPCLD) website on November 14, 2014, and can be found here: <http://dpclد.defense.gov/Privacy/SORNsIndex/DODComponentArticleView/tabid/7489/Article/570396/n06500-1.aspx>.

The MCP SORN has been recently reviewed and found to comply with all current applicable laws and regulations. Documentation for this review has been submitted as a part of this project.

The MCP has been evaluated and it was determined that a PIA is not required. The MCS and the FCS have been assessed under similar evaluations as a PIA and as a result, neither study requires a Privacy Impact Assessment (PIA). In accordance with DoD 5400.16, Enclosure 3, 1. d.:

"d. No PIA is required where information relates to internal U.S. Government operations, when information has been previously assessed under an evaluation similar to a PIA (e.g., data use agreement), where privacy issues are unchanged from a previous assessment of PII, or as stated in paragraphs 1d(1) through 1d(3) of this section, in accordance with Reference (d).

(1) For U.S. Government-run public websites where the user is given the option of contacting the site operator for the limited purpose of providing feedback (e.g., questions or comments) or obtaining additional information.

(2) When all elements of a PIA are addressed in a matching agreement governed by the computer matching provisions of sections 552a(a)(8-10), (e)(12), (o), (p), (q), (r), and (u) of Title 5, United States Code, also known as the Privacy Act of 1974 (Reference (h)), which specifically provides privacy protection for matched information.

(3) When all elements of a PIA are addressed in an interagency agreement permitting the merging of data for strictly statistical purposes and where the resulting data are protected from improper disclosure and use."

Documentation supporting this waiver has been submitted as a part of this project.

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.

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.

As an identity verification measure, all participants are asked to provide the last four digits of their Social Security Number (question 111 on the 2017 baseline survey and 108 on the follow-up survey). As a security measure, FCS participants are asked to login to the secure online survey using the last four digits of the Social Security Number of their Service member spouse. Additionally, FCS participants are asked to provide their Social Security Number as an identity verification measure on the survey (question 140). The Social Security Number Justification Memo has been included as part of this package.

There are two questions, (83f and 83g in the 2017 MCS baseline survey, 82f and 82g in the follow-up survey, 48g and 48h in the FCS baseline and follow-up surveys) 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; Q9a21 & Q9a22), and have been reviewed by the DoD Sexual Assault Prevention and Response Office. If a responder marks “yes” to either of the above two items on the web version of the MCS survey, six additional items will be asked (i) frequency of events (ii) year of most recent experience, (iii) tactics employed by offender, (iv) location of the incident(s), (v) gender of offender, and (vi) military status of the offender. If a responder marks “yes” to either of the above screener items (48g and 48h) on the FCS surveys, six additional items will be asked (i) frequency of events, (ii) age at most impactful event, (iii) type of experiences, (iv) tactics employed by offender, (v) military status at time of event, and (vi) reporting of event.

There are three questions, (52-54) on the MCS baseline survey, and one question (51) on the follow-up survey addressing sexual orientation. All three items were listed in Best Practices for Asking Questions about Sexual Orientation on Surveys (Badgett, M V Lee. (2009) and reviewed by DoD and academic subject-matter experts. The first question was developed at the National Center for Health Statistics (NCHS) and the second question was taken from the National Study of Family Growth (see OMB #0920-0314). While these questions are similar to the items used by the National Center for Health Statistics, they are slightly different in order to align with federal surveys, appropriately target our military population, and remain consistent with previous survey waves. These questions were added to the MCS surveys in response to the increased need for sound facts and analyses on lesbian, gay, and bisexual (LGB) policy issues to inform program evaluation, public health, and health services; this information cannot otherwise be obtained without specific survey questions pertaining to sexual orientation. These items were approved for inclusion on the Millennium Cohort surveys by USD(PR). These items were not approved for the Millennium Cohort Family Study surveys. The approval memo has been submitted as a part of this project.

Also included is one question, (32o and 34o in the MCS baseline and follow-up surveys respectively) asking participants whether in the past four weeks they have had little or no sexual desire. This question (21n) is also asked on the FCS baseline and follow-up surveys. This question was derived from the Patient Health Questionnaire (PHQ) (Spitzer R, Williams J, Kroenke K, et al.) (Q12). The MCS baseline and follow-up surveys also include one item (question 25vv) that asks if the individual has ever been diagnosed with a sexual dysfunction. In addition, question 76e in the FCS surveys from the National Survey of Families and Households, asks how happy the participant is with their “sexual relationship” with their spouse. These questions were added to the surveys to help the DoD and the VA gauge Service member sexual relationships and any effect it may have on mental health.

There is one set of questions that focuses on childhood experiences. In the MCS baseline survey, question 87 focuses on adverse childhood experiences of physical abuse, sexual abuse, psychological/emotional abuse, and neglect. This question is a modified version of a question from the Juvenile Victimization Questionnaire (JVQ). A similar item (B13) is included in the FCS baseline survey. This question is a modified version of the Adverse Childhood Experiences (ACE) questionnaire. Responses from this set of questions provide useful insight into an individual's current and historical quality of life and into possible clinical psychiatric status. The questions described above are commonly asked as part of clinical psychiatric assessments and are important to assess when examining long-term health outcomes.

There are two items, questions 82 and 83, on the FCS surveys that ask 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. 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. They have also been vetted through the NHRC IRB.

In addition, deployment-specific exposures are included to differentiate stressful exposures during deployment. Several questions, including question 96m in the MCS baseline survey, 94m in the MCS follow-up survey and question 67m 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 assess as these exposures are associated with numerous health outcomes.

The FCS baseline questionnaire has two items, question B3 and B4, that ask about race and ethnicity while the FCS follow-up does not ask these questions, since this is a static data point that does not need to be tracked over time. Neither the baseline nor the follow-up MCS questionnaires ask questions on this topic. These data points are acquired from DMDC records.

12. Respondent Burden and its Labor Costs

a. Estimation of Respondent Burden

1. Millennium Cohort Study Follow-Up Survey

- a. Number of Respondents: 55,652
- b. Number of Responses Per Respondent: 1
- c. Number of Total Annual Responses: 55,652
- d. Response Time: 45min

e. Respondent Burden Hours: 41,739 hours

1. Millennium Cohort Family Study Follow-Up Survey

- a. Number of Respondents: 4,449
- b. Number of Responses Per Respondent: 1
- c. Number of Total Annual Responses: 4,449
- d. Response Time : 45min
- e. Respondent Burden Hours: 3,337 hours

1. Millennium Cohort Family Study Baseline Survey

- a. Number of Respondents: 74,250
- b. Number of Responses Per Respondent: 1
- c. Number of Total Annual Responses: 74,250
- d. Response Time: 45min
- e. Respondent Burden Hours: 55,688 hours

2. Total Submission Burden

- a. Total Number of Respondents: 134,351
- b. Total Number of Annual Responses: 134,351
- c. Total Respondent Burden Hours: 100,764 hours

b. Labor Cost of Respondent Burden

1. Millennium Cohort Study Follow-Up Survey

- a. Number of Total Annual Responses: 55,652
- b. Response Time: 45 min
- c. Respondent Hourly Wage: \$23.86
- d. Labor Burden per Response: \$17.89
- e. Total Labor Burden: \$995,892.54

1. Millennium Cohort Family Study Follow-Up Survey

- a. Number of Total Annual Responses: 4,449
- b. Response Time: 45 min
- c. Respondent Hourly Wage: \$23.86
- d. Labor Burden per Response: \$17.89
- e. Total Labor Burden: \$79,614.86

1. Millennium Cohort Family Study Baseline Survey

- a. Number of Total Annual Responses: 74,250
- b. Response Time: 45 min
- c. Respondent Hourly Wage: \$23.86
- d. Labor Burden per Response: \$17.89
- e. Total Labor Burden: \$1,328,703.75

2. Overall Labor Burden

- a. Total Number of Annual Responses: 134,351
- b. Total Labor Burden: \$2,404,211.15

The respondent hourly wage was estimated using the mean hourly wage for all occupations documented within the May 2016 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.

13. Respondent Costs Other Than Burden Hour Costs

There are no annualized costs to respondents other than the labor burden costs addressed in Section 12 of this document to complete this collection.

14. Cost to the Federal Government

a. Labor Cost to the Federal Government

1. Millennium Cohort Study Follow-Up Survey

- a. Number of Total Annual Responses: 55,652
- b. Processing Time per Response: 0.5 hours
- c. Hourly Wage of Worker(s) Processing Responses: \$25.00
- d. Cost to Process Each Response: \$12.50
- e. Total Cost to Process Responses: \$695,650.00

1. Millennium Cohort Family Study Follow-Up Survey

- a. Number of Total Annual Responses: 4,449
- b. Processing Time per Response: 0.25 hours
- c. Hourly Wage of Worker(s) Processing Responses: \$25.00
- d. Cost to Process Each Response: \$6.25
- e. Total Cost to Process Responses: \$27,806.25

1. Millennium Cohort Family Study Baseline Survey

- a. Number of Total Annual Responses: 74,250
- b. Processing Time per Response: 0.25 hours
- c. Hourly Wage of Worker(s) Processing Responses: \$25.00
- d. Cost to Process Each Response: \$6.25
- e. Total Cost to Process Responses: \$464,062.50

2. Overall Labor Burden to Federal Government

- a. Total Number of Annual Responses: 134,351
- b. Total Labor Burden: \$1,187,518.75

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.

b. Operational and Maintenance Costs

- a. Equipment: \$11,000
- b. Printing: \$604,958
- c. Postage: \$647,981
- d. Software Purchases: \$0
- e. Licensing Costs: \$0
- f. Other: \$1,624,985.50
- g. Total: \$2,888,924.50

- 1. Total Operational and Maintenance Costs: \$2,888,924.50
- 2. Total Labor Cost to the Federal Government: \$1,187,518.75
- 3. Total Cost to the Federal Government: \$4,076,443.25

15. Reasons for Change in Burden

The calculated public burden for the previously approved 2014-2016 data collection was 35,060 hours for the MCS and 2,682 for the FCS, for a combined total of 37,742 hours. The estimated public burden for the 2018 data collection is 41,739 hours for the MCS and 59,025 hours for the FCS for a combined total of 100,764 hours. The change in burden results in an overall increase of 63,022 burden hours.

The large increase in burden for the FCS is due to the planned invitation of 212,500 spouses of Active Duty Service members during the next survey cycle. Based on past online response rates and current trends with online questionnaires, the FCS team is expecting a 40% response rate that will result in an additional 85,000 participants enrolled in the study. For reference, please see the detailed table in section 2.

16. Publication of Results

MCS researchers have published or have in press 96 peer-reviewed publications and the FCS has 4 peer-reviewed publications to date. A complete list of MCP publications to date has been submitted as a part of this project.

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.