

## **SUPPORTING STATEMENT FOR PAPERWORK REDUCTION ACT SUBMISSION**

### SUPPORTING STATEMENT – PART A Prospective Studies of US Military Forces: The Millennium Cohort Study

#### A. JUSTIFICATION

##### 1. Need for the Information Collection

The concept and design manifest in the Millennium Cohort Study 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.”

Language in the Floyd D. Spence FY2001 National Defense Appropriations Act “... longitudinal studies of military personnel before they are deployed to potentially hostile situations and after their return”, funded the activity.

The Millennium Cohort Study was designed in response to the IOM recommendation and to Congress’ authorization and funding, as a prospective, 21-year-long, multi-panel and wave, cohort investigation.

The main objectives of the Millennium Cohort Study 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, and (2) to better define the nature of and risk factors for the development of post war illness among US military personnel. 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. A survey instrument is used to collect self-reported baseline data as well as a series of follow-up surveys that are collected in 3-year intervals through at least 2022. Given that military experiences may contribute to health outcomes with long latencies along with the goal to evaluate the total life cycle of the service member, the study may include future follow-ups beyond 21 years. For approximately 50% of the population, we are able to capture pre- and post-deployment metrics due to the timing of deployments. Participants are encouraged to complete follow-up surveys even after they separate from military service.

Based on random, probability-based samples of service members who are serving in the Armed Forces at the time of initial contact, the Cohort currently includes over 200,000 service members and veterans representing all service branches and components (including Reserve and National Guard). Participants are requested to complete an in-depth survey approximately every 3 years regardless of whether they are still serving or have left the service. Self-reported data are linked to more objective data sources. Certain groups were oversampled to ensure sufficient statistical power to reveal findings if they exist in these smaller subgroups of the study population. Ryan MA, Smith TC, Smith B, Amoroso P, Boyko EJ, Gray GC, Gackstetter GD, Riddle JR, Wells TS, Gumbs G, Corbeil TE, Hooper TI, for the Millennium Cohort Study Team. Millennium Cohort: Enrollment begins a 21-year contribution to understanding the impact of military service. *Journal of Clinical Epidemiology*. 2007 Feb;60(2):181-91.

The influential role that military families play in the armed forces' ability to maintain readiness and retain personnel, as well as the level of sacrifice that military families make, has been recognized by civilian and military policy makers and leaders, and has made quality of life for military families a growing national priority. Indeed, the Department of Defense (DoD), the Department of Veterans Affairs (VA), the American Psychology Association (APA) and the White House have expressed concern for the potential effects of military deployment on service members as well as their families and have demonstrated a deep commitment to supporting them (US DoD Task Force on Mental Health, 2007; Presidential Proclamation, 2010, Presidential Study Directive, 2010, Strengthening our Military Families initiative and Joining Forces campaign, 2011 ). Understanding the impact of military service on family members' health is a critical step in developing interventions and support mechanisms to build resilience and reduce stress. In order to examine the health of service members' families, a fourth panel and a family component were included as part of the 2011-2012 survey cycle.

The overarching goals of the Millennium Cohort Family Study are to assess the impact of military service, including deployment, on the health and well-being of the family and to examine the relationships between the family members and the service member. These findings will then provide strategic evidence that will help inform policy and guide interventions This DoD capability will be the first of its kind by using a large population-based cohort to assess the 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.

By July 1, 2003, 77,047 (36%) had returned a Panel 1 baseline questionnaire. Panel 1 targeted 256,400 service members of whom 213,949 had valid addresses allowing for study contact attempt.

Among Panel 1 participants, 55,021 submitted the first follow-up survey (71%), and 54,790 submitted the second follow-up survey (71%). Participation in the second follow-up survey consisted of 84% web and 16% paper responders. Of those that did not submit their first follow-up survey, 8,259 submitted their second follow-up survey. Of Panel 1 participants, 46,439 have completed all of the first three surveys (baseline plus two follow-up surveys).

As of November 5, 2012, the survey cycle is still open and collection is still underway for the following:

- Panel 1, third follow-up survey;
- Panel 2, second follow-up survey;
- Panel 3, first follow-up survey;
- Panel 4, baseline survey; and
- Family Study, baseline survey.

As of November 5, 2012, there have been 48,421 (63%) Panel 1 participants who submitted the third follow-up survey, with 85% responding via web and 15% via paper.

Panel 2 targeted 150,000 of whom 122,410 were determined to have valid addresses allowing for a documented study contact attempt. Of those, 31,110 (25%) returned a Panel 2 baseline questionnaire.

Among Panel 2 participants, 17,151 submitted a first follow-up survey (55%), and participation consisted of 83% web and 17% paper responders. As of November 5, 2012, there have been 13,799 (44%) Panel 2 participants who have submitted the second follow-up survey, with 83% responding via web and 17% via paper.

Panel 3 targeted 200,000 of whom 153,650 were determined to have valid addresses allowing for a documented contact attempt. Of those, 43,440 had returned a baseline questionnaire with 93% of responses occurring via web and 7% via paper.

By November 5, 2012, there have been 20,107 Panel 3 participants who have submitted the first follow-up survey (46%), and participation has consisted of 85% web and 15% paper responders.

For the 2011-12 survey cycle, we are attempting to contact 250,000 service members to enroll 50,000 individuals in Panel 4. As of November 5, 2012, there have been 43,383 (17%) who have returned a Panel 4 baseline questionnaire. The spouses of married service members who enroll in Panel 4 are invited to participate in the Millennium Cohort Family Study. The team anticipates enrolling approximately 10,000 spouses of whom about half will be married to service members who have deployed in support of the conflicts in Iraq and Afghanistan. As of November 5, 2012, there have been 6,438 (47%) Family Study participants who have returned a Family Study baseline questionnaire.

Since enrollment began in 2001 and up to November 5, 2012 there have been 195,125 service members who have consented and submitted a baseline survey (36.0%, 25.4%, 28.3%, and 17.4% baseline response rates for Panels 1, 2, 3, and 4, respectively).

To continually examine potential for nonresponse and attrition bias, OMB placed specific Terms of Clearance on our previous ICR. We were able to partially meet the 2011 Terms of

Clearance required by OMB. Further analysis is ongoing and the 2011 Terms of Clearance will be fully met by 2015.

## 2. Use of the Information

As noted in the response to item 1, overall, the purpose of the information collected by the Millennium Cohort Study is to assist US policy makers with understanding long-term health outcomes that may be associated with military service, especially of deployment and service in hostile operations. Specifically, the study seeks to track the development of major chronic, physical, and psychiatric illnesses among service members and veterans, and establish risk factors through temporal sequence of exposure and health outcome.

With the addition of surveying spouses of service members, the impact of military service and deployment on the health of service members, their spouses and co-resident children will be examined. Furthermore, the quality of the relationships between service members, spouses and their children will be evaluated. Understanding the impact of military service on family members' health is a critical step in developing interventions and support mechanisms to build resilience and reduce stress.

DoD and Department of Veterans Affairs (DVA) policy makers and researchers will use these prospective strategic analyses 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

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 data. Self-reported health status information is obtained both during and after military service when participants complete either a paper or web-based health status questionnaire, every 3 years, through at least 2022.

The designers of the Millennium Cohort Study have not made 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 Millennium Cohort participants. However, due to the complexities of the Millennium Cohort Family Study, such as the accounting for divorced, separated, or widowed spouses, the team has decided to only offer a web-based survey to the Family participants. The online survey employs 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 specific information obtained from the participant, which helps to clarify the questions. Since it was not possible to create a paper Family survey that would be clear and easy to follow for these military spouses, it was decided that the Family participants will only have the option to complete the web survey.

For the 2011-2012 survey cycle, a majority of Millennium Cohort responders completed the questionnaire online (n= 108,694, 86%), however, some are still choosing to complete the paper questionnaire (n=16,980, 14%). Similarly, (n=5,805, 90%) of Family Study participants completed the online questionnaire while (n=633, 10%) completed a paper survey.

For the 2014-15 Millennium Cohort Study follow-up survey, all of the questions appear the same way on both the paper and web versions.

However, there are additional items for four questions on the web survey version that do not appear on the paper version. To reduce burden, the automatic skip functions will be utilized on the web version, so that questions that do not apply to the individual will be skipped. Documents listing the Millennium Cohort Study web only questions have been submitted as a part of this project.

The follow-up web survey question 59, states, “From the following list, indicate if you have used each health practice in the last 12 months”. If Yes is chosen for “a. Acupuncture” or “o. Meditation”, then 3 additional questions appear asking for (i) reason/condition for using this health practice, (ii) the year started, and (iii) frequency of use.

Additionally, questions 85f & 85g on the follow-up web survey, address potential exposures to traumatic life events, in which participants are asked whether they have ever been (a) been sexually assaulted, or (b) sexually harassed. If a responder marks “yes” to either (a) or (b) above, then four additional questions will be asked only on the web version of the Millennium Cohort Study follow-up survey about (i) number of events in the past 3 years, (ii) location of the events (deployed or non-deployed location), (iii) characteristics of person (higher or lower rank/grade, government, or civilian person) and (iv) gender(s) of the offender.

The combined entry of the subject's randomly assigned study ID and last 4 digits of their SSN are verified prior to allowing access to the questionnaire or entry of any survey responses. All exchanges between survey participant web browsers and web server software are made over secure (128-bit encrypted) connections based upon well-established and widely accepted Secure Sockets Layer (SSL) technology.

#### 4. Non-duplication

Independent high echelon reviews conducted by the Defense Technical Objectives Board prior to the beginning and since completion of Panel 1 indicate that the work of the Millennium Cohort Study is not being duplicated anywhere else in DoD, or indeed, across the Federal Government. Regular reviews by the independent American Institute of Biological Sciences (AIBS) similarly have reported no duplication of effort. On-going oversight by the Millennium Cohort External Advisory Board (EAB), made up of high-level civilian and military science professionals continues to report that this investigation remains unique among government funded military investigations. Lastly, yearly review by the DoD Defense Health Board further indicates no duplications of efforts with any other federal agency. In sum, at this

time the Millennium Cohort Study and the Family Study do not duplicate any other federally sponsored military data collection effort.

#### 5. Burden on Small Business

This collection of information does not involve small businesses or other small 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 Millennium Cohort Study protocol has found that the frequency of data collection, i.e., every 3 years for 21 years, 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 2-8. A three-year survey strategy was implemented due to the chronic nature of many of the surveyed endpoints, the logistics of surveying nearly 200,000 participants in each wave, and the addition of subsequent panels designed to be temporally different from one another.

All respondent contact that will be sent throughout the 2014-15 effort has been submitted as part of this project.

#### 7. Paperwork Reduction Act Guidelines

There have been (and we continue to anticipate) no special circumstances requiring the collection to be conducted in a manner inconsistent with the guidelines in 5 CFR 1320.5 (d) (2).

#### 8. Consultation and Public Comments

An initial 60-day Federal Register Notice for this collection was published in Volume 77 Number 173 on 06 September 2012. In response to the published Federal Register Notice, an inquiry was received on 20 September 2012 by Ms. Lisa Schnall, Senior Attorney Advisor for the Office of Legal Counsel with the U.S. Equal Employment Opportunity Commission, requesting copies of the proposed information collection and associated collection instruments for the Millennium Cohort Study and the Family Study. On 25 September 2012 draft copies of the survey instruments were sent to Ms. Schnall. No further inquiries or questions were received as a result of this Federal Register Notice.

A second 60-day Federal Register Notice was published in Volume 79 Number 5 on 08 January 2014. No comments were received.

A 30-day Federal Register Notice was published in Volume XX Number X on XX March 2014.

A committee within the Psychological Health and Resilience Program Area of the Military Operational Medicine Research Program which include former and current service members as well as physicians, statisticians, and epidemiologists meet monthly to review direction and progress. An External Advisory Board (EAB) consisting of ten civilian and military experts in epidemiology, preventive medicine, statistics, questionnaire design, survey methodology, and veterans affairs, provides strategic scientific planning advisement on the study on an on-going basis. This committee meets at least annually to review progress and recommend course corrections when needed. In addition, the Study's staff confers regularly with subject matter experts in various medical fields, and in the nature and availability of demographic, deployment, and healthcare data from the Defense Manpower Data Center, Monterey CA.

Other consultation and oversight of the Millennium Cohort Study includes annual reviews by the NHRC internal Institutional Review Board Office of Budget and Management (OMB), and Defense Health Board. See attached reports of approval.

#### 9. Gifts or Payment

The Millennium Cohort Study investigators and survey methodologists decided that (1) the establishment of group identity among study participants would be critical to long-term (21-year) viability of the investigation 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 study team subsequently designed and implemented a plan to employ modest incentives to serve these ends. The Institutional Review Board (IRB) at the Naval Health Research Center has reviewed changes to the original study protocol providing for the delivery of modest (under \$10) incentives, such as coins hats and gift cards (\$5 for Millennium Cohort Study participants and \$10 for Millennium Cohort Family Study participants), to participants who fill out and submit the questionnaire over the secure internet site. The NHRC IRB continues to monitor use of incentives closely.

An investigation into whether response rates differed by incentives offered prior to enrollment was conducted during the pilot phase of the Millennium Cohort Study. No differences in response rates were found including those who did not receive an incentive. Following this research, the Millennium Cohort Team chose to offer cost savings initiatives to motivate survey response via the internet. Cost-saving initiatives, while offered in return to those who complete the survey via the web, are unconditional and may be obtained upon request by any participant.

Based on findings from the RTI nonresponse study, during the 2007-2008 cycle several other incentivizing tactics were tested on consented participants, including sending automated voice messages, adding a \$5 Starbucks gift card to the survey packet, and offering a hat incentive up front to encourage response. During the 2007-08 cycle, of the Panel 1 participants that did not submit their first follow-up survey, 8,259 submitted their second follow-up survey.

#### 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 Millennium Cohort and Family Study Questionnaires. The surveys will also include the 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.

There were no firmly established procedures for on-line informed consent for the field of human subjects research as this protocol was being reviewed and initially implemented. However, a report sponsored by the American Association for the Advancement of Science released in November 1999, focused on internet-based human subject research. The report, titled, "Ethical and Legal Aspects of Human Subjects Research on the Internet," states that the three principles of protecting human subjects: autonomy, beneficence, and justice, must be applied in on-line informed consent documents. The informed consent document used for the Millennium Cohort and Family Studies meets these principles, outlining risks for both on-line and paper-based questionnaire completion and is closely reviewed by the NHRC IRB. Further, regarding the issue of a participant's signature, a main concern for on-line consent focuses on the validity of the consent with respect to the researcher not knowing the "age, competency, or comprehension" of the participant. These concerns are mitigated for the Millennium Cohort Study since the study population is drawn from a known source, rather than soliciting unknown responders. Additionally, a validity check at the very beginning of the survey process and at the end of the informed consent document will confirm that the participant is part of the known sample population.

In addition, the Principal Investigator and all study team members are held responsible for performing and monitoring the research under the protocol titled, "Prospective Studies of US Military Forces: The Millennium Cohort Study". They have read and understood the provisions of Title 32 Code of Federal Regulations Part 219 (Protection of Human Subjects), DoD Directive 3216.2 (Protection of Human Subjects in DoD Supported Research), Secretary of the Navy Instruction (SECNAVINST) 3900.39B (Protection of Human Subjects), Naval Medical Command Instruction (NAVMEDCOMINST) 6710.4 "Use of Investigational Agents in Human Beings" if applicable), and Naval Medical Research and Development Command Instruction (NMRDCINST) 3900.2 (Protection of Human Research Volunteers from Research Risks), SECNAVINST 5370.2H (Standards of Conduct) (and local instructions, as applicable). They have agreed to abide by all applicable laws and regulations, and agreed that in all cases, the most restrictive regulation related to a given aspect of research involving protection of research volunteers will be followed. In the event that they have a question regarding their obligations during the conduct of this DoD-sponsored project, they have ready access to each of these regulations, as either a personal copy or as available on file from the Chair, Committee for the Protection of Human Subjects at the NHRC, San Diego. They understand that their immediate resource for clarification of any issues related to the protection of research volunteers is the Chair, Committee for the Protection of Human Subjects.

## 11. Sensitive Questions

It is understood by the Study's Principal Investigator and the Study's staff that all questions regarding health can be understood as 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.

In regard to particularly sensitive topics, no questions concerning religious beliefs are included in the survey. There are two questions, (questions 85f & 85g in the 2014-15 Millennium Cohort Study follow-up survey, and questions 43e and 43f in the Millennium Cohort Family Study follow-up 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. See OMB # 2900-0558 - Expiration Date 9/98; Q9a21 & Q9a22). If a responder marks "yes" to either (a) or (b) above, then four additional questions will be asked only on the web version of the Millennium Cohort Study follow-up survey to ask about (i) number of events in the past 3 years, (ii) location of the events (deployed or non-deployed location), (iii) characteristics of person (higher or lower rank/grade, government, or civilian person) and (iv) gender(s) of the offender.

There are two questions, (question 53 and 54 in the Millennium Cohort Study follow-up survey) addressing sexual orientation. Both items were listed in Best Practices for Asking Questions about Sexual Orientation on Surveys (Badgett, M V Lee. (2009). 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).

Also included is one question, (question 40c in the Millennium Cohort Study follow-up survey asking participants whether in the past four weeks they have had little or no sexual desire, or taken little pleasure in sex. This question was derived from the Patient Health Questionnaire (PHQ) (Spitzer R, Williams J, Kroenke K, et al. (Q12)), which is framed to provide insight into a participant's recent experience with depressive symptoms. In addition, question A7e in the Millennium Cohort Family Study follow-up survey from the National Survey of Families and Households, asks how happy the participant is with their "sexual relationship" with their spouse.

There is one additional question that focuses on childhood adversity. In the Millennium Cohort Study follow-up 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 Adverse Childhood Experiences (ACE) scale. Responses from this question provide useful insight into an individual's current and historical quality of life and into possible clinical psychiatric status. The question described above is commonly asked as part of clinical psychiatric assessments.

In addition, deployment-specific exposures are included to differentiate stressful exposures during deployment. Several questions, including question 98m in the Millennium Cohort Study follow-up survey, and question 63m in the Millennium Cohort Family Study follow-up survey, "...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).

Lastly, question C2 in the Millennium Cohort Family Study follow-up survey asks widowed spouses to provide "the main cause of your spouse's death." Response options include "combat, accident (on-duty), accident (off-duty), illness/disease, homicide, suicide, other, unknown."

## 12. Respondent Burden, and its Labor Costs

### a. Estimation of Respondent Burden

Based on experience from Panels 1, 2, 3, and 4, both the Millennium Cohort follow-up questionnaire, whether web or paper-based and the Family Cohort follow-up questionnaire, take approximately 45 minutes to complete for the average individual. The total time for the entire public component of the Millennium Cohort Study sample will be 35,060 hours. The total time for the public component of the Family Study sample will be 2,682 hours. The combined burden estimate for both Millennium Cohort Study and Family Study will be: 37,742 hours.

### b. Labor Cost of Respondent Burden

Millennium Cohort follow-up study

Average respondent salary: \$17.30 per hr

Number of respondents: 46747

Hours per survey: .75 hrs

Cost to respondent:  $\$17.30 \times 46747 \times .75 = \$606,542$

Millennium Cohort Family follow-up study

Average respondent salary: \$7.25 per hr

Number of respondents: 3576

Hours per survey: .75 hrs

Cost to respondent:  $\$7.25 \times 3576 \times .75 = \$19,445$

## 13. Respondent Costs Other Than Burden Hour Costs

There is no respondent cost other than burden hour cost for this project.

14. Cost to the Federal Government

The estimated total annualized cost to the Federal Government for this collection is \$2,014,107.

The total annualized cost was calculated by taking the cost of the Millennium Cohort Study's eighteen month survey cycle, (which includes printing, postage, services, equipment purchases, and salaries), and multiplying that by 23% and 95% respectively (the proportion of Panel 1, 2, 3, and 4 participants and Millennium Cohort Family Study participants we estimate will be separated by 2014-15).

<b>Millennium Cohort Follow-up Study</b>	
<b>Element</b>	<b>Amount</b>
Printing and services	\$1,183,970
Postage	\$692,427
Equipment	\$10,000
Support Staff	\$1,436,659
<b>Total</b>	<b>\$3,323,056</b>
<b>Labor Costs for Government Staff</b>	
GS-13 at 53.13 per hr	\$8,957
GS-13 at 53.13 per hr	\$17,914
GS-12 at 47.09 per hr	\$86,108
<b>Total</b>	<b>\$112,979</b>
<b>Total for Millennium Cohort follow up study</b>	<b>\$3,436,035</b>
<b>Millennium Cohort Family Follow-up Study</b>	

<b>Element</b>	<b>Amount</b>
Printing and services	\$379,023
Postage	\$17,808
Equipment	\$1,000
Support Staff	\$838,735
<b>Total</b>	<b>\$1,236,566</b>
<b>Labor Costs for Government Staff</b>	<b>Amount</b>
GS-12 at 47.09 per hr	\$51,664
<b>Total for Millennium Cohort Family follow up study</b>	<b>\$1,288,230</b>
<b>Total for both Millennium Cohort follow-up and Millennium Cohort Family follow up study</b>	<b>\$4,724,265</b>

15. Reasons for Change in Burden

For the 2011-12 data collection phase the calculated public burden amounted to 33,824 hours. The estimated public burden for the 2014-15 data collection phase is 35,060 hours for the Millennium Cohort Study and 2,682 hours for the Millennium Cohort Family Study, for a combined total of 37,742 hours. There is a total change in burden of positive 3,918 hours when taking into account both studies.

This increase in public burden hours for the next wave of data collection is directly proportional to the number of study subjects that were Active Duty military personnel during the previous wave of data collection and have since separated from the military. Therefore, the current public burden hours calculation includes these study subjects that have transitioned to the civilian population. The current calculation also considers the public population participating in the Family Study follow-up survey.

From our first OMB approval in September 2003 forward, and throughout the course of the study, proportions of military participants will decrease with a commensurate increase in the proportion of public participants.

#### 16. Publication of Results

The information will be collected for the Millennium Cohort follow-up study and the Millennium Cohort Family follow-up study over an 18-month period during this current collection wave. Collection will begin approximately one month after receiving OMB approval. Follow-up surveys are collected in 3-year intervals through at least 2022. Given that military experiences may contribute to health outcomes with long latencies along with the goal to evaluate the total life cycle of the service member, the study is planning to collect future follow-up data, approximately every 3 years beyond 21 years.

The DoD Center for Deployment Health Research, as the lead agent for implementing the Millennium Cohort Study, including the Millennium Cohort Family Study, has responsibility for all data collection and management, all data security, the maintenance of all assurances including but not limited to human subjects protection, and other Privacy Act considerations. As part of these responsibilities the Center has defined a set of parameters for the maintenance of data security and integrity, a process for submission and review of collaborative research requests, and a set of requirements and guidelines, with which collaborators must comply during the investigative process.

Millennium Cohort Study researchers have published or have in press 67 peer-reviewed publications. There is currently one publication in press for the Millennium Cohort Family Study. By 2014, the baseline data collected from the Millennium Cohort Family Study survey would provide descriptive analyses of the enrolled cohort (and potentially to assess the predictors of non-response and generalizability to larger populations). A complete list of Millennium Cohort publications to date has been submitted as a part of this project.

#### 17. Non-Display of OMB Expiration Date

DoD is not seeking an exception to displaying the expiration date of this information collection.

#### 18. Exceptions to "Certification for Paperwork Reduction Submissions"

There are no exceptions to the certification statement in Item 19 of OMB Form 83-1.