



INSTITUTIONAL REVIEW BOARD RECOMMENDATION

CONTINUING REVIEW

Date of Review: 04 January 2018 Protocol Number: NHRC.2000.0007

Protocol Title: Prospective Studies of U.S. Military Forces: The Millennium Cohort Study

Principal Investigator: Rudolph Rull, Ph.D.

Work Unit/JON: Deployment Health Research, #60002; JON: 8LH2HA

The principal investigator submitted a continuing review application for a protocol that was previously classified as minimal risk. The objective of this research is to examine any trends in the health of U.S. service members and their families over time. Toward that end, the health of a cohort of regular active-duty, National Guard, and Reserve military personnel will be followed for 18 years via surveys administered at three-year intervals. Participants are allowed to complete the questionnaire by paper-and-pencil or online. A total of 202,160 subjects have been enrolled in the Millennium Cohort study. Due to attrition, there are 197,374 personnel currently enrolled. Re-survey of Panels 1-4 has been completed and recruitment for a new panel is under consideration for the next survey cycle that will launch in 2017.

The continuing review submission requested to: 1) add Deanne Millard (HJF) and Lexi Takata (HJF) to the protocol as key personnel; 2) remove Christopher Lo; and 3) change Alejandro Esquivel to an analyst position. No adverse events have been reported. The principal investigator indicated compliance with all relevant human subject protection regulations.

The NHRC IRB Chair reviewed this submission under the expedited review authority and permitted under 32 CFR §219.110(b)(1), Federal Register expedited review category 9. The 32 CFR §219.111 criteria for the approval of research have been met. The NHRC Chair recommends approval of this research.

The current IRB approval period expires on 19 January 2019.

W.J. BECKER, Ph.D.
Chair, NHRC IRB

Signature

01/10/2018
Date



DETERMINATION OF APPROVING AUTHORITY

1. I concur with the recommendation of the IRB, and I approve continuation of this research.

Next review is required no later than: 19 January 2019

2. I concur with the recommendations of the IRB, but I require additional modifications or restrictions prior to providing continuing approval (Attach modifications or restrictions required).

Next review is required no later than:

3. I disagree with the recommendations of the IRB and recommend (Attach statement regarding recommendations and reasons).

Signature

Date (MM/DD/YY)

M. R. MONTEVILLE, CAPT, MSC, USN
Commanding Officer

01/12/18

**HUMAN USE PROTOCOL
ROUTING SLIP**

FROM (Principal Investigator):

Rudy Rull, PhD


 (PI SIGNATURE)

In accordance with NAVHLTHRSCHCENINST 3900.2G, I am submitting the attached human use protocol for consideration.

TITLE OF PROTOCOL: Prospective Studies of U.S. Military Forces: The Millennium Cohort Study

ABBREVIATED TITLE: The Millennium Cohort Study

PROPOSED DATES OF RESEARCH: 2000/10/01 to 2068/09/30

FUNDING SOURCE: USAMRMC (MOMRP) / VA (VHA, OPH, ORD)
 MOMRP: 67 years (see Appendix A) / VA: 5 years (2018 June)

WORK UNIT TITLE AND NUMBER: Deployment Health Research, 60002

JON FUNDING THE PROTOCOL: 8LH2HA

SUBMISSION (CHECK ONE):


- INITIAL SUBMISSION
 MODIFICATION OF PREVIOUS SUBMISSION
 CONTINUING/ANNUAL REVIEW

PROTOCOL OBJECTIVE (Brief sentence or two): The primary objective is to determine how the health of U.S. military veterans changes over time and compare the adjusted incidence of chronic disease between cohorts

DoD PROTOCOL NUMBER: NHRC.2000.0007

Note: You must obtain required signatures before you submit the protocol to the IRB.		Date Received	Date Reviewed	Initials	Approved JON Initials	NOTES
1	DEPARTMENT HEAD	2 Jan 2018		RR	RR	
2	DIRECTOR*				N/A	
3	SCIENCE DIRECTOR*				N/A	
4	IRB ADMINISTRATOR	JAN 02 2018	N/A	JLD	N/A	

**HUMAN USE PROTOCOL
ROUTING SLIP**

FROM (Principal Investigator): Rudy Rull, PhD	 (PI SIGNATURE)
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In accordance with NAVHLTHRSCHCENINST 3900.2G, I am submitting the attached human use protocol for consideration.

TITLE OF PROTOCOL: Prospective Studies of U.S. Military Forces: The Millennium Cohort Study
 ABBREVIATED TITLE: The Millennium Cohort Study

PROPOSED DATES OF RESEARCH: 2000/10/01 to 2068/09/30

FUNDING SOURCE: USAMRMC (MOMRP) / VA (VHA, OPH, ORD)
 MOMRP: 67 years (see Appendix A) / VA: 5 years (2018 June)
 WORK UNIT TITLE AND NUMBER: Deployment Health Research, 60002
 JON FUNDING THE PROTOCOL: 8LH2HA

SUBMISSION (CHECK ONE):

INITIAL SUBMISSION
 MODIFICATION OF PREVIOUS SUBMISSION
 CONTINUING/ANNUAL REVIEW

PROTOCOL OBJECTIVE (Brief sentence or two): The primary objective is to determine how the health of U.S. military veterans changes over time and compare the adjusted incidence of chronic disease between cohorts

DoD PROTOCOL NUMBER: NHRC.2000.0007

Note: You must obtain required signatures before you submit the protocol to the IRB.	Date Received	Date Reviewed	Initials	Approved JON Initials	NOTES
1 DEPARTMENT HEAD					
2 DIRECTOR*				N/A	
3 SCIENCE DIRECTOR*				N/A	
4 IRB ADMINISTRATOR	JAN 09 2018	N/A	AMS	N/A	

30 December, 2017
Revised 04 January 2018

From: Rudy Rull, PhD, Principal Investigator
To: Chair, Institutional Review Board, Naval Health Research Center, San Diego, CA
Subj: CONTINUING REVIEW OF PROTOCOL # NHRC.2000.0007, PROSPECTIVE STUDIES OF U.S. MILITARY FORCES: THE MILLENNIUM COHORT STUDY”
Ref: (a) NAVHLTHRSCHCENINST 3900.2G
Encl: (1) Continuing Review Summary for Protocol # NHRC.2000.0007
(2) List of all current Study Personnel (with company affiliations and research role)
(3) Investigator Compliance Attestation
(4) Full Current Protocol (clean)

1. Enclosure (1) is submitted to fulfill the reference (a) requirement for the Institutional Review Board (IRB) to review all work conducted under previously approved research protocols at least annually.
2. Point of contact for further information is at 553-9267, rudolph.p.rull2.civ@mail.mil. My alternative point of contact is Denise Lovec-Jenkins at 553-7433, denise.e.lovec-jenkins.ctr@mail.mil.
3. I certify that all study personnel have been informed of and accept any proposed changes.



Rudy Rull, PhD
PI Signature and Date

Continuing Review Summary of Protocol Number NHRC.2000.0007
Title: Prospective Studies of U.S. Military Forces: The Millennium Cohort Study
Principal Investigator: Rudy Rull, PhD

Background: In 1990 and 1991, the United States deployed approximately 700,000 troops to the Persian Gulf. Many individuals returned from the conflict with unexplained symptoms and illnesses. The patterns of symptoms and potential etiologic agents have been extensively studied in an attempt to identify the sources of illnesses and select effective courses of treatment. The lack of pre-deployment health data and deployment exposure data has been an important limitation to examining Gulf War Veteran morbidity questions. External review panels have recommended the development of systems for longitudinal tracking of health.

Objectives: The purpose of this study is to determine how the health of U.S. military veterans changes over time by analyzing the adjusted incidence of chronic disease within the cohort.

Research Methods: Regular active duty, National Guard, and Reserve military personnel will be followed via serial postal surveys with online completion options. Stratified random sampling will be used for cohorts in 2001, 2004, 2007, and 2011. These cohorts will be followed with repeat surveys at 3-year intervals through at least 2067. The surveys consist of standardized assessments of self-reported medical conditions and symptoms, general health and functional status, and psychiatric conditions. Supplemental medical and administrative data will be obtained from military and government databases.

Risks: The primary risks are those associated with inappropriate disclosure of sensitive information. The sensitive information certainly includes health data. Some career history data might also be considered sensitive.

Risk Mitigation: Standard NHRC procedures for constructing and maintaining electronic databases are being followed. These procedures include the assignment of a project-specific subject identification number (SID). Standard identifiers (e.g., SSN) will be used to match information from different databases, but only the SID will be included in the analytical database. The procedures for protecting data transmitted during online completion of the questionnaire were reviewed and approved by qualified computer experts.

Risk Classification: This study is classified as minimal risk.

Comments: The first phase of enrollment (Panel 1) ended in June 2003. Enrollment of Panel 2, and the re-survey of Panel 1 began in May 2004 and ended in March of 2006. Enrollment of Panel 3 began in May of 2007 and ended in December 2008, along with the re-survey of Panel 1 and Panel 2. Enrollment of Panel 4 began in May 2011 and ended April 2013, along with the re-survey of Panels 1, 2, and 3. The re-survey of Panels 1-4 launched October 24, 2014. Recruitment for another new panel did not occur at this time.

Due to logistical reasons, the Family component of the Millennium Cohort study was submitted to the Naval Health Research Center's Institutional Review Board and approved as a standalone sub-study in April 2015 (NHRC.2015.0019). All outside regulatory approvals/requirements related to the Millennium Cohort Family remain under the Millennium Cohort regulatory approvals (OMB Control Number 0720 – 0029 RCS: DD-HA(AR) 2016 and SORN N06500-1). The continuing review and any modifications related to the Millennium Family Cohort sub-study will be submitted under the standalone sub-study (NHRC.2015.0019)

CONTINUING REVIEW FOR IRB PROTOCOL NUMBER NHRC.2000.0007

1. **PROTOCOL NUMBER:** NHRC.2000.0007
2. **PROTOCOL TITLE:** Prospective Studies of U.S. Military Forces: The Millennium Cohort Study
3. **WORK UNIT TITLE AND NUMBER:** Deployment Health Research, 60002
4. **PRINCIPAL INVESTIGATOR(S):** Rudy Rull PhD
5. **UPDATE OF RESEARCH BACKGROUND**

The research literature relevant to this project appearing in print since the last IRB review of this protocol has been surveyed. The research issues addressed in this research protocol have not been resolved. No additional risks or benefits have been identified from the review of the recent literature. Based on this review, the utility of the research and the risk-benefit ratio have not changed.

6. **CHANGES SINCE LAST REVIEW**

1. Under this continuing review report, we respectfully request to modify the study protocol to add Deanne Millard and Lexi Takata as key personnel. Their roles are outlined below:

Alexis Takata will be located at the Naval Health Research Center and will serve as key support staff as a research assistant. She will collect and organize survey data and forms for research projects. In addition, her duties will include scanning and verifying survey data, performing data entry and literature searches, and assisting with the maintenance of databases for research projects.

Deanne Millard will be located at the Naval Health Research Center and will serve as key support staff as a research assistant. She will collect and organize survey data and forms for research projects. In addition, her duties will include scanning and verifying survey data, performing data entry and literature searches, and assisting with the maintenance of databases for research projects.

Additionally, Alejandro Esquivel, MPH has been moved to an Analyst position due to a promotion and Christopher Lo is being removed from the protocol due to his recent resignation.

7. **SUBJECTS**

To date, there have been 202,160 participants enrolled in the Millennium Cohort Study and due to attrition at each wave (2001, 2004, 2007, 2011 and 2014) our current enrollment is 197,374. Since last continuing review 13 participants have withdrawn and 119 are deceased. Re-survey of Panels 1-4 was launched on October 24, 2014 and this cycle closed August 25, 2016. To date our response rate has been (57.3%).

8. **ADVERSE/UNEXPECTED EVENTS**

There have been no untoward events, complications, or injuries.

9. **MEDICAL CARE**

It has not been necessary to provide medical care to any study participants.

10. INFORMED CONSENT

Informed consent has been obtained from all study participants by providing them with a copy of the consent form approved by the IRB, giving them time to read it, and answering any questions they had about the protocol. The voluntary nature of participation has been stressed, and no supervisors or superior officers who might have applied pressure to coerce participation were involved in the process. Originals of the signed Consent Documents from subjects enrolled are stored on-site electronically and/or by paper by the Millennium Cohort Study team. The 2014-15 Millennium Cohort survey cycles did not elicit new panels of participants, therefore new versions of the informed consent documents will not be submitted for review.

11. RESEARCH AND SAFETY PROCEDURES

All research and safety procedures have faithfully conformed to the descriptions in the protocol as approved by the IRB.

12. FINDINGS TO DATE

Data collection is an on-going process. All published articles since the study's last review were reviewed and approved for public release through the Command's review process. We would be happy to provide published papers to the IRB Chair, if necessary. A synopsis of each of the study findings is listed below:

Donoho CJ, Bonanno GA, Porter B, Kearney L, Powell TM. A decade of war: prospective trajectories of post-traumatic stress disorder symptoms among deployed US military personnel and the Influence of combat exposure. *American Journal of Epidemiology*; In press.

Seelig AD, Rivera AC, Powell TM, Williams EC, Peterson AV, Littman AJ, Maynard C, Street AE, Bricker JB, Boyko EJ. Patterns of smoking and unhealthy alcohol use following sexual trauma among U.S. Service Members. *Journal of Traumatic Stress*. 2017 Sep; Epub ahead of print.

Porter B, Bonanno GA, Frasco MA, Dursa EK, Boyko EJ. Prospective post-traumatic stress disorder symptom trajectories in active duty and separated military personnel. *Journal of Psychiatric Research*. 2017 Jun;89:55-64.

Kaur N, Porter B, LeardMann CA, Tobin TE, Lemus H, Luxton DD. Evaluation of a modified version of the Posttraumatic Growth Inventory-Short Form. *BMC Research Methodology*. 2017 Apr;17(1):69.

Porter CK, Welsh M, Riddle MS, Nieh C, Boyko EJ, Gackstetter GD, Hooper TI. Epidemiology of inflammatory bowel disease among participants of the Millennium Cohort: incidence, deployment-related risk factors, and antecedent episodes of infectious gastroenteritis. *Alimentary Pharmacology & Therapeutics*. 2017 Apr;45(8):1115-1127.

Ippolito AC, Seelig AD, Powell TM, Conlin AMS, Crum-Cianflone NF, Lemus H, Sevick CS, LeardMann CA. Risk factors associated with miscarriage and impaired fecundity among United States servicewomen during the recent conflicts in Iraq and Afghanistan. *Women's Health Issues*; 2017 Feb;27(3):356-365.

13. COMPLIANCE WITH REGULATIONS

To the best of my knowledge, this project has been conducted in compliance with all of the requirements of NAVHLTHRSCHCENINST 3900.2G and the related instructions and regulations cited therein.

14. PERSONNEL QUALIFICATIONS

All personnel are appropriately trained and qualified for their work on the project.

15. MAINTENANCE OF RECORDS


All IRB-relevant records are properly kept and securely stored as described in the protocol approved by the IRB.

16. CONFLICT OF INTEREST

No persons involved in the design, conduct, or reporting of research has a financial or other interest that could reasonably appear to be affected by the carrying out or the results of the research

17. COLLABORATING INSTITUTIONS

Currently this protocol does not involve collaboration with any other institutions, so there has not been and will not be a continuing review by any other Institutional Review Board.



Rudy Rull, PhD
PI Signature and Date

INVESTIGATOR COMPLIANCE ATTESTATION

As a researcher or team member responsible for performing and monitoring the research under the protocol titled The Millennium Cohort Study, I have read and understand the provisions of Title 32 Code of Federal Regulations Part 219 (Protection of Human Subjects), Department of Defense (DoD) Directive 3216.02 (Protection of Human Subjects in DoD-Supported Research), DoD Instruction 6025.18-R (Privacy Rule), SECNAV Instruction 3900.39D (Human Research Protection Program), OPNAV Instruction 5300.8C (Personnel Surveys), NAVHLTHRSCHCEN Instruction 3900.2F (Protection of Human Subjects), NAVHLTHRSCHCEN Notice 6500 (Protection of Health Information in Research), Title 21 Code of Federal Regulations Parts 50, 56 if applicable (clinical investigations regulated by the FDA), and all relevant local instructions. I have disclosed all potential and actual conflict of interest(s) related to the design, conduct, analysis, or reporting of this research. I will abide by all applicable laws and regulations, and I agree 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 I have a question regarding my obligations during the conduct of this Navy-sponsored project, I have ready access to each of these regulations, as either my personal copy or available on file from the Chairperson of the Institutional Review Board. I understand that my immediate resource for clarification of any issues related to the protection of research volunteers is the Chairperson of the Institutional Review Board.

Signatures and dates:

(DD/MM/YY)



28 / 12 / 17

Rudolph Rull, PhD
Principal Investigator
Naval Health Research Center



27 / 12 / 17

Lexi Takata
Key Personnel—Research Assistant
Henry M. Jackson Foundation, Inc.



27 / 12 / 17

Deanne Millard
Key Personnel—Research Assistant
Henry M. Jackson Foundation, Inc.

**HUMAN USE PROTOCOL
ROUTING SLIP**

FROM (Principal Investigator):

Rudolph Rull, PhD
(TYPED NAME)

(PI SIGNATURE)

In accordance with NAVHLTHRSCHCENINST 3900.2G, I am submitting the attached human use protocol for consideration.

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FUNDING SOURCE: USAMRMC (MOMRP) / VA (VHA, OPH, ORD)

MOMRP: 67 years (see Appendix A) / VA: 5 years (2018 June)

WORK UNIT TITLE AND NUMBER: Deployment Health Research, 60002

JON FUNDING THE PROTOCOL: 8LH2HA

SUBMISSION (**CHECK ONE**):

- INITIAL SUBMISSION
 MODIFICATION OF PREVIOUS SUBMISSION
 CONTINUING/ANNUAL REVIEW

PROTOCOL OBJECTIVE (Brief sentence or two): The primary objective is to determine how the health of U.S. military veterans changes over time and compare the adjusted incidence of chronic disease between cohorts

DoD PROTOCOL NUMBER (Assigned by IRB Administrator upon submission for initial review. Be sure to add this number where indicated on the title page): NHRC.2000.0007

Note: You must obtain required signatures before you submit the protocol to the IRB.		Date Received	Date Reviewed	Initials	Approved JON Initials	NOTES
1	DEPARTMENT HEAD					
2	DIRECTOR*				N/A	
3	SCIENCE DIRECTOR*				N/A	
4	IRB ADMINISTRATOR		N/A		N/A	

I. COVER PAGE(S)

- 1. Protocol Number:** NHRC.2000.0007 (previously 32227)
- 2. Title:** Prospective Studies of U.S. Military Forces: The Millennium Cohort Study
- 3. Date of Submission:** originally August 2000
- 4. Approved Work Unit Title:** Deployment Health Research, 60002
- 5. Approximate Dates of Research:** 10/01/2000 to 09/30/2067
- 6. Principal Investigators:**
Rudolph Rull, PhD
Deployment Health Research Department
Naval Health Research Center, San Diego, CA
- 7. Co-Investigators:**
Valerie Stander, PhD
NHRC, San Diego, CA
- 8. Key Support**
Denise Lovec-Jenkins
NHRC, San Diego, CA
Henry M. Jackson Foundation, Inc

Beverly Sheppard
NHRC, San Diego, CA
Henry M. Jackson Foundation, Inc

Jennifer Walstrom
NHRC, San Diego, CA
Henry M. Jackson Foundation, Inc

Lauren Bauer, MPH
NHRC, San Diego, CA
Henry M. Jackson Foundation, Inc

Gia Gumbs, MPH
NHRC, San Diego, CA
Henry M. Jackson Foundation, Inc

Evelyn Sun, MPH
NHRC, San Diego, CA
Henry M. Jackson Foundation, Inc

Anet Petrosyan
NHRC, San Diego, CA
Henry M. Jackson Foundation, Inc

Alexis Takata
NHRC, San Diego, CA
Henry M. Jackson Foundation, Inc.

Deanne Millard
NHRC, San Diego, CA
Henry M. Jackson Foundation, Inc.

Steven Speigle
NHRC, San Diego, CA
Henry M. Jackson Foundation, Inc

William Lee
NHRC, San Diego, CA
Henry M. Jackson Foundation, Inc

Daniel Vaughan
NHRC, San Diego, CA
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Gordon Lynch
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Jacqueline Pflieger, PhD
NHRC, San Diego, CA
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Sabrina Richardson, MPH
NHRC, San Diego, CA
Henry M. Jackson Foundation, Inc

Chris Phillips, MD, MPH
NHRC, San Diego, CA

Ben Porter, PhD
NHRC, San Diego, CA
Henry M. Jackson Foundation, Inc

Teresa Powell, MS
NHRC, San Diego, CA
Henry M. Jackson Foundation, Inc

Cynthia LeardMann, MPH
NHRC, San Diego, CA
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Daniel Trone, PhD
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Deborah Bookwalter, PhD
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Richard Armenta, PhD
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Chiping Nieh, PhD
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Rayna Matsuno, PhD
NHRC, San Diego, CA
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Marleen Welsh, PhD
NHRC, San Diego, CA
Henry M. Jackson Foundation, Inc

Zeina Khodr, PhD
NHRC, San Diego, CA
Henry M. Jackson Foundation, Inc

Adam Cooper, PhD
CPT, MSC, US Army
NHRC, San Diego, CA

Anna Bukowinski
NHRC, San Diego, CA
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Satbir Boparai, MBA
NHRC, San Diego, CA
Henry M. Jackson Foundation, Inc

Toni Geronimo, MPH
NHRC, San Diego, CA
Henry M. Jackson Foundation, Inc

Claire Kolaja, MPH
NHRC, San Diego, CA
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Alejandro Esquivel, MPH
NHRC, San Diego, CA
Henry M. Jackson Foundation, Inc

Carlos Carballo, MA
NHRC, San Diego, CA
Henry M. Jackson Foundation, Inc

Kelly Woodall, MPH
NHRC, San Diego, CA
Henry M. Jackson Foundation, Inc

Kimberly Roenfeldt, MAS
NHRC, San Diego, CA
Henry M. Jackson Foundation, Inc

Steven Warner, MPH
NHRC, San Diego, CA
Henry M. Jackson Foundation, Inc

9. Identification Research Monitor/Ombudsman
N/A

10. Primary Performing Institution(s):

Deployment Health Research Department, Naval Health Research Center, San Diego, CA

11. Collaborators / Collaborating Institution(s):

Edward Boyko, MD, MPH
Seattle ERIC, Seattle, WA

Gary Gackstetter, DVM, MPH, PhD
ANSER, Inc., Washington, DC

Tomoko Hooper, MD, MPH
USUHS, Bethesda, MD

- The Millennium Cohort team provides de-identified datasets to the following two institutions for specific projects: Walter Reed National Military Medical Center

Uniformed Services University of the Health Sciences. DUAs are approved or pending and collaborations were approved.

- The following are unfunded collaborators. Individuals from these institutions work on projects with our team, but are not funded to do so.
 - USAPHC
 - WRAIR
 - USARIEM
 - WRNMC
 - Keller Army Hospital, West Point
 - NMCPHC
 - NMRC
 - NMCS D
 - Navy Hospital Camp Pendleton
 - VA Medical Centers
 - Veterans Affairs
 - Columbia University
 - Pace University
 - San Diego State University
 - University of California, San Diego
 - University of Connecticut
 - University of Minnesota
 - Boston University
 - University of Washington
 - University of Cincinnati
 - Loma Linda University
 - University of Pennsylvania
 - University of Arizona
 - University of Washington
 - University of South Carolina
 - Uniformed Services University of the Health Sciences
 - King's College London
 - Duke University
 - Yale University
 - Pearson Knowledge Technologies
 - Children's Hospital, Boston
 - National Intrepid Center of Excellence
 - US Army Center for Health Promotion & Preventive Medicine (USACHPPM)
 - Armed Forces Medical Examiner System
 - Bureau of Medicine and Surgery
 - West Point NY
 - WRAMC
 - Medical University of South Carolina
 - Purdue University
 - Analytic Services Inc (ANSER)
 - National University
 - Madigan Army Medical Center
 - Fred Hutchinson Cancer Research Center

12. Funding Source

USAMRMC (MOMRP) / VA (VHA, OPH, ORD) MOMRP: 67 years; VA: 5 years (2018 June)

13. Number of MilCo Subjects: 202,160

- a. Number of Female Subjects: TBD, approximately 20%
- b. Number of Male Subjects: TBD, approximately 80%
- c. Number of Civilian Subjects:
- d. Number of Active-Duty Subjects: 100% initially

14. Is an IAIR/IIR needed? [If yes, submit draft agreement(s) with protocol]

N/A

II. SIGNATURE PAGE(S)

1. Principal Investigators:

Rudolph Rull, PhD,
NHRC, San Diego, CA

2. Directorate Head/Dept. Head:

Natalie Wells, MD, MPH
CDR, MSC, USN
NHRC, San Diego, CA

Susan Farrish, MD, MPH
LtCol, USAF, MC
Department Head, Deployment Health Research Dept.
NHRC, San Diego, CA

3. Principal Director of Research

Kenneth Earhart, MD
NHRC, San Diego, CA

4. Ombudsman:

N/A

5. Research Monitor:

N/A

6. Commanding Officer:

M. R. MONTEVILLE
CAPT MSC USN

III. RECORD OF CHANGES TO THE PROTOCOL

December 2017 – Continuing Review

1. Under this continuing review report, we respectfully request to modify the study protocol to add Deanne Millard and Alexis Takata as key personnel. They will be located at the Naval Health Research Center and will serve as key support staff as research assistants.

Additionally, Alejandro Esquivel, MPH has been moved to an Analyst position due to his promotion and Christopher Lo is being removed from the protocol due to his recent resignation.

September 2017 Staff and Mailing Update

We respectfully request the review of the following:

1. This protocol has undergone a change of staff. CDR Dennis Faix had received transfer orders; therefore, Dr. Rudolph Rull will assume the role of Principle Investigator. In addition, due to Danielle Mitchell's and Kyna Long's recent resignations, they are being removed from the protocol.

We also request permission to add Zeina Khodr, PhD, Christopher Lo, BS and Daniel Vaughn, BS as key personnel. Lastly, due to promotions, Alejandro Esquivel, MPH has been moved to a Research Assistant position and Toni Geronimo, MPH has been moved to an Analyst position.

2. We are submitting to the IRB for review and approval the text for the upcoming Veterans Day Postcard and email contacts that are within the previously approved number of contacts.

April 2017 Staff Update

We respectfully request the review of the following staff update:

1. We request permission to add Sabrina Richardson, PhD and Marleen Welsh, PhD as key personnel. Their roles are outlined below:

Dr. Sabrina Richardson will serve as key support staff as a Research Psychologist. Her duties will include assisting in program design and maintenance of survey instruments alongside the research team; planning epidemiologic studies and designing the study methodology; performing statistical analyses for diverse research projects with complex study designs; working with team members to derive an in-depth understanding of the data findings; drafting proposals and writing peer-reviewed publications.

Dr. Welsh will serve as key support staff as an Epidemiologist. Her duties will consist of planning epidemiologic studies and designing the study methodology; performing statistical analyses for diverse research projects with complex study designs; working with team members to derive an in-depth understanding of the data findings; drafting proposals and writing peer-reviewed publications.

The training certificates (HIPAA, CITI and Research Integrity and Responsible Conduct) for Dr. Richardson's are currently on file with the IRB and Dr. Welsh's are included with this submission.

March 2017 Staff Update and Mailings

We respectfully request the review of the following:

1. We are submitting to the IRB for review and approval the text for next set of email and postal contacts that are within the previously approved number of contacts.
2. In addition, this protocol has undergone a change of staff and we request permission to add Kimberly Roenfeldt, MAS and Steven Warner, MPH as key personnel. Their roles are outlined below:

Kimberly Roenfeldt will be located at the Naval Health Research Center and will serve as key support staff as an Analyst. Her duties will include providing statistical and analytical support for diverse research projects; assist in processing and maintenance of research databases; assist in writing of reports and scientific manuscripts for peer-reviewed professional journals and presentations.

Mrs. Roenfeldt's training certificates (HIPAA, CITI and Research Integrity and Responsible Conduct) are included with this submission.

Steven Warner will be located at the Naval Health Research Center and will serve as key support staff as an Analyst. His duties will include providing statistical and analytical support for diverse research projects; assist in processing and maintenance of research databases; assist in writing of reports and scientific manuscripts for peer-reviewed professional journals and presentations.

Mr. Warner's training certificates (HIPAA, CITI and Research Integrity and Responsible Conduct) are included with this submission.

Memorial Day 2017 Post Card

Post Card Front: In memory of many, in honor of all.

Back: On this Memorial Day, we remember those Servicemen and women who have given their lives so that we and our nation may be free. No words can express the debt we owe to these brave men and women.

The information provided by Cohort members makes it possible to understand long term health outcomes of military service and will help shape military policy now and in the future.

Please know that you will make a difference by remaining engaged in the Cohort over time. You will receive your next survey to complete later this year.

Very Respectfully,
Dennis Faix, CDR, MC, USN
On Behalf of the Millennium Cohort Study Team

Primary Institutional Review Board Protocol Naval Health Research Center.2000.0007.

Memorial Day Email plain text version
Subject line: We Remember

Dear {NAME},

On this Memorial Day, we remember those Servicemen and women who have given their lives so that we and our nation may be free. No words can express the debt we owe to these brave men and women.

The information provided by Cohort members makes it possible to understand long term health outcomes of military service and will help shape military policy now and in the future.

Please know that you will make a difference by remaining engaged in the Cohort over time. You will receive your next survey to complete later this year.

You will also receive a Memorial Day postcard in the mail from the Millennium Cohort Study team. You can view it online at <link>

Thank you for your continued support of this important project!

Very Respectfully,

Dennis Faix, CDR, MC, USN
On Behalf of the Millennium Cohort Study Team

*** This is an automated message, please do not reply***

For any questions, please contact the Millennium Cohort Team at dod.milcohortinfo@mail.mil or info@millenniumcohort.org. Or call toll free 1-888-942-5222 or DSN 553-7465, and reference your Subject Id: <SID>

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Millennium Cohort Study - Protecting Service Member Health

Memorial Day Email HTML version
Subject line: We Remember

Dear {NAME},

On this Memorial Day, we remember those Servicemen and women who have given their lives so that we and our nation may be free. No words can express the debt we owe to these brave men and women.

The information provided by Cohort members makes it possible to understand long term health outcomes of military service and will help shape military policy now and in the future.

Please know that you will make a difference by remaining engaged in the Cohort over time. You will receive your next survey to complete later this year.

<link>

Thank you for your continued support of this important project!

Very Respectfully,

Dennis Faix, CDR, MC, USN
On Behalf of the Millennium Cohort Study Team

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<link>

Millennium Cohort Study - Protecting Service Member Health

Millennium Cohort Desktop Calendar

Dear {Name},

The Millennium Cohort Study Team would like to thank you for your continued involvement in this important program. Only through your continued participation will we be able to understand how military service affects service members' long-term health.

As a token of our appreciation for your continued involvement, we have enclosed a 2017-2018 desktop calendar. We truly value your time and input. You will receive your next survey to complete later this year.

Very Respectfully,

Dennis Faix, CDR, MC, USN
On Behalf of the Millennium Cohort Study Team

November 2016 Continuing Review (Year 2017)

We respectfully request to modify the study protocol to remove the following individuals as they no longer have an affiliation with the study:

Col Paul Amorose, Tim Wells, PhD, CAPT Margaret Ryan, Dennis Hernando, CPT Carrie Donoho, Dr. Hector Lemus, Dr. Amy Millikan, Kathleen Gunn, and Kristin Motylinski.

We would also like to update Anna's name to reflect her name change from Nagel to Rivera as well as update the Scientific Director from Dr. Richard Shaffer to Dr. Kenneth Earhart.

In addition, we would like to add Chiping Nieh, PhD as key personnel. Her role is outlined below:

Chiping Nieh, PhD will serve as key support staff as an Analyst. Her duties include providing statistical and analytical support for diverse research projects; assist in processing and maintenance of research databases; assist in writing of reports and scientific manuscripts for peer-reviewed professional journals and presentations.

November 2016 (IRB APPROVAL RECEIVED 09JAN2017)

We respectfully request the following modification to the protocol:

We would like to request permission to obtain selected variables regarding military assessment and treatment provision, as well as other medical care referral from the Department of Defense and Service specific Family Advocacy Program (FAP) Central Registry Databases. The Family Advocacy program provides various treatment and support services for perpetrators and victims, and makes referrals for additional care where needed. Within the DON, the Family Advocacy Program services are provided as part of the Fleet and Family Counseling Support Centers. We would request the specified variables for all incidents involving Millennium Cohort Study research participants, with recurring data extracts to be completed annually or triannually.

Permission to receive these data will be obtained from DoD and the Service specific FAP offices, as well as from the Defense Manpower Data Center (DMDC) which maintains the DoD-level repository for cases meeting full criteria as family violence incidents. We currently have a Memorandum of Understanding (MOU) in place with DMDC and an existing approved data request for FAP data for Millennium Cohort Family Study participants. The existing DMDC request has been updated to include all Millennium Cohort participants (see attached); and once IRB approval has been received, NHRC will provide a list of the SSNs for Millennium Cohort Study participants to DMDC. DMDC will then provide NHRC with all matching records in the DoD Central Registry for those SSNs. Separate data use agreements will be established with the Service specific FAP offices in order to obtain additional information regarding suspected incidents meeting partial criteria. Similar procedures will be used for data matching with Service specific registries, and all data transfers will be made using encrypted files either using the Army's AMRDEC Safe Site or a secure data transfer site supported by DMDC.

The requested variables include the following personnel and treatment information for Service members in the Millennium Cohort Study with substantiated cases of intimate partner violence victimization or intimate partner/child abuse offending:

Name

Social Security Number

Incident report date

Legal event context code (emotional maltreatment, neglect, physical abuse, sexual abuse)

Person Association reason code (only codes AA = spouse, AD=parent, BH=former spouse, BE=intimate partner, CC=relationship unknown)

Victim maltreatment severity level (mild, moderate, severe)

Clinical intervention program provided to Family Study participant as a victim (FAP, Other DoD, Other Non-DoD, None, missing)

Clinical intervention program provided to Family Study participant as an offender (FAP, Other DoD, Other Non-DoD, None, missing)

September 2016

We respectfully request the following modification to the protocol:

1. We are submitting to the IRB for review and approval the text for the annual Veterans Day postcard and email.
2. In addition, this protocol has undergone the following staff changes; therefore we respectfully request permission to:

Remove Soyeon Kong, PhD from the protocol as she has resigned and is no longer affiliated with NHRC, and

Add Kelly Woodall, MPH as key personnel. Her role is outlined below:

Kelly Woodall will be located at the Naval Health Research Center and will serve as key support staff as an Analyst. Her duties include providing statistical and analytical support for diverse research projects; assist in processing and maintenance of research databases; assist in writing of reports and scientific manuscripts for peer-reviewed professional journals and presentations.

Ms. Woodall's training certificates (HIPAA, CITI and Research Integrity and Responsible Conduct) are included with this submission.

Veteran's Day Postcard-2016

On this Veterans Day, the Millennium Cohort Study Team thanks all who have served to preserve this Nation's freedom.

Information provided by you and your fellow Cohort members helps make it possible to understand long-term health outcomes of military service, and will help shape military policy both now, and in the future.

We will be in contact with you again in 2017 to learn about any changes that may have occurred in your health and well-being since we last heard from you.

Thank you again for your selfless service and your continued support of this important project!

Very Respectfully,

Dennis Faix, CDR, MC, USN
On Behalf of The Millennium Cohort Study Team

Veteran's Day Email-2016 Plaintext

Subject line: This Veterans Day We Salute Your Service

Dear <NAME>,

On this Veterans Day, the Millennium Cohort Study Team thanks all who have served to preserve this Nation's freedom.

Information provided by you and your fellow Cohort members helps make it possible to understand long-term health outcomes of military service, and will help shape military policy both now, and in the future.

We will be in contact with you again in 2017 to learn about any changes that may have occurred in your health and well-being since we last heard from you.

You will receive a Veterans Day postcard in the mail from the Millennium Cohort Study team. You can also view it online at <link>

Thank you again for your selfless service and your continued support of this important project!

Very Respectfully,

Dennis Faix, CDR, MC, USN

On Behalf of The Millennium Cohort Study Team

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Millennium Cohort Study - Protecting Service Member Health

Veteran's Day Email-2016 HTML

Subject line: This Veterans Day We Salute Your Service

Dear <NAME>,

On this Veterans Day, the Millennium Cohort Study Team thanks all who have served to preserve this Nation's freedom.

Information provided by you and your fellow Cohort members help makes it possible to understand long-term health outcomes of military service, and will help shape military policy both now, and in the future.

We will be in contact with you again in 2017 to learn about any changes that may have occurred in your health and well-being since we last heard from you.

<link>

Thank you again for your selfless service and your continued support of this important project!

Very Respectfully,

Dennis Faix, CDR, MC, USN

On Behalf of The Millennium Cohort Study Team

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Millennium Cohort Study - Protecting Service Member Health

July 2016

We respectfully request the following modification to the protocol:

The contacting of Millennium Cohort Study (MCS) participants to inform them of the opportunity to enroll in the Million Veteran Program (MVP) study in support of the national Precision Medicine Initiative (PMI). The MVP is a national, voluntary research program conducted by the Department of Veterans Affairs (VA) Office of Research and Development (ORD). A data use agreement between NHRC/MCS and VA/MVP is pending to cover the activities listed here, specifically the bi-directional sharing of contact information to determine appropriate MCS participants to contact. No research data will be sent to the MVP until these agreements are in effect.

This effort will initially be restricted to Millennium Cohort Study (MCS) participants who have separated from active duty service, but is planned to also include active duty MCS participants once appropriate high-level DoD and VA agreements are in place. Additional restrictions will apply depending on the study panel. For Panel 1 and 2 participants, only those participants who meet the following criteria will be contacted:

1. Have a good postal address.
2. Answered YES to question #114 in the 2014 MCS follow-up survey: "A great deal has been learned from this study and as a result we may be asked to consider other research possibilities. If other related research studies become available, may we contact you to let you know about them?"
3. Have not already enrolled or refused to enroll in MVP.

For Panel 3 and 4 participants, only those participants who meet the following criteria will be contacted:

1. Have a good postal address.
2. Have not answered NO to question #114 on the 2014 MCS follow-up survey.
3. Have not already enrolled or refused to enroll in MVP.

In order to determine those MCS participants who have already enrolled in MVP or refused to join MVP, MVP study staff will send to MCS encrypted social security numbers (SSNs) of those MCS participants. These data will be sent via the U. S. Army Aviation and Missile Research Development and Engineering Center (AMRDEC) Safe Access File Exchange (SAFE) site. Upon receipt of these data, MCS staff will remove these participants with matching SSNs from the list of MCS participants who have met the other eligibility criteria. These remaining eligible participants will be sent one postal contact with information about enrolling in MVP along with the option to opt out from receiving any information. This letter includes information about PMI. Those participants who do not wish to receive information and enrollment materials from MVP will be asked to tear off the postcard on the bottom portion of the letter and return it to the Millennium Cohort Study within 30 days of receipt of the letter. After 60 days of the expected receipt of the letter, MCS study staff will generate lists of SSNs of eligible participants who did not return the postcard along with their respective current contact addresses. This list will be encrypted and sent to MVP staff via the AMRDEC SAFE site. The MVP will then send these individuals an invitation to enroll in the MVP study.

MVP Postal Mailing

Dear {Participant},

Your participation in the Millennium Cohort Study is invaluable to our understanding of the long-term health of military Service members. Thank you!

We are committed to improving the health of former, current, and future Service Members, and by working closely with other research efforts, we are now better equipped to reach this goal. As a participant of the Millennium Cohort Study, we would like to let you know about an exciting research opportunity available to you from the Department of Veterans Affairs.

The Millennium Cohort Study, along with the Department of Veterans Affairs Million Veteran Program (MVP), will be working to understand how health and lifestyle factors affect military Service members and Veterans. MVP is a national research program that is seeking to enroll 1 million Veterans to study how genes, lifestyle, and military exposures affect health and illness. The Millennium Cohort Study and MVP are two leading research initiatives of the Precision Medicine Initiative (PMI) - a national research effort developed to revolutionize how we improve health and treat disease.

As a valued participant in the Millennium Cohort Study, we invite you to consider joining MVP. **Participation in MVP is entirely voluntary and will not in any way affect your access to health care or benefits.** For additional information about MVP, please visit <http://www.research.va.gov/mvp>.

Thank you for your continued participation in the Millennium Cohort Study. We hope you will consider this opportunity to further our understanding of Service member and Veteran health outcomes.

Very respectfully,

If you do not wish to receive information about the Million Veteran Program (MVP) at this time, please tear off the bottom portion of this letter and return it in the next 30 days. Your decision regarding participation in MVP will not affect your status in the Millennium Cohort Study.

June 2016

We respectfully request the IRB approval to incorporate:

1. The linkage with Global Assessment Tool (GAT) data.

The Millennium Cohort Study (MCS) seeks to understand the impact of military service on the short-and long- term health of service members and veterans. This mission would be enhanced by connecting with the Global Assessment Tool (GAT) implemented by the Comprehensive Soldier and Family Fitness Program (CSF2) person-event data environment (PDE) built by the Army Analytics Group (AAG).

The GAT is a confidential self-assessment tool that includes information on Soldiers well-being, resilience, and their overall health. The MCS collects data on the well-being of military members from all services, however, does not have data on resilience or other factors included in the GAT that may be useful.

GAT data is stored in the PDE, a virtual secure platform designed for integrating data, linking commands for analysis, and conducting studies/projects. This repository is an ever-evolving cloud-based, virtual technology that provides strong protections of human subjects via encoded and de-identified data. It boasts Personally Identifiable Information (PII) protection and data security and information assurance. To link MCS data with the GAT data, MCS data must be uploaded into the PDE and linked to the GAT data. To link the data sources SSNs of MCS participants must be uploaded, however, all other PII will be stripped from the dataset before it is uploaded.

NHRC will conduct analyses with the linked MCS and GAT data using the PDE environment, which includes statistical analysis tools. All results from analyses will be reported in aggregate. Linking to the GAT will allow NHRC researchers to conduct research to address study aims to better understand factors associated with the long term health of military service members. Please refer to the “Supplemental Information: Person-Event Data Environment” attachment for further details regarding the use and security measures.

2. A staff change to include Satbir Boparai as key personnel. Also, in compliance with the Army Analytics Group’s (AAG) policies, the AAG’s Person-Event Data Environment (PDE) Team coding specialists that AAG refers to as ETL will need to be added to the protocol; therefore in addition to the staff changes previously mentioned we are adding Dr. Kevin Mason and Mr. Brian Hufford AAG’s PDE team members as key personnel.

Satbir Boparai will be located at the Naval Health Research Center and will serve as key support staff as Data Manager. As data manager, Ms. Boparai will be responsible for processing and managing data and related programs.

Ms. Boparai’s CITI and HIPAA training certificates are included with this submission.

Dr. Kevin Mason is the AAG certified Database Manager for handling PHI and ensuring PDE HIPAA compliance. Dr. Mason will assist in de-identification using the SQL data-scrubbing procedures and will ensure there is no leakage of PHI across the physical servers (PDE-S to PDE-A). He will create Oracle Tables containing the various de-identified data assets, conduct validity checks, and provide metadata for any new data assets obtained for the project.

Mr. Brian Hufford is an SME Database Developer for AAG. He is responsible for creating fully scrubbed and de-identified Oracle Tables with both PHI and PII data. He has experience in the SharePoint environment that serves as the interface for collaboration among PDE-A researchers. He is the lead developer for the PDE software system with Oracle, .NET, SAS and Web service training. He is by training a systems engineer with experience in the design and execution of complex computer systems.

3. In addition to the data linkage request above, we have removed Serguey Parkhomovosky from the protocol as he has resigned and is no longer affiliated with the Deployment Health Research at the Naval Health Research Center, San Diego.

May 2016

We are submitting to the IRB for review and approval the text for the annual Memorial Day email and postal contact.

April 2016

We respectfully request the review of the following:

1. We are submitting to the IRB for review and approval the text for next set of email and postal contacts that are within the previously approved number of contacts.
2. In addition this protocol has undergone a change of staff and we request permission to Carlos Carballo, MA as key personnel. His role is outlined below:

Carlos Carballo will be located at the Naval Health Research Center and will serve as key support staff as an Analyst. His duties will include providing statistical and analytical support for diverse research projects; assist in processing and maintenance of research databases; assist in writing of reports and scientific manuscripts for peer-reviewed professional journals and presentations.

Mr. Carballo's training certificates (HIPAA, CITI and Research Integrity and Responsible Conduct) are included with this submission.

Also, due to Kari Sausedo's and Christopher O'Malley's recent resignations we are removing them from the protocol

Along with the above-mentioned protocol changes, we request to add Theatre Medical D Store data as we have received permission to access Theatre Medical D Store (TMDS) data; therefore the rationale for this request is that the protocol depends on the healthcare encounter data, lab data, procedure data, and pharmacy data delivered at any military treatment facility, including the first echelons of care at deployed locations, which will now be available via the TMDS datasets. These data will help us fully describe the burden of disease and health outcomes during wartime.

April Email 1

Dear <NAME>,

What lasting effect does military service have on the health of the men and women of our armed forces? When you joined the Millennium Cohort, you took a step towards helping answer this important question. Your continued participation is vital to the success of this project!

The survey cycle is closing soon. Even if you have no current health issues or are no longer on active military service, we want to hear from you!

Please take a moment to log on to our website and begin your survey by copying and pasting the following web address into your browser:

<link>

Thank you again for your service to all future military members by participating in the Millennium Cohort!

This survey is "Official Business". Military members may complete this at their duty station, using government equipment. If you choose, you can also complete the survey at home or elsewhere.

Very Respectfully,

Dennis Faix, CDR, MC, USN
On Behalf of The Millennium Cohort Study Team

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<link>

Millennium Cohort Study - Protecting Service Member Health

Email (Panel 4 Married Version)

To be sent to the Panel 4 non-responders whose Family Study spouse has completed their survey and self-reported being married.

Dear [\[name\]](#),

When you joined the Millennium Cohort Study and your spouse, [<name>](#), joined the Family Study a few years ago, you became part of a special community of couples. The survey responses you provide inform leadership, guide interventions and shape support programs designed to target the specific needs of military couples and families.

[<Spouse name>](#) has already completed the Family Study follow-up survey, but we have yet to hear from you. The participation of both you and your spouse is what makes the Millennium Cohort Study and the Family Study such powerful resources for understanding the impact of military life. We hope you will complete the Millennium Cohort follow-up survey designed for current and former Service members soon.

In order to complete your survey, please click on the following link:

[link]

Thank you again for working with us to protect the health of current and future members of our military and their families.

Very Respectfully,
Dennis Faix, CDR, MC, USN
On Behalf of the Millennium Cohort Study Team

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Millennium Cohort Study - Protecting Service Member Health

Email (Panel 4 Married Version)

To be sent to the Panel 4 non-responders whose Family Study ex-spouse has completed their survey.

Dear [\[name\]](#),

When you joined the Millennium Cohort Study and <spouse name> joined the Family Study a few years ago, you became part of a special community of people. Our records indicate that your marital status has changed since your last survey, so we are especially interested in hearing from you. A better understanding of your situation helps inform leadership, guide interventions and shape support programs designed to target the specific needs of military couples and families.

<Spouse name> has already completed the Family Study follow-up survey. The participation of both of you is what makes the Millennium Cohort Study and the Family Study such powerful resources for understanding the impact of military life on couples and families. We hope you will complete the Millennium Cohort follow-up survey designed for current and former Service members soon.

In order to complete your survey, please click on the following link:

[link]

Thank you again for working with us to protect the health and well-being of current and future members of our military and their families.

Very Respectfully,
Dennis Faix, CDR, MC, USN
On Behalf of the Millennium Cohort Study Team

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For any questions, please contact the Millennium Cohort Team at dod.milcohortinfo@mail.mil or info@millenniumcohort.org. Or call toll free 1-888-942-5222 or DSN 553-7465, and reference your Subject Id: <SID>

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Millennium Cohort Study - Protecting Service Member Health

April Email 2

Dear <Name>,

We hope you are considering completing the selected questions from the Millennium Cohort Study survey we mailed to you last week. Your participation will help to evaluate the impact of military service on your health.

Every survey counts, which is why it is essential to stay involved with the Study even if you have separated from service, or currently have no health concerns.

If you have already completed your survey, we wish to thank you. If you have not yet had time to consider our request, we hope you will be able to do so soon. Simply complete the brief paper version of the survey and return it in the postage pre-paid envelope.

Alternatively, if you prefer to complete the full online survey, please log on to our website and begin your survey by copying and pasting the following web address into your browser:

<link>

Thank you again for your time and continued participation.

Very Respectfully,

Dennis Faix, CDR, MC, USN
On Behalf of the Millennium Cohort Study Team

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For any questions, please contact the Millennium Cohort Team at dod.milcohortinfo@mail.mil or info@millenniumcohort.org. Or call toll free 1-888-942-5222 or DSN 553-7465, and reference your Subject Id: <SID>

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<link>

Millennium Cohort Study - Protecting Service Member Health

Final Email

Dear <Name>,

As the Millennium Cohort survey cycle comes to a close I am reaching out one final time to let you know that your opportunity to participate in this important study will be ending soon. I would like to encourage you to take a few minutes and complete your online survey. Even if you have no current health issues or are no longer on active military service, we want to hear from you!

To complete your survey online, please copy and paste the following web address into your browser:

<link>

Thank you for considering this final opportunity to respond – we truly appreciate your participation!

Very Respectfully,

Dennis Faix, CDR, MC, USN
On Behalf of the Millennium Cohort Study Team

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For any questions, please contact the Millennium Cohort Team at dod.milcohortinfo@mail.mil or info@millenniumcohort.org. Or call toll free 1-888-942-5222 or DSN 553-7465, and reference your Subject Id: <SID>

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<link>

Millennium Cohort Study - Protecting Service Member Health

Short Survey 2 Cover Letter

Dear <Name>,

By joining the Millennium Cohort Study a few years ago, you became part of a select group of individuals who help inform policy, guide leadership and shape programs designed to target the specific needs of military service members. Only through the continued involvement of all Study participants can we begin to understand the complexities of military life and make an impact in the lives of our Service members and Veterans.

We realize that your time is valuable, which is why we have created a shortened paper version of our online survey with carefully selected questions. Please consider taking 5 minutes to complete this very brief survey and return it in the postage pre-paid envelope.

Alternatively, if you would prefer to complete the full survey, please visit our study website, www.millenniumcohort.org, click "Start Survey" and enter your Subject ID: XXXXXXXX.

Thank you for your continued commitment to current, former and future Service members.

Very Respectfully,

Dennis Faix, CDR, MC, USN
On Behalf of the Millennium Cohort Study Team

The Millennium Cohort Study is an authorized Department of Defense project. Note Defense Manpower Data Center Reference # 00-0019, Report Control Symbol # DD-HA(AR)2106, Office of Management and Budget Approval # 0720-0029, Office of the Assistant Secretary of Defense (Health Affairs), TRICARE Management Activity Protocol # CDO-06-206, and Primary Institutional Review Board Protocol # NHRC.2000.0007.

2016 Continuing Review

Under the Continuing Review we request permission to update the protocol to include Armed Forces Health Surveillance Center (AFHSC) as a resource used to obtain data that will supplement the survey instruments enhancing the ability to track study outcomes.

In addition this protocol has undergone a change of staff and we request permission to add CPT Adam Cooper as key personnel. His role is outlined below:

CPT Cooper will be located at the Naval Health Research Center and will serve as key support staff as an Epidemiologist. His duties will consist of planning epidemiologic studies and designing the study methodology; performing statistical analyses for diverse research projects with complex study designs; working with team members to derive an in-depth understanding of the data findings; drafting proposals and writing peer-reviewed publications.

10 December 2015

We respectfully request the review of the following:

1. We are submitting to the IRB for review and approval the text for next set of email and postal contacts that are within the previously approved number of contacts.
2. In addition this protocol has undergone a change of staff and we request permission to add Rayna Matsuno PhD, and Soyeon "Joyce" Kong PhD, as key personnel. Their roles are outlined below:

Dr. Rayna Matsuno will be located at the Naval Health Research Center and will serve as key support staff as an Epidemiologist. Her duties will consist of planning epidemiologic studies and designing the study methodology; performing statistical analyses for diverse research projects with complex study designs; working with team members to derive an in-depth understanding of the data findings; drafting proposals and writing peer-reviewed publications.

Dr. Joyce Kong will be located at the Naval Health Research Center and will serve as key support staff as an Epidemiologist. Her duties will consist of planning epidemiologic studies and designing the study methodology; performing statistical analyses for diverse research projects with complex study designs; working with team members to derive an in-depth understanding of the data findings; drafting proposals and writing peer-reviewed publications.

Desktop Calendar Cover Letter

Dear **Name**,

The Millennium Cohort Study Team would like to wish you a Happy New Year!

As we enter into this New Year, we would like to encourage you to take some time to fill out your Millennium Cohort Survey. As a token of our appreciation for your continued involvement, we have enclosed a 2016 desktop calendar featuring the artwork of some of our past holiday postcards. We truly value your time and input in order to complete the survey.

If you have not already done so please complete your survey by going to www.millenniumcohort.org, click Start Survey, and enter your Subject ID: xxxxxx.

Thank you for your continued participation in this important project.

Very Respectfully,

Dennis Faix, CDR, MC, USN
On Behalf of the Millennium Cohort Study Team

Thank You Coin Mailer

Launched in the summer of 2001, the Millennium Cohort Study has become the largest health study in military history, and one of the largest cohort studies in the world! The information provided by members like you makes it possible to better understand the long-term health of our Service members and Veterans!

Thank You Coin Mailer Card

Dear **Name**,

Thank you for you submitting your Millennium Cohort survey in **<Date>**. We would like to offer this challenge coin as a token of our appreciation for your continued involvement in this important study. Only through your continued participation will we be able to understand how military service affects service members' long-term health. Remaining engaged in the Cohort over time makes it possible for us to better understand the long-term health of our Service members and Veterans, which ultimately can help lead to changes in healthcare and other DoD and VA policies.

Very Respectfully,

Dennis Faix, CDR, MC, USN
On Behalf of the Millennium Cohort Study Team

Incomplete Reminder email

Dear **Name**,

Thank you for logging on to the Millennium Cohort website to begin your survey!

By participating in this study, you are helping to determine the potential health effects of military service. The information you provide will significantly help generations of U.S. service members.

We understand your time is valuable. Please return to the website to complete your survey now, or as soon as you have a moment. If you need to stop and continue at a later time, your responses will be saved. All information will be kept confidential.

Please go to:

<https://secure.MillenniumCohort.org/users/login/sid:xxxxxx>

Your Subject ID is: xxxxxx

If you have any questions or concerns, please email info@millenniumcohort.org or call our team toll free at 1-888-942-5222. If you have questions on the legitimacy of this DoD-sponsored survey, please contact DSN: 553-7465, Phone: 619-553-7465 or E-Mail: milcohortinfo@med.navy.mil

Thank you for your time and for your participation in the Millennium Cohort Study!

If you have already completed your survey, please disregard this email and accept my thanks for your continued voluntary participation in this important work.

Very Respectfully,

Dennis Faix, CDR, MC, USN
On Behalf of the Millennium Cohort Study Team

*** This is an automated message, please do not reply***

For any questions, please contact the Millennium Cohort Team at milcohortinfo@med.navy.mil or info@millenniumcohort.org. Or call toll free 1-888-942-5222 or DSN 553-7465, and reference your Subject Id: 103.

The Millennium Cohort Study is an authorized Department of Defense project. Note Defense Manpower Data Center Reference # 00-0019, Report Control Symbol # DD-HA(AR)2106, Office of Management and Budget Approval # 0720-0029, Office of the Assistant Secretary of Defense (Health Affairs), TRICARE Management Activity Protocol # CDO-06-206, and Primary Institutional Review Board Protocol # Naval Health Research Center.2000.0007.

If you would like this email address to be removed from our email list, please visit (unsubscribe link)

Millennium Cohort Study - Protecting Service Member Health

17 November 2015

We respectfully request the review of the following:

1. We are submitting to the IRB for review and approval the text for next set of email contacts that are within the previously approved number of contacts.
2. Also, the Millennium Cohort Study had previously planned and implemented a shorter, condensed contact schedule. However, due to logistical challenges, this condensed plan was interrupted. As a result, response rates have been lower than expected. Therefore in order to increase response rates to at least 55%, we are requesting permission to add 5 additional postal contacts for a total of 18 postal contacts for the survey cycle. Thus, the survey cycle will continue for an additional 5 months for a total of 20 months as in previous survey cycles. We have included for IRB review the text for 2 of the 5 additional contacts (scheduled one month between postal mailings).
3. In addition this protocol has undergone a change of staff and we request permission to add Alejandro (Alex) Esquivel and Isabel Jacobson, MPH, as key personnel. Their roles are outlined below:

Alex Esquivel will be located at the Naval Health Research Center and will serve as key support staff. He will collect and organize survey data, perform data entry, literature searches, and assist with maintenance of databases for research projects.

Isabel Jacobson will be located at the Naval Health Research Center and will serve as key support staff as an Epidemiologist. Her duties will consist of planning epidemiologic studies and designing the study methodology; performing statistical analyses for diverse research projects with complex study designs; working with team members to derive an in-depth understanding of the data findings; drafting proposals and writing peer-reviewed publications.

December Email

Dear **name**,

Thank you for your past participation in the Millennium Cohort Study, the largest health study in US history.

You are one of only 2% of military and veteran men and women who have been chosen to represent their fellow Service members in this important project. Your experiences, including those after you leave the military, are vital to understanding how military service affects your long-term health.

In the next few weeks you should receive a questionnaire asking for your continued help in learning how military service affects your health.

You may also complete your questionnaire online by going to:

<link>

Your Subject ID: (SID)

The Millennium Cohort Study is a DoD authorized project being conducted by the Naval Health Research Center in San Diego California. The study team is comprised of active duty, retired and prior service personnel from the Air Force, Navy and Army as well as civilian researchers. Several of the study's staff members are also military spouses who provide insight into daily military life.

Whether you are still actively serving, or if you have separated from the service, your continued participation is critical to the success of this study.

Very Respectfully,

Dennis Faix, CDR, MC, USN
On behalf of
The Millennium Cohort Study Team

For any questions, please contact the Millennium Cohort Team at milcohortinfo@med.navy.mil or info@millenniumcohort.org. Or call toll free 1-888-942-5222 or DSN 553-7465, and reference your Subject Id: [SID]

The Millennium Cohort Study is an authorized Department of Defense project. Note Defense Manpower Data Center Reference # 00-0019, Report Control Symbol # DD-HA(AR)2106, Office of Management and Budget Approval # 0720-0029, Office of the Assistant Secretary of Defense (Health Affairs), TRICARE Management Activity Protocol # CDO-06-206, and Primary Institutional Review Board Protocol # NHRC.2000.0007.

If you would like this email address to be removed from our email list, please visit link [UNSUBSCRIBE LINK]

Millennium Cohort Study - Protecting Service Member Health

January Email

Dear [\[name\]](#),

Last week you should have received a follow-up survey to update your current health information. Your continuing participation and dedication make it possible to learn about the long-term impact of military service, even after you have left the service.

Since you enrolled in the Millennium Cohort Study, you have been asked to complete a health survey every 3 years. Each survey asks some of the same questions over time about health topics such as physical activity. Habits may change over time, and asking about these factors every 3 years provides a series of “snapshots” that will help give us a better picture over time. Even if little has changed or if you have remained healthy, keeping your information up to date is crucial to being able to draw the right conclusions from this study.

If you have already completed your survey, please accept our sincere thanks. If you would like to complete the survey online, you can do so at www.millenniumcohort.org; just click **Start Survey** and enter your **Subject ID: xxxxxx**.

We hope to hear from each one of you, so that the study is as informative as it can be to you and to future generations of Service members and Veterans.

Very respectfully,

Dennis Faix, CDR, MC, USN
On Behalf of the Millennium Cohort Study Team

For any questions, please contact the Millennium Cohort Team at milcohortinfo@med.navy.mil or info@millenniumcohort.org. Or call toll free 1-888-942-5222 or DSN 553-7465, and reference your Subject Id: [SID]

The Millennium Cohort Study is an authorized Department of Defense project. Note Defense Manpower Data Center Reference # 00-0019, Report Control Symbol # DD-HA(AR)2106, Office of Management and Budget Approval # 0720-0029, Office of the Assistant Secretary of Defense (Health Affairs), TRICARE Management Activity Protocol # CDO-06-206, and Primary Institutional Review Board Protocol # NHRC.2000.0007.

If you would like this email address to be removed from our email list, please visit link [\[UNSUBSCRIBE LINK\]](#)

Millennium Cohort Study - Protecting Service Member Health

February Email Separated

Dear [\[name\]](#),

You should have received a newsletter last week highlighting why it is important to continue to fill out the Millennium Cohort Study survey every few years. In a nutshell, your continued participation is vital!

Using data that you previously provided, we were able to investigate changes in meeting federal Physical Activity Guidelines following military discharge. Moderate to vigorous activity declined for former service members that were active duty, had deployed with combat exposure, had 14-25 years of service, and had separated within the past year. In a separate study researchers also found that vigorous physical activity was associated with decreased symptoms of PTSD. For the full text of this article, please see the publications page on our website.

Now that you have left the service, we will be able to get a better sense of the present issues that our Veterans are facing today by you telling us your current experiences through our survey. Please go to www.millenniumcohort.org, click **Start Survey** and enter your **Subject ID: xxxxxx** to take your survey.

Thank you for being part of this important study.

Very Respectfully,

Dennis Faix, CDR, MC, USN
On Behalf of the Millennium Cohort Study Team

For any questions, please contact the Millennium Cohort Team at milcohortinfo@med.navy.mil or info@millenniumcohort.org. Or call toll free 1-888-942-5222 or DSN 553-7465, and reference your Subject Id: [SID]

The Millennium Cohort Study is an authorized Department of Defense project. Note Defense Manpower Data Center Reference # 00-0019, Report Control Symbol # DD-HA(AR)2106, Office of Management and Budget Approval # 0720-0029, Office of the Assistant Secretary of Defense (Health Affairs), TRICARE Management Activity Protocol # CDO-06-206, and Primary Institutional Review Board Protocol # NHRC.2000.0007.

If you would like this email address to be removed from our email list, please visit link [\[UNSUBSCRIBE LINK\]](#)

Millennium Cohort Study - Protecting Service Member Health

February Email Active Duty

Dear [\[name\]](#),

You should have received a newsletter last week highlighting why it is important to continue to fill out the Millennium Cohort Study survey every few years. In a nutshell, your continued participation is vital!

Using data that you previously provided, researchers found that vigorous physical activity was associated with decreased symptoms of PTSD. For the full text of this article, please see the publications page on our website.

By letting us know your current experiences, even if you have never deployed, we will be able to get a better sense of the present issues that our Service members are facing today, and how those issues may affect their health in the future. Please go to www.millenniumcohort.org, click **Start Survey** and enter your **Subject ID: xxxxxx** to take your survey.

Thank you for being part of this important study.

Very Respectfully,

Dennis Faix, CDR, MC, USN
On Behalf of the Millennium Cohort Study Team

For any questions, please contact the Millennium Cohort Team at milcohortinfo@med.navy.mil or info@millenniumcohort.org. Or call toll free 1-888-942-5222 or DSN 553-7465, and reference your Subject Id: [SID]

The Millennium Cohort Study is an authorized Department of Defense project. Note Defense Manpower Data Center Reference # 00-0019, Report Control Symbol # DD-HA(AR)2106, Office of Management and Budget Approval # 0720-0029, Office of the Assistant Secretary of Defense (Health Affairs), TRICARE Management Activity Protocol # CDO-06-206, and Primary Institutional Review Board Protocol # NHRC.2000.0007.

If you would like this email address to be removed from our email list, please visit link [\[UNSUBSCRIBE LINK\]](#)

Millennium Cohort Study - Protecting Service Member Health

December Q4 Cover Letter

Dear {Name}

Recently, we sent you an invitation to complete a follow-up survey for the Millennium Cohort Study. By continuing to participate in this study, you are helping to determine both current and long-term health effects of military service that may be relevant to you and will help future generations of service members.

Your response is crucial, even if you have never deployed or if you have left military service!

You can also complete the survey online at:

<http://www.MillenniumCohort.org>

Enter your unique Subject ID: xxxxxx

If you have any questions, please call DSN 553-7465 or toll-free 1-888-942-5222. You may also email milcohortinfo@med.navy.mil or use the contact form at <http://www.MillenniumCohort.org>.

If you have already completed your survey, please accept my thanks and disregard this packet.

Very respectfully,

(insert signature)

CDR Dennis Faix, MC, USN,
for the Millennium Cohort Study Team

P.S. for families: We would like to hear from all invited participants, even those deployed or away for other reasons. If possible, please forward this message to the military family member addressed above.

Be assured that this is an authorized study supported by the highest levels of the Department of Defense. Defense Manpower Data Center Reference # 00-0019, Report Control Symbol # DD-HA(AR)2106, Office of Management and Budget Approval # 0720-0029, Office of the Assistant Secretary of Defense (Health Affairs), TRICARE Management Activity Protocol # CDO-06-206, and Primary Institutional Review Board Protocol #NHRC.2000.0007.

January Newsletter

Address page

How do I fill out my survey?

If you haven't already, you can complete your survey online:

www.millenniumcohort.org

Click on *Start Survey* and enter your Subject ID located below the barcode on the address side of this newsletter.

Feel free to contact us with questions:

Toll-free: 1-888-942-5222

DSN: 553-7465

Email: info@millenniumcohort.org

Thank you

Special thanks to those who have completed your 2014-2015 survey. It's still not too late! We hope to hear from **each one of you**, so that the study is as informative as it can be to you and to future generations of Service members and Veterans.

Another survey? Why?

Since you enrolled in the Millennium Cohort Study, you have been asked to complete a health survey every 3 years.

The study is designed as a “follow-up study” where the same participants are followed over time. No one can take your place. This type of study helps researchers to examine a variety of factors and their influence on a variety of health conditions that may occur **over the course of a lifetime**. This is the largest follow-up study of its kind in military history, and you are key to its success.

*Your continuing **participation** and **dedication** make it possible to learn about the long-term impact of military service, even after you have left the service.*

But the same questions... again?

Each survey cycle, we ask many of the same questions, such as level of physical activity and amount of cigarette smoking. Habits **may change** over time, and asking about these factors every 3 years provides a series of “snapshots” that will help give us a better picture over time.

Even if not very much has changed, or if you have stayed healthy, **we ask that you respond**. Keeping your information up to date is critical to our ability to draw the correct conclusions from this kind of study.

What about new questions?

As we learn more as time goes on, we may add new survey questions to better understand the various health concerns of Service members and Veterans.

For example, on the current survey, we have added questions about diagnoses of **traumatic brain injury** and **degenerative joint disease**. Rest assured that when we add new questions, we will work to prioritize and scale back other questions. We value your time and appreciate your ongoing help.

08 October 2015

We are submitting to the IRB for review and approval, the Veteran's Day and November contact material that is within the permissible number of contacts.

In addition this protocol has undergone a change of staff; therefore, we request approval to remove Madeline Cross and Navjot Kaur as their roles within the department have changed and they are no longer involved with the study. We also request permission to add Claire Kolaja and Kyna Long as key personnel. Their roles are outlined below:

Claire Kolaja, MPH and Kyna Long, will be located at the Naval Health Research Center and serve as key support staff as a Data Analyst. Their duties will include providing statistical and analytical support for diverse research projects; assist in processing and maintenance of research databases; assist in writing of reports and scientific manuscripts for peer-reviewed professional journals and presentations.

25 August 2015

This protocol has undergone staff changes due to Dr. Luxton's recent resignation and Chelsea Schafer no longer being affiliated with NHRC. Therefore with the IRB's approval, Dr. Faix, a co-investigator, will now assume the role of Principal Investigator (PI) and Dr. Luxton along with Chelsea Schafer will be removed from the study protocol.

As a result of the PI change, the recently approved Phase 2 participant contacts have been updated to remove Dr. Luxton and are included for IRB re-approval.

Email

Dear {Name},

A week ago we sent you a newsletter highlighting just a few pieces of information that we have been able to gather from contributions to an important health study called the Millennium Cohort Study. The new information that we are collecting on the 2014-2015 survey will provide a more complete picture of the health of current and former Service members.

Why take up some of your time to complete this survey? Everyone has his or her own reasons...

For some who have already completed this survey, it was simply a matter of duty, of doing the right thing. For others, it was more personal - having suffered health problems themselves during or after their service. And for others still, giving some of their time was driven by a concern for the health of future generations who will serve in the US military.

Whatever your reason, we ask that you take few minutes to begin your survey today.

We are sending this by email in the hopes that it will make it easier for you to respond. Just go to www.millenniumcohort.org, click **Start Survey** and enter your **Subject ID: xxxxxx**.

Thank you for working with us to protect the health of our military service members and for helping to make this the largest and most important DoD health study in US military history.

Very Respectfully,

Dennis Faix, CDR, MC, USN
On Behalf of the
The Millennium Cohort Study Team

For any questions, please contact the Millennium Cohort Team at milcohortinfo@med.navy.mil or info@millenniumcohort.org. Or call toll free 1-888-942-5222 or DSN 553-7465, and reference your Subject Id: [SID]

The Millennium Cohort Study is an authorized Department of Defense project. Note Defense Manpower Data Center Reference # 00-0019, Report Control Symbol # DD-HA(AR)2106, Office of Management and Budget Approval # 0720-0029, Office of the Assistant Secretary of Defense (Health Affairs), TRICARE Management Activity Protocol # CDO-06-206, and Primary Institutional Review Board Protocol # NHRC.2000.0007.

If you would like this email address to be removed from our email list, please visit link [UNSUBSCRIBE LINK]

Millennium Cohort Study - Protecting Service Member Health

Email

Dear [\[name\]](#),

Over (insert number) of your fellow Soldiers, Sailors, Airmen, and Marines have already completed their 2014-2015 surveys, but every individual response is needed for us to understand the potential impact of military service on the health and well-being of our Service members and veterans.

Therefore, we are sending this email to provide an electronic link, which we hope will make it easier for you to respond. Just go to www.millenniumcohort.org and click **Start Survey** and enter your **Subject ID: xxxxxx**.

Even if you are no longer serving, or do not presently have any health concerns we still hope that you will complete your survey. Ultimately, the greatest benefits of this study will not be known for many years. This is why it is essential to stay involved with the study even after you have left the service or if you are not currently having any health concerns.

Thank you for working with us to protect the health of our military service members and for helping to make this the largest and most important DoD health study in US military history.

Very Respectfully,

Dennis Faix, CDR, MC, USN
On Behalf of the
The Millennium Cohort Study Team

For any questions, please contact the Millennium Cohort Team at milcohortinfo@med.navy.mil or info@millenniumcohort.org. Or call toll free 1-888-942-5222 or DSN 553-7465, and reference your Subject Id: [SID]

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If you would like this email address to be removed from our email list, please visit link [UNSUBSCRIBE LINK]

Millennium Cohort Study - Protecting Service Member Health

Email

Dear **name**,

We recently sent you a paper copy of the 2014-2015 Millennium Cohort Study. We understand that your time is very valuable, so we've also included a link to our online version of the survey. When completing the survey online, you can come back to your survey at any time, and the website will automatically open to the next unanswered question.

Just go to www.millenniumcohort.org and click **Start Survey** and enter your **Subject ID: xxxxxx**.

Even if you are no longer serving, or do not presently have any health concerns we still hope that you will complete your survey. Ultimately, the greatest benefits of this study will not be known for many years. This is why it is essential to stay involved with the study even after you are out of the service or if you are not currently having any health concerns.

Thank you for your continued help in making this the largest and most important DoD study in US military history and working with us to protect the health of members of our military service.

Very Respectfully,

Dennis Faix, CDR, MC, USN
On Behalf of the
The Millennium Cohort Study Team

For any questions, please contact the Millennium Cohort Team at milcohortinfo@med.navy.mil or info@millenniumcohort.org. Or call toll free 1-888-942-5222 or DSN 553-7465, and reference your Subject Id: [SID]

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If you would like this email address to be removed from our email list, please visit link [UNSUBSCRIBE LINK]

Millennium Cohort Study - Protecting Service Member Health

Dear Name,

As a Millennium Cohort Study participant, you have been selected to represent your fellow Service members in the largest health study in military history. Even if you have never deployed or are no longer in the service, your contribution is still very important.

Your past participation, and the participation of others like you, has already helped us better understand how deployments and other military experiences impact Service members' physical and mental health. For example, we found that combat-related trauma and predeployment insomnia symptoms increased the risk for developing post-traumatic stress symptoms, depression, and anxiety following deployment.

So far only {30%} of our participants have responded to our requests to submit their survey. **The survey cycle is ending soon, so your response is vital.**

We thank you for completing the enclosed survey and returning it in the postage-paid envelope. Or, if you would prefer to complete the survey online, please go to the website:

<http://www.MillenniumCohort.org>
Enter your unique Subject ID: **xxxxxxx**.

We look forward to hearing from you as one of our valued Millennium Cohort members!

Very Respectfully,

Dennis Faix, CDR, MC, USN
On Behalf of the
The Millennium Cohort Study Team

If you have any questions, please contact the Millennium Cohort team at our toll-free number, 1-888-942-5222, or DSN 553-7465, or email info@millenniumcohort.org.

Be assured that this is an authorized study supported by the highest levels of the Department of Defense. Defense Manpower Data Center Reference # 00-0019, Report Control Symbol # DD-HA(AR)2106, Office of Management and Budget Approval # 0720-0029, Office of the Assistant Secretary of Defense (Health Affairs), TRICARE Management Activity Protocol # CDO-06-206, and Primary Institutional Review Board Protocol #NHRC.2000.0007.

Dear {Name}

Thank you for your past participation in the Millennium Cohort Study. The current survey cycle is ending soon and we would still like to hear from you. We understand that your time is valuable and you may not have had the opportunity to fill out our previous surveys. For this reason we have included a small selection of survey questions on the included 4 page questionnaire.

The Millennium Cohort Study is unique in that it is designed to survey participants once every 3 years over the course of their military career and beyond. We are interested in your health during and long after your military commitment is up.

The success of this study depends on you and others like you. We thank you for completing the enclosed survey and returning it in the postage-paid envelope. Or, if you would prefer to complete the full survey, please go to our website:

<http://www.MillenniumCohort.org>
Enter your unique Subject ID: xxxxxx.

Very Respectfully,

Dennis Faix, CDR, MC, USN
On Behalf of the
The Millennium Cohort Study Team

If you have any questions, please contact the Millennium Cohort team at our toll-free number, 1-888-942-5222, or DSN 553-7465, or email info@millenniumcohort.org.

Be assured that this is an authorized study supported by the highest levels of the Department of Defense. Defense Manpower Data Center Reference # 00-0019, Report Control Symbol # DD-HA(AR)2106, Office of Management and Budget Approval # 0720-0029, Office of the Assistant Secretary of Defense (Health Affairs), TRICARE Management Activity Protocol # CDO-06-206, and Primary Institutional Review Board Protocol #NHRC.2000.0007.

August 2015

A request to link Millennium Cohort Study datasets to existing DoD datasets currently at NHRC containing modeled environmental exposures occurring during the Gulf War. Specifically, we will link to datasets containing potential exposure to neurological agents from demolitions at Khamisiyah and exposure to oil well smoke. These data were compiled and sent to NHRC by US Army Center for Health Promotion and Preventive Medicine (now US Army Public Health Command). The Naval Health Research Center currently maintains these datasets detailing potential exposure to oil well smoke and chemical weapons occurring in 1991 during the Gulf War. SSN's will be used to link data, but will not be transmitted externally, and will be confidentially maintained on-site.

In addition this protocol has undergone a change of staff; therefore, a request approval to remove Laura Tobin, MPH as she is no longer affiliated with the study and to add Chelsea

Schafer, Jacqueline Pflieger, PhD, and Deborah Bookwalter, PhD, as key personnel. Their roles are outlined below:

Chelsea Schafer will be located at the Naval Health Research Center and will serve as key support staff as a Research Intern. As a Research Intern she will collect and organize survey data and forms for research projects. In addition, her duties will include scanning and verifying survey data, performing data entry and literature searches, and assisting with the maintenance of databases for research projects.

Jacqueline Pflieger, PhD will be located at the Naval Health Research Center and will serve as key support staff as Research Psychologist. Her duties will include assisting in program design and maintenance of survey instruments alongside research team; planning epidemiologic studies and designing the study methodology; performing statistical analyses for diverse research projects with complex study designs; working with team members to derive an in-depth understanding of the data findings; drafting proposals and writing peer-reviewed publications.

Deborah Bookwalter, PhD will be located at the Naval Health Research Center and will serve as key support staff as an Epidemiologist. Her duties will consist of planning epidemiologic studies and designing the study methodology; performing statistical analyses for diverse research projects with complex study designs; working with team members to derive an in-depth understanding of the data findings; drafting proposals and writing peer-reviewed publications.

Along with the above updates, we are also submitting to the IRB for review and approval, the remainder of the participant contact material that is within the permissible number of contacts.

WWW.MILLENNIUMCOHORT.ORG
 David O. Linton
 Principal Investigator and Military Veteran

Very sincerely,
 with a comprehensive picture of our most valuable asset: you.
 This important research study which will provide insight in a year or
 two into how you have been, the hope you have for the future, and
 how you are now, is a study designed to improve the health and well-being of fellow service members and Veterans.
 Please visit our website and log in to update your information.
 Use your Subject ID located below the banner on the address side of this newsletter to log in and update your personal information.
 Please visit our website and log in to update your information.
 If you are new to the study, your participation is essential for improving the quality of the future service members. By participating in a study designed to last more than 20 years, you are contributing to an important effort to improve the health and well-being of fellow service members and Veterans.
 Whether you have been a member of this study for over 10 years, or if you are new to the study, your participation is essential for improving the quality of the future service members. By participating in a study designed to last more than 20 years, you are contributing to an important effort to improve the health and well-being of fellow service members and Veterans.

Never in history has such a large group of active-duty, Reservists, Guardsmen and Veterans, from all service branches, been included in a health study of this magnitude.
 Please visit our website and log in to update your information.
 Use your Subject ID located below the banner on the address side of this newsletter to log in and update your personal information.
 Please visit our website and log in to update your information.
 If you are new to the study, your participation is essential for improving the quality of the future service members. By participating in a study designed to last more than 20 years, you are contributing to an important effort to improve the health and well-being of fellow service members and Veterans.

PLEASE KEEP US UPDATED
 Have your name changed?
 Have you recently moved or changed your email address?

Through our Experiences and Dedication we are committed to helping protect service member health

WWW.MILLENNIUMCOHORT.ORG
 SUMMER NEWSLETTER 2015

Millennium Cohort Study
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 San Diego, CA 92165-5777
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THE MILLENNIUM COHORT STUDY
PROTECTING SERVICE MEMBER HEALTH

Your continued participation is critical, whether or not you are still serving in the military, and the information you provide will be confidential whether or not you are still serving.

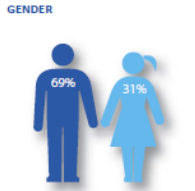
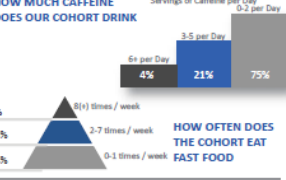
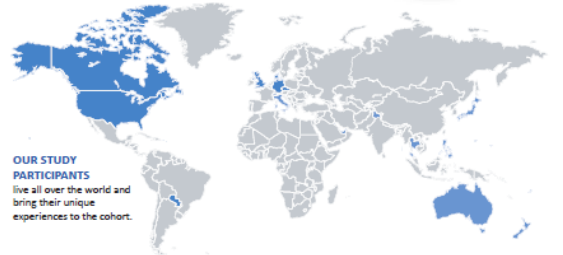
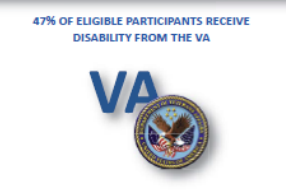
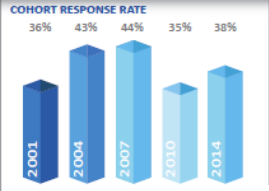
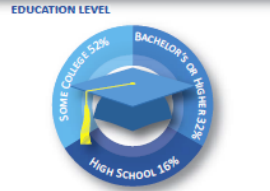
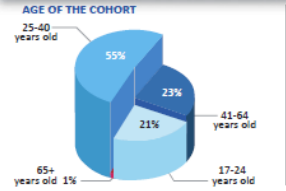
TAKE ACTION

If you haven't already, complete your survey today! By sharing your personal experiences, you can make a real difference. Log in at www.millenniumcohort.org

LT. GEN. Patricia D. Horoho
 Surgeon General of the Army

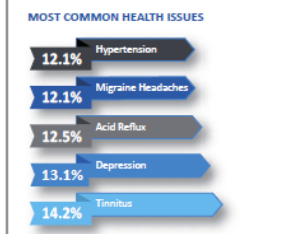
Primary Institutional Review Board Protocol # NHRC.2000.0007

A SNAPSHOT OF THE MILLENNIUM COHORT STUDY



WHY SHOULD YOU CONTINUE TO PARTICIPATE?

The purpose of this study is to assess the health risks of military deployment, military occupations, and general military service. You were selected to represent your fellow soldiers, sailors, airmen, and Marines, and your continued participation positively impacts former, current and future Service members. Ultimately, the greatest benefits of this study will not be known for many years. This is why it is essential to stay involved with the study even after you are out of the service.



Email

Dear {Name},

A week ago we sent you a newsletter highlighting just a few pieces of information that we have been able to gather from contributions to an important health study called the Millennium Cohort Study. The new information that we are collecting on the 2014-2015 survey will provide a more complete picture of the health of current and former Service members.

Why take up some of your time to complete this survey? Everyone has his or her own reasons...

For some who have already completed this survey, it was simply a matter of duty, of doing the right thing. For others, it was more personal - having suffered health problems themselves during or after their service. And for others still, giving some of their time was driven by a concern for the health of future generations who will serve in the US military.

Whatever your reason, we ask that you take few minutes to begin your survey today.

We are sending this by email in the hopes that it will make it easier for you to respond. Just go to www.millenniumcohort.org, click **Start Survey** and enter your **Subject ID: xxxxxx**.

Thank you for working with us to protect the health of our military service members and for helping to make this the largest and most important DoD health study in US military history.

Very Respectfully,

Dr. David D. Luxton
Principal Investigator and Military Veteran

For any questions, please contact the Millennium Cohort Team at milcohortinfo@med.navy.mil or info@millenniumcohort.org. Or call toll free 1-888-942-5222 or DSN 553-7465, and reference your Subject Id: [SID]

The Millennium Cohort Study is an authorized Department of Defense project. Note Defense Manpower Data Center Reference # 00-0019, Report Control Symbol # DD-HA(AR)2106, Office of Management and Budget Approval # 0720-0029, Office of the Assistant Secretary of Defense (Health Affairs), TRICARE Management Activity Protocol # CDO-06-206, and Primary Institutional Review Board Protocol # NHRC.2000.0007.

If you would like this email address to be removed from our email list, please visit link [UNSUBSCRIBE LINK]

Millennium Cohort Study - Protecting Service Member Health

Email

Dear [\[name\]](#),

Over (insert number) of your fellow Soldiers, Sailors, Airmen, and Marines have already completed their 2014-2015 surveys, but every individual response is needed for us to understand the potential impact of military service on the health and well-being of our Service members and veterans.

Therefore, we are sending this email to provide an electronic link, which we hope will make it easier for you to respond. Just go to www.millenniumcohort.org and click **Start Survey** and enter your **Subject ID: xxxxxx**.

Even if you are no longer serving, or do not presently have any health concerns we still hope that you will complete your survey. Ultimately, the greatest benefits of this study will not be known for many years. This is why it is essential to stay involved with the study even after you have left the service or if you are not currently having any health concerns.

Thank you for working with us to protect the health of our military service members and for helping to make this the largest and most important DoD health study in US military history.

Very Respectfully,

Dr. David D. Luxton
Principal Investigator and Military Veteran

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If you would like this email address to be removed from our email list, please visit link [\[UNSUBSCRIBE LINK\]](#)

Millennium Cohort Study - Protecting Service Member Health

Email

Dear **name**,

We recently sent you a paper copy of the 2014-2015 Millennium Cohort Study. We understand that your time is very valuable, so we've also included a link to our online version of the survey. When completing the survey online, you can come back to your survey at any time, and the website will automatically open to the next unanswered question.

Just go to www.millenniumcohort.org and click **Start Survey** and enter your **Subject ID: xxxxxx**.

Even if you are no longer serving, or do not presently have any health concerns we still hope that you will complete your survey. Ultimately, the greatest benefits of this study will not be known for many years. This is why it is essential to stay involved with the study even after you are out of the service or if you are not currently having any health concerns.

Thank you for your continued help in making this the largest and most important DoD study in US military history and working with us to protect the health of members of our military service.

Very Respectfully,

Dr. David D. Luxton
Principal Investigator and Military Veteran

For any questions, please contact the Millennium Cohort Team at milcohortinfo@med.navy.mil or info@millenniumcohort.org. Or call toll free 1-888-942-5222 or DSN 553-7465, and reference your Subject Id: [SID]

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If you would like this email address to be removed from our email list, please visit link [UNSUBSCRIBE LINK]

Millennium Cohort Study - Protecting Service Member Health

Dear Name,

As a Millennium Cohort Study participant, you have been selected to represent your fellow Service members in the largest health study in military history. Even if you have never deployed or are no longer in the service, your contribution is still very important.

Your past participation, and the participation of others like you, has already helped us better understand how deployments and other military experiences impact Service members' physical and mental health. For example, we found that combat-related trauma and predeployment insomnia symptoms increased the risk for developing post-traumatic stress symptoms, depression, and anxiety following deployment.

So far only {30%} of our participants have responded to our requests to submit their survey. **The survey cycle is ending soon, so your response is vital.**

We thank you for completing the enclosed survey and returning it in the postage-paid envelope. Or, if you would prefer to complete the survey online, please go to the website:

<http://www.MillenniumCohort.org>
Enter your unique Subject ID: **xxxxxxx**.

We look forward to hearing from you as one of our valued Millennium Cohort members!

[Insert Signature]

Very Respectfully,
Dr. David D. Luxton
Principal Investigator and Military Veteran

If you have any questions, please contact the Millennium Cohort team at our toll-free number, 1-888-942-5222, or DSN 553-7465, or email info@millenniumcohort.org.

Be assured that this is an authorized study supported by the highest levels of the Department of Defense. Defense Manpower Data Center Reference # 00-0019, Report Control Symbol # DD-HA(AR)2106, Office of Management and Budget Approval # 0720-0029, Office of the Assistant Secretary of Defense (Health Affairs), TRICARE Management Activity Protocol # CDO-06-206, and Primary Institutional Review Board Protocol #NHRC.2000.0007.

Dear {Name}

Thank you for your past participation in the Millennium Cohort Study. The current survey cycle is ending soon and we would still like to hear from you. We understand that your time is valuable and you may not have had the opportunity to fill out our previous surveys. For this reason we have included a small selection of survey questions on the included 4 page questionnaire.

The Millennium Cohort Study is unique in that it is designed to survey participants once every 3 years over the course of their military career and beyond. We are interested in your health during and long after your military commitment is up.

The success of this study depends on you and others like you. We thank you for completing the enclosed survey and returning it in the postage-paid envelope. Or, if you would prefer to complete the full survey, please go to our website:

<http://www.MillenniumCohort.org>
Enter your unique Subject ID: xxxxxx.

Very Respectfully,

[Insert Signature]

Dr. David D. Luxton
Principal Investigator and Military Veteran

If you have any questions, please contact the Millennium Cohort team at our toll-free number, 1-888-942-5222, or DSN 553-7465, or email info@millenniumcohort.org.

Be assured that this is an authorized study supported by the highest levels of the Department of Defense. Defense Manpower Data Center Reference # 00-0019, Report Control Symbol # DD-HA(AR)2106, Office of Management and Budget Approval # 0720-0029, Office of the Assistant Secretary of Defense (Health Affairs), TRICARE Management Activity Protocol # CDO-06-206, and Primary Institutional Review Board Protocol #NHRC.2000.0007.

1. In general, would you say your health is: (Please select only one)

- Excellent Very good Good Fair Poor

2. What is your **current** marital status?

- Single, never married Now married Separated Divorced Widowed

3a. What is your **current** weight? pounds

3b. How tall are you? feet inches

4. Over the **past month**, how many hours of sleep did you get in an average 24-hour period? hours

5. During the **past 4 weeks**, how much of the time has your **physical health** or **emotional problems** interfered with your social activities (like visiting with friends, relatives)?

- None of the time A little of the time Some of the time Most of the time All of the time

6. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

- Not at all A little bit Moderately Quite a bit Extremely

7. Over the **past 3 years**, have you had back pain, back aching, or back stiffness almost every day that lasted for 3 months or more in a row?

- No Yes

8. In the **last 3 years**, has your doctor or other health professional told you that you have any of the following conditions?

Hypertension (high blood pressure)	<input type="radio"/> No <input type="radio"/> Yes	Sinusitis	<input type="radio"/> No <input type="radio"/> Yes
High cholesterol requiring medication	<input type="radio"/> No <input type="radio"/> Yes	Chronic bronchitis	<input type="radio"/> No <input type="radio"/> Yes
Coronary heart disease	<input type="radio"/> No <input type="radio"/> Yes	Emphysema	<input type="radio"/> No <input type="radio"/> Yes
Heart attack	<input type="radio"/> No <input type="radio"/> Yes	Asthma	<input type="radio"/> No <input type="radio"/> Yes
Angina (chest pain)	<input type="radio"/> No <input type="radio"/> Yes	Memory loss or memory impairment	<input type="radio"/> No <input type="radio"/> Yes
Diabetes or sugar diabetes	<input type="radio"/> No <input type="radio"/> Yes	Tinnitus/ringing of the ears	<input type="radio"/> No <input type="radio"/> Yes
Significant hearing loss	<input type="radio"/> No <input type="radio"/> Yes	Migraine headaches	<input type="radio"/> No <input type="radio"/> Yes
Sleep apnea	<input type="radio"/> No <input type="radio"/> Yes	Cancer (please specify)	<input type="radio"/> No <input type="radio"/> Yes
Significant vision loss even with glasses or contact lenses	<input type="radio"/> No <input type="radio"/> Yes	<input type="text"/>	

9. The following questions are about activities you might do during a **typical day**. Does **your health now limit you** in these activities? If so, how much?

	No, not limited at all	Yes, limited a little	Yes, limited a lot
a. Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Climbing several flights of stairs?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

10. During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

	No, none of the time	Yes, a little of the time	Yes, some of the time	Yes, most of the time	Yes, all of the time
a. Accomplished less than you would like	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Were limited in the kind of work or other activities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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11. During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

	No, none of the time	Yes, a little of the time	Yes, some of the time	Yes, most of the time	Yes, all of the time
a. Accomplished less than you would like	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Didn't do work or other activities as carefully as usual	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

12. During the **past 4 weeks**, how much of the time: (Select the **single best** answer for each question)

	None of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
a. Have you felt calm and peaceful ?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Did you have a lot of energy ?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Have you felt downhearted and blue ?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

13. Over the **last 2 weeks**, how often have you been bothered by any of the following problems?

	Not at all	Several days	More than half the days	Nearly everyday
a. Little interest or pleasure in doing things	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Feeling down, depressed, or hopeless	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Trouble falling or staying asleep, or sleeping too much	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Feeling nervous, anxious, or on edge	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e. Not being able to stop or control worrying	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

14. Are you **currently** taking any medicine for anxiety, depression, or stress? No Yes

15. During the **past 3 years**, have you been **PERSONALLY** exposed to any of the following? (Do not include TV, video, movies, computers, or theater)

	No	Yes, 1 time	Yes, more than 1 time	If YES, list most recent year of exposure				
a. Witnessing a person's death due to war, disaster, or tragic event ..	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	→ <table border="1"><tr><td>2</td><td>0</td><td>1</td><td></td></tr></table>	2	0	1	
2	0	1						
b. Witnessing instances of physical abuse (torture, beating, rape)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	→ <table border="1"><tr><td>2</td><td>0</td><td>1</td><td></td></tr></table>	2	0	1	
2	0	1						
c. Dead and/or decomposing bodies	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	→ <table border="1"><tr><td>2</td><td>0</td><td>1</td><td></td></tr></table>	2	0	1	
2	0	1						
d. Maimed soldiers or civilians	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	→ <table border="1"><tr><td>2</td><td>0</td><td>1</td><td></td></tr></table>	2	0	1	
2	0	1						
e. Prisoners of war or refugees	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	→ <table border="1"><tr><td>2</td><td>0</td><td>1</td><td></td></tr></table>	2	0	1	
2	0	1						

16. In the **past month** have you experienced...?

	Not at all	A little bit	Moderately	Quite a bit	Extremely
a. Repeated, disturbing memories of stressful experiences from the past	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Feeling very upset when something happened that reminds you of stressful experiences from the past	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Feeling distant or cut off from other people	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Feeling irritable or having angry outbursts	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e. Difficulty concentrating	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
f. Efforts to avoid activities or situations because they remind you of stressful experiences from the past	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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17. In the **past 3 years**, have any of the following life events happened to you?

	No	Yes					
a. Suffered forced sexual relations or sexual assault	<input type="radio"/>	<input type="radio"/>	→ <table border="1"><tr><td>2</td><td>0</td><td>1</td><td></td></tr></table>	2	0	1	
2	0	1					
b. Experienced sexual harassment	<input type="radio"/>	<input type="radio"/>	→ <table border="1"><tr><td>2</td><td>0</td><td>1</td><td></td></tr></table>	2	0	1	
2	0	1					
c. Suffered a violent assault	<input type="radio"/>	<input type="radio"/>	→ <table border="1"><tr><td>2</td><td>0</td><td>1</td><td></td></tr></table>	2	0	1	
2	0	1					

18. In the **last 12 months**, have any of the following happened to you **more than once**?

a. You drank alcohol even though a doctor suggested that you stop drinking because of a problem with your health	<input type="radio"/> No	<input type="radio"/> Yes
b. You drank alcohol, were high from alcohol, or hung over while you were working, going to school, or taking care of children or other responsibilities	<input type="radio"/> No	<input type="radio"/> Yes
c. You missed or were late for work, school, or other activities because you were drinking or hung over	<input type="radio"/> No	<input type="radio"/> Yes
d. You had a problem getting along with people while you were drinking	<input type="radio"/> No	<input type="radio"/> Yes
e. You drove a car after having several drinks or after drinking too much	<input type="radio"/> No	<input type="radio"/> Yes

19. a. In your lifetime, have you smoked at least 100 cigarettes (5 packs)?

No Yes

b. If **YES**, have you ever tried to quit smoking? Yes, and succeeded Yes, but not successfully No

20. In the **past year**, have you smoked any cigarettes (tobacco)?

No Yes

21. Have you **ever** had an injury, such as from a fall, blow to the head, blast exposure, motor vehicle crash, sports, or any other cause that resulted in any of the following?

	No	Yes	Don't know
a. Being dazed right after the injury?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Being confused or not thinking clearly right after the injury?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Not remembering the actual injury right after it happened?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Not remembering things that happened right after the injury?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e. Losing consciousness or being knocked out?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

22. If **YES** to any item in question 21 above, how many total lifetime injuries have occurred?

Prior to joining the service	<table border="1"><tr><td></td><td></td></tr></table> injuries		
During the service	<table border="1"><tr><td></td><td></td></tr></table> injuries		
After leaving the service	<table border="1"><tr><td></td><td></td></tr></table> injuries		

23. Please provide your email address(es): (Separate multiple email addresses with a space)

24. What year were you born?

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25. What are the last four digits of your Social Security Number?

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Thank you very much for helping us out by answering this brief questionnaire. These are just a subset of the questions on the survey. To complete the remaining questions over the web, just go to: www.MillenniumCohort.org

JULY 2015: WITHDREW MODIFICATION REQUEST

In order to increase response rates, the Millennium Cohort Study requests permission to use a third party calling service, Infinity (based in Cedar Rapids, Iowa), to call approximately 16,000 follow-up participants who have not received any postal mailings since the beginning of the 2014-2015 survey cycle due to a bad address. Updated contact information for participant bad addresses is usually obtained by utilizing IRS address updates; however, we are experiencing some logistical challenges with the renewal of the NIOSH agreement (still pending).

Therefore, we request approval to use Infinity to only call those participants who provided a phone number on their baseline or previous follow-up survey as a means to remain in contact. Calls will be made by Infinity, contracted for the sole purpose of this phone call outreach task. Infinity will sign confidentiality and a non-disclosure agreement prior to initiating the task, and will return all logs upon completion of the calls. All callers will be required to follow the approved script (A copy of the script is included for IRB review).

Infinity staff will attempt to contact participants via telephone Monday through Friday between the hours of 8am and 8pm within the respective time zones of study participants. Infinity will adhere to all state specific calling laws and will not call a participant if state law dictates an earlier end time. A maximum of three phone call attempts will be made per participant and a log of each attempt will be maintained. An Infinity employee will leave a live message on the participant's voicemail if a participant cannot be reached by the third phone call attempt. Infinity calling service will not collect any information from participants, and if a participant has any questions or concerns, they will be immediately directed to call the study staff at NHRC.

In addition this protocol has undergone a change of staff; therefore, we request approval to add Jacqueline Pflieger, PhD, as key personnel. Her role is outlined below:

Jacqueline Pflieger, PhD will be located at the Naval Health Research Center and will serve as key support staff as Research Psychologist. Her duties will include assisting in program design and maintenance of survey instruments alongside research team; planning epidemiologic studies and designing the study methodology; performing statistical analyses for diverse research projects with complex study designs; working with team members to derive an in-depth understanding of the data findings; drafting proposals and writing peer-reviewed publications

2015 Bad Address Non-responder Millennium Cohort Study Phone Call Script

Phase II 2015: Contact by Phone

Subjects will be contacted via telephone Monday through Friday between the hours of 8am and 8pm within their respective time zones. Infinity will adhere to all state specific calling laws and will not call a participant if state law dictates an earlier end time. A maximum of three phone call attempts will be made per participant and a log of each attempt will be maintained. An Infinity employee will leave a live message on the participant's voicemail if a participant cannot be reached by the third phone call attempt.

Script

Hello, my name is (insert name) and I'm calling on behalf of the Department of Defense Millennium Cohort Study. Am I speaking with (participant name)?

[When participant is clearly not the one answering]

May I please speak with (insert participant name)?

❖ [If not available] Is there a better time for me to call to speak to (insert name)?

[When number is incorrect]

I apologize for the inconvenience. Have a nice day. [Mark the number as a wrong phone number in the call log]

[When speaking to the correct participant]

A few years ago you participated in a very important Department of Defense study designed to understand the impact of deployment on the health and well being of Service members. We have been trying to reach you over the last several months to ask for your continued participation in the Millennium Cohort Study, and to provide you with a small token of our appreciation.

Unfortunately it seems that we do not have current contact information on file for you. We want to make sure that our gifts of appreciation are making it to your door. Would you like to update your contact information, so we can make sure that you receive your invitation to take the survey?

- ❖ **[If Yes]** Great! Thank you for providing the study team with updated contact information. You can securely and simply update it via the study website. Go to www.millenniumcohort.org and select "Update Contact Information." Your continued participation makes it possible to provide evidence-based policy recommendations to military and civilian leaders and to guide interventions that have the potential to make life better for Service members. Thank you for your participation in the Millennium Cohort Study. Have a nice day!
- ❖ **[If No]** Your email and home address information make it possible for us to send you study updates and gifts of appreciation. The survey is only once every three years and is the Department of Defense's largest study of the military over time, and includes all branches of the military, including Reserve and National Guard. Even if you have separated from the military, your participation is still vital!
 - Would you like to speak to a member of the Millennium Cohort Study research team to find out more about the study?
 - ◆ **[If Yes]** Please let me know the best time to call and I will have a member of the research team call you at this number. (Record suggested time and a phone number to call if different.)
 - Thank you. A team member will call you in a few days. We appreciate your interest in the Millennium Cohort Study and your participation. Have a nice day.
 - ◆ **[If No]** Would you like the website address so you can update your contact information simply and securely?
 - **[If Yes]** Just go to www.millenniumcohort.org and select "Update Contact Information." We hope you choose to complete the follow-up survey. From the website you can easily select the "Start Survey" button to complete your survey.

- **[If No]** We hope you choose to complete your follow-up survey. Thank you for your time, have a nice day.

[When leaving a message]

Hello, my name is (insert name) and I'm calling (insert name) on behalf of the Department of Defense Millennium Cohort Study. A few years ago you participated in a very important project designed to follow Service members over time called the Millennium Cohort Study. You are one of a select group chosen to represent the military from all branches of service, including the Reserve and National Guard. Your feedback allows us to provide military and civilian leaders with evidence-based policy recommendations and helps guide the development of interventions that have the potential to improve the lives of Service members. We hope you choose to complete this year's survey by visiting our study website www.millenniumcohort.org. Thank you for your past participation and for your service.

[If at any time a participant has any questions or concerns]

I apologize, but I am unable to help you with your request. I can provide you with the direct number of the study staff, and they would be happy to help you to (insert issue).

June 2015 No and/or Bad Address/Participant Calls—(IRB APPROVAL RECINDED—NEW MODIFICATION SUBMITTED JULY 2015—SEE ABOVE)

In order to increase response rates, the Millennium Cohort Study requests permission to call approximately 16,000 follow-up participants who have not received any postal mailings since the beginning of the 2014-2015 survey cycle due to a bad address. Updated contact information for participant bad addresses is usually obtained by utilizing IRS address updates; however, we are experiencing some logistical challenges with the renewal of the NIOSH agreement.

Therefore, approval to only call those participants who provided a phone number on their baseline or previous follow-up survey as a means to remain in contact from IRB is being sought. Attempts to contact participants via telephone Monday through Friday will be between the hours of 8am and 7pm within their respective time zones. A maximum of three phone call attempts will be made per participant and a log of each attempt will be maintained. A message will be left on the participant's voicemail if a person cannot be reached by the third phone call attempt. A copy of the script is included for IRB review and approval.

2015 Bad Address Non-responder Millennium Cohort Study Phone Call Script

Phase II 2015: Contact by Phone

Subjects will be contacted via telephone Monday through Friday between the hours of 8am and 7pm within their respective time zones. A maximum of three phone call attempts will be made per participant and a log of each attempt will be maintained. A message will be left on the participant's voicemail if a person cannot be reached by the third phone call attempt.

Script

Hello, my name is (insert name) and I'm calling on behalf of the Department of Defense Millennium Cohort Study. Am I speaking with (participant name)?

[When participant is clearly not the one answering]

May I please speak with (insert participant name)?

❖ [If not available] Is there a better time for me to call to speak to (insert name)?

[When number is incorrect]

I apologize for the inconvenience. Have a nice day. [Mark the number as a wrong phone number in the call log]

[When speaking to the correct participant]

A few years ago you participated in a very important Department of Defense study designed to understand the impact of deployment on the health and well being of Service members. We have been trying to reach you over the last several months to ask for your continued participation in the Millennium Cohort Study, and to provide you with a small token of our appreciation.

In the last several months have you received emails from the Millennium Cohort Study team?

[If Yes or No]

We have also attempted to send Postal mailings that have included postcards, a survey, and a small gift but unfortunately it seems that we do not have a current mailing address on file for you. We want to make sure that our gifts of appreciation are making it to your door. Would you like to update your contact information, so we can make sure that you receive your invitation to take the survey and study gifts?

❖ **[If Yes]** Great! Thank you for providing the study team with updated contact information. If your contact information changes in the future, you can securely and simply update it via the study website. Go to www.millenniumcohort.org and select "Update Contact Information." Your continued participation makes it possible to provide evidence-based policy recommendations to military and civilian leaders and to guide interventions that have the potential to make life better for Service members. Thank you for your participation in the Millennium Cohort Study. Have a nice day!

❖ **[If No]** Your email and home address information make it possible for us to send you study updates and gifts of appreciation. The survey is only once every three years and is the Department of Defense's largest study of the military over time, and includes all branches of the military, including Reserve and National Guard. Even if you have separated from the military, your participation is still vital!

- Would you like to speak to a member of the Millennium Cohort Study research team to find out more about the study?

◆ **[If Yes]** Please let me know the best time to call and I will have a member of the research team call you at this number. (Record suggested time and a phone number to call if different.)

- Thank you. A team member will call you in a few days. We appreciate your interest in the Millennium Cohort Study and your participation. Have a nice day.
- ◆ **[If No]** Would you like the website address so you can update your contact information simply and securely?
 - **[If Yes]** Just go to www.millenniumcohort.org and select “Update Contact Information.” We hope you choose to complete the follow-up survey. From the website you can easily select the “Start Survey” button to complete your survey.
 - **[If No]** Would you like to be removed from this wave of the study, and touch base again during the next follow-up?
 - **[If Yes]** We respect your decision. You will be removed from future contacts for this follow-up period. Have a nice day.
 - **[If No]** We hope you choose to complete your follow-up survey. Thank you for your time, have a nice day.

[When leaving a message]

Hello, my name is (insert name) and I’m calling (insert name) on behalf of the Department of Defense Millennium Cohort Study. A few years ago you participated in a very important project designed to follow Service members over time called the Millennium Cohort Study. You are one of a select group chosen to represent the military from all branches of service, including the Reserve and National Guard. Your feedback allows us to provide military and civilian leaders with evidence-based policy recommendations and helps guide the development of interventions that have the potential to improve the lives of Service members. We hope you choose to complete this year’s survey by visiting our study website www.millenniumcohort.org. Thank you for your past participation and for your service.

May 2015: Millennium Fourth of July Mailings

In accordance with the guidance received on April 9, 2015 regarding an additional contact, the Millennium Cohort Study Independence Day Postcard (2 versions responder and non-responder) and Millennium Cohort Study Independence Day e-mail (2 versions responder and non-responder) were submitted for IRB review and approval. This will modify the total approved contacts for this cycle to 13 mail items.

Independence Day 2015 Postcard

Responder

Subject Line: Independence Day-Celebrating Our Freedom

As we celebrate our nation's freedom on this Independence Day, we also honor the courageous men and women dedicated to preserving it.

We would like to thank you for completing your 2014-2015 questionnaire. Never in history has such a large group of active duty Service members, Reservists, National Guardsmen and Veterans from all military branches been included in a health study of this magnitude. By understanding how military factors contribute to long term health, military and VA leaders will be provided with valuable information to improve Service members' quality of life.

Thank you for your continued support of this important project!

Respectfully,

David D. Luxton, PhD
Principal Investigator and Military Veteran
DoD Center for Deployment Health Research, San Diego, CA
Primary Institutional Review Board Protocol # NHRC.2000.0007

Independence Day 2015 Postcard
Non-Responder
Subject Line: Independence Day-Celebrating Our Freedom

As we celebrate our nation's freedom on this Independence Day, we also honor the courageous men and women dedicated to preserving it.

The Millennium Cohort Study is currently mid-cycle for the 2014-2015 survey effort. If you have already completed and submitted the survey, please accept our sincere thanks.

If you have not already done so, please use your Subject ID located below the barcode to complete your survey online at www.millenniumcohort.org.

Thank you for your continued support of this important project!

Respectfully,

David D. Luxton, PhD
Principal Investigator and Military Veteran
DoD Center for Deployment Health Research, San Diego, CA

Primary Institutional Review Board Protocol # NHRC.2000.0007

**Independence Day 2015 e-mail
Responder
Subject Line: Independence Day-Celebrating Our Freedom**

As we celebrate our nation's freedom on this Independence Day, we also honor the courageous men and women dedicated to preserving it.

You should receive an Independence Day postcard in the mail from the Millennium Cohort Study team. You can also view it online at [link]

We would like to thank you for completing your 2014-2015 questionnaire. Never in history has such a large group of active duty Service members, Reservists, National Guardsmen and Veterans from all military branches been included in a health study of this magnitude. By understanding how military factors contribute to long term health, military and VA leaders will be provided with valuable information to improve Service members' quality of life.

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Respectfully,

David D. Luxton, PhD
Principal Investigator and Military Veteran
DoD Center for Deployment Health Research, San Diego, CA

For any questions, please contact the Millennium Cohort Team at milcohortinfo@med.navy.mil or info@millenniumcohort.org. Or call toll free 1-888-942-5222 or DSN 553-7465, and reference your Subject ID: [SID]

The Millennium Cohort Study is an authorized Department of Defense project. Note Defense Manpower Data Center Reference # 00-0019, Report Control Symbol # DD-HA(AR)2106, Office of Management and Budget Approval # 0720-0029, Office of the Assistant Secretary of Defense (Health Affairs), TRICARE Management Activity Protocol # CDO-06-206, and Primary Institutional Review Board Protocol # NHRC.2000.0007.

If you would like this email address to be removed from our email list, please visit [link]

Millennium Cohort Study - Protecting Service Member Health

Independence Day 2015 e-mail

Non-Responder

Subject Line: Independence Day-Celebrating Our Freedom

As we celebrate our nation's freedom on this Independence Day, we also honor the courageous men and women dedicated to preserving it.

You should receive an Independence Day postcard in the mail from the Millennium Cohort Study team. You can also view it online at
[link]

The Millennium Cohort Study is currently mid-cycle for the 2014-2015 survey effort. If you have already completed and submitted the survey, please accept our sincere thanks.

If you have not already done so, please take a moment to complete your questionnaire by following the link below:
[link]

Thank you for your continued support of this important project!

Respectfully,

David D. Luxton, PhD
Principal Investigator and Military Veteran
DoD Center for Deployment Health Research, San Diego, CA

For any questions, please contact the Millennium Cohort Team at
milcohortinfo@med.navy.mil or info@millenniumcohort.org. Or call toll free 1-888-942-5222 or DSN 553-7465, and reference your Subject ID: [SID]

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If you would like this email address to be removed from our email list, please visit [link]

Millennium Cohort Study - Protecting Service Member Health

April 2015: Millennium Cohort Staff Updates/Mailings

This protocol has undergone a change of staff; therefore, we request approval to remove Lauren Kearney, MPH, Jill MacDougall, MPH, and Andrew Lin as they are no longer affiliated with the study. We also request approval to add Kristin Motylinski, Toni Geronimo, and Richard Armenta, MPH, as key personnel. Their roles are outlined below.

Kristin Motylinski and Toni Geronimo, will be located at the Naval Health Research Center and will serve as key support staff as Research Interns. As Research Interns they will collect and organize survey data and forms for research projects. In addition, their duties as an intern are to scan and verify survey data, perform data entry, literature searches, and assist with maintenance of databases for research projects.

Richard Armenta, MPH, will be located at the Naval Health Research Center and will serve as key support staff as a Biostatistician. His duties will include assisting in program design and maintenance of survey instruments alongside research team; planning epidemiologic studies and designing the study methodology; performing statistical analyses for diverse research projects with complex study designs; working with team members to derive an in-depth understanding of the data findings; drafting proposals and writing peer-reviewed publications

March 2015: Millennium Cohort and Family Separation/Staff Updates/Mailings

Due to logistical reasons, we respectfully request approval from the IRB to separate the Family component of the Millennium Cohort study. Dr. Valerie Stander will assume the role of Principal Investigator for the Family component and will formally submit to the IRB the initial sub-study for review and approval by the IRB. For all regulatory approvals/requirements related to the Millennium Cohort Family study up to and through the 2014-2015 survey cycle remain under the Millennium Cohort regulatory approvals (OMB Control Number 0720 – 0029 RCS: DD-HA(AR) 2016 and SORN N06500-1). Any future regulatory approvals needed for the Millennium Cohort Family study will be submitted under the standalone sub-study.

Also, this protocol has undergone a change of staff; therefore, we request approval to remove Donald Slymen, MS, PhD, as he is no longer affiliated with the study. We also request approval to update Dr. Valerie Stander's, role from Key Personnel to Co-Investigator and to add Evelyn Sun, MPH as key personnel. Their roles are outlined below.

Valerie Stander, PhD, will be located at the Naval Health Research Center and serve as co-investigator. She has considerable experience conducting epidemiological studies among military populations. She will plan epidemiologic studies and designing the study methodology; performing statistical analyses for diverse research projects with complex study designs; working with team members to derive an in-depth understanding of the data findings; drafting proposals and writing peer-reviewed publications.

Evelyn Sun, Assistant Study Coordinator for the Millennium Cohort Family study will serve as key support staff and will work with the Millennium Cohort study team with coordinating the study and sub-study data as well as web site and survey testing.

The protocol has also been updated to clarify the mortality data request are submitted to the Armed Forces Medical Examiner System (AFMES) at the Joint Pathology Center (JPC) formerly known as the Armed Forces Institute of Pathology AFIP.

Along with the above-mention updates, we are also submitting to the IRB for review and approval the remaining of the Phase 1 participant contact material which is within the permissible number of contacts.

Endorsement Letter Email
Subject: Endorsement of DoD Health Study

Dear [\[name\]](#)

Last week we sent you a postal letter to share with you [\[endorsement name\]](#) support for our DoD study of the health concerns and needs of military members.

This request was sent to you because you had previously completed a survey and we are especially interested in hearing about any changes to your health that have occurred since your last survey, whether or not you are still serving in the military. Your participation will help provide greater insight into the issues facing today's military Service members and Veterans.

If you have already completed the online questionnaire, we wish to thank you. If you have not yet had time to consider our request, we hope you will be able to do so soon.

Please follow the link below to complete your survey:

[\[link\]](#)

Thanks so much for being a part of this important study.

Very respectfully,

David D. Luxton
Principal Investigator and Military Veteran
DoD Center for Deployment Health Research
San Diego, CA
www.millenniumcohort.org

For any questions, please contact the Millennium Cohort Team at milcohortinfo@med.navy.mil or info@millenniumcohort.org. Or call toll free 1-888-942-5222 or DSN 553-7465, and reference your Subject Id: [SID]

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If you would like this email address to be removed from our mailing list, [click here](#).

Millennium Cohort Study - Protecting Service Member Health

Q2 Cover Letter

Dear [\[name\]](#),

We have contacted you a few times this year to ask for your help with a DoD survey of the current health status of current and former members of the military. We are writing to you again to remind you about this important survey. The sooner we receive your survey, the sooner we are able to begin answering important questions about the health and well-being of Service members and Veterans.

We are very pleased with the large number of Service members – both former and current- who have already sent back their surveys. We hope that you too will help us to improve the lives of future military members.

We have sent this paper survey to you because your response is important in making sure this study provides accurate results. However, if you prefer to complete your survey online, please visit www.millenniumcohort.org, click on **Start Survey** and enter your **Subject ID: xxxxxx**.

Thank you for considering our request, and we hope to hear from you soon!

Very respectfully,

David D. Luxton
Principal Investigator and Military Veteran
DoD Center for Deployment Health Research
San Diego, CA
www.millenniumcohort.org

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**Memorial Day 2015 Postcard
Responder**

On this Memorial Day, we recognize the valiant efforts of the hundreds of thousands of men and women who put country before self and gave their lives for our nation. They felt a sense of duty, and they dedicated their lives to fulfill that duty.

We would like to thank you for completing your 2014-2015 questionnaire. We appreciate the time that you took in providing information about your current health on our recent survey. By understanding how military factors contribute to long term health, military and VA leaders will be provided with valuable information to improve Service members' quality of life.

Thank you for your continued support of this important project!

Respectfully,

David D. Luxton, PhD
Principal Investigator and Military Veteran
DoD Center for Deployment Health Research, San Diego, CA

Primary Institutional Review Board Protocol # NHRC.2000.0007

**Memorial Day 2015 Postcard
Non-Responder**

On this Memorial Day, we recognize the valiant efforts of the hundreds of thousands of men and women who put country before self and gave their lives for our nation. They felt a sense of duty, and they dedicated their lives to fulfill that duty.

The Millennium Cohort Study is currently mid-cycle for the 2014-2015 survey effort. If you have not already done so, please use your Subject ID located below the barcode to complete your survey online at www.millenniumcohort.org.

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DoD Center for Deployment Health Research, San Diego, CA

Primary Institutional Review Board Protocol # NHRC.2000.0007

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DoD Center for Deployment Health Research, San Diego, CA

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Millennium Cohort Study - Protecting Service Member Health

Memorial Day 2015 Email Non-Responder

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Millennium Cohort Study - Protecting Service Member Health

2015 Continuing Review

Changes made under the 2015 continuing review submission were related to the Millennium Cohort Family study. Please refer to Appendix J for modification request and Appendix L for copies of mailings.

**FOR HISTORICAL PROTOCOL MODIFICATIONS
PLEASE REFER TO APPENDIX E –J**

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IV. SCIENTIFIC BACKGROUND AND OBJECTIVES

1. Background

In response to Iraq's invasion of Kuwait (August 2, 1990) the United States began deploying troops to the Arabian Gulf region five days later in Operation Desert Shield (Operation Desert Storm, 1997). A total of 40 coalition countries deployed troops to the region, including the United Kingdom, Canada, and France. On January 17, 1991, the air war against Iraq began (Operation Desert Storm), which was followed by a 4-day ground war starting on February 24, 1991.

By the end of active hostilities on February 28, 1991, the United States had deployed approximately 697,000 troops to the theater of operations, the British had deployed 53,000 troops, and the Canadians had deployed 4,500 military personnel. In contrast to previous conflicts, a larger proportion of U.S. troops were from the reserves/National Guard (17%) and were female (7%). Mortality and morbidity rates during the fighting were markedly lower than expected. By May 1991, most U.S. military personnel had left the theater of operations.

Beginning soon after the Desert Storm fighting ended in 1991, numerous Gulf War veterans complained of morbidity that they attributed to their deployment exposures. With the aid of a number of expert external review panels,¹⁻⁵ the U.S. government created intensive health registry examinations,^{6,7} sponsored medical research,⁸ and created large investigative organizations with a focus of risk management.⁹ As of 1999, the U.S. government has invested approximately one billion dollars (Riddle, LTC James R., OASD/HA, personal communication) in examining the health of Gulf War veterans.

Expert External Review Panels

The federal government has commissioned numerous external review panels to examine the health of Gulf War veterans or to monitor actions of the federal government in conducting such examinations. The external review panels have included:

- Defense Science Board^{1,10}
- Presidential Advisory Committee on Gulf War Veterans' Illnesses^{2,5,11}
- Institute of Medicine(IOM) Committee on Measuring Health of Gulf War Veterans^{3,4,12-16}
- General Accounting Office¹⁷⁻²⁹
- Presidential Special Oversight Board for Department of Defense Investigations of Gulf War Chemical and Biological Incidents^{30,31}

While it is beyond the scope of this introduction to review the findings of the external review panels, it should be recognized that review panel findings have greatly influenced the directions of clinical care, research, public relations, and veteran compensation.

Health Registry Evaluations

The Department of Veterans Affairs (DVA) established comprehensive clinical evaluations of Gulf War veterans in 1992. The Department of Defense (DoD) followed this example in establishing similar structured evaluations in 1994. The United Kingdom established similar evaluations soon thereafter. In the United States more than 150,000 Gulf War veterans and family members have registered in these programs.^{6,32} In the United Kingdom more than 1,000 Gulf War veterans have been evaluated.³³

Since registry participants are self-referred, registry health findings are really a series of cases. While these case series are not generally valuable in determining exposure risk, they have been valuable in demonstrating that few Gulf War veterans have unexplained symptoms without a recognized medical condition or diagnoses.^{7,32} They have also been helpful in identifying the most frequent self-reported symptoms among Gulf War veterans and in demonstrating that among symptomatic Gulf War veterans, many would meet diagnostic criteria for multi-symptom conditions, such as chronic fatigue syndrome and posttraumatic stress disorder (PTSD).³⁴

Previous Gulf War Veteran Research

The investment in medical research concerning Gulf War veterans has resulted in numerous important findings. Research reports and manuscripts are best chronicled in the DVA Annual Report to Congress⁸ and in a 4,462-citation Topical Bibliography of Published Works Regarding the Health of Veterans of the Persian Gulf War.³⁵

Much of Gulf War veteran research has involved epidemiological studies. Empirically, we categorized these studies into four areas:

- Studies of mortality—Several studies have examined deaths among Gulf War veterans,³⁶⁻³⁸ and with the exception of increased deaths due to accidents,³⁸ found little evidence of unexplained deaths associated with service in the Gulf War.
- Studies of hospitalizations—Numerous comparisons of post-1991 hospitalizations of Gulf War veterans and those of other veterans of the same era have been published.³⁹⁻⁴³ Data from DoD, VA, and California hospitals do not support arguments that Gulf War veterans are being hospitalized at a higher rate for Gulf War-related conditions.
- Studies of symptoms—Controlled studies of Gulf War veterans unanimously document that Gulf War veterans report more conditions and have evidence of more psychological morbidity.⁴⁴⁻⁴⁸ However, investigators have not been able to implicate specific Gulf War exposures as causing these symptoms. While one team of scientists used factor analysis to suggest unique aggregations of symptoms among Gulf War veterans,⁴⁹ other investigators have found the same factor-analysis symptom aggregations among non-deployed veterans.⁵⁰⁻⁵²
- Studies of reproductive outcomes—While a number of news reports have suggested that Gulf War veterans are experiencing unusual reproductive outcomes, published research studies have not validated these reports. Thus far, researchers have not found increases in the number of birth defects among the offspring of Gulf War veteran families.⁵³⁻⁵⁶
- Etiologic exposures—A number of investigators have championed hypotheses concerning the cause of increased symptom reporting among Gulf War veterans. While often not in the mainstream of etiologic thinking, these hypotheses have influenced some investigative research.^{4,15,57,58} These hypotheses have implicated:
 - Mycoplasma fermentans⁵⁹⁻⁶¹
 - Pyridostigmine bromide^{62,63}
 - Multiple chemical sensitivity⁶⁴
 - Depleted uranium⁶⁵
 - Sand exposure⁶⁶
 - Deployment vaccinations⁶⁷
 - Chemical agent resistant coating (CARC)
 - Oil well fires¹⁷
 - Nerve agents⁴²

In general, no one specific exposure or group of exposures has been implicated as the cause of illnesses among Gulf War veterans.

Data Limitations

The lack of predeployment health data and deployment exposure data have been chief limitations in examining Gulf War veteran morbidity questions. Numerous improvements have or are being made to gain such data for future U.S. military deployments. These efforts include capturing better service-entry health data, before and after deployment health data, environmental and morbidity data during deployments; improving communications regarding deployment risks; and focusing clinical and epidemiological research programs on deployed populations.^{13,68-71}

Risk Management

Following the Gulf War, veterans from the 123rd Army Reserve Unit in Indiana began to complain of health problems they associated with their service in the Gulf. An investigation by the Army Medical Corps was unrevealing. Soon afterward, stories of individual illnesses and clusters of illnesses came to public attention. The media soon labeled these illnesses Gulf War syndrome. The DVA (1992) and DoD (1994) responded to veterans' concerns with initiation of two comprehensive self-referral clinical evaluation programs. Early reports finding neither common illnesses nor a specific cause for Gulf War syndrome, were attacked as incomplete by veterans' groups and the media. More vocal commentators pointed to a "conspiracy of silence" and a large-scale coverup. In late 1996, the story acquired new urgency, with several reports documenting the "probable" exposure of U.S. personnel to enemy chemical weapons destroyed in the Khamisiyah area in March 1991 and highlighting the lapses of Pentagon authorities in publicizing that information. In 1996, the Special Assistant to the Deputy Secretary of Defense for Gulf War Illnesses (OSAGWI) was appointed to investigate the possible chemical and biological events and environmental exposures during Operations Desert Shield and Desert Storm that might have caused veterans' illnesses. Over the ensuing months, news reports appeared almost daily focusing on "hidden" exposures, new and often not biologically plausible hypotheses about disease causation, and strident criticisms of government efforts to address the problems of Gulf War illnesses.⁷² Since then, OSAGWI, comprising over 100 risk management and medical staff, has done much to investigate and inform veterans of exposures and health risks concerning their Gulf War service. OSAGWI has published a number of case narratives and environmental exposure reports, which have been disseminated via the Internet:(see <http://www.gulflink.osd.mil/>)

Recommendations for the Longitudinal Study of Deployed Forces

The 1999 IOM Measuring Health Report¹² surmised that numerous investigations and research efforts have been undertaken because of concern about the impact of the Gulf War on the health of U.S. troops who served in that conflict. Some of these efforts addressed the federal government's preparedness to meet its obligations and responsibilities to protect U.S. military service members, veterans, and their families. Others attempted to determine what health effects might be attributed to service in the Gulf War. Still others have identified possible causes for the myriad reports of health problems among Gulf War veterans.

IOM also recognized that the continuing focus on the health problems of Gulf War veterans is attributable in no small part to the efforts of individual veterans and the organizations that represent them. They have tirelessly pressured policy officials and the Congress that more needs to be done to help those Gulf War veterans who are experiencing health problems. In its report

on measuring health, the IOM committee recommended implementation of a research portfolio centered on a prospective cohort study of deployed forces. The IOM committee maintained that establishing a prospective cohort study of deployed forces would lead to a greater understanding of the longer-term health effects of military service, including service in deployments such as the Gulf War.

IOM also noted that a schism has developed, with ill veterans and their representatives on one side and the federal agencies charged with addressing veterans' health problems on the other. IOM recommended that coordinated and concerted efforts must be made to bridge this gap. The IOM committee believes that if DoD and DVA initiate the recommendations in this report, the actions will greatly facilitate that unification process.

One of the current difficulties inherent in researching deployment health concerns is the lack of a system for monitoring the longitudinal health of active, reserve, and National Guard forces, as well as the health of veterans and their families. The VA and DoD have developed health registries for active-duty service members and for veterans involved in specific events and deployments. While these registries serve useful purposes, they reflect the health of a self-selected sample of veterans, and thus they are not representative of the active-duty and veteran population in general. Of fundamental importance is the development of a longitudinal monitoring system that is representative of active-duty, National Guard, reserve troops, and veterans; that measures health at specific time points; and that measures changes in health over time.

The 1999 IOM report presents a research portfolio and prospective cohort study that could, with appropriate extension, provide a model for a long-term tracking system of the health of veterans of military deployments. The portfolio encompasses three principal categories of research: population studies, health-services research, and clinical and biomedical investigations. An essential feature of the research portfolio is facilitating linkages across individual studies through the collection of a core set of key data elements (describing health, individual, and cultural characteristics) in order to provide for comparisons across all research.

Additionally, future efforts to measure the health of those individuals deployed to military conflicts and peacekeeping missions should include, to the extent possible, information obtained before, during, and after deployment. The National Academy of Sciences is currently conducting an evaluation of strategies to protect the health of deployed U.S. forces, and a component of this study examines improvements in keeping medical records and documenting exposures, treatment, tracking of individuals through the medical evacuation system, and health/administrative outcomes. Data obtained before, during, and after deployment through the kinds of systems reviewed in this forthcoming Academy report will be important components of future deployment-related health research.

Section 743 of the Strom Thurmond National Defense Authorization Act for Fiscal Year 1999 authorized the Secretary of Defense to establish a center devoted to "...longitudinal study to evaluate data on the health conditions of members of the Armed Forces upon their return from deployment..." On September 30, 1999, Dr. Sue Bailey, Assistant Secretary of Defense, Health Affairs, under delegated authority from the Secretary of Defense directed the Services to establish a Research and Clinical Center for Deployment Health. The research component of the Center has been designated as a responsibility of the Naval Health Research Center (NHRC), San Diego, California.

Planning, funding, and implementing the deployed forces study recommended in the IOM report is the next logical course. No other national studies provide follow-up of active military forces that explicitly address exposures specific to operational deployments.

Future Efforts

Federal Gulf War veteran research is coordinated by the Research Working Group of the Military and Veterans Health Coordinating Board. This body also guides new research activity.^{8,73}

In 1998, considering all the completed and existing research regarding Gulf War veterans, the Research Working Group established four priorities for future research:

- Research on treatments for Gulf War veterans' illnesses
- Longitudinal follow-up of Gulf War veterans' illnesses
- Research on improved disease prevention, especially in the area of stress-related symptoms
- Research to improve environmental and occupational hazard identification and risk assessment

Various new studies have been commissioned in accordance with these priority areas.

In response to health questions following the Gulf War and the increasing demands of a series of hazardous deployments, the military health system has undergone a fundamental reorientation. A new strategy has been developed and is being implemented to protect U.S. forces against all foreseeable physical and psychological threats. This "Force Health Protection" strategy balances our key responsibilities to (1) promote and sustain health and wellness throughout each person's military service; (2) prevent acute and chronic casualties; (3) rapidly stabilize, treat, and evacuate casualties; and (4) perform medical surveillance, longitudinal health studies, and ensure adequate medical records documentation and clinical follow-up for deployed forces. The Force Health Protection strategy has played a key role in further reductions in illness and injury rates since the Gulf War.

In the report to the Committee on National Security, House of Representatives and the Armed Services Committee, U.S. Senate on *Effectiveness of Medical Research Initiatives Regarding Gulf War Illnesses*, the DoD identified the need for a coordinated capability to apply epidemiological research to determine whether deployment-related exposures are associated with postdeployment health outcomes. The proposed Millennium Cohort Study, a prospective study of U.S. military forces, responds to this need and to recent recommendations from IOM to systematically collect population-based demographic and health data on service personnel throughout their military careers and after leaving military service. IOM, in making the recommendations that initiated this study, recognized that the study will be challenging and that it will require a sustained commitment of resources by Congress, DVA, and DoD, and of time and cooperation by study participants. Nevertheless, IOM felt that these commitments are important and worthwhile if the nation is to adequately understand and respond to the health needs of not only Gulf War veterans, but veterans of future conflicts in which U.S. military forces are committed.

IOM recognized that if a prospective study had been ongoing at the time of the Gulf War, many of the problems researchers have faced in attempting to resolve Gulf War veterans' health issues

several years removed from the end of that conflict, could have been eliminated. The IOM, DoD, and DVA agreed that such efforts would contribute greatly to our understanding of the impact of military conflict on the health of the men and women who served in those conflicts. This study design will permit estimation of the distribution within the population of a broad variety of health-related measurements, including psychological measurements. The study design will also capitalize on existing and planned DoD and VA infrastructure and resources to track and measure the health of military forces and veterans.

The proposed Millennium Cohort Study is an essential component of DoD's Force Health Protection strategy. The lack of ongoing prospective longitudinal health studies was recognized as a critical shortfall in our ability to answer questions concerning illness among Gulf War veterans. The planning, funding, and development of the infrastructure to accomplish population-based prospective studies to examine the impact of military service, including deployments, on the physical and mental health of veterans has been ongoing for several years.

Million Veteran Program (MVP)

The MVP is a national, voluntary research program conducted by the Department of Veterans Affairs (VA) Office of Research and Development (ORD). A data use agreement between NHRC/MCS and VA/MVP is pending to cover the activities listed here, specifically the bi-directional sharing of contact information to determine appropriate MCS participants to contact. No research data will be sent to the MVP until these agreements are in effect.

This effort will initially be restricted to Millennium Cohort Study (MCS) participants who have separated from active duty service, but is planned to also include active duty MCS participants once appropriate high-level DoD and VA agreements are in place. Additional restrictions will apply depending on the study panel. For Panel 1 and 2 participants, only those participants who meet the following criteria will be contacted:

1. Have a good postal address.
2. Answered YES to question #114 in the 2014 MCS follow-up survey: "A great deal has been learned from this study and as a result we may be asked to consider other research possibilities. If other related research studies become available, may we contact you to let you know about them?"
3. Have not already enrolled or refused to enroll in MVP.

For Panel 3 and 4 participants, only those participants who meet the following criteria will be contacted:

1. Have a good postal address.
2. Have not answered NO to question #114 on the 2014 MCS follow-up survey.
3. Have not already enrolled or refused to enroll in MVP.

In order to determine those MCS participants who have already enrolled in MVP or refused to join MVP, MVP study staff will send to MCS encrypted social security numbers (SSNs) of those MCS participants. These data will be sent via the U. S. Army Aviation and Missile Research Development and Engineering Center (AMRDEC) Safe Access File Exchange (SAFE) site. Upon receipt of these data, MCS staff will remove these participants with matching SSNs from the list of MCS participants who have met the other eligibility criteria. These remaining eligible

participants will be sent one postal contact with information about enrolling in MVP along with the option to opt out from receiving any information. This letter includes information about PMI. Those participants who do not wish to receive information and enrollment materials from MVP will be asked to tear off the postcard on the bottom portion of the letter and return it to the Millennium Cohort Study within 30 days of receipt of the letter. After 60 days of the expected receipt of the letter, MCS study staff will generate lists of SSNs of eligible participants who did not return the postcard along with their respective current contact addresses. This list will be encrypted and sent to MVP staff via the AMRDEC SAFE site. The MVP will then send these individuals an invitation to enroll in the MVP study.

Military Significance

This study is supported by the highest officials in the DoD healthcare system. It will serve as a foundation for many future health policy decisions and as the framework for numerous follow-on studies. The information is not known to be collected in this format across DoD at this time.

Background: Family Study Component

Due to logistical reasons, the Family component of the Millennium Cohort study was separated as a standalone sub-study. Dr. Valerie Stander assumed the role of Principal Investigator for the Family component and formally submitted to the IRB the initial sub-study for review and approval by the IRB in March 2015. All regulatory approvals/requirements related to the Millennium Cohort Family study up to and through the 2014-2015 survey cycle remain under the Millennium Cohort regulatory approvals (OMB Control Number 0720 – 0029 RCS: DD-HA(AR) 2016 and SORN N06500-1). Any future regulatory approvals needed for the Millennium Cohort Family study will be submitted under the standalone sub-study.

2. Objectives

- To determine how the health of U.S. military veterans changes over time.
- a. **Primary Objective:**
 - To compare the adjusted incidence of chronic disease between cohorts.
- b. **Secondary Objectives:**
 - To compare the adjusted change in health between cohorts by Short Form-36 Questions/Veterans (SF-36V) scores.⁷⁴
 - To compare the change in health between cohorts by Patient Health Questionnaire (PHQ) score diagnostics.⁷⁵
 - To serve as the foundation for a portfolio of future studies of the impact of military service, including anthrax vaccination, on the health of members of the armed forces.

VI. EXPERIMENTAL METHODS

1. Experimental Procedures and Rationale

a. Subjects

This prospective cohort study will follow regular active duty, National Guard, and reserve military personnel.

The cohorts will be followed via serial postal surveys with on-line completion options and telephone interviews. The sample will be drawn randomly from the electronic rosters

of active-duty and reserve personnel at Defense Manpower Data Center (DMDC), California. The cohort will be selected as a probability sample, stratified for deployment vs. nondeployment, active duty vs. reserve, and male vs. female. Subjects will be contacted in four phases.

1. First Phase: 2001 Cohort (Millennium Cohort). Panel 1 members included regular active duty, National Guard, and Reserve U.S. military personnel. A probability-based sample of 256,400 active duty and reserve military personnel was randomly drawn from the electronic service member rosters at the Defense Manpower Data Center (DMDC), Seaside, California, as of October 1, 2000. Veterans who served in Southwest Asia, Bosnia, and Kosovo (after 1997) made up 18% of the military population at this time but were over-sampled such that 30% of the population was invited to participate. Females comprised 15% of the military population at this time but were over-sampled such that 24% of females were invited. The expected cohort response of 100,000 will represent approximately a 3.7% sample of the 2.7 million persons in uniform at that time.
2. Second Phase: 2004 Cohort. Panel 2 members included regular active duty, National Guard, and Reserve U.S. military personnel with 1 - 2 years of service. A probability-based sample of 150,000 service members was randomly drawn from the electronic rosters of active duty and reserve personnel as of October 1, 2003 at Defense Manpower Data Center (DMDC), Seaside, California. To achieve a higher proportion of Marines, the population was comprised of 20% Marines and 80% other service branches (Army, Navy, Air Force, and Coast Guard). Females were also over-sampled; the 80% non-Marine group was comprised of 70% males and 30% females with random distributions of all other variables.
3. Third Phase: 2007 Cohort. Panel 3 members included regular active duty, National Guard, and Reserve U.S. military personnel with 1-3 years of service. A probability-based sample of 250,000 service members was randomly drawn from the electronic rosters of active duty and reserve personnel as of October 1, 2007. To achieve a higher proportion of Marines, the population was comprised of 20% Marines and 80% other service branches (Army, Navy, Air Force, and Coast Guard). Females were also over-sampled; the 80% non-Marine group was comprised of 70% males and 30% females with random distributions of all other variables.
4. Fourth Phase: 2011 Cohort. Panel 4 members included regular active duty, National Guard, and Reserve U.S. military personnel with 2-5 (24-60 months) years of service. A probability-based sample of 250,000 service members was randomly drawn from the electronic rosters of active duty and reserve personnel as of October 1, 2010 at Defense Manpower Data Center (DMDC), Seaside, California. To achieve a higher proportion of married participants, the population was comprised of 80% male and 20% female service members. For each gender, the sample was comprised of 50% married and 50% not married with random distributions of all other variables.

These cohorts will be followed with repeat surveys at 3-year intervals through the year 2068 (8 samplings for 2001 cohort).

b. Methods

General Approach

The specific goal of the Millennium Cohort Study is to identify and prospectively follow health outcomes in future U.S. military cohorts beginning in the year 2001. The prospective methodology will permit the accurate description of the incidence and natural history of medical conditions in this population. Most importantly, the impact of future deployments will be captured and addressed by determining whether conditions brought to medical attention postdeployment represent new occurrences or predeployment health states. In this study, we intend to adapt and possibly guide the dynamic medical information systems that are currently being developed such that future investigators will not need special investigative studies to aggregate disparate data sets in determining the effects of military deployments. The data from the survey will not be weighted, and findings from all subgroups will be reported.

Outcomes

We plan to evaluate the following:

- Self-reported medical conditions (primary objective)
- SF-36V score⁷⁶—provides physical and mental health component score
- PHQ score⁷⁵—self-administered screening for mental health diagnoses
- Medical conditions classified by International Classification of Diseases, 9th Revision (ICD-9) code from inpatient and outpatient encounters
- A limited array of self-reported symptoms
- PTSD Checklist-17 (PCL-17) score – screening for PTSD
- Mortality
- CAGE questions – alcohol use
- Tobacco use

These outcomes were chosen because of their representative value as diverse core measures of health. As per IOM Committee on Measuring Health of Gulf War Veterans¹³ recommendations, these outcomes will include measures of:

- Death and duration of life
- Impairment
- Functional status
- Health perceptions
- Opportunity (the capacity for health, the ability to withstand stress, and physiological reserve)

The selection of outcomes for this study was made after numerous considerations. Of primary importance, we wanted to satisfy the IOM recommendations.¹³ However, adopting all IOM recommendations would cause the postal survey instrument to be too long and likely detract from participation. With time economy in mind, we chose an empirical target postal survey completion time of 30 min and believe, after some piloting among research staff, that we have achieved this goal. Additionally, standardized instruments (SF-36V, Patient Health Questionnaire, and PCL-17) were chosen because of their use in previous veterans studies and published data of their reliability and validity.

Assessment of Medical Conditions and Symptoms

Survey data collection will include participant's self-reported medical conditions. A survey instrument composed specifically for this study and modeled after the DVA National Health Survey of Persian Gulf War Era Veterans will provide the framework to ask participants about current and historical medical conditions, health complaints and symptoms, and approaches to self-medication and self-care. A random subsample of subjects will be chosen for validation using DoD or non-DoD medical records. The questionnaire assessment of symptoms will include a short list of items based on those reported most frequently in recent studies that have focused on the health effects of deployment, including the Seabees Study and the DVA National Health Survey of Persian Gulf War Era Veterans.

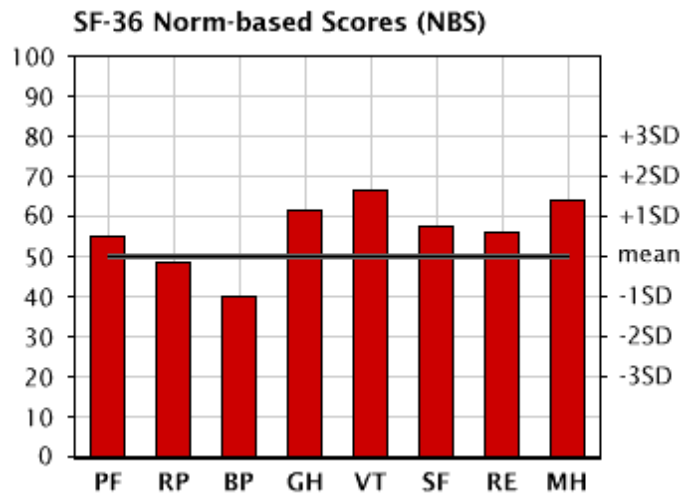
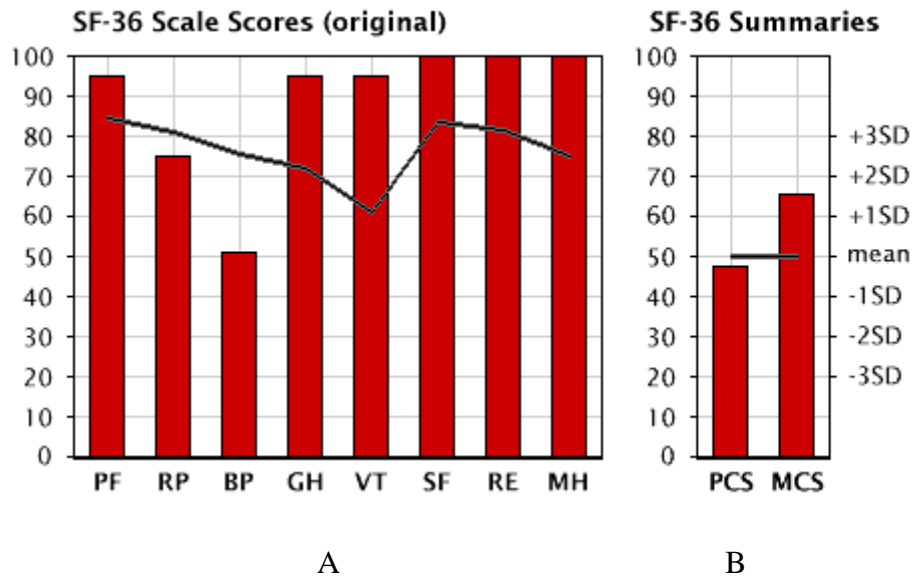
As previous federal research has shown, veterans often request disease-specific risk factor comparisons. For this reason we have made self-reported medical conditions our primary outcome from which to derive sample size needs. When it is not possible to determine in advance which medical conditions will be of most concern to veterans regarding future deployments, it seems prudent to plan for relatively infrequent conditions. Gulf War veterans have requested studies of Goldenhar syndrome,⁵⁶ lupus, amyotrophic lateral sclerosis,⁷⁷ *Mycoplasma fermentans* infections,⁶¹ and leishmaniasis infections⁷⁸ (all are infrequent conditions). Similarly, expert panel reviews of the Air Force Ranch Hand Study (Agent Orange exposed) have criticized the inability of the small cohort size to determine risk.⁷⁹ Investigators for the Women's Health Initiative have similarly targeted infrequent medical conditions.⁸⁰ Hence, we have guided sample size estimations based on relatively infrequent medical conditions.

Evaluating General Health and Functional Status

The SF-36 has been widely used in clinical and epidemiological studies to assess functional status and general health across eight dimensions. A veteran-specific instrument has been developed that differs only slightly from the original instrument in providing for a spectrum of responses to two items dealing with work or leisure-time limitations due to physical or emotional problems.^{81,82} This instrument has been used to assess functional status in over 1.5 million veterans who receive care at a VA medical facility. Therefore, a rich database exists to serve as a point of reference and comparison for the data to be collected using this instrument in the Millennium Cohort Study.

The SF-36 (and SF-36V) measures health status over eight dimensions: physical functioning (PF), role physical (RP), body pain (BP), general health (GH), vitality (VT), social function (SF), role emotional (RE) and mental health (MH). Two summary scales are generated based on the scoring in these eight dimensions: Physical Component Summary (PCS) Score, whose main elements include physical functioning, role physical, and body pain; and Mental Component Summary (MCS) Score, whose main elements include mental health, role emotional and social functioning. These dimensions are shown in the figure below, graph A. The solid line indicates the mean for the U.S. population. Scores for each dimension are standardized to a 0 to 100 point scale. For the MCS and PCS, scores are standardized to a "50-10" scale, with 50 being the mean score for the general U.S. population, and the standard deviation being a 10 unit difference (figure, graph B). Similar scoring schemes have been used for presentation and interpretation of the scores on the eight dimensions as well (figure, graph C).

Figures (www.sf-36.com)



The advantages of the SF-36V includes its measurement of health status across several dimensions, its brevity and ease of administration in both interviewer- and self-administered settings, and its ability to measure health status in ranges where changes and effects are most likely to be detected. Limitations include lack of condition specificity. It has been shown that disease-specific instruments outperform the SF-36 when the primary research focus in on a particular pathologic process (e.g., inflammatory bowel disease, coronary artery disease).^{83,84} Since no one disease entity is targeted in the Millennium Cohort Study, this limitation is not pertinent to the proposed research design. Furthermore, there is no basis in selecting one disease focus, given that no one entity seemed to occur with higher incidence as a result of military deployment in the Gulf War.

These statements apply to medical disease only. The issue of measurement of psychiatric diseases as outcomes will be covered in the following text.

The Short Form-12 Question and Short Form-12 Questions/Veterans have also been developed as even briefer measures of functional status. Although the SF-12 scores explain 85% of the various of SF-36 scores when measured in identical populations, the SF-12 output only includes the MCS and PCS, and does not provide information on the eight dimensions covered by the SF-36. Given this deficiency, and given the fact that a much greater track record exists for the SF-36V than the SF-12V in veterans, we have decided to use the SF-36V in the Millennium Cohort Study.

Other instruments exist to assess general health and quality of life. The Sickness Impact Profile contains 136 items and can be self- or interviewer-administered.⁸⁵ The characteristics that make it unsuitable for the Millennium Cohort Study are the time needed for completion, and its utility for health status measurement exists mainly in sicker individuals. The Duke Health Profile is primarily suited for health status measurement over a brief (1-week) time interval, and may therefore be less stable than the SF-36V in capturing one's usual state of health. Other instruments available through the Medical Outcomes Trust (www.outcomes-trust.org/instruments) for generic health status measurement that we considered include the London Handicap scale, which was developed mainly for persons with chronic diseases, and the Quality of Well-Being Scale, which must be interviewer-administered. For these reasons, neither seems suitable for the proposed research.

Assessment of Psychiatric Conditions

The assessment of psychiatric outcomes in a brief, self-administered format presents a particular challenge in this study. We propose that the general assessment of psychiatric comorbidity be performed using the PHQ derived from the Primary Care Evaluation of Mental Disorders (PRIME-MD) interviewer-administered instrument.^{75,86} The PHQ consists of 15-16 questions (one additional question is included for women to capture premenstrual stress and reproductive information). The following psychiatric disorders are captured by this instrument: depression, somatization, panic disorder, anxiety, alcohol abuse/dependence, binge eating disorder, and bulimia nervosa. The diagnostic properties of the PHQ compare favorably to clinician psychiatric diagnoses using the Diagnostic and Statistical Manual of Mental Disorders, 4th edition, with specificities >90% and sensitivities of 62% to 89%.⁸⁶ The PHQ requires a clinician interview for final interpretation of results. For example, to properly attribute somatization disorder to a patient on the basis of PHQ responses, the developers of this instrument recommend clinician assessment to rule out underlying organic diseases responsible for the reported symptoms. This will not be possible in the proposed study due to the large size of the cohort and the expected infrequency of chronic disorders responsible for such symptoms. The medical disease checklist that will be used in this survey will help in some degree to capture this information. A computerized coding algorithm will be used to perform batch analyses of completed PHQ instruments.

Due to the high incidence of PTSD following traumatic events of the type experienced during military service and deployment, we will use an instrument to specifically assess the presence or absence of this outcome. We have chosen the PCL-17, since it can be

self-administered in a brief period of time.⁸⁷ It consists of 17 items, and has been validated extensively in male Vietnam veterans and small samples of trauma-exposed women.⁸⁸

Assessment of Physical Conditions

Those military personnel who deploy and sustain an injury and are in both the Millennium Cohort Study and Joint Theater Trauma Registry (JTTR) will be looked at over the long term in order to better understand the effects of combat injuries on psychological and functional health outcomes. The JTTR provides data in detail about wounds received and the medical care provided from combat support hospitals, aboard ships and aircraft, and throughout the course of their treatment.

Morbidity Tracking

Self-reported morbidity data may be validated by a variety of methods. While receiving care in DoD medical treatment facilities, veteran healthcare data, including diagnoses, may be obtained from the Standard Ambulatory Data Record (SADR) and Standard Inpatient Data Record (SIDR) inpatient and outpatient billing data. Similarly, various DVA databases will be examined for DVA healthcare utilization. These electronic records archive diagnoses in the ICD-9 format.

Questionnaire Development

Teleform scanned mark-sense questionnaires will be used. This method has been shown to greatly reduce data entry error. To maximize data quality, study instruments will be evaluated by multiple focus groups and via a pilot survey of 1,000 respondents (2,564 surveyed). We plan to run the pilot test as if it were the actual study.

Address Finding

One of the most difficult challenges in studying military populations is gaining accurate addresses. Numerous Gulf War veteran surveys have shown that once found, veterans willingly participate in mail and telephone surveys.^{13,44,48,91} Fortunately, for cohorts who remain affiliated with the military, address finding is much simpler than attempts at finding the addresses of separated veterans. Investigators have access to Defense Enrollment Eligibility Reporting (DEERS) which has recently been found to be 93% accurate in address recording. Hence, we hope to experience better address finding than the 65% we found in the Seabee Health Study among non-Gulf War veteran Seabees (60% participated). With a goal of studying 1,000 subjects in the pilot study and 100,000 subjects in the actual Millennium Cohort Study, and conservatively estimating 65% good addresses and 60% responses among those we find, we derived the following number of necessary initial postcard mailings:

Desired respondents: $X(0.65)(0.60)$

Pilot study (1,000 respondents desired): $X=2564$

The Millennium Cohort Study (100,000 respondents desired): $X=256,400$ (Appendix L)

Deployed service personnel will be oversampled to comprise 30% of the study population. This will result in an oversampling of deployed reservists, women, and deployed women reservists. Nondeployed service personnel will comprise 70% of the study population. Women will be oversampled in this strata to consist of 30% of the nondeployed, and reservists will be oversampled to consist of 50% of the nondeployed.

Maximizing Participation

Another difficult aspect of this type of study is gaining and maintaining sufficient participation. We plan to follow standard techniques^{92,93} of gaining high participation percentages: presurvey introductory postcard mailing, cover letter with survey, postcard reminders, and three repeat survey mailings (Appendix H). We will mail the subjects a preliminary postcard to alert them to the forthcoming survey. This will also allow us to gather address information inexpensively for subjects who have changed addresses after our data extraction. The questionnaire will next be sent by first-class U.S. mail, with a cover letter describing the study, and a consent form. The investigators will employ a commercial address tracking company to locate subjects with inaccurate addresses. One month after the initial mailing, a postcard reminder will be sent. Two months after the first survey mailing, a second survey with a cover letter will be mailed, and this will again be followed with another reminder postcard 1 month later. Four months after the second questionnaire mailing, a final questionnaire with cover a letter will be mailed, and this mailing will again be followed with a third postcard reminder. After three survey mailings, a tracking service and additional data updates will be used to find correct addresses for undelivered mail. Previous research at NHRC has shown that the use of minor incentives (such as photographs, military pencils, and phone cards) may be helpful in increasing participation rates. We plan to use such incentives. DSN and regular-line phone numbers will be given to permit veterans to gain answers to questions regarding the study. A web site has been established at <http://www.MillenniumCohort.org> to keep study participants informed and to facilitate address changes. The paper form of the survey will be mailed to the subject's home to be filled out there at his or her convenience.

All items mailed to the subject will be identified by bar codes, which will contain embedded Subject Identification Numbers (SID), mailing numbers, and item codes. The SID is randomly generated and unique to each participant. It is assigned and attached to each record that is obtained from DoD health and administrative files upon receipt at NHRC. From all the files that come to NHRC, two databases will be created for study use. The first database will contain participant data such as name, current address, address history, last 4-digits of the social security number, and SID. This database will be the source of names and addresses when the questionnaire is mailed out and will be used for tracking purposes. The questionnaire will have the SID bar coded onto it when it is mailed to the participant and scanned for identification purposes once returned. The second database will contain participant questionnaire responses along with corresponding information linked by SID from administrative and medical files. This procedure will separate individual identifiers from participant data, while making it possible to pair names and addresses with SIDs for update and tracking purposes. Once all the files (survey response, medical, and administrative) have been matched by SID, the SID will be stripped from this database at the end of all data collection. A list pairing the SID with the last 4-digits of the social security number will be created and stored by the Principal Investigator in a locked file cabinet.

Outgoing envelopes will be hand-scanned when returned by the United States Postal Service as undeliverable due to bad address and this will identify subjects having invalid addresses. Business reply envelopes (BRE) will also be identified with a bar code. When scanned, the BRE bar code will identify the subject as a tentative respondent. A

final bar code will appear on the questionnaire itself. This bar code, when hand-scanned during data review, will identify the subject as a true respondent if the questionnaire has been filled out substantially complete, and will delete him/her from the next mailing list. The questionnaire bar code will also be read into the data file created by the questionnaire scanner so as to eliminate the need for hand entry of subject ID numbers into data records.

As noted above, a subject is presumed to have received a questionnaire if the postal service does not return it as undeliverable. Some subjects presumed to have received the survey instrument will return the questionnaire uncompleted. Under these circumstances, we will continue to send surveys to them until one of the following occurs: (a) we receive a completed survey from them; (b) they explicitly decline to participate; or (c) they do not respond after three questionnaires have reached them successfully.

Further, plans have been established to make the questionnaire available on the Internet at the above mentioned web site. The electronic form of the questionnaire will be accessible from any PC with an Internet connection. Subjects who so choose will be able to complete the questionnaire electronically and send an encrypted copy of their completed survey to NHRC over Secure Sockets Layer (SSL) data transmission lines. Participants will take the survey in much the same manner as the hard copy. On-line participants will go to the web site where they will be able to read background information and preview the survey. Electronic versions of the introduction and endorsement letters will be available for review. The participant will select from the menu to complete the questionnaire on-line. Then the participants will be prompted to enter their unique, encrypted SID (as described above) from the postal correspondence and the last four digits of their social security number. Only valid entries will be allowed to participate in the study. Valid entries will then proceed to the informed consent document automatically. The informed consent document will be exactly the same in content as the hard-copy version. The only difference will lie in the acknowledgment of consent. The electronic version of informed consent will have a "YES, I AGREE" box and "NO, I DO NOT AGREE" box that the participant may check to show whether or not they understand the purpose and risks of their participation and still wish to participate in the study. Participants who check "NO" will be thanked and then returned to the study home page. Participants who check "YES" will be asked to again enter their study ID number and last four digits of their social security number that is then encrypted and will serve as their "digital signature." Each encrypted digital signature is solitary and unique to every study participant and confirms that the consent came from only that individual. This signature would be confirmed by the system as valid before acceptance of the agreement. The use of digital signatures has been established as accepted procedure in lieu of physical signatures for Internet commerce for the past few years.^{100,101}

There are no firmly established procedures for on-line informed consent as of yet for the field of human subjects research.¹⁰² A report sponsored by the American Association for the Advancement of Science was released in November, 1999, focused on human subject research on the Internet.¹⁰³ 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 still be met in on-line informed

consent documents. The informed consent document to be used for the Millennium Cohort Study will meet those principles, outlining risks for both on-line and hardcopy completion. Further, in terms of the physical signature issue, a main concern for on-line consent deals with the validity of the consent in terms of the researcher not knowing the “age, competency, or comprehension”¹⁰³ of the participant. The Millennium Cohort Study does not have those concerns since the study population will be drawn from a known source, rather than soliciting unknown respondents. Additionally, the 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.

Plans to create an organization page on the Facebook platform as well as a Millennium Cohort Study Facebook application is underway. Participants will be sent an email with a link to be able to "Like" the Millennium Cohort Organization page. The link to our Facebook page may also be included on our webpage and in some of the study materials sent as part of the routine mailings (these will be submitted prior to mailing). Millennium Cohort Study administrators will post links on the Facebook page about recent study findings and provide updates on survey cycles. We will restrict posting on the Facebook page to only authorized users, in this case it would be the Millennium Cohort Study team. The linkage will only be used to send information about the survey and its findings to individuals who “Like” the Millennium Cohort Organization page; no collection of information about the individuals “liking” Millennium Cohort will be accessed, collected, or maintained.

- Individuals “liking” the Millennium Cohort Organization page will be reminded that they can “Edit Privacy” on each site they like to limit those who can see their “likes.”

The communications described above will also include a link for those interested in the Facebook application. To use the application, the participant must provide consent after reading a disclosure statement (a standard feature for getting an app on Facebook). Authorized users (i.e., Millennium Cohort investigators) can control the information shown in the application, and therefore we can ensure privacy in the application itself by never exposing personal information/details of individual members. Similar to ‘liking’ the Millennium Cohort Facebook Page, visibility of a specific user as having added the Millennium Cohort application is based on their privacy settings. This information is generally not available to the public unless the user allows for it.

The Facebook application will be hosted at the same secure co-location center as the Millennium Cohort web surveys. The application will be used to send participants study information. We will not collect any data from their profile. The Facebook page and application are voluntary features and a person can cancel their consent or involvement with the Facebook site at any time. When a user removes the app from their profile, we are sent a de-authentication notice and at that time we can remove their data from our server (the user ID and information is no longer given to the application). Both the application and organization page are still under development, but a few screen shots are enclosed for review. Screen shots of both items in their entirety will be sent for IRB review once constructed.

The Millennium Cohort Study, received approval to call those participants who completed the paper survey, but failed to sign the informed consent form in the survey

document. These phone calls will be the last contact attempt during the cycle in attempt to have the subject provide consent, and hence for the study team to utilize their survey data. Approximately 460 participants will be called. Those who did not sign the consent and who did not complete at least 75% of the survey will not be contacted rather they will simply be excluded from the study.

Subjects will be contacted via telephone Monday through Friday between the hours of 8 am to 8 pm within their time zone, and/or Saturday between 10 am to 6 pm in their time zone. No calls will be made on Sundays. A maximum of 5 phone call attempts will be made per subject and a log of every attempt will be kept. Staff making phone calls will not leave a voice message on the first four attempts and only then would leave a message on the fifth attempt. A verbal “yes” or “no” reply will be accepted as the subject’s consent and documented by caller who will be a member of the study team. If the subject responds with a “no”, they will no longer be contacted and their survey data will not be utilized. Calls will end once the 5 call limit occurs or we are able to reach the participant in person, whichever occurs first. All participants who agree to consent to the study will be offered a copy of the consent form which will be mailed to them.

A log of all of the phone calls will also be kept. A copy of the log is also submitted for review.

The script for the phone calls is as follows:

Hi (interviewee name):

My name is (caller name), and I am calling from the Naval Health Research Center. We appreciate the time you spent completing our survey on (Date) for the Millennium Cohort Study which is being conducted by the Department of Defense.

When we reviewed your survey, we noticed that you did not sign the consent form on the 2nd page of the survey. In order to use your data for our study, we would need to have your consent to participate in the study. Will you give your consent for participation?

If the subject responds yes:

Thank you. We will document your response. We know your time is valuable and we thank you for helping with this important project. We would be happy to send you a copy of the study’s consent to your home address? Would you like a copy? If yes, (confirm address).

If the subject responds no:

Thank you. We will document your response. Unfortunately, we will not be able to use the information you gave us in the survey you completed. Thank you for your time.

Sampling Non-respondents

Computer-assisted telephone interview (CATI) techniques will be used to reach a 3% sample of nonrespondents. CATI survey work will be performed via contract with survey consultants. A similar procedure will be employed to obtain reliability estimates from respondents.

Reliability Evaluation

We plan to resample 5% of the respondents in the first wave with a briefer study instrument to evaluate questionnaire reliability. This will likely occur in the third mailing.

Bias and External Validity

The evaluation of response bias is a key component to assessing the validity of a prospective study. For example, those who consent to participate in a long-term prospective study may be more motivated to do so if they have more health concerns than those who do not. Alternatively, those with serious health problems may not participate because they are too ill to do so. In either case, this may result in the participant population not well representing the target population.

Service members decline to participate in one of two ways: they either ignore all invitations, or they submit a response that clearly shows they decline the invitation for enrollment. All such cases are considered non-participants, and none of these receive further invitations or contact.

Analysis of response bias, however, requires accessing existing information on healthcare utilization among both participants and non-participants. Existing data sources include, but are not limited to, demographic files from the Defense Manpower Data Center, and healthcare utilization data from the Tricare, Executive Information and Decision Support Program, Management Analysis and Reporting Tool (M2).

In assessing existing DoD data on non-participants, as well as participants, extreme care is taken to protect personal identifying information. Such data are used for linking purposes only. After linking, only de-identified demographic, administrative, and medical data for non-responders and decliners will be maintained to explore potential differences between survey participants and non-participants.

Supplemental Medical and Administrative Data

- NHRC manages or has access to numerous established military data sets. Information from these data sources can be used to supplement the survey instruments and enhance the ability to track study outcomes. Data linkage for the Millennium and Family Cohort will be linked to Department of Defense personnel and medical records obtained from the following sources: DMDC (Data Manpower Data Center) and Defense Health Administration. For mortality data, we submit requests to Armed Forces Medical Examiner System (AFMES), Armed Forces Health Surveillance Center (AFHSC), JPC (Joint Pathology Center), NDI (National Death Index), Defense Suicide Prevention Office (DSPO), DMDC and VA (US Department of Veterans Affairs). In addition, if the spouse is an active duty member and retires or separates from military service and utilizes Department of Veterans Affairs for medical services, we will link to VA medical and personnel data as well as the DoD Joint Theater Trauma Registry and the Navy/Marine Corps Trauma Registry. These data will complement subjective measures with objective measures of exposures and health outcomes. These databases are accessed electronically through secure computers located at the Naval Health Research Center. Unique identifiers are used

to link each participant with their electronic data; however, in some cases name and SSN will be provided. All data upon receipt will be confidentially maintained on-site in our secure computer database. No data regarding a child and his/her health will be linked from any source for the purposes of this study. Appropriate agreements/approvals will be in place prior to any data sharing for any linkages. Additionally the following sources are available:

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)-CHAMPUS contains one record for each claim voucher for care by a civilian provider. Care is rendered to dependents of the military, and retirees and their dependents who are not Medicare eligible. These files contain historical data from December 1979.

Defense Enrollment Eligibility Reporting (DEERS)-DEERS is the central source for personnel information from the DoD personnel community. This database is used to determine medical benefits eligibility, insurance, immunizations, and patient information. This data set is thought to be 93% accurate for the addresses of military personnel, and the accuracy continues to improve.

Defense Outplacement Referral System (DORS)-DORS is a national resume and referral network established to help separating DoD personnel transition into civilian life. DORS provides private and public sector employers with immediate access to resumes from transitioning service members and federal civilian employees.

DoD Birth Defects Registry-Beginning in January 1999, a DoD Birth Defect Registry was established at NHRC. The registry uses a hybrid system of intensive active surveillance among the largest military population in the United States (Naval Medical Center San Diego) and passive surveillance via electronic hospitalization databases for the rest of the DoD dependents.

Health Enrollment Assessment Review (HEAR)-HEAR was created to assist providers and managers in identifying individuals and groups of individuals in their panel who require proactive interventions. Soon to be routinely administered to all active-duty personnel, HEAR identifies patients whose clinical preventive services are not current or have never been performed. Additionally, HEAR describes a patient's risk factors, his or her chronic medical conditions, and whether the enrollee falls into the high resource utilization category.

Master Crosswalk File-This file provides "crosswalks" between military occupational codes of the four military services and the Coast Guard and their civilian counterparts as defined by the standard occupational classification codes, occupational employment statistics codes, census codes, Office of Personnel Management codes, and classification of instructional programs codes.

Military Operation Rosters-As DoD deploys large groups of military personnel for sustained time periods, participants are recorded by the various services and compiled in databases at DMDC. Such military operation databases are now available for the Gulf War, Bosnia, and Kosovo. The latter two operations continue to document new participants.

Recruit Assessment Program (RAP)-This electronic database is in pilot testing. RAP will represent a collection of baseline demographic, medical, psychological, occupational, and risk factor data from all U.S. military personnel at the time of their entry into military service.

Pre and Post-Deployment Health Assessments (DD2795 and DD2796) - Health assessments prior to and following deployments are forwarded to the Army Medical Surveillance Activity (AMSA) where they are scanned and entered into the Defense Medical Surveillance System (DMSS). Information regarding health status, health perceptions, mental health screening and potential environmental exposures are captured by these health assessments as well as relevant medical referrals and dispositions before and after deployment.

Department of Defense Trauma Registry (DoDTR) U.S. Army Institute of Surgical Research - The DoDTR captures details about wounds received and the medical care provided from combat support hospitals, aboard ships and aircraft, and throughout the course of their treatment, as well as the results.

Theatre Medical Data Store (TMDS). TMDS provides healthcare encounter data, lab data, procedure data, and pharmacy data delivered at any military treatment facility, including the first echelons of care at deployed locations,

Army Center for Substance Abuse Programs' (ACSAP) Drug and Alcohol Management Information System (DAMIS). The ACSAP and DAMIS will allow us to capture individual data on drug test positivity among participants who screened positive during their service time.

Global Assessment Tool (GAT). The GAT is a confidential self-assessment tool that includes information on Soldiers well-being, resilience, and their overall health. GAT data is stored in the PDE, a virtual secure platform designed for integrating data, linking commands for analysis, and conducting studies/projects. This repository is an ever-evolving cloud-based, virtual technology that provides strong protections of human subjects via encoded and de-identified data.

Family Advocacy Program (FAP). We would like to request permission to obtain selected variables regarding military assessment and treatment provision, as well as other medical care referral from the Department of Defense and Service specific Family Advocacy Program (FAP) Central Registry Databases. The Family Advocacy program provides various treatment and support services for perpetrators and victims, and makes referrals for additional care where needed. Within the DON, the Family Advocacy Program services are provided as part of the Fleet and Family Counseling Support Centers. We would request the specified variables for all incidents involving Millennium Cohort Study research participants, with recurring data extracts to be completed annually or triannually.

Permission to receive these data will be obtained from DoD and the Service specific FAP offices, as well as from the Defense Manpower Data Center (DMDC) which maintains the DoD-level repository for cases meeting full criteria as family violence incidents. We currently have a Memorandum of Understanding (MOU) in place with DMDC and an existing approved data request for FAP data for Millennium Cohort

Family Study participants. The existing DMDC request has been updated to include all Millennium Cohort participants (see attached); and once IRB approval has been received, NHRC will provide a list of the SSNs for Millennium Cohort Study participants to DMDC. DMDC will then provide NHRC with all matching records in the DoD Central Registry for those SSNs. Separate data use agreements will be established with the Service specific FAP offices in order to obtain additional information regarding suspected incidents meeting partial criteria. Similar procedures will be used for data matching with Service specific registries, and all data transfers will be made using encrypted files either using the Army's AMRDEC Safe Site or a secure data transfer site supported by DMDC.

The requested variables include the following personnel and treatment information for Service members in the Millennium Cohort Study with substantiated cases of intimate partner violence victimization or intimate partner/child abuse offending:

Name

Social Security Number

Incident report date

Legal event context code (emotional maltreatment, neglect, physical abuse, sexual abuse)

Person Association reason code (only codes AA = spouse, AD=parent, BH=former spouse, BE=intimate partner, CC=relationship unknown)

Victim maltreatment severity level (mild, moderate, severe)

Clinical intervention program provided to Family Study participant as a victim (FAP, Other DoD, Other Non-DoD, None, missing)

Clinical intervention program provided to Family Study participant as an offender (FAP, Other DoD, Other Non-DoD, None, missing)

In addition, the DVA has agreed to collaborate regarding mortality studies using its previous mortality study approach.^{89,90} The following databases are available for use through the DVA:

Beneficiary Identification and Records Locator System (BIRLS)–BIRLS provides the social security number and the state in which death occurred for all veterans whose survivors apply for a death benefit. This database is updated quarterly and contains 8.32 million records that are in SAS file format.

National Patient Care Database (NPCD)–NPCD combines several DVA databases, including Patient Treatment File (PTF) and Outpatient Clinic File (OPC). NPCD is currently under development.

National VA Enrollment File–This database consists of veterans eligible for care and is currently under development.

Outpatient Clinic File–OPC provides information regarding principal diagnosis and location of all VA-provided episodes of outpatient care. The database contains over 20 million records per year with weekly updates.

Patient Treatment File– PTF contains up to 10 discharge diagnoses and 5 procedure codes for all VA-provided hospital care. PTF is updated weekly.

Veterans Information Systems Technology Architecture (VISTA)—This is a comprehensive clinical and administrative database that contains laboratory, radiology, and pharmacy data. Access to VISTA is usually made through individual DVA medical centers.

Statistical Analysis

Comparing the adjusted probabilities of new onset chronic disease between cohorts will be conducted by examining self-reported data, and by validating these data with electronic data systems (SIDR and SADR) when possible. One difficulty in study design is determining which chronic disease outcomes to select for sample size estimation. For purposes of this example, we have selected outcomes that we would generally expect a survey respondent to accurately report, most of which are drawn from the DVA's National Health Survey of Persian Gulf War Era Veterans: all-cause hospitalization, hypertension, diabetes, stroke, myocardial infarction, renal failure, and asthma. These outcomes should be relatively rare for the generally young and healthy military population that we will target in the future study years.

Covariate adjustment will include age, gender, occupation, marital status, race, ethnicity, deployment status, branch of service, income, and length of service. Multivariable Cox proportional hazard modeling will be used for each outcome. SAS statistical analysis program software (SAS Institute, Inc., Cary, NC) will be used.

Interpretation of Results

Study work will be guided by a Scientific Steering and Advisory Committee. This Committee will be composed of 5 distinguished external researchers and 3 representatives from veterans service organizations. This group first met June 22-23, 2000, in San Diego to finalize study design. The group will continue to review study design, progress, and data analyses and serve to frequently advise investigators. We expect to conduct Committee meetings approximately twice a year.

All research work will be reviewed and approved by the NHRC's Committee for the Protection of Human Subjects (CPHS). Investigators will report study results to various policy groups including:

Research Working Group-In conjunction with other deployment health research, the Research Working Group will receive annual progress updates and review study progress in light of other federally sponsored veteran research. The Research Working Group update will be included in the annual report to Congress.

U.S. Army Medical Research Acquisition Activity Annual Peer Review-This annual review is generally conducted by the American Institute of Biological Sciences (AIBS). Several AIBS scientists are invited to review deployment health research programs.

Missing Data/Attrition

We have identified subject matter experts from the Institute for Measurement, Methodology, Analysis and Policy (IMMAP) at Texas Tech University to assist us in meeting the OMB requirement to provide an approach to handle missing data and

adjustments for selective attrition. Faculty and scientific staff of IMMAP will be provided with raw numbers which have no identifiers. There will be no need for the researchers to have access to the key that identifies the data. A subcontract between NHRC/Henry Jackson Foundation and Texas Tech will be in place before any data analysis is performed. The Naval Health Research Center's IRB will serve as the primary IRB.

Methodology of Family Component:

2. Sample Size Determination

We estimated the necessary study sample sizes by knowing the estimated incidence for our healthy young population and using the following equation⁹⁴:

Formula 1:
$$N = \frac{\{Z_{\alpha}\sqrt{P(1-P)} (1/q_1+1/q_2) + Z_{\beta}\sqrt{P1 (1-P1) (1/q_1) +P2 (1-P2) (1/q_2)}\}^2}{(P1-P2)^2}$$

- Where
- P1 = rate of outcome of interest in exposed group
 - P2 = rate of these outcomes in nonexposed group
 - N= estimated minimum sample size required
 - Z_α = standardized normal deviate for a two-tailed probability of an α-error
 - Z_β = standardized normal deviate for a two-tailed probability of a β-error
 - q₁ = proportion of sample population in group 1
 - q₂ = proportion of sample population in group 2
 - P = q₁P1+ q₂P2

The level of acceptable alpha error was set at ≤0.05, and beta error at 0.20 (statistical power at ≥0.80). The statistical power of this study depends on the incidence of the conditions of interest in the comparison groups. Estimates of incidence of hospitalization in the active-duty military population for the chronic diseases were calculated by scanning for the specific disease in fiscal year 1995 hospitalization data. These data were output and match-merged by social security number to any hospitalization with that specific disease for fiscal years 1989 to 1994. If a match occurred, that record was dropped, resulting in only new diagnoses of the specific disease. The minimum sample sizes required to detect a significant difference for the overall hospitalization incidence and incidence of specific chronic diseases over a 3-year and over a 6-year period are calculated in Tables 1 and 2 respectively. Included are various relative risks for power equal to 0.80 and 0.90.

Table 1. Sample Size Necessary at Different Levels of Statistical Power to Detect a Difference of Given Magnitude in Incidence (as Reflected by Relative Risk) Over Three Years. Population Numbers

Reflect Total of Two Equal Cohort Sizes.

Outcome (ICD-9 Codes)	Incidence Rate	Relative Risk	80% Power	90% Power
Any cause hospitalization	0.222	1.2	2,934	3,927
		1.5	508	679
		2.0	139	185
Hypertension (401-404)	0.0035	1.2	245,449	328,650
		1.5	44,602	59,720
		2.0	13,367	17,897
Diabetes (250)	0.0016	1.2	538,049	720,436
		1.5	97,802	130,953
		2.0	29,327	39,267
Stroke (436)	0.0001	1.2	8,623,049	11,546,086
		1.5	1,567,802	2,099,253
		2.0	470,327	629,757
Myocardial infarction (410)	0.0005	1.2	1,723,849	2,308,198
		1.5	313,402	419,637
		2.0	94,007	125,873
Renal failure (584)	0.0001	1.2	8,623,049	11,546,086
		1.5	1,567,802	2,099,253
		2.0	470,327	629,757
Asthma (743)	0.0004	1.2	2,155,049	2,885,566
		1.5	391,802	524,613
		2.0	117,527	157,365

In addition to hospitalization data from DoD facilities, we searched the medical literature to obtain reasonable incidence rates of these medical conditions to confirm or refute our hospitalization-based estimates. We found, as expected, for most conditions that data from population-based studies yielded higher incidence rates for conditions that do not usually require hospitalization for diagnosis and treatment. This means that the sample size calculations that we have presented are likely to represent conservative estimates, and that smaller effect sizes (i.e., relative risks) will be detectable with 80% power than are shown in Tables 1 and 2.

Hypertension incidence in middle-aged men in the Atherosclerosis Risk in Communities Study was estimated at 0.172 over a 6-year follow-up period, for an annual incidence of 0.032.⁹⁵ A similar estimate of hypertension incidence comes from an additional study of middle-aged normotensive subjects (mean age 44 years) followed over a 7-year period (cumulative incidence 0.255, annual incidence 0.042).^{96,97} These estimates are considerably smaller than the cumulative incidence estimate of 0.0035 over 3 years (or approximately 0.0012 annually) used in the sample size calculations. The same is true for asthma, with an annual incidence reported in the literature of 0.001, compared with the 3-year cumulative incidence of 0.0004 (or 0.00013 annually) based on DoD hospitalization data, and diabetes mellitus (0.0016 per 3 years based on hospitalization data or 0.0005 annually, compared to an annual incidence of 0.0018 in the U.S. in the 25-44 year age category based on data from the 1990-92 National Health and Nutrition Examination Survey (<http://diabetes-in-america.s-3.com/contents.htm> - Chapter 4).

Yearly incidence of stroke based on U.S. national data was 0.00017 for persons ages 24-34 year old and 0.00045 for 35-44 years. Both of these estimates exceed that of 0.0001 per 3 years based on hospitalization data used in the power calculations. Sparse data exist on myocardial infarction incidence in younger subjects. In one British study, this outcome occurred in 0.00029 men aged 49 years or younger, and 0.00004 women annually in this same age range.⁹⁸ These estimates exceed the 0.0005 per 3-year incidence obtained from hospitalization data (0.00017 annually) for men but do not exceed the incidence for younger women reported in the literature. Yearly incidence for end stage renal disease incidence estimates that come from the U.S. Renal Data System for subjects ages 25-44 years, where new cases occurred in 1999 at an incidence of 0.0001 (http://www.usrds.org/1999_adr.htm - Chapter 2). This rate also exceeds the hospital-based rate of 0.0001 over 3 years.

Table 2. Sample Size Necessary at Different Levels of Statistical Power to Detect a Difference of Given Magnitude in Incidence (as Reflected by Relative Risk) Over 6 Years. Population Numbers Reflect Total of Two Equal Cohort Sizes.

Outcome (ICD-9 Codes)	Incidence Rate	Relative Risk	80% Power	90% Power
Any cause	0.444	1.2	991	1,326
		1.5	155	206
		2.0	33	43
Hypertension (401-404)	0.0070	1.2	122,249	163,688
		1.5	22,202	29,727
		2.0	6,647	8,899
Diabetes (250)	0.0032	1.2	268,549	359,581
		1.5	48,802	65,343
		2.0	14,627	19,584
Stroke (436)	0.0002	1.2	4,311,049	5,772,406
		1.5	783,802	1,049,493
		2.0	235,127	314,829
Myocardial infarction (410)	0.0011	1.2	783,049	1,048,486
		1.5	142,347	190,599
		2.0	42,691	57,161
Renal failure (584)	0.0002	1.2	4,311,049	5,772,406
		1.5	783,802	1,049,493
		2.0	235,127	314,829
Asthma (743)	0.0009	1.2	957,271	1,281,766
		1.5	174,024	233,013
		2.0	52,194	69,885

Another objective is to compare the age- and gender-adjusted change in health between cohorts by SF-36V scores. The SF-36V has a Physical Component Summary Scale (PCS) and a Mental Component Summary (MCS) Scale. SF-36V data from healthy military populations are not available. However, Ware et al.⁹⁹ have reported that among adults with chronic disease, approximately 20% will have more than a 5.43-point increase in the PCS scores one year from baseline. Changes in scores among a healthy population should be much smaller. If we assume, as have previous DVA Gulf War study planners, that a 7-point change in PCS score is a significant change and further assume that on average between 5% and 10% of subjects will report such a 7-point increase (health decline) after 3 years, we can then use this 5-10% as the

estimated incidence of a new condition. Table 3 demonstrates the necessary total sample size (using equal groups) to detect a small effect size difference of between 5-20%.

In a similar fashion, if we compare the difference in incidence of psychiatric diagnoses between cohorts by the Patient Health Questionnaire and further estimate that the incidence of the 18 different mental health conditions detected by the Patient Health Questionnaire ranges from 0.01 to 0.10 every 3 years, we can infer from Tables 1-3 that we should be able to detect small risk differences between cohorts.

Table 3. Sample Size Necessary to Detect Differences Between Cohorts at Different Levels of Statistical Power With an Expected 5% or 10% Incidence Over 3 Years (2-Tailed)

Expected Incidence	Effect size to detect	Power			
		.80	.85	.90	.95
.05	5%	243,877	279,944	326,505	404,180
	10%	62,350	71,566	83,464	103,311
	15%	28,322	32,507	37,909	46,919
	20%	16,274	18,677	21,779	26,954
.10	5%	115,301	132,344	154,345	191,046
	10%	29,422	33,766	39,374	48,728
	15%	13,339	15,307	17,846	22,082
	20%	7,650	8,777	10,232	12,658

From our previous studies, we can estimate that among the 2.7 million U.S. servicepersons serving on January 1, 2001, less than 20,000 (<0.7%) will have served in the Gulf War, 185,703 (6.9%) will have served in Southwest Asia (since August 1991), 86,263 (3.2%) will have served in the Bosnia conflict (since December 1995), and 18% will have served in more than one conflict. Approximately 15% of the force will be women. These data will be used in planning the stratified, probability-based sampling.

In selecting the deployed and nondeployed groups for the Millennium Cohort Study, we will avoid selecting servicepersons who have been deployed to the Gulf War, or who have been deployed to Southwest Asia, Bosnia, or Kosovo prior to September 1997.

The study group sizes are:

Southwest Asia, Bosnia, Kosovo Veterans-30,000

Millennium Cohort-70,000

From our previous experience, we found good addresses for about 65% of Gulf War veterans potential subjects and among those we reached approximately 65% agreed to participate in our postal surveys.

With this percentage in mind, we will send the initial preliminary postcard mailing to 256,400 subjects with the goal of gaining the 100,000 respondents.

In summary, the large sample size and follow-up for up to 20 years should assure excellent power to detect small effects on health outcomes occurring with a frequency similar to that of many important chronic diseases. Using the cohort sizes of 50,000 will give us considerable power to detect small differences in risk for chronic diseases, such as hypertension, diabetes, myocardial infarction, and asthma during the first 9 years of observation. Less common disease risks will take longer.

A large sample size is fundamental to the successful detection of disease-exposure relationships in a timely fashion such that preventive measures may be taken to reduce risk for future deployments. It is difficult to predict which diseases will merit study for possible associations with future deployments. Some may be too rare to study, but it seems prudent to have a significant sample size to evaluate most common chronic diseases.

3. Justification for Exclusion of Specific Groups

Other than the selection exclusion criteria mentioned previously, no specific groups will be excluded.

4. Required Equipment and Supplies

Supplies needed for this protocol will include postage for the introductory postcard, three first-class mailings, address correction, and business reply returns. A mail contractor will coordinate the mailings. Office supplies will include NHRC letterhead, envelopes, and business reply envelopes. Questionnaire printing and optical scanning as well as a professional address tracking service will be used. One new microcomputer will be used. An additional license copy for the SAS statistical analysis program software will be obtained. Finally, several four-drawer lockable, lateral filing cabinets will be obtained to organize proper filing of project documents in a secure environment.

VII. ORGANIZATION OF RESEARCH EFFORT

1. Duties and Responsibilities

Rudolph Rull, PhD, will serve as a Principal Investigator for this study. He will be responsible to NHRC's IRB, and to the various external review bodies for the financial accounting and scientific merit of the study. He will also be responsible for ensuring that all NHRC personnel involved with this protocol are properly trained and qualified.

Edward Boyko, MD, MPH, will serve as the senior VA investigator in this project. He has extensive experience conducting epidemiological studies of chronic disease among veteran populations and will lend much knowledge to investigators in selecting and interpreting survey instruments. It is likely that he will pursue follow-on clinical studies based on foundation data collected from survey instruments. He will coordinate other VA collaborative studies using study data and share in data analysis and interpretation.

Gary Gackstetter, DVM, MPH, PhD, will serve as a study investigator, an expert epidemiological consultant, and the senior Uniformed Services University of the Health Sciences (USUHS) liaison. Dr. Gackstetter is the Director of Graduate Programs at USUHS and teaches epidemiological methodology and infectious disease epidemiology to masters and doctoral level

graduate students, as well as medical students. He has extensive experience as a senior health policy analyst and research scientist investigating health outcomes in military and veteran populations.

Tomoko Hooper, MD, MPH, of the USUHS, will serve as an investigator for this study. She will assist in study design, coordination of USUHS Institutional Review Board review and facilitate Millennium Cohort Study promotion as a potential source of USUHS graduate student projects.

Valerie Stander, PhD, will be located at the Naval Health Research Center and serve as co-investigator. She has considerable experience conducting epidemiological studies among military populations. She will plan epidemiologic studies and designing the study methodology; performing statistical analyses for diverse research projects with complex study designs; working with team members to derive an in-depth understanding of the data findings; drafting proposals and writing peer-reviewed publications.

Denise Lovec-Jenkins will serve will serve as key support staff as the Regulatory Affairs Manager. She will prepare IRB submission and other research activities to ensure compliance with relevant federal and local regulations and policies of research for this protocol.

Beverly Sheppard will serve as key support staff as Study Coordinator. Her duties will include assisting in program design and maintenance of survey instruments alongside research team, as well as assisting with writing peer-reviewed publications; assisting in the development of strategies to maintain study participant retention, including the utilization of newsletters, mailers, and other incentives.

Jennifer Walstrom will serve as key support staff as Assistant Study Coordinators and will assist with coordinating the study, and web site and survey testing. She will manage and organize the on-site work, including responding to any emails from participants.

Lauren Bauer, MPH, Study Coordinator for the Millennium Cohort Study and **Evelyn Sun, MPH** study will serve as key support staff and will work with the Millennium Cohort study team with coordinating the Millennium Cohort Family study and sub-study data as well as web site and survey testing.

Gia Gumbs, MPH, Study Coordinator for the Birth and Infant Health Research Study will serve as key support staff and will work with the Millennium Cohort study team with coordinating the Birth and Infant Health Research study data.

Anet Petrosyan, Alexis Takata and Deanne Millard will be located at the Naval Health Research Center and will serve as key support staff as Research Assistants. As Research Assistants they will assist in the preparation of technical research reports, summaries, literature reviews, and scholarly presentations and/or publications as well as maintain clear and accurate research records, inventories, logbooks, and standard operating procedures. She will also assist with data collection, data entry, and data clean-up for research project.

Steven Speigle and William Lee have extensive knowledge in computer and internet technology, website maintenance and development. They will work to ensure data security and integrity, as well as designing, creating, modifying, and updating web pages. They will also be responsible for building and maintaining the web-based component of the survey in addition to cleaning and maintaining email addresses, as well as implementing a system to track incorrect email addresses.

Daniel Vaughan, BS will be located at the Naval Health Research Center and will serve as key support staff as a Programmer Analyst. His duties will include ensuring data security and integrity and assist in processing and maintenance of research databases. He will also be responsible for cleaning and maintaining email addresses, and maintaining the current system to track incorrect email and postal addresses.

Gordon Lynch will be located at the Naval Health Research Center and will serve as key support staff as Web Developers. Their duties will include ensuring data security and integrity, as well as designing, creating, modifying, and updating web pages. They will also be responsible for building and maintaining the web-based component of the survey.

Jacqueline Pflieger, PhD and Sabrina Richardson, PhD will be located at the Naval Health Research Center and will serve as key support staff as Research Psychologists. Their duties will include assisting in program design and maintenance of survey instruments alongside the research team; planning epidemiologic studies and designing the study methodology; performing statistical analyses for diverse research projects with complex study designs; working with team members to derive an in-depth understanding of the data findings; drafting proposals and writing peer-reviewed publications.

Christopher Phillips, MD, MPH, / Ben Porter, PhD, / Teresa Powell, MS and Richard Armenta, PhD will be located at the Naval Health Research Center and will serve as key support personnel as a Biostatistician. Duties will include assisting in program design and maintenance of survey instruments alongside research team; planning epidemiologic studies and designing the study methodology; performing statistical analyses for diverse research projects with complex study designs; working with team members to derive an in-depth understanding of the data findings; drafting proposals and writing peer-reviewed publications.

Cynthia LeardMann, MPH, / Daniel Trone, PhD, / Deborah Bookwalter, PhD, / Anna Rivera, MPH, / Isabel Jacobson, / MPH, / Rayna Matsuno, PhD, / Zeina Khodr, PhD, , and Adam Cooper, PhD will be located at the Naval Health Research Center **along with Chiping Nieh, PhD and Marleen Welsh** who will serve as key support staff as Epidemiologists. Their duties will consist of planning epidemiologic studies and designing the study methodology; performing statistical analyses for diverse research projects with complex study designs; working with team members to derive an in-depth understanding of the data findings; drafting proposals and writing peer-reviewed publications.

Anna Bukowinski and Satbir Boparai, MBA will be located at the Naval Health Research Center and will serve as key support staff as Data Managers. As data mangers, Ms. Bukowinski and Ms. Boparai will be responsible for processing and managing data and related programs.

Toni Geronimo, MPH / Clair Kolaja, MPH / Carlos Carballo, MA, / Kelly Woodall, MPH, / Kimberly Roenfeldt, MAS, / Steven Warner, MPH, and Alejandro Esquivel will be located at the Naval Health Research Center and serve a key support staff as Data Analysts. Their duties will include providing statistical and analytical support for diverse research projects; assist in

processing and maintenance of research databases; assist in writing of reports and scientific manuscripts for peer-reviewed professional journals and presentations.

Key support staff at NHRC will carry out the day-to-day duties of study implementation and analysis. They will report directly to the PI, Dr. Rudolph Rull.

2. Chain of Command

Dr. Rudolph Rull serves as the principal investigator on this study. All investigators and collaborators will coordinate study activities with him. Dr. Rudolph Rull will report to the Commanding Officer.

VIII. RISKS AND DISCOMFORTS TO RESEARCH VOLUNTEERS

1. Risk to the Volunteer and Means of Mitigation

This research study will collect self-reported mail and telephone survey responses. Study staff will store data in secure locations and maintain limited password access to digital data. All results will be reported as aggregate data without identifying individuals. Thus, this study poses no physical risk to the participant. When the participants receive the introductory letter and questionnaire, the letter will explain that their participation is voluntary and the Privacy Act Statement will be the first item on the cover of the questionnaire.

The data of interest are of a highly confidential nature, and strict procedures will be followed to minimize any risk of mental or emotional distress to the participant.

The following procedures will be followed to ensure that confidential information will not be used or abused in ways that might directly or indirectly harm the individuals involved:

Administrative

- All study staff will receive training in confidentiality protection procedures.
- Supervisors will monitor staff to ensure that they follow proper confidentiality procedures.
- An annual review of confidentiality procedures will be conducted.
- If study staff resign or otherwise leave the program, they will remain under obligation to protect the confidentiality of all data collected as part of the study.

Procedural

- The respective service survey approval managers will review the introductory letter and mail questionnaire. Their approval will be required before initiating the mailing.
- The participants will be informed of the process that will be used to link their answers with pre-existing data. It is required that NHRC's CPHS permit the investigators to forgo use of the formal informed consent documentation.
- Study staff will store study paper records in locked metal cabinets at NHRC. Paper records that are no longer needed will be shredded.

Computer Security

- To gain entry into the study database, staff will be required to enter their personal ID numbers and password.
- Study staff will download study data from the Corporate Executive Information System

(CEIS) and DEERS through secure data transmission links meeting standard DoD requirements. The database will be stored on existing NHRC information systems network. This system meets current DoD data security requirements.

- Supervisors will grant access to the confidential database only to those staff who require it.
- The NHRC network fire wall is in place to deter unauthorized access to these files.
- All data will be carefully guarded and used only to meet the stated study objectives.
- Personal identifying information will be removed from the analytic database once the survey, medical facility use, and demographic information are linked and stored separately. Only the statistician, who is familiar with the database, will link personal identifiers with the data for the initial match or any subsequent matches, and the identifiers will again be stripped following the match.
- The study database will reside within the NHRC network environment. There are no subcontractors who would have access to or possession of this database at any time. A public-release database will be created with the social security number and any other identifying data removed. DMDC will also receive a full copy of this database once it has been created.
- Information transmitted over the Internet will be done so using SSL-encrypted transmission lines. Further, users will have to enter their unique study ID number and last four digits of their social security number to send completed questionnaires.
- NHRC will periodically review the computer security procedures, including challenges to the security fire wall erected to assure its integrity.

None

3. Safety Precautions and Emergency Procedures

None.

4. Assessment of Sufficiency of Plans to Deal With Untoward Events or Injuries

Previous studies at NHRC involving similar procedures have not led to significant injury of a subject. The use of standard Navy medical procedures has been deemed sufficient to deal with any untoward events and/or injuries.

5. Qualification of Medical Monitor and Medical Support Personnel

N/A

IX. DESCRIPTION OF THE SYSTEM FOR MAINTENANCE OF RECORDS

1. Experimental Data

All study data, including paper questionnaires, will be managed by the principal investigator and stored in locked rooms at NHRC. Computerized Privacy Act data will be similarly handled in a confidential, controlled access fashion in compliance with NAVHLTHRESCENINST 3900.2F and NAVHLTHRESCENINST 6500.1A.

2. Research Protocol, Consent Forms, and Related Documents for Protection of Human Research Volunteers

The principal investigator will keep the research protocols and consent forms in a locked file

at NHRC. Computer data files will be stored in compliance with NAVHLTHRESCENINST 3900.2F and NAVHLTHRESCENINST 6500.1A.

3. Individual Medical Records

Individual computerized medical records will be used to abstract demographics, lifestyle, and medical data into the study database. Personal identifiers will be stored in a separate data file that can be linked only by the study statistician.

X. APPENDICES

APPENDIX A: Consent Documents



NHRC 2000
0007-CR13-EP9-A_Cc

APPENDIX B. INVESTIGATOR ASSURANCE AGREEMENT(s)

INVESTIGATOR ASSURANCE AGREEMENT

I, the Department Head, Principal Investigator or Co-Investigator, cited as responsible for performing and monitoring the research under the protocol titled, "Prospective Studies of U.S. Military Forces: The Millennium Cohort Study" have read and understand the provisions of Title 32 Code of Federal Regulations Part 219 (Protection of Human Subjects), Department of Defense (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). I will abide by all applicable laws and regulations, and I agree 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 I have a question regarding my obligations during the conduct of this Navy-sponsored project, I have ready access to each of these regulations, as either my personal copy or available on file from the Chair, Committee for the Protection of Human Subjects. I understand that my immediate resource for clarification of any issues related to the protection of research volunteers is the Chair, Committee for the Protection of Human Subjects.

Signatures and dates:

(DD/MM/YY)

COL Paul Amoroso, MD, MPH
Co-Investigator

___/___/___

Edward Boyko, MD, MPH
Co-Investigator

___/___/___

Gary Gackstetter, DVM, MPH, PhD
Co-Investigator

___/___/___

Tomoko Hooper, MD, MPH
Co-Investigator

___/___/___

INVESTIGATOR ASSURANCE AGREEMENT

I, the Department Head, Principal Investigator or Co-Investigator, cited as responsible for performing and monitoring the research under the protocol titled, "Prospective Studies of U.S. Military Forces: The Millennium Cohort Study" have read and understand the provisions of Title 32 Code of Federal Regulations Part 219 (Protection of Human Subjects), Department of Defense (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). I will abide by all applicable laws and regulations, and I agree 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 I have a question regarding my obligations during the conduct of this Navy-sponsored project, I have ready access to each of these regulations, as either my personal copy or available on file from the Chair, Committee for the Protection of Human Subjects. I understand that my immediate resource for clarification of any issues related to the protection of research volunteers is the Chair, Committee for the Protection of Human Subjects.

Signatures and dates:

(DD/MM/YY)

Tyler Smith, MS, PhD
Principal Investigator

___/___/___

Col Tim Wells, BSC, USAF
Co-Investigator

___/___/___

INVESTIGATOR COMPLIANCE ATTESTATION

I, the Department Head, Principal Investigator and/or Co-Investigator(s), cited as responsible for performing and monitoring the research under the protocol titled, "Prospective Studies of U.S. Military Forces: The Millennium Cohort Study," have read and understand the provisions of Title 32 Code of Federal Regulations Part 219 (Protection of Human Subjects), Department of Defense (DoD) Directive 3216.2 (Protection of Human Subjects in DoD-Supported Research), DoD Instruction 6025.18-R (Privacy Rule), SECNAV Instruction 3900.39D (Human Research Protection Program), OPNAV Instruction 5300.8C (Personnel Surveys), NAVHLTHRSCHCEN Instruction 3900.2E (Protection of Human Subjects), NAVHLTHRSCHCEN Notice 6500 (Protection of Health Information in Research), Title 21 Code of Federal Regulations Parts 50, 56 if applicable (clinical investigations regulated by the FDA), and all relevant local instructions. I have disclosed all potential and actual conflict of interest(s) related to the design, conduct, analysis, or reporting of this research. I will abide by all applicable laws and regulations, and I agree 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 I have a question regarding my obligations during the conduct of this Navy-sponsored project, I have ready access to each of these regulations, as either my personal copy or available on file from the Chairperson of the Institutional Review Board. I understand that my immediate resource for clarification of any issues related to the protection of research volunteers is the Chairperson of the Institutional Review Board.

Signatures and dates:

(DD/MM/YY)

Nancy F. Crum-Cianflone, MD, MPH
Department Head, Deployment Health Research Department
Principal Investigator, Millennium Cohort Study

_____/_____/_____

CAPT Margaret Ryan, MD, MPH
Co-Investigator

_____/_____/_____

APPENDIX B. INVESTIGATOR ASSURANCE AGREEMENT(s)

Key support personnel have all signed this agreement in separate documentation.

APPENDIX C. REFERENCES

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APPENDIX D. NONTECHNICAL SYNOPSIS

The Millennium Cohort Study is a probability-based, cross-sectional sample of 100,000 military personnel (as of October 2000) who will be followed prospectively by postal surveys with options of on-line completion every 3 years over a 21-year period. The 100,000 persons will be composed of 30,000 veterans who have been deployed to Southwest Asia, Bosnia, or Kosovo since August 1997, and 70,000 veterans who have not been deployed to these conflicts. In October 2004 and October 2007, 20,000 new military personnel will be added to the cohort. The total of 140,000 veterans will be followed until the year 2022.

The primary objective of this study is to compare change in health status between deployed and nondeployed personnel and the adjusted incidence rates of chronic disease between cohorts. Secondary objectives include comparing the adjusted change in health between the cohorts as reflected by Short Form-36 Questions/Veterans Health Survey scores and the Patient Health Questionnaire diagnostic assessment.

This study will serve as a foundation upon which other routinely captured medical and deployment data may be added to answer future military questions regarding the health risks of military deployments, military occupations, and general military service.

APPENDIX E. RECORD OF CHANGES TO THE PROTOCOL CONTINUED

Continuing Review 2015:

We respectfully request review of the proposed subject communications; these are within the number of contacts previously approved by the IRB.

1. Millennium Cohort Family Study targeted letters; 7 versions for specific sub-groups
 - Millennium Cohort Family Study Non-responder letter
 - Millennium Cohort Family Study Non-responder with Panel 4 Responder letter
 - Millennium Cohort Family Study Male Non-responder letter
 - Millennium Cohort Family Study Dual-military Non-responder letter
 - Millennium Cohort Family Study Reserve/Guard Non-responder letter
 - Millennium Cohort Family Study Non-responder with children letter
 - Millennium Cohort Family Study Widowed Non-responder letter
2. Millennium Cohort Family Study targeted emails; 7 versions for specific sub-groups
 - Millennium Cohort Family Study Non-responder email
 - Millennium Cohort Family Study Non-responder with Panel 4 Responder email
 - Millennium Cohort Family Study Male Non-responder email
 - Millennium Cohort Family Study Dual-military Non-responder email
 - Millennium Cohort Family Study Reserve/Guard Non-responder email
 - Millennium Cohort Family Study Non-responder with children email
 - Millennium Cohort Family Study Widowed Non-responder email
3. Millennium Cohort Family Study Month of the Military Child postcard; 2 versions
 - Millennium Cohort Family Study Month of the Military Child Non-responder postcard
 - Millennium Cohort Family Study Month of the Military Child Responder postcard
4. Millennium Cohort Family Study Month of the Military Child Non-responder email
5. Millennium Cohort Family Study Non-responder phone call pilot test procedure and script

January 26, 2015

This protocol has undergone a change of staff; therefore, we respectfully request approval to remove Martin White, Toni Rush and Lawrence Wang from the study as they are no longer affiliated with NHRC as well as add Danielle Mitchell and Kathleen Gunn as key personnel. *Their roles are outlined below.*

Danielle Mitchell will be located at the Naval Health Research Center and will serve as key support staff as a Research Assistant. As a Research Assistant she will assist in the preparation of technical research reports, summaries, literature reviews, and scholarly presentations and/or publications as well as maintain clear and accurate research records, inventories, logbooks, and standard operating procedures. She will also assist with data collection, data entry, and data clean-up for research project.

Kathleen Gunn will be located at the Naval Health Research Center and will serve as key support staff as a Research Intern. As a research Intern she will collect and organize survey data and forms for research projects. In addition, her duties as an intern are to scan and verify survey data, perform data entry, literature searches, and assist with maintenance of databases for research projects.

In addition we provided clarification within the study protocol that database linkages which are accessed electronically through secure computers located at the Naval Health Research Center using unique identifiers such as SIDs or via the participant's name and SSN are performed under both the Millennium and Family Cohort and is only done when appropriate agreements/approvals are in place prior to any data sharing.

Along with the above-mentioned modifications, we have identified subject matter experts from the Institute for Measurement, Methodology, Analysis and Policy (IMMAP) at Texas Tech University to assist us in meeting the OMB requirement to provide an approach to handle missing data and adjustments for selective attrition. Faculty and scientific staff of IMMAP will be provided with de-identified data under federal regulations before being transferred. A subcontract between NHRC/Henry Jackson Foundation and Texas Tech will be in place before any data analysis is performed. The Naval Health Research Center's IRB will serve as the primary IRB.

Also, included for IRB review and approval are the next set of emails/mailings to be sent to the study population. These mailings are within the permissible number of contacts (See Appendix K and L).

- Incomplete reminder – sent to those MilCo and Family participants that have logged into the web survey, but have not completed
- Graphic Postcard – 3 versions: Active Duty Non-responder, Separated Non-responder, and Incomplete (MilCo participants that have logged into the web survey, but have not completed)
- Reminder email – 2 versions: Panel 4 non-responders whose Family Study spouse has completed their survey, and one to all other non-responders
- Endorsement letter – 2 versions: One including VADM Nathan's endorsement, and one including LTG Horoho's endorsement.

We would also like to take this opportunity to notify the IRB that a new protocol will be submitted shortly that encompasses the family cohort effort that has been part of this protocol.

November 2014 Millennium Family Holiday Mailings and Staff Update) This protocol has undergone a change of staff; therefore, we respectfully request approval to remove Julia Schwartz from the study as she is no longer affiliated with NHRC. In addition, we are submitting the following Millennium Cohort Family study mailings for review:

1. December reminder e-mail, thank you letter, holiday postcard and postcard e-mail. The thank you letter mailing will include a five dollar gift card to Starbucks, and will be sent to our early responders as a token of appreciation for prompt response. The envelope will not have any notation that a gift card is included nor will the contents of the mailing be visible. These mailings and the two e-mails are within the permissible number of contacts (See Appendix L).

October 2014 (Millennium Family Cohort Month of the Military Family and Staff Update) This protocol has undergone a change of staff; therefore, we respectfully request

approval to remove Alka Malhotra, PhD from the study as she is no longer affiliated with NHRC. In addition, we are submitting the following Millennium Cohort Family study mailings for review:

1. Month of the Military Family cover letter, the Month of the Military Family envelopes, the Month of the Military Family e-mail, and the November reminder e-mail. The Month of the Military Family mailing will include a five dollar gift card to Starbucks as a pre-incentive. In order to understand the impact of using Priority Mail, half of the participants will receive this mailing in a Priority Mail envelope, while the other half will receive the mailing in a graphic envelope. Neither of the envelopes will have any notation that an incentive is included nor will the contents of the mailing be visible. This mailing and the two e-mails are within the permissible number of contacts (see Appendix L).

October 2014 (Millennium Cohort Veterans Day Postcard/Follow-up correspondence)

Millennium Cohort Study Veterans Day Postcard (2 versions responder and non-responder), follow-up email, cover letter for the questionnaire, and endorsement letter mailing (2 versions Army and Navy). These emails and mailings will be within the permissible number of contacts.

October 2014 (Milco Study Extension/Family Mailing and Survey Skip Patterns Update)

Submitted for IRB review was the extension of the Millennium Cohort study to 67 years: 2000/10/01 to 2067/09/30 (MOMRP memo attached). Millennium Cohort Family Study follow-up email, sample survey cover letter, sample survey, and sample survey email. These emails and mailings will be within the permissible number of contacts.

We have made one revision to the skip pattern included in the previously approved 2014 follow-up Family survey. The questions were not altered in any way. The only changes made were to the title of the section and the skip pattern. The skip pattern outlined in the previously approved survey originally only directed spouses of active duty Service members to answer one section of the survey. This skip pattern has now been changed to direct all participants, except those who select 'Widowed' as their marital status, to now answer these questions.

September 2014 (Survey/Staff Update)

The Dual Military Families email which was cued for last submission did not get included; therefore, a request to review the email under this submission made. The IRB was reassured that this email contact is within the permissible number of contacts.

In addition, a change in staff occurred. Teresa Powell, MS has rejoined the Millennium Cohort study team. She will be located at the Naval Health Research Center and will serve as key support staff as a Biostatistician. Her duties will include assisting in program design and maintenance of survey instruments alongside research team; planning epidemiologic studies and designing the study methodology; performing statistical analyses for diverse research projects with complex study designs; working with team members to derive an in-depth understanding of the data findings; drafting proposals and writing peer-reviewed publications.

Along with the changes mentioned above, the surveys for both the Millennium and Family Cohort Studies have been updated in preparation for the upcoming survey cycle.

For the Millennium Cohort Study, a combined document including all questions from the paper and web survey versions was submitted for IRB review and approval. A clean copy and another highlighted where changes have been made, in addition to a document outlining the items that were deleted from the 2011 survey was included for the IRB's convenience. Please note that the variables are visible on the copy of the web based survey provided but will not be visible to the participant once we receive IRB approval and officially launch the survey.

For the Millennium Cohort Family Study, the web address and a created login for the 2014 web based Follow-up survey has been included. Included in this submission is a document highlighting the questions that have been added to the 2014 survey, and a copy of the 2011 Baseline survey with highlighted questions that have been removed from the 2014 Follow- Up survey. Please note that the Family study will only be utilizing the web based survey this cycle, there will be no paper version of the 2014 Follow-Up survey.

Also, to get a sense of how the survey will be displayed to the participants and how the participant will navigate the web based surveys, we have provided the links to both the Millennium Cohort and Family Cohort surveys as well as established the following pseudo Subject IDs for the IRB's use. In order to allow maximum visibility of the questions, the Family Subject ID was created as if the subject's Millennium Cohort Panel 4 spouse provided secondary consent at baseline. Therefore, this should allow the IRB to see the section entitled 'Your Spouse's Behavior'. This section will only be viewed by participants whose Panel 4 spouse provided secondary consent at baseline. Please note the sites are not live and will not be made available to our participants until IRB approval has been received.

<https://devmilco2014.millenniumcohort.org/>

Subject ID : 10001

Last 4: 9999

<http://devfamily2014.millenniumcohort.org/>

Subject ID: 10000

Last 4: 9999

We have also enclosed under this submission the OMB approval for the IRB's records.

July 2014 (Staff/Mailings/Website)

This protocol has undergone a change of staff; therefore, we respectfully request approval to remove Melissa Frasco, PhD and Evelyn Davila, PhD, MPH as their employment as contractors for NHRC has ended and would like to add Alka Malhotra, PhD, Rudolph Rull, PhD, Andrew Lin, Anna Bukowinski and Serguey Parkhomovsky. *Their roles are outlined below.*

Duties and Responsibilities of new staff

Alka Malhotra, PhD, will be located at the Naval Health Research Center and will serve as key support staff as an Epidemiologist. Duties will include planning epidemiologic studies and designing the study methodology; performing statistical analyses for diverse

research projects with complex study designs; working with team members to derive an in-depth understanding of the data findings; drafting proposals and writing peer-reviewed publications.

Rudolph Rull, PhD, will be located at the Naval Health Research Center and serve as key support staff as a Data Analyst. Duties will include providing statistical and analytical support for diverse research projects; assist in processing and maintenance of research databases; assist in writing of reports and scientific manuscripts for peer-reviewed professional journals and presentations.

Anna Bukowinski and Andrew Lin, will be located at the Naval Health Research Center and will serve as key support staff as Data Managers. As data managers, Ms. Bukowinski and Mr. Lin will be responsible for processing and managing data and related programs.

Serguey Parkhomovsky will be located at the Naval Health Research Center and will serve as key support staff as a database programmer. As the database programmer, Mr. Parkhomovsky will be responsible for creating and maintaining the study database.

Millennium Cohort Study

Also, because we were alerted that some of our official study emails are being delivered to junk or spam folders, along with the staff update we respectfully request a review and approval of the attached spam email. This email was developed with the intent to alert our participants of this possibility so they can make the necessary adjustments allowing our emails to reach their inbox.

Millennium Family Cohort Study

Along with the above-mentioned documents, we have made revision to the previously approved Millennium Family Cohort participant mailings and have attached a copy for IRB review and approval as well as images of the lunch bag pre-incentive and card insert and provided its text and the follow-up email text.

Millennium Cohort and Family Cohort

In addition we have included in this submission is a PDF version of the updated study websites for both the ***Millennium Cohort and Family Cohort*** studies. The websites contents differ tremendously from the already/live websites. The updates include recent briefings, press, publications, mailings, study findings and information regarding the upcoming survey cycle. Both websites were modified to enhance usability and improve site navigation.

The following are links that will allow you to peruse the website (please note the sites are not live and will not be made available to our participants until IRB approval has been received).

<http://devnewmilco.millenniumcohort.org/>

<http://devnewfamily.familycohort.org/>

July 2014 (Staff/Family Mailings)

This protocol has undergone a change of staff; therefore, we respectfully request the review and approval to add Christopher O'Malley, Julia Schwartz, Anet Petrosyan,

Madeline Cross and Navjot Kaur. *Their roles are outlined below and their training certificates (CITI and HIPAA) are being submitted at this time.*

Duties and Responsibilities of new staff

Dr. Dennis Faix the current Principal Investigator (PI), will relinquish his role as PI to Dr. David Luxton who recently accepted the Millennium Cohort Study Principal Investigator position. Dr. Luxton will be responsible to NHRC's IRB, and to the various external review bodies for the financial accounting and scientific merit of the study. He will also be responsible for ensuring that all NHRC personnel involved with this protocol are properly trained and qualified. *Dr. Dennis Faix*, will remain on the protocol as a co-investigator. His experience with epidemiological studies and the previous Millennium Cohort PI will lend much to the investigation team in form of background knowledge.

Christopher O'Malley, MPH, will be located at the Naval Health Research Center and serve a key support staff as a Data Analyst. Duties will include providing statistical and analytical support for diverse research projects; assist in processing and maintenance of research databases; assist in writing of reports and scientific manuscripts for peer-reviewed professional journals and presentations.

Julia Schwartz, will be located at the Naval Health Research Center and will serve as key support staff as a Research Assistant. As a Research Assistant she will assist in the preparation of technical research reports, summaries, literature reviews, and scholarly presentations and/or publications as well as maintain clear and accurate research records, inventories, logbooks, and standard operating procedures. She will also assist with data collection, data entry, and data clean-up for research project.

Anet Petroysan will be located at the Naval Health Research Center and will serve as key support staff as a Research Assistant. As a Research Assistant she will assist in the preparation of technical research reports, summaries, literature reviews, and scholarly presentations and/or publications as well as maintain clear and accurate research records, inventories, logbooks, and standard operating procedures. She will also assist with data collection, data entry, and data clean-up for research project.

Madeline Cross and Navjot Kaur will be located at the Naval Health Research Center and will serve as key support staff as a Research Interns. As a research Interns they will collect and organize survey data and forms for research projects. In addition, their duties as an intern are to scan and verify survey data, perform data entry, literature searches, and assist with maintenance of databases for research projects.

Millennium Family Cohort Study

Along with the above-mentioned modification the attached ***Millennium Family Cohort Study*** mailings are being submitted for review and approval. These mailings are within the IRB's protocol's approved allowable contacts.

May 2014 (Staff/Family Collaboration/Mailings/Incentives)

This protocol has undergone a change of staff; therefore, we respectfully request the review and approval of the following modification to the protocol:

- To remove Isabel Jacobson, MPH and Raechel Del Rosario, MPH as they have resigned and their employment with NHRC has ceased. In addition, to the above staff

modification, we respectfully request permission to modify the Millennium Cohort Family study to include the following six primary aims that include objectives and specific study questions:

- Explore the association between service member deployment (e.g. combat, duration, dwell time, and frequency) and the health and well-being of spouses and children.
- Explore the association between service member readjustment issues (e.g., PTSD, anxiety, depression, alcohol misuse/abuse) and the health and well-being of spouses and children.
- Examine factors related to resiliency and vulnerability that moderate the association between deployment experiences and service member readjustment issues, and the health and well-being of spouses and children.
- Examine factors related to marital quality and family function.
- Evaluate methodological approaches to ensure adequate representation of spouses from all service branches, Reserve and National Guard; and assess validity of assessment measures and instruments.
- Contribute data to the service member cohort study on spouse and child factors that are associated with service member health and well-being, as well as length of service.

We will collaborate with Abt Associates and their subcontractors Duke University (Duke) and New York University (NYU) to accomplish these objectives. NHRC will not transfer any data involving names, dates (including dates of birth), social security numbers, or any contact information to Abt Associates. Proposals will be written for each proposed analysis using the Family Study data containing a list of required data elements and investigators which will be provided to the IRB at the study's annual review or at the time of development should any data requirements and/or aims fall outside those presented under this modification. Data transfers will only occur through secure means using password-protected encrypted files. The data provided by NHRC to the Abt Associates team is restricted to the minimum necessary to complete the approved Family sub-studies and access to these data will be limited to a minimum number of individuals necessary at each institution to achieve the purpose. Data will be stored in a manner consistent with Federal and DoD regulations and data security best practices.

Millennium Cohort Study

Along with the above-mentioned modifications the following ***Millennium Cohort Study*** mailings are being submitted for review and approval. These mailings are within the IRB's protocol's approved allowable contacts.

The postal mailer text and email text for the upcoming survey cycle have been included review under Appendix K. The timeframe listed for each item is approximate, and may be adjusted due to survey operation logistical reasons.

As part of the ***Millennium Cohort's*** mailing, in order to understand the impact of including cash as a pre-incentive on the study population, we request permission to send a letter to all participants in panels 1-4 (*3a and 3b mailings*) which will include one of five versions of a randomly assigned pre-incentive:

- Group one will receive a cash pre-incentive in the form of either two, one dollar bills, or a two dollar bill
- Group two will receive an equivalent material gift (magnet)
- Group three will receive only the invitation card - no cash or gift card included
- Group four will receive a five dollar gift card
- Group five will be put into a drawing. For every 500 survey responses received from participants included in this group, 1 participant will be randomly selected to receive an iPad or its equivalent. The drawing will be completed using computerized random selection from the database of eligible participants who return their completed survey within the specified timeframe.

Please note: The envelopes will not have any notation that an incentive is included nor will any of these mailings be sent using an envelope where the contents are visible. The *Millennium Cohort* mailings for Phase 1 are scheduled to launch June/July 2014: The following provides the IRB with an outline of the timelines proposed.

1. Pre-notice letter with key study findings graphic insert (week 1)
 - a. Active Duty
 - b. Separated/Retired
2. Pre-notice email: (week 3)
3. Card (week 8)
 - a. NOT LINKED to Family participant
 - b. LINKED to Family participant
4. Email (week 9)
 - a. Active Duty NOT LINKED to Family participant
 - b. Separated/Retired NOT LINKED to Family participant
 - c. Active Duty LINKED to Family participant
 - d. Separated/Retired LINKED to Family participant

In addition, we have included the *Millennium Cohort Family* mailing scheduled to be mailed within the first couple weeks of June for IRB review.

April 2014

- For the *Millennium Cohort Study*, the Memorial Day Postcard and email text was submitted for IRB review and approval. The postcards/emails will be sent to Millennium Cohort participants and fall within the protocol's approved number of contacts allowed during a survey cycle.

February 2014

- Mr. Martin White will no longer serve as interim Principal Investigator on this protocol, due to the arrival of the Department Head, CDR Dennis Faix. CDR Faix will now serve as the Principal Investigator for this protocol. Updated HIPAA and CITI documents will be provided to Ms. Kathy Snell.
- In order to obtain some data from non-responders towards the end of the survey cycle, we are seeking to use a 4-page short survey as the last postal item for the Millennium Cohort Study. There will be two versions of the short survey, one for

Active Duty participants and one for retired/separated participants, which will only contain a few core questions. The two versions of the MilCo short surveys are submitted for review.

- Samples of postal mailer text and email text for the upcoming survey cycle are included for review. The timeframe listed for each item is approximate, and may be adjusted due to survey operation logistical reasons. Artwork for additional items will be submitted for review as it is created.
- The Report Control Symbol (RCS: DoD RCS#DD-HA(AR)2106) expires 31 March 2014. Approval is still pending and will be submitted to NHRC IRB once obtained.
- Office of Management and Budget (OMB #0720-0029) expires 31 March 2014. The 2014 survey instruments for both MilCo and Family were submitted for OMB review in November 2012. Approval is still pending and will be submitted to NHRC IRB once obtained.
- Because OMB and DoD approvals for surveys are still pending, finalized surveys will be submitted for IRB review after those approvals are obtained. Please note that during the next survey cycle no recruitment will be done—only follow-up will be done at this point. Also, under this continuing review submission because this study has undergone further staff changes we are seeking IRB approval to modifying the protocol removing LTCOL Nisara Granado, LCDR Kendall Egan, Ms. Andrea Ippolito and Emma Schaller as well as Mr. James Whitmer from the protocol as they no longer work for the DoD Center for Deployment Health Research. Along with the removal of the above- mentioned key personnel, we would like approval to add Drs. Hector Lemus, Amy Bell and Ben Porter as well as Lawrence Wang and Lauren Kearney. Their roles are outlined below and their training certificates (CITI and HIPAA) are being submitted at this time.

Duties and Responsibilities of new staff

Hector Lemus, DrPh will be located at the Naval Health Research Center and will serve as key support personnel and co-investigator as a Biostatistician. Duties will include assisting in program design and maintenance of survey instruments alongside research team; planning epidemiologic studies and designing the study methodology; performing statistical analyses for diverse research projects with complex study designs; working with team members to derive an in-depth understanding of the data findings; drafting proposals and writing peer-reviewed publications.

Amy Millikan Bell, MD, MPH, manager of the Behavioral and Social Health Outcomes Program (BSHOP) for the Army Institute of Public Health, U.S. Army Public Health Command., has been added to the study team/protocol as a consultant in which she will participate in the interpretation of the data analyses, and the drafting and publishing of manuscripts. In her role, Dr. Bell will not have access to identifiable data.

Ben Porter, PhD, will be located at the Naval Health Research Center and will serve as key support personnel and co-investigator as a Biostatistician. Duties will include assisting in program design and maintenance of survey instruments alongside research team; planning epidemiologic studies and designing the study methodology;

performing statistical analyses for diverse research projects with complex study designs; working with team members to derive an in-depth understanding of the data findings; drafting proposals and writing peer-reviewed publications.

Lauren Kearney, MPH, will be located at the Naval Health Research Center and serve as a key support staff as a Data Analyst. Duties will include providing statistical and analytical support for diverse research projects; assist in processing and maintenance of research databases; assist in writing of reports and scientific manuscripts for peer-reviewed professional journals and presentations.

Lawrence Wang, MPH, will be located at the Naval Health Research Center and serve as key support staff as a Data Analyst. Duties will include providing statistical and analytical support for diverse research projects; assist in processing and maintenance of research databases; assist in writing of reports and scientific manuscripts for peer-reviewed professional journals and presentations.

October 2013

This protocol has undergone staff changes. LTCOL Nisara Granado, MPH, PhD has been added as new key support personnel.

October 2013

Prior to the submission of this study protocol modification, the Millennium Cohort Study team sought and received permission from the Institutional Review Board Chairman, Mr. Jay Heaney to implement the following “Document retention/Shredding” Policy.

Document Retention/Shredding Policy:

All Millennium Cohort paper surveys will be digitized and a permanent electronic copy will be maintained. After a minimum 3 years of storage, the survey portion will be securely destroyed by a shredding company performing on-site service. Paper consent pages will NOT be destroyed. The paper consent will be removed from the survey, stored separately, and retained permanently in a secured location.

In addition, this protocol has undergone staff changes. Mr. John Wesner no longer works for the DoD Center for Deployment Health Research and Valerie Stander, PhD has been added as new key support personnel.

Duties and Responsibilities of new staff

Valerie Stander, PhD, will be located at the Naval Health Research Center and serve as key support staff as an Epidemiologist. Duties will include planning epidemiologic studies and designing the study methodology; performing statistical analyses for diverse research projects with complex study designs; working with team members to derive an in-depth understanding of the data findings; drafting proposals and writing peer-reviewed publications.

Along with the above-mentioned modifications, the Millennium Cohort Veteran’s Day postcard as well as the National Military Family Month” postcard for the Family study are being submitted for review and approval (Appendix K and L). The postcards will be sent within the protocol's approved contacts via an email.

September 2013

This protocol has undergone a change of staff. Dr. Crum-Cianflone has resigned, therefore, Martin White, MPH will assume the role of Principle Investigator. In addition Ms. Michelle Linfesty, Jaime Horton, Teresa Powell, and Amber Seelig no longer work for the DoD Center for Deployment Health Research. Laura Tobin has been added as new key support personnel. *The training certificates (CITI and HIPAA) for Martin White and Laura Tobin are being submitted at this time.*

Please note that the informed consent(s) for this study provides the participant with an email and phone number that is sent to the PI of the study if the participant has questions or wishes to end their participation; therefore no change to the informed consent is required.

Duties and Responsibilities of new staff

Martin White, MPH, will serve as a Principal Investigator for this study. He will be responsible to NHRC's IRB, and to the various external review bodies for the financial accounting and scientific merit of the study. He will also be responsible for ensuring that all NHRC personnel involved with this protocol are properly trained and qualified

Laura Tobin will be located at the Naval Health Research Center and will serve as key support staff as a Research Intern. As a research Intern she will collect and organize survey data and forms for research projects. In addition, her duties as an intern are to scan and verify survey data, perform data entry, literature searches, and assist with maintenance of databases for research projects.

- We request permission to create an organization page on the Facebook platform as well as a Millennium Cohort Study Facebook application. Participants will be sent an email with a link to be able to "Like" the Millennium Cohort Organization page. The link to our Facebook page may also be included on our webpage and in some of the study materials sent as part of the routine mailings (these will be submitted prior to mailing). Millennium Cohort Study administrators will post links on the Facebook page about recent study findings and provide updates on survey cycles. We will restrict posting on the Facebook page to only authorized users, in this case it would be the Millennium Cohort Study team. The linkage will only be used to send information about the survey and its findings to individuals who "Like" the Millennium Cohort Organization page; no collection of information about the individuals "liking" Millennium Cohort will be accessed, collected, or maintained. Individuals "liking" the Millennium Cohort Organization page will be reminded that they can "Edit Privacy" on each site they like to limit those who can see their "likes."

The communications described above will also include a link for those interested in the Facebook application. To use the application, the participant must provide consent after reading a disclosure statement (a standard feature for getting an app on Facebook).

Authorized users (i.e., Millennium Cohort investigators) can control the information shown in the application, and therefore we can ensure privacy in the application itself by never exposing personal information/details of individual members. Similar to 'liking' the Millennium Cohort Facebook Page, visibility of a specific user as having added the Millennium Cohort application is based on their privacy settings. This information is generally not available to the public unless the user allows for it.

The Facebook application will be hosted at the same secure co-location center as the Millennium Cohort web surveys. The application will be used to send participants study information. We will not collect any data from their profile. The Facebook page and application are voluntary features and a person can cancel their consent or involvement with the Facebook site at any time. When a user removes the app from their profile, we are sent a de-authentication notice and at that time we can remove their data from our server (the user ID and information is no longer given to the application). Both the application and organization page are still under development, but a few screen shots are enclosed for review. Screen shots of both items in their entirety will be sent for IRB review once constructed.

Also for the Millennium Cohort Study, similar to that for the Family Study, we are seeking permission to call those participants who completed the paper survey, but failed to sign the informed consent form in the survey document. These phone calls will be the last contact attempt during the cycle in attempt to have the subject provide consent, and hence for the study team to utilize their survey data. Approximately 460 participants will be called. Those who did not sign the consent and who did not complete at least 75% of the survey will not be contacted, rather they will simply be excluded from the study.

Subjects will be contacted via telephone Monday through Friday between the hours of 8 am to 8 pm within their time zone, and/or Saturday between 10 am to 6 pm in their time zone. No calls will be made on Sundays. A maximum of 5 phone call attempts will be made per subject and a log of every attempt will be kept. Staff making phone calls will not leave a voice message on the first four attempts and only then would leave a message on the fifth attempt. A verbal “yes” or “no” reply will be accepted as the subject’s consent and documented by caller who will be a member of the study team. If the subject responds with a “no”, they will no longer be contacted and their survey data will not be utilized. Calls will end once the 5 call limit occurs or we are able to reach the participant in person, whichever occurs first. All participants who agree to consent to the study will be offered a copy of the consent form which will be mailed to them.

A log of all of the phone calls will also be kept. A copy of the log is also submitted for review.

The script for the phone calls is as follows:

Hi (interviewee name):

My name is (caller name), and I am calling from the Naval Health Research Center. We appreciate the time you spent completing our survey on (Date) for the Millennium Cohort Study which is being conducted by the Department of Defense.

When we reviewed your survey, we noticed that you did not sign the consent form on the 2nd page of the survey. In order to use your data for our study, we would need to have your consent to participate in the study. Will you give your consent for participation?

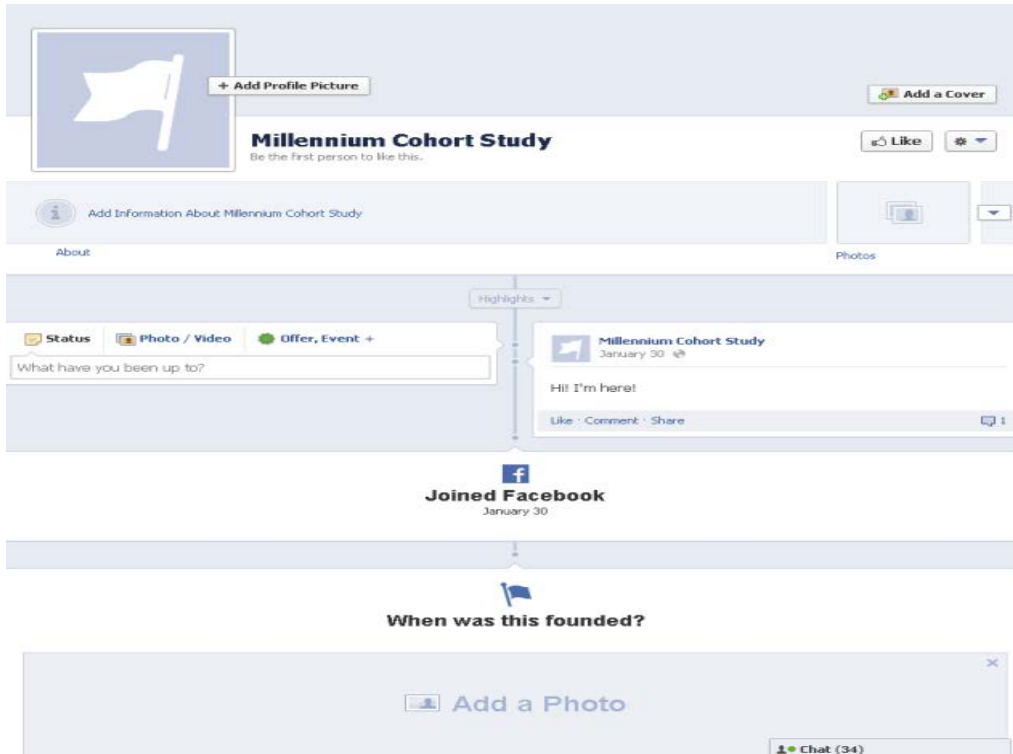
If the subject responds yes:

Thank you. We will document your response. We know your time is valuable and we thank you for helping with this important project. We would be happy to send you a copy of the study’s consent to your home address? Would you like a copy? If yes, (confirm address).

If the subject responds no:

Thank you. We will document your response. Unfortunately, we will not be able to use the information you gave us in the survey you completed. Thank you for your time.

1. Millennium Cohort Organization page:



2. Main page of Facebook App:

facebook Search for people, places and things

The Millennium Cohort Study Facebook Application

PROTECTING SERVICE MEMBER HEALTH
A U.S. DEPARTMENT OF DEFENSE STUDY

Notice
This application is under development and the information below contains placeholder text. The information presented is not representative of the Millennium Cohort Study.

You are viewing the Millennium Cohort Facebook application.

70%
of Millennium Cohort participants reported poor sleep patterns within the last 3 years

General Dempsey endorses the Millennium Cohort Study!

The current survey cycle is
2010-2013

Have you received your Veterans Day 2013 postcard? Let us know what you think!

Have you moved or changed addresses? Click here to update your address!

[Click here to visit the Millennium Cohort Study Website](#)

July 2013

- With respect to our June 12, 2013 modification request; we appreciate the IRB's review and consideration however, based on the comments, we would like to withdraw our June 12, 2013 submission and resubmit for review once we have adequately researched the IRB's concerns and obtain science signoff. ***In addition to our withdraw request, we respectfully request review of the following drug data use and family modification:***

Recently, we obtained IRB approval to investigate the prevalence and types of illicit drug use as detected by DoD mandatory drug screens among Army active duty members within the Millennium Cohort Study. The Army has a direct interest in better understanding the risk factors for illicit drug use within their service branch and the recent IOM report has highlighted the need for further research in this area.

After IRB approval, we received the following data from the office that maintains drug screen results for the Army. Of a total of 89,303 Army participants, 77,861 had at least one drug test performed in the databank, and 2,844 had a positive drug screen. This is 3.7% of participants screened positive during their service time. The most common drugs were THC, cocaine, and amphetamines/methamphetamines.

Given the adequacy of the sample size, we wish to now request obtaining individual data on drug test positivity among this group. A DUA will be signed between NHRC and the Army Center for Substance Abuse Programs' (ACSAP) Drug and Alcohol Management Information System (DAMIS). Similar to the last request, we propose to create an

encrypted password protected disk, and send it to the DAMIS program manager, Mr. Michael Biggerstaff (ACSAP), Building 1467, Fort Knox, KY 40121. In return, we will be provided with the date and the result of the test for our Army Cohort members via an encrypted CDROM that will also be sent to our site via FedEx. Upon arrival, the data would securely be stored on our in-house computers and the SSN would be replaced with the subject identification number for ensuring confidentiality. The original data file provided to DAMIS will be destroyed in accordance with INFOSEC guidelines.

We will utilize this data to perform statistical analyses to examine if specific military experiences increase the likelihood of a positive drug screen. Hypotheses will include that deployments and combat experiences (traumatic events) increase the likelihood of drug use and that injury relating from military service (e.g., leg amputation) increase the likelihood of drug use.

Once all final projects are performed, the drug use data may be destroyed as advised by the IRB.

- For the Millennium Cohort Family Study, we are seeking permission to call those participants who completed the paper survey, but failed to sign the informed consent form in the survey document. These phone calls will be the last contact attempt during the cycle in attempt to have the subject provide consent, and hence for the study team to utilize their survey data. Approximately 100 participants will be called. Those who did not sign the consent and who did not complete the majority of the survey will not be contacted, rather they will simply be excluded from the study.

Subjects will be contacted via telephone during Monday through Friday between the hours of 8 am to 8 pm within their time zone, and/or Saturday between 10 am to 6 pm in their time zone. No calls will be made on Sundays. A maximum of 10 phone call attempts will be made per subject and a log of every attempt will be kept. Staff making phone calls will not leave a voice message. A verbal “yes” or “no” reply will be accepted as the subject’s consent and documented by caller who will be a member of the study team. If the subject responds with a “no”, they will no longer be contacted and their survey data will not be utilized. Calls will end once the 10 call limit occurs or we are able to reach the participant in person, whichever occurs first. All participants who agree to consent to the study will be offered a copy of the consent form which will be mailed to them.

The script for the phone calls is as follows:

Hi (interviewee name):

My name is (caller name), and I am calling from the Naval Health Research Center. We appreciate the time you spent completing our survey on (Date) for the Family Study which is being conducted by the Department of Defense.

When we reviewed your survey, we noticed that you did not sign the consent form on the 2nd page of the survey. In order to use your data for our study, we would need to have your consent to participate in the study. Will you give your consent for participation?

If the subject responds yes:

Thank you. We will document your response. We know your time is valuable and we thank you for helping with this important project. We would be happy to send you a copy of the study's consent to your home address? Would you like a copy? If yes, (confirm address).

If the subject responds no:

Thank you. We will document your response. Unfortunately, we will not be able to use the information you gave us in the survey you completed. Thank you for your time.]

June 2013

MODIFICATION WITHDRAWN—WILL RESUBMIT ONCE PRIVACY ISSUES CAN BE INVESTIGATED AND PROPERLY ADDRESSED—SEE JULY MODIFICATION BELOW FOR WITHDRAWAL NOTIFICATION

- This protocol has undergone a change of staff. Ms. Jaime Horton no longer works for the DoD Center for Deployment Health Research.
- With the longitudinal design of the Millennium Cohort Study, we would like to utilize new technologies to keep in contact with our participants and to provide those interested with study updates (e.g., when the next survey cycle is starting). Therefore, we request permission to create an organization page on the Facebook platform and a Millennium Cohort Study Facebook application. Participants will be sent an email with a link to be able to "Like" the Millennium Cohort Organization page which allows for posts on their home feed. The link to our Facebook page may also be included in some of the study materials sent as part of the routine mailings and these will be submitted prior to mailing. Millennium Cohort Study administrators will post links on the Facebook page about recent study findings and provide updates on survey cycles.

The communications described above will also include a link for those interested in the Facebook application. Some of the benefits of accessing the Facebook application include (1) a user experience more tailored for Millennium Cohort Participants, (2) the ability to receive Facebook notifications of study updates, (3) access to Millennium Cohort media and select survey statistics, and (4) streamlined survey tools that make actions such as updating address and contact information easier. To use the application, the participant must provide consent (a standard feature for getting an app on Facebook). As part of this process, the Millennium Cohort Study team can also visualize their Facebook public profile, friend list, email address, relationships, birthday, work history, and education history that they've chosen to make public. The information may be used to inform the study team of areas of health concern, help determine survey questions, and target study finding emails.

The Facebook application will be hosted at the same secure colocation center as the Millennium Cohort web surveys. The application will only collect information that it has been given permission to access via the Facebook API platform. The Facebook page and application are voluntary features and a person can cancel their consent or involvement with the Facebook site at any time. When a person turns off the application, the user ID and information is no longer given to the application.

Both the application and organization page are still under development, but a few screen shots are enclosed for review. Screen shots of both items in their entirety will be sent for IRB review once constructed.

May 2013

- This protocol has undergone a change of staff. Ms. Kelly (Jones) Woodall and LtCOL Nisara Granado no longer works for the DoD Center for Deployment Health Research. Ms. Evelyn Davila, PhD, MPH, Ms. Denise Lovec-Jenkins, Ms. Sara Echols, and CPT Carrie Donoho, PhD have been added as new key support personnel.

April 2013

- The following people have been added as new key support personnel to the protocol: Kartavya Vyas and Anna Nagel.
- The last decade of sustained and straining military operations has been witnessed an increase in not only alcohol use but also the use of illicit substances and misuse of prescription medications, including controlled substances (Blume et al., 2010; Bray et al., 2010; Horgan et al., 2001; Marshall et al., 2012; Rosenbaum et al., 2012; SAMHSA, 2011; U.S. Air Force Special Operations Command, 2011). A recently published paper reported the prevalence of any illicit drug use, to include prescription drug misuse, significantly increased from 5% in 2005 to 12% in 2008 (IOM, 2012). In response to such findings, the Army has expressed concern about the increasing availability and use of prescription resulting in higher rates of abuse (U.S. Army, 2012). While illicit drug use, not including prescription drug misuse, has remained relatively stable according to official urinalysis testing figures, those testing positive represent an at-risk population, which warrants further scientific study as to better understand the underlying causes of use and to inform prevention and intervention programs. Also, this percentage might not fully represent the prevalence of the problems as self-reports in the HRB Survey reported the rate of illicit drug use at 2.3% (Bray et al., 2009).

Despite efforts to prevent and mitigate such issues, substance misuse and abuse continue to present concerns for the DoD leadership (IOM, 2012). Additionally, current DoD policies do not fully address evolving patterns of drug and alcohol use in an empirically driven manner (IOM, 2012). Given this shortcoming, there exists a need to study the relationship between illicit drug and prescription medication, the indication for which the medication was prescribed (e.g., pain, sleep disorder, anxiety disorder, obesity), and the environmental and individual factors contributing to drug/medication abuse. We are therefore interested in determining the feasibility of incorporating data from the Army Center for Substance Abuse Program (ACSAP) into our Millennium Cohort study to address this need. ACSAP routinely tests Soldiers for Codeine, Morphine, Amphetamines, Methamphetamines, Oxycodone, OxyMorphone, Hydrocodone, Hydromorphone, and five types of benzodiazepines. In addition to monitoring illicit drug use, all of these drugs can test positive due to a valid prescription or by illegal misuse (i.e., using a controlled substance without a prescription, taking a controlled substance after the prescription has expired).

We request approval to match Millennium Cohort Study participants who have served in the Army to the Army Center for Substance Abuse Program (ACSAP) database to ascertain the aggregate number of Soldiers from our Cohort who have been tested and screened positive for a monitored substance. To accomplish this, under Millennium Cohort SORN N06150-5 and Army Substance Abuse Program SORN A0600-85, we propose sending SSN information via a password protected, encrypted CDROM sent via FedEx with a tracking number, to the Department of the Army Management Information System (DAMIS) program manager, Mr. Michael Biggerstaff (ACSAP), Building 1467, Fort Knox, KY 40121. In return, we will be provided with the overall number and types of results and tests with positive results for our Army Cohort members via an encrypted CDROM that will also be sent to our site via FedEx. No individual data will be provided to us. After one week, the original data file provided to DAMIS will be destroyed IAW with INFOSEC guidelines.

We previously requested approval to obtain individual identifiable results, however, the IRB at that time (8/29/2012) expressed concerns about the number of results available (i.e., study feasibility), availability of data from other service branches, as well as the sensitive nature of individual data. Given these concerns, we have modified our request to simply explore the number and types of results and positive tests to determine the feasibility of future analyses of substance use in the Millennium Cohort Study. If deemed feasible based on the number of tests and positive screens, we would subsequently propose to link to the ACSAP dataset by submitting a modification request to the IRB to request individual results from the Army as well as the other branches. Beginning with the Army is an important first step as it is the most represented branch in the Millennium Cohort Study (n=63,006, 42% of the cohort) and it has been heavily burdened by recent combat operations. It should also be noted that other DoD-sponsored research studies (e.g., the \$60 million Army Study to Assess Risk and Resilience in Service members) routinely pulls identifiable data from ACSAP.

- For the Family Study, we are seeking permission to send a postal letter to those participants who signed the consent on the web, but failed to complete the survey. There are to be a total of three remaining contacts which include two emails and a \$5 pre-incentive mailing. At present, one email has already been sent this month of April. If the subject does not complete the survey after the \$5 pre-incentive mailing is sent, a final email will be sent and this will be the last contact during the cycle. The postal letter is enclosed for review.

February 2013

- This protocol has undergone a change of staff. Ms. Melissa Bagnell, Ms. Charlene Wong, and Ms. Hope McMaster no longer work for the DoD Center for Deployment Health Research.

Updates have been made to both the Millennium Cohort Study and Family Study Informed Consent Document for the 2014 survey cycle. Documents are enclosed for review.

- A previous protocol modification was approved in November 2012 with email text to Panel 4 participants who submitted a paper survey, but had not submitted a signed consent form. We have revised the email text, which is submitted for review. We sent

the original email version to 216 Panel 4 participants, but only received 42 responses back. For the Family Study, 125 emails were sent, but only 50 responses were received. Because these individuals put in the time and effort to fill out the survey and mail it back to us, we would like to make another attempt to obtain their consent by sending the revised email.

- Report Control Symbol review and renewal of survey instruments was completed in 2013; documentation attached. DoD RCS#DD-HA(AR)2106 (expires 03/31/14).
- Office of Management and Budget (OMB) review and approval of survey instruments was completed in 2011; documentation attached. OMB #0720-0029 (expires 03/31/14).

January 2013

- The following people have been added as new key support personnel to the protocol: Dr. Melissa Frasco and Dr. Daniel Trone.
- The Millennium Cohort Study 2014 survey versions were previously IRB approved in June 2012. One section of both the Follow-Up and New Enrollee approved surveys included a 10-item question on Adverse Childhood Experiences (ACE). Recommendations were made from a subject matter expert to condense the 10-item question into a comparable 4-item question. Therefore we request approval of the following 4-item question for inclusion into the 2014 Millennium Cohort Surveys. The old version of the 10-item question is attached for reference.

“ It would be helpful for this study to know about the background experiences that may have happened to some people:

 - a. Before the age of 18, how often did a parent or other adult in your home ever hit, beat, kick, or physically hurt you in any way?
Answer choices: Never, Once, More than once, Prefer not to answer
 - b. Before the age of 18, how often did a parent or other adult in your home ever touch your private parts when they shouldn't have or make you touch their private parts? Or did a parent or other adult that took care of you force you to have sex?
Answer choices: Never, Once, More than once, Prefer not to answer
 - c. Before the age of 18, how often did you get scared or feel really bad because a parent or other adult in your home called you names, said mean things to you, or said that they didn't want you?
Answer choices: Never, Once, More than once, Prefer not to answer
 - d. When someone is neglected, it means that the grown-ups in their life don't take care of them the way that they should. They might not get enough food, take them to the doctor when they are sick, or make sure they have a safe place to stay. At any time before the age of 18, were you neglected?
Answer choices: Never, Once, More than once, Prefer not to answer”
- Despite utilizing DMDC information, we still have a significant amount of outdated contact information for participants, resulting in a large amount of returned mail. We request the ability to use the MDR for both the Millennium Cohort Study and the Family Study as a means to obtain updated contact info.

December 2012

- In order to increase the number of spouses referred to the Family Study from our New Enrollee service members, we request permission to change the referral web page so that it no longer asks for secondary consent from service members. We've removed all items requiring secondary consent. This page will only ask the New Enrollee for their spouse's contact information. A PDF of the web page is attached for review.
- The following questions were added to the 2014 Family Study Follow-Up Survey (approved June 8, 2011) :
 - To best understand the dynamics of health care utilization and the needs of service members and their families, are you willing to allow us to link your survey data to DoD medical records of any children you may have that are under the age of five years old?
 - A great deal has been learned from this study, and as a consequence we've been asked to consider other research possibilities. If other related research studies become available, is it ok to contact you to let you know about these opportunities?
 - The 2014 Family Follow-Up Survey is attached.
 - A Welcome to the Family Study holiday card will be sent to those subjects who have completed the Family Study. A PDF of the card is attached for review.

October 2012

- The following people have been added as new key support personnel to the protocol: LCDR Kendall Egan, and Jill MacDougall.
- We wish to obtain data from two DoD data sources to use in analyses. The first is to re-establish a link to the Department of Defense Trauma Registry (DoDTR) (previously JTTR). Name and SSN will be provided to the DoDTR via established encrypted methods (POC Susan West Susan A. West, BSN, Institute of Surgical Research, 3698 Chambers Pass Bldg 3611, Fort Sam Houston, TX 78234-6315) for a query against the DoDTR for injury data. Data on occurrence and types of injuries will be obtained and utilized in our analyses looking at long-term health outcomes among deployed personnel. The second linkage request is with the United States Army Physical Disability Agency (USAPDA). Information on physical disabilities among service members and those separating will be obtained. Specifically we will explore the deployment history of the participant and causes for disability with the specific interest in respiratory causes of disability as an extension of the prior respiratory work in the Cohort. SSN information on participants would be provided to USAPDA (POC: Mr. Harold Alexander, 2900 Crystal Drive, Suite 386, Arlington, VA 22202) and then data on physical disabilities would be provided using a password protected CD Rom disk mailed via FedEx. All data upon receipt will be confidentially maintained on-site in our secure computer database. DUAs will be written and approved in advance of any data sharing for both linkages.
- In May 2012, a cover letter was approved to send to Panel 4 participants who submitted a paper survey but had not signed or submitted a consent form. We are seeking permission to send an email first to these participants, to request an electronic consent. We would like to offer this option first, as this method is easier and is less burdensome on the participant. We also recognize that a paper responder may have a preference to responding via paper again. Therefore if the participant does not respond to the email consent request, then we seek permission to send the originally approved cover letter and

paper consent along with a \$5 Starbucks gift card via postal mail. The email text is enclosed for review.

- Subject matter experts have been identified and we request their collaboration on several Millennium Cohort sub-study projects. Several of these investigators have been on prior projects and previously provided to the IRB. They will not have access to any personally identifiable information or access to the database. Those affiliated with USUHS and WRAIR have limited access to the data via prior IRB approvals and a LDUA/DUA. A file with the information on the sub-study topic and the collaborators are attached.
- Data Recognition Corporation (DRC), a survey scanning organization, will provide bulk receiving, scanning services and bulk return-shipping of paper surveys for the Millennium Cohort Family Study. DRC will be given limited access to the data. Surveys will be sent from NHRC to DRC without direct identifiers such as names, social security numbers, and addresses. Data from surveys will include information such as: demographics, occupation, mental health symptoms, physical conditions, functional health, habits (smoking, drinking, exercise, and diet), and other non-identifiable data. Consent pages will also be removed before sending surveys to DRC. At the end of the project, DRC will bulk ship scanned paper surveys back to NHRC and will send NHRC data files via a secure file transfer site. DRC will provide services within a DoD Defense Information Assurance Certification and Accreditation Process (DIACAP) environment and so all information transmitted is stored and processed in accordance with DoD security requirements. All research data will be returned to NHRC at the conclusion of the work. The LDUA is attached.

August 2012

- The protocol has undergone a change of staff. Lawrence Wang no longer works for the Deployment Health Research Department. Emma Schaller, Toni Rush, and Raechel Del Rosario have been added as new key support personnel.
- The study previously received approval to directly contact spouses of Panel 4 married Millennium Cohort Study responders who "skip" the Family Study secondary consent/referral page. A 10-week mailing schedule has been designed, which will involve directly contacting spouses with a Family Study invitation. In order to test the effectiveness of two mailing approaches, we will randomly assign these spouses to one of two groups (Group A or Group B).

GROUP A:

- A1: Magnet Frame and Card (week 1)
- A2: Postcard (week 2)
- A3: Sample Survey with \$5 Starbucks (week 5)
- A4: Letter along with Deanie Dempsey endorsement letter (week 6)
- A5: Survey sent FedEx (week 9)
- A6: Postcard (week 10)

GROUP B:

- B1: Survey with Magnet Frame (week 1)
- B2: Postcard (week 2)
- B3: Survey with \$5 Starbucks (week 5)

B4: Letter along with Deanie Dempsey endorsement letter (week 6)

B5: Survey sent FedEx (week 9)

B6: Postcard (week 10)

We currently have 9,909 spouses who we will approach with this process.

Group A began on August 2, 2012 with mailing A1 (Magnet Frame and card) to 2,478 spouses.

Group B will begin mid-September 2012 with B1 (Survey with Magnet Frame) to 2,477 spouses.

Once we have response data on Groups A and B, we will determine the approach that will be utilized for the remaining 4,954 spouses. The mailing cycle for both groups will be complete after approximately 10 weeks, and for the spouses that do not complete their survey we have no planned further contact for this group.

Non-referred spouses that continue to “roll in” with Panel 4 service member responders will be assigned to Group A, on an ongoing basis. Similarly, all referred spouses will also be assigned to Group A, and will receive emails as previously approved in the study protocol. All contact are planned to stop for referred and non-referred spouses after approximately 10 weeks once they completed a cycle in Group A. Artwork for all items will be submitted for review as it is created.

July 2012

- We request to add CPT Dale Russell as a collaborator onto the study. CPT Russell is an active duty Army member identified by the sponsor of the Millennium Cohort Study, MOMRP, as a potential collaborator to the Millennium Cohort Study Team. In the near future, there is a plan for him to PCS to NHRC as a staff member. In the interim, it is requested that CPT Russell assist with the study in a specified capacity without remote access to any secure databases. Specifically, he will assist with writing emails, administrative duties including helping with strategies for study non-response, and assisting in the conduct of sub-studies. In addition, he may be listed as the signatory on outgoing emails to participants. CPT Russell’s HIPAA and CITI certificates are enclosed.
- Previous Millennium Cohort outgoing emails were blocked by AKO and marked as SPAM. This may be one of the reasons why the Army participant response rates have been low. In an effort to remedy this impediment and increase the Army representation in our study population, we request to send an email specifically for Army participants. The text for this email is enclosed for review and lists CPT Dale Russell as the signatory.
- We request additional response options to be added onto the preapproved 2014 New Enrollee and Follow Up Millennium Cohort Study survey versions. The following are the added responses:
 - Preapproved question: “Since 2001, have you taken any educational course?”
 - Response added: “Yes, trade or technical school”
 - Preapproved question: “If you did NOT seek care, what were some of the reasons why you did NOT seek care?”
 - Response added: “Cannot afford treatment/no health insurance”

June 2012

- The Millennium Cohort Study and Family Study have revised survey instruments for the 2014 cycle. There are four survey versions for Millennium Cohort, which include: (1) New Enrollee-web version, (2) New Enrollee- paper version, (3) Follow-Up – web version, and (4) Follow-Up – paper version. There are 3 survey versions for the Family Study, which include: (1) Baseline, (2) Follow-up, (3) Follow-Up for divorced, separated, and widowed participants. All versions are submitted for review.
- In March 2012, we obtained IRB approval to mail a \$5 gift card as a pre-incentive to obtain more referrals to the Family Study. The pre-incentive will go to Panel 4 married participants who have completed their survey and did not explicitly refuse to refer their spouse to the Family Study. This mailer will be known as the New Enrollee pre-referral. We would like to pair this mailer with an email, and therefore are requesting permission to send a follow-up email to these recipients. The email text is submitted for review.

May 2012

- We would like to add a text box to the web version of both the Follow Up and New Enrollee surveys above the contact information section. The intent of the text box is to provide an explanation as to why we are asking for participant’s mailing and email address. The text will read:

“Thank you so much for responding to this health issues survey. We would like to verify your contact information. Although we obtain address information from DoD sources, we would like to ensure that we have the best information to reach you. We will also use this data to send you a token of appreciation after completion of the survey. If you have any questions or concerns, you can contact the Millennium Cohort Study Team at toll-free (888) 942-5222 or DSN 553-7465. You can also email us at milcohortinfo@med.navy.mil.”
- We are limited to the email and mailing addresses provided in DMDC, which are not always accurate. We would like to update participant email and mailing addresses with the one provided on the New Enrollee and Follow Up web surveys for individuals who had consented to and started the web survey, but did not fully complete the survey. The provided email addresses can then be used in sending incomplete reminder emails (previous approval). This will assist in limiting the number of follow-up emails since more accurate information will be utilized. We would also like to use the mailing address the participant provided to send a \$5 incentive to complete the survey (Artwork to be submitted).
- We also request permission to contact participants who have completed and returned a paper survey but did not sign or send back their consent form. Participants will be sent a \$5 incentive to return a signed consent document. This cover letter is attached for review.
- We request to remove the “Survey Complete – Submit” button on the bottom of the web survey pages. This button may be causing confusion for our participants, who may be hitting this button instead of the “Next” button and inadvertently not completing the whole survey. On the last page of the survey questions, we will update the text box to state “This is the last page of the survey, please click ‘Continue to Incentive’. Thank you for participation in this important study!” The “Survey Complete-Submit” button

will be changed to state “Continue to Incentive”.

- We request to update the Online Survey Instructions to read:
“Here are three suggestions that you might find helpful for completing this survey.
 - To move backwards or forward in the survey use the dark blue **PREVIOUS** and **CONTINUE** arrows, which save your completed answers. Please do not use the browser’s back button.
 - If you lose connectivity all of your completed answers will be saved, so you can sign on later to finish without having to start over at the beginning.
 - The **SAVE & CONTINUE LATER** button is on each page in case you need to temporarily stop and finish answering later.”
- We request to add the following text to the top of the Consent Form web page:
“In order for you to participate in this study, we need for you to check below that you “consent to participate”. We are required to obtain your consent to ensure that all participants are informed of what is expected of them, the potential risks of participation (if any), and how their questionnaire answers are protected. If you wish to print and keep a copy of the consent form you can do that by clicking here.
- The Millennium Cohort Study team requests approval for collaborating with Dr. Andrew Golub, National Development and Research Institutes (NDRI) on a project entitled “Veteran Reintegration, Mental Health and Substance Abuse in the Inner-City” (National Institute on Alcohol Abuse and Alcoholism, NIAAA, Project #R01 AA020178). The study involves examining Millennium Cohort Study participants who reside in specific locations in New York to investigate the sociodemographics as well as the mental and physical outcomes of this subset of the Millennium Cohort Study. The specific aims and usage of the Millennium Cohort data are described in pages 23-26 of the grant (attached). All data analyses will occur at NHRC, and no access to identifiable data or subjects will be provided. Aggregate information on the prevalence of conditions and demographics of this subset will be shared with collaborators, and we will work together to co-author presentations and/or publications from these data. No financial support for this substudy work will be obtained.

March 2012

- To increase Family Study response rates, we request permission to directly contact spouses of Panel 4 married Millennium Cohort Study responders who “skip” the Family Study secondary consent/referral page, as well as Panel 4 married responders that complete a paper survey.
 - Panel 4 responders that said “No” to the Family Study referral page will not be further contacted.
 - In addition, the current enrollment process will remain for Panel 4 married responders that gave their secondary consent and referred their spouse to the Family Study.
- This new enrollment process will require the following changes to the current spouse enrollment protocol:
 - The spouse consent form will need to be updated to remove text referring to the Panel 4 service member referral. The third sentence of the first section will be edited to “You were selected to be a part of this study because your spouse is a participant of

- the Millennium Cohort Study.”
- Invitation Email text, as well as the Reminder Email text, will be slightly modified to remove text referring to the Panel 4 service member referral.
 - The Survey Log-in page and “Having Trouble Logging In? Click Here.” webpage will be updated to remove text referring to the Panel 4 service member referral.
 - The Study Update, What’s New and About the Study www.familycohort.org webpages will be updated to reflect the new enrollment process.
 - Since secondary consent from the Panel 4 service member will not be attained, the following questions in the section, “Your Spouse’s Behavior” will be removed from the Family Study web survey:
 - How often have you observed these behaviors **IN YOUR SPOUSE** within the **PAST MONTH (or the most recent month your spouse was home)**?
 - a) Sudden bad memories/flashbacks
 - b) Spaces out
 - c) Lack of interest in sex/intimacy
 - d) Difficulty sharing thoughts and feelings
 - e) Avoids former interests/activities
 - f) Hyper-alert/startles easily
 - g) Anxious/nervous
 - h) Fearful
 - i) Withdrawn/detached
 - j) Irritable
 - k) Quick temper
 - l) Secretive
 - m) Difficulty falling or staying asleep
 - n) Nightmares or bad dreams
 - o) Taking more risks with his/her safety
 - p) Lack of interest in parenting/children (skip to the next question if you don't have children)Response Options:
 - Never
 - Seldom
 - Sometimes
 - Often
 - Very often
 - Within the **PAST MONTH (or the most recent month your spouse was home)** how **DIFFICULT** has it been for **YOUR SPOUSE** to do the following:
 - a) Do his/her work
 - b) Take care of things at home
 - c) Get along with other people
 - d) Fulfill supporting role as spouse/parentResponse Options:
 - Not at all
 - Somewhat
 - Very
 - Extremely

- In your opinion, does **YOUR SPOUSE** consume too much alcohol in a typical week when he/she is at home?
 - No
 - Yes

- Millennium Cohort investigators request evaluating response rates to determine potential biases among the study population by comparing non-responders and responders to the study invitation. These data are essential to determine the representativeness of the current study population. In order to complete these comparisons, we request comparing the demographic information among panel 2 and 3 responders and nonresponders which have already been collected from DMDC during the enrollment process, and in addition compare deployment experiences and prior health care utilization prior to the enrollment cycle among these two groups. These data are critical in determining any differences between responders/nonresponders and the utility of the current study data and its interpretation.

February 2012

- The protocol has undergone a change of staff. Ms. Michelle Linfesty and Charles Nesbitt have been added as new key support personnel.
- We request permission to disseminate a Millennium Cohort Study Newsletter. It will be mailed to the study population and will list recent publications, presentations, and key findings. The newsletter may help build participant interest and can be of great assistance in obtaining more completed surveys. The art and text is submitted for approval.
- We request permission to mail a \$5 gift card as a pre-incentive to obtain more referrals to the Family Study. The pre-incentive will go to Panel 4 married participants who have completed their survey and did not explicitly refuse to refer their spouse to the Family Study. The art and text for the gift card mailer is to be completed and submitted for approval.
- Previously the IRB approved an email reminder to be sent to all individuals who began the online survey but failed to complete or submit the survey (July 2005). We request permission to send this email twice a month as a reminder to these individuals. The text for these incomplete reminder emails for both Follow-Up and New Enrollee individuals are submitted for approval.
- In order to validate Air Force self-reported height and weight data reported on Millennium Cohort Study questionnaires, we would like to link Millennium Cohort data to height and weight data from annual fitness test scores from June 2001 to December 2008 at Health Care Informatics Division (HCID), Lackland Air Force Base. NHRC will send an encrypted password protected text file through a secure website, ARMDEC Safe Access File Exchange. This file will contain a list of social security numbers of all Airmen that are participants in the Millennium Cohort Study from June 2001 to December 2008. HCID will send an encrypted password protected text file through the ARMDEC secure website back to NHRC with SSN linked height, weight, and dates. HCID will destroy the social security numbers after completing the linkage, and will have no interactions with any record holders.
- An error in the New Enrollee web survey was previously discovered and reported in

September 2011. Questions designed only for women on the New Enrollee web survey were omitted from 7 June 2011 to 22 August 2011. The participants who were affected were given the opportunity to complete those questions through a mailed paper version or on the web. We are requesting to send these women who have not yet responded to the questions, an email reminder to complete them. The email text is enclosed for approval.

- Report Control Symbol review and approval of survey instruments was completed in 2010; documentation attached. DoD RCS#DD-HA(AR)2106 (expires 01/31/13).
- Office of Management and Budget (OMB) review and approval of survey instruments was completed in 2011; documentation attached. OMB #0720-0029 (expires 03/31/14).
- As a note of clarification, the following people are listed as study collaborators, and not co-investigators
 - Dr. Tomoko Hooper at Uniformed Services University of the Uniformed Health Sciences
 - Dr. Edward Boyko at the VA Puget Sound/University of Washington
 - Dr. Paul Amoroso at MultiCare Health System Research Institute
 - Dr. Margaret Ryan at Naval Hospital Camp Pendleton
 - Dr. Gary Gackstetter at Analytic Services Inc. (ANSER)
 - Dr. Tyler Smith at National University Technology and Health Sciences Center
 - Dr. Timothy Wells at Advanced Analytics Optum Insight

January 2012

- This protocol has undergone a change of staff. Dr. Besa Smith no longer works for the DoD Center for Deployment Health Research. She will continue to be a collaborator on this study, and will not have access to the data files, but rather will serve in an advisory role to the study and its publications. In addition, the following people have been added as new key support personnel: Sheila Medina-Torne, Andrea Ippolito, and John Wesner.
- To increase response rates, we request permission to use different versions of email messages to the study population. These emails will be sent out within previously approved timelines (See attached “NE_E8_Single.doc”, “NE_E8_Married.doc”, “NE_E9_Single.doc”, “NE_E9_Married.doc”, “NE_E10_Single.doc”, “NE_E10_Married.doc”, “NE_E11_Single.doc”, “NE_E11_Married.doc”, “Follow-Up_E9”)
- The IRB previously approved permission to mail a \$5 gift card as a pre-incentive to Family Study participants that have been invited to participate, but did not respond to the initial invitation email. The gift card will be inserted in a Family Study note card. The art for this note card is submitted for approval. (See attached, “pre_incentive_inside_panel_v2.pdf”, “pre_incentive_outside_panel_v3.pdf”). The inside panel text was slightly modified from the pdf version and is submitted for review (See attached, “pre-incentive-inside modified txt.doc”)
- The Publications section of the Millennium Cohort Study webpage will be updated with graphics consisting of publication journal logos (See example attached, “publication webpage.pdf”).

November 2011

- This protocol has undergone a change of staff. Dr. Donald Slymen has been added as new key support personnel to the Millennium Cohort Study data analyst team.
- This protocol involves consultation with researchers, Dr. Karen S. Mitchell, a Clinical Research Psychologist at the Women's Health Sciences Division, National Center for PTSD and an Assistant Professor at Boston University for the Department of Psychiatry VA Boston Healthcare System and Dr. Alison E. Field, at the Children's Hospital Boston, Division of Adolescent/Young Adult Medicine. No data will be provided to Dr. Mitchell and Dr. Field and Dr. Mitchell and Dr. Field will have no interactions with any record holders.
- In order to offer New Enrollees that complete their survey by paper an opportunity to refer their spouses to the Family Study, we request permission to send them an email one time (see attached previously approved "Automated Email Panel 4 Spouse Referral Reminder.doc"). To refer their spouse, participants will use an email link to be taken to a new landing page (see attached previously approved "Spouse Referral Landing Page.png"). Once logged in, New Enrollees will be taken to the secondary consent form (see attached previously approved "FamilyInvitePage2.png") and then see a thank you page (see attached previously approved "FamilyInvitePage3.png").
- We request permission to include an insert (art and text to be completed and submitted for approval) describing the Family Study in incentive mailers (gift cards, coins and hats). The insert will direct New Enrollees to the new landing page (see attached previously approved "Spouse Referral Landing Page.png"), and they will be taken through the same process as described above. Please note that New Enrollees that select "NO, you do not have permission to contact my spouse" on the secondary consent form will NOT receive this insert.
- We request permission to mail a \$5 gift card as a pre-incentive to Family Study participants that have been invited to participate, but did not respond to the initial invitation email. On a monthly basis, \$5 gift cards will be mailed to all referred spouses that are obtained during the month, but that do not respond to the initial invitation email. The gift card will be inserted in a Family Study note card (art and text to be completed and submitted for approval).

September 2011

- This protocol has undergone a change of staff. Mr. Lawrence Wang has been added as new key support personnel. Lawrence will be assisting with mail processing of returned Millennium Cohort Study surveys, postcards and incentives, as well as verifying completed paper surveys.
- Based on suggestions from Dr. Don Dillman, a highly respected survey methodologist known for the "Dillman Method" of survey implementation, we have revised many of our marketing materials, including the attached emails, cover letters, Blast automated call scripts, and Veterans Day postcard (see attached).
- We discovered an error in the New Enrollee web survey. The questions designed for only women to answer didn't appear from 7 June 2011 until the problem was discovered on 22 August 2011. This affected approximately 5,200 participants. We would like to mail these participants paper versions of the questions, see attached "Women only questions to be mailed.pdf," along with a \$5 Starbucks gift card. A cover letter (see attached "Women

Only Questions Cover Letter.doc”) will be sent with the mailing to inform participants that they can also go online to complete the questions. To log-in to complete the questions, participants will be taken to a new landing page (see attached “Women Only Landing Page.png”). Once logged-in, participants will see the following page “ConfirmQuestions_AlreadySubmitted.png” where they can complete the questions.

- Female participants that began but didn’t submit their survey during these dates will see the questions at the end of the survey, when they log back in to complete their survey - see attached “ConfirmQuestions.png”.
- In order to increase the number of New Enrollees referring their spouses to the Family Study, we request permission to use a web page (see attached “FamilyInvitePage1.png”) prior to secondary consent form (referral form) to succinctly describe the Family Study. This page will allow the participant to choose to a) read more about the study by continuing to the secondary consent form on the next page or b) skip to the “select gift” page. The consent form will not be changed except for design/graphic elements (see attached “FamilyInvitePage1.png”, “OriginalFamilyConsent_2.PNG”). The secondary consent form will include a “print” function that allows the participants to print a full copy of the consent with the contact information they provide (see FamilyConsent_Printable.PNG”).
- In order to offer New Enrollees that skip the page describing the Family Study an opportunity to refer their spouses to the Family Study in a different context, we request permission to send them an email one time (see attached “Automated Email Panel 4 Spouse Referral Reminder.doc”). To refer their spouse, participants will use an email link to be taken to a new landing page (see attached “Spouse Referral Landing Page.png”). Once logged in, New Enrollees will be taken to the secondary consent form (see attached “FamilyInvitePage2.png”) and then see a thank you page (see attached “FamilyInvitePage3.png”). Please note that New Enrollees that select “NO, you do not have permission to contact my spouse” on the secondary consent form will NOT be contacted with the proposed automated email.

August 2011

- This protocol has undergone a change of staff. Dr. Tim Wells no longer works for the DoD Center for Deployment Health Research, but will remain listed as a “Co-Investigator” on the protocol; Dr. Wells will not have access to the data files, but rather will serve in an advisory role to the study and its publications. We also wish to clarify the role of Dr. Tyler Smith who also recently resigned. He will continue to be a collaborator on this study with the same role (no access to the data files, but rather will serve in an advisory role to the study and its publications).
- To increase response rates, we request permission to send married New Enrollees that haven’t completed the survey a large format postcard that describes both the Millennium Cohort Study and the Family Study, in addition to the regularly scheduled postcards previously approved. We further request permission to randomly assign married New Enrollees to receive one of the three versions of the postcard, in order to determine the most effective postcard format (see attached).
 - ~24,000 Letter Size Postcards (6.125 X 11.5) without survey images

- ~24,000 Jumbo Postcards (9 x 12) with survey images on front
- ~24,000 Jumbo Postcards (9x12) without survey images on front
- ~24,000 No Special Mailing (standard reminder postcard)

We request permission to send non-married New Enrollees an additional standard reminder postcard (previously approved) in order to maintain a consistent number of postal contacts for married and non-married participants.

July 2011

- This protocol has undergone a change of staff. Dr. Marleen Welsh, Mr. Travis LeLeu, Ms. Jamie McGrew, and Ms. Stacie Nguyen no longer work for the DoD Center for Deployment Health Research. Mrs. Jennifer Walstrom and Mr. William Lee have been added as new key support personnel.
- Based on pilot testing that resulted in an increased response rate, we request permission to call the study population using an automated tailored voice message one time during the survey cycle. The message will encourage participation, but state that this is a voluntary study. The provider uses a web-based auto dialer. The message will be left whether or not the call reaches a live person or an answering machine. Overseas phone numbers will not be included. See attached for a script of the messages (married, single, and follow-up versions).
 - The system will dial each number up to 3 times to attempt to connect. Upon completion of each call, the result will be logged into the software's database (i.e. human pick up, voice machine, busy, not in service). If a number is answered by a person or the answering machine picks up, the report will indicate a successful delivery, and the number will not be dialed again. If a number is not in service, does not answer, is invalid or hangs up after connection, the result is listed as a failed connection in the database, and the number will not be called again. If however, a number experiences a technical error, or is busy, the system will attempt 2 additional times (5 minutes apart) and then list the final status on the database report. Once the list has been executed a comma delimited text file will be exported and uploaded into our database. The data results file will be used to remove bad telephone numbers and identify successful call attempts.
 - The provider has a technical support team in-house 24 hours a day to monitor the software and ensure there aren't any technical malfunctions, and to answer calls.
 - To ensure that auto dialing will only take place during reasonable hours telephone numbers will be categorized by time zone and the software will be set-up to call during mid-day in all time zones. If the list is not completed within the time limit that we specify for that day, the calls will be stopped and resumed the next day during the specified time frame.
- To increase response rates, we request permission to increase email contact with the study population from one time per month to two times per month during the survey cycle.
- To increase response rates, we request permission to send weekly emails (4 emails) during one month of the survey cycle to New Enrollees and Family Study participants.

- In order to understand the impact of increasing email contact on the study population, we request permission to follow-up any request to unsubscribe from emails with one question regarding the reason for unsubscribing. The follow-up question is not a required field to unsubscribe from the email list.

Please let us know your main reason for unsubscribing:

- I am not the intended recipient for this survey
 - I do not want to participate in this survey
 - I do not have time to participate in the survey
 - I am concerned that this is Spam or Phishing
 - I have privacy concerns
 - I received too many e-mails from this study team
 - I receive too many e-mails in general
 - I do not want to provide a reason for unsubscribing
 - Other (open text field)
- In order to better understand barriers to responding, we request permission to ask a single question when a participant leaves the survey before submitting.

Please let us know why you are not submitting your survey.

- I don't have time now, but will complete the survey later
- I only wanted to see the questions and I don't plan to complete the survey
- The questions are too personal, so I don't plan to complete the survey
- The survey is too long, so I don't plan to complete the survey
- Other (open text field)

May 2011

- In order to complete a study on hearing loss that will include analyses of all services, we would like to link Millennium Cohort Study data to the Defense Occupational and Environmental Health Readiness System, Data Repository (DOEHRS-DR), which is located at the US Army Public Health Command (Provisional), Aberdeen Proving Ground, MD. LT Jason M. Jones, an audiologist at Camp Pendleton, will sponsor Amber Seelig, a Millennium Cohort Study team member, in obtaining a DOEHRS-DR account. LT Jones will serve as an expert in the field of hearing loss. No Millennium Cohort Study data will be provided to LT Jones, and LT Jones will have no interactions with any record holders. Amber Seelig will use secure web-based interfaces to pull SSN-matched audiometric data for Millennium Cohort Study participants. All data will be stored on secure NHRC servers.

April 2011

- This protocol has undergone a change of staff. Dr. Tyler Smith will no longer serve as Principal Investigator on this protocol, due to his resignation from his position with the Deployment Health Research Department at the Naval Health Research Center. Dr. Nancy Crum-Cianflone will continue to serve as the Principal Investigator for this protocol. The informed consent document for this study has been reviewed and remains accurate, indicating consistent general information for contact of the Principal Investigator. In addition, Dr. Chris Phillips has been added as new key support personnel.

March 2011

- This protocol has undergone a change of staff. Dr. Don Sandweiss no longer works for the Deployment Health Research Department. Carter Sevick and Dr. Marleen Welsh have been added as new key support personnel. Dr. Nancy Crum-Cianflone has replaced Dr. Tyler Smith as Department Head, Deployment Health Research Department. CAPT Margaret Ryan has been added to the protocol as a co-investigator. CAPT Ryan was previously designated as a medical monitor, however, it has been determined that a medical monitor is not necessary for this protocol.
- Dr. Nancy Crum-Cianflone will be added to the protocol as a Principal Investigator. Dr. Smith and Dr. Crum-Cianflone will share Principal Investigator duties. The informed consent document for this study has been reviewed and remains accurate, indicating consistent general information for contact of the Principal Investigator.
- In order to complete a study on physical activity and fitness in the Air Force, we would like to link Millennium Cohort data to annual fitness test scores from May 2007 to December 2008 at Health Care Informatics Division (HCID) at Brooks Air Force Base. NHRC will FedEx an encrypted password protected text file burned to a CD to HCID with the list of social security numbers of active duty Airmen that are participants in the Millennium Cohort study. HCID will FedEx an encrypted password protected text file burned to a CD back to NHRC with SSN linked fitness test scores and dates. HCID will destroy the social security numbers after completing the linkage, and will have no interactions with any record holders.
- The following changes have been made to the Millennium Cohort Study Follow-up and New Enrollee questionnaires:
 - The paragraph following Question 19 on Follow-up and Question 20 on New Enrollee has been removed. The paragraph states, “If you have been bothered by any of the items listed above on this page, you may want to seek help from a health professional in your area” has been removed. This paragraph is no longer required to follow this question because question 19i and question 20i “Thoughts that you would be better off dead or of hurting yourself in some way” has been removed.
- The following change has been made to the Millennium Cohort Study New Enrollee questionnaire:
 - Due to the delay in receiving OMB approval, we decided to pull a new sample based on an October 2010 snapshot of military rosters. The language in the first section of the consent form has been changed to reflect this - October 2009 was changed to October 2010.
 - The risk statement has been updated to “The main risks to you are those associated with the inappropriate disclosure of data that we collect from or about you. While inappropriate disclosure has the potential to impact your reputation, insurability, or employability, it is important for you to understand that this research group has collected similar information from numerous studies over many years without any cases of inappropriate disclosure.”
 - The Consent Button at the top of the Consent Form has been removed and a link to download the consent has been added (online questionnaire).

- When developing the Millennium Cohort Family Study e-survey, the following changes from the print version were made in order to improve comprehension and usability:

Descriptive headings, introductory paragraphs, and informational icons were added and question order was modified.

- Headings: Background Information, Physical Health, Well-Being, Coping Skills, Life Experiences, Your Alcohol And Tobacco Use, Your Alcohol Use, Your Tobacco Use, Your Sleep Quality, Your Military Service, Relationship With Your Spouse, Your Spouse's Deployment, Deployment Return And Reunion, Your Spouse's Behavior, Military Life, Your Family, Demographics, Contact Information, Open Response
- Introductory Paragraphs:
 - To get started, we would like to ask you some background questions. These questions are used to determine which sections of the survey apply to you and your family, so the questions may seem unrelated to each other.
 - We'd like to remind you that all your answers are strictly confidential.
 - Now, we would like to ask you some questions about your physical health, how you feel, and how well you are able to do your usual activities. These items allow us to assess changes in your general health over time and if these changes may be related to other information you provide.
 - We would like to end this section by asking about your (or your spouse's) pregnancy and fertility history.
 - Now, we would like to ask you about your mental well-being. These questions are about how you feel and how things have been going over the last month. Some of these questions will seem slightly repetitive, but we assure you that they are actually different and each has a specific purpose. Remember, there are no right or wrong answers.
 - Below is a list of problems and complaints that people sometimes have in response to stressful life experiences. Some of these may not apply to you, however, please read each one carefully and mark the answer that best reflects how much you have been bothered by each problem in the last month.
 - The next several questions focus on your eating behavior.
 - Now, we would like to ask you how you've been feeling in the last 2 weeks.
 - Because we will re-survey you every three years, the last question of this section asks you to think back three years and compare yourself to now.
 - Now we'll ask you about the coping skills you use in daily life. In order to determine some that you might use, we have included a list below.
 - One example of an action-based coping mechanism is seeking care for a mental health, emotional, or stress related reason. Even if you haven't sought such care, we'd like to know what reasons might prevent you from seeking care.
 - The following section concerns life experiences that have the potential to act as protective or risk factors. We are aware that many of these questions are quite personal, but we would appreciate your candid response.
We'd like to remind you that all your answers are strictly confidential.
 - Now we would like to ask you some questions about your drinking and smoking behavior.

- Now we would like to ask you some questions about how you are sleeping. Even if you are pregnant or have a newborn that is disturbing your sleep, please answer the questions by reflecting on your current sleep pattern.
- In order to better understand how military life affects families, this next section includes questions about your relationship with your spouse.
Once again, we'd like to remind you that all your answers are strictly confidential.
- Now, we would like to ask you some questions regarding the deployment experience.
- The deployment return and reunion process can often be challenging, so the next several questions are about that experience.
- Your perception of your spouse's behavior is very important to the study.
Please be assured that your answers will NEVER be shared with your spouse or your spouse's supervisors.
- Now, we'd like to ask you some questions about the stress of military life and the military's efforts to help you and your family deal with those stressors.
- We would now like to ask you some questions about your family. By family we mean you, your spouse, and your children (if applicable).
- Now, we would like to ask you about your children. We realize that these questions are sensitive, but it is important to answer them as accurately as you can. Your answers will provide insight into how families and children are coping with military life and deployment.
We want to remind you that this is a population-based study and data collected will not be used to make decisions about treatment. If you feel your child needs medical care or counseling, you should make contact with the appropriate medical personnel.
- Because we're interested in how military life and deployment affect families over time, it is important for us to have contact information that you will have for at least the next three years. We realize that many of you will be moving locations before then, but you may have cell phones and email addresses that you will maintain for long periods of time.
- To help us contact you in the future, please provide the name and contact information for two people who are likely to know where you can be reached. Please do not include individuals that live in your household. We will NOT share your questionnaire responses with these individuals and they will ONLY be contacted if we have difficulty contacting you.
Please make sure these individuals are willing to provide your contact information if they are contacted by the Family Study team.
- The following questions were removed:
 - M26: Sea Bee: Chronic Multi-symptom Illness measure
 - M91: WRAIR Land Combat Study – except for item h
- The following response methods were changed from a “Yes/No” to an affirmative response text box:

- M89: Core Data Set and M92: CDC Children's Health
 - In order to assess the validity of responses for M89 and M92, the "page load to page submittal" time will be collected for pages 29 and 30 of the e-survey.
- The following text box was removed:
 - If you have been bothered by any of the items listed above, you may want to seek help from a health professional in your area.
- Spouses that don't have SSNs in DEERS will be asked for their full SSN after they submit their survey using the following text:
 - We were not able to retrieve your full Social Security Number (SSN) from your sponsor's record. In order to assist us in maintaining contact with you and to be included in all analyses, please provide your full SSN. Your full SSN will not be stored with your survey responses and will never be shared with anyone outside the study. Thank You!
- Additional Information Icons were added:
 - M58. Military members meet deployment criteria anytime they leave the physical locale of the parent command and enter an environment for operational deployment or are stationed in hostile territory.
 - M25. Hospitalized means that you were admitted to the hospital for treatment. Please do not check if you went to the ER, but were not admitted to the hospital.
 - M24. Serious means that you experience depression, anxiety, irritability, anger, or mood swings.
 - M69. This question refers to your spouse's current military job.
 - M76. Never experienced in the last 12 months.
 - M17. Please include your sponsor even if currently deployed, on temporary duty, or in training, if he/she lives and sleeps in your household the majority of the time. Please DO NOT include anyone that does not live and sleep in your household the majority of the time (e.g. visiting relatives).
 - M6. This information is used to verify your identity against our records. It will also be used as your login for follow-up surveys.
 - M87. Please include any biological, adopted, or foster children that are 21 years old or younger, if they live and sleep in your household the majority of the time.
 - M16. A mutually agreed upon commitment to one another involving exclusivity, honesty, or some other agreed upon behavior.
 - M61e. Refers to the act of communicating and emotionally connecting with your spouse.
 - M61f. Refers to your ability to make contact via email, phone, or web cam.

The risk statement has been updated to “The main risks to you are those associated with the inappropriate disclosure of data that we collect from or about you. While inappropriate disclosure has the potential to impact your reputation, insurability, or employability, it is important for you to understand that this research group has collected similar information from numerous studies over many years without any cases of inappropriate disclosure.”

- Report Control Symbol approval has been obtained. DoD RCS#DD-HA(AR)2106 (expires 01/31/13). See attached renewal document, “Millennium Cohort Studies - RCS renewal DD-HA(AR)2106.pdf”.

- Office of Management and Budget (OMB) approval has been obtained. OMB #0720-0029 (expires 03/31/14). See attached renewal document “Prospective Studies of US Military Forces The Millennium Cohort Study_OMB #0720-0029_March 2011.pdf”.

August 2010

- This protocol has undergone a change of staff. Dr. Hope McMaster, Ms. Stacie Nguyen, and Ms. Lauren Kipp have been added as new key support personnel.
- Attached are all marketing materials for the 2010-11 Millennium Cohort Study and Millennium Cohort Family Study survey cycle. Items include emails, postcards, cover letters, envelopes, and the Family Cohort refrigerator magnet.
- This protocol involves consultation with a researcher, Dr. Tomoko Hooper, at Uniformed Services University of the Uniformed Health Sciences (USUHS). Data to be provided to Dr. Hooper will not contain any direct or indirect identifiers and Dr. Hooper will have no interactions with any record holders.
- A pilot study has been added to the protocol that involves 200 Panel 4 Millennium Cohort Study participants taking the web version of the survey. Once subjects have consented to participate in the Millennium Cohort Study, and have indicated their marital status as “now married” in the first section of the survey, they will be randomly assigned to one of two groups. Group 1 will see the Family Cohort Permission Form immediately after indicating marital status, and Group 2 will see the Family Cohort Permission Form after they submit their completed survey. All 200 participants will be given the opportunity to view the Family Cohort survey when they see the Family Cohort Permission Form.
- The rationale for this pilot is to investigate the effect of effort justification (cognitive dissonance) on recruitment into the Millennium Cohort Family Study. Discovering methods of increasing enrollment in the Millennium Cohort Family Study is of considerable value.

March 2010

- This protocol has undergone a change of staff. Mrs. Lacy Farnell and Mrs. Molly Kelton no longer work for the DoD Center for Deployment Health Research. Mrs. Beverly Sheppard, Mrs. Teresa Powell, Ms. Amanda Pietrucha, Ms. Melissa Bagnell and Mr. Dennis Hernando have been added as new key support personnel.
- Based on external consultant review and sponsor driven additions, the following changes have been made to the Panels 1, 2 and 3 “follow-up” questionnaires, the Panel 4 “new enrollee” questionnaire, and the Millennium Cohort Family Study questionnaire:
 - Follow-up:
 - Q13 (b) - Changed answer choice titles to sentence caps.
 - Q18 (m-n) - Added “Ringing in the ears” and “Difficulty with balance.”
 - Informational blue box underneath Q19, added words “above on this page” for clarity.
 - Q27-29 – Added questions to measure infertility in both men and women.
 - Q57 – Added question to measure support.

- Q62 – Posttraumatic Growth Inventory (PTGI): the Millennium Cohort Study team and the Psych Health Program Area Team developed (Bliese, P., Hoge, C., Smith, T., Smith, B., & Adler, A). Moved from the deployment section of the survey to a general area so all participants complete the question.

The items are now written in the present tense and without reference to changes since the traumatic event in order to remove retrospective bias (a criticism of the original version of the scale). Because the Millennium Cohort study surveys people over time, some individuals will be surveyed before and after exposure to deployment/traumatic events. So any changes following deployment can be directly examined by comparing attitudes pre and post deployment. PTGI research has not historically been able to assess people pre-exposure so they've had to rely on retrospective recall.

The directions and response options were changed in order to match the item edits. Previously, the response options had reflected how much change had occurred since the traumatic event, now the items can be matched in terms of how much an individual feels the statements are true for them.

One item was added so it is now an 11 item scale (since the item about how you "learned a great deal about how wonderful people are" is awkward and previous publications suggest that an alternative item has equally good psychometric properties, the item about compassion was added).

- Q82-83 – Revision of injury variable to better assess injury and cause of injury with ability to crosswalk back to previously collected data.
- Q89 – Added a 3 item measure to determine resiliency.
- Q100 - Added a question on use of a separate location decompression program.
- New Enrollee:
 - Q14 (b) - Changed answer choice titles to sentence caps.
 - Q19 (m-n) - Added “Ringing in the ears” and “Difficulty with balance.”
 - Informational blue box underneath Q20, added words “above on this page” for clarity.
 - Q28-30 – Added questions to measure infertility in both men and women.
 - Q58 – Added question to measure support.
 - Q63 – Posttraumatic Growth Inventory (PTGI): the Millennium Cohort Study team and the Psych Health Program Area Team developed (Bliese, P., Hoge, C., Smith, T., Smith, B., & Adler, A). Moved from the deployment section of the survey to a general area so all participants complete the question.

The items are now written in the present tense and without reference to changes since the traumatic event in order to remove retrospective bias (a criticism of the original version of the scale). Because the Millennium Cohort study surveys people over time, some individuals will be surveyed before and after exposure to deployment/traumatic events. So any changes following deployment can be directly examined by comparing attitudes pre and post deployment. PTGI research has not historically been able to assess people pre-exposure so they've had to rely on retrospective recall.

The directions and response options were changed in order to match the item edits. Previously, the response options had reflected how much change had

occurred since the traumatic event, now the items can be matched in terms of how much an individual feels the statements are true for them.

One item was added so it is now an 11 item scale (since the item about how you "learned a great deal about how wonderful people are" is awkward and previous publications suggest that an alternative item has equally good psychometric properties, the item about compassion was added).

- Q84-85 – Revision of injury variable to better assess injury and cause of injury with ability to crosswalk back to previously collected data.
 - Q91 – Added a 3 item measure to determine resiliency.
 - Q98 - Added a question on use of a separate location decompression program.
 - Due to survey movement the Privacy Act Statement and Q99 were able to be moved back onto the 24-page survey instrument rather than be an additional page as previously submitted.
- **Family:** Many of the below question additions were added to remain consistent with the Millennium
 - Cohort Study questionnaires. Various minor formatting revisions have also been made since initial IRB approval.
 - Consent Form – Replaced language of gift card incentive to generalize the various options we'll offer.
 - Q21-23 - Added questions to measure infertility in both men and women.
 - Q24 – Moved “Are you currently pregnant?” to e instead of a. Removed h and i to avoid repetition with new infertility questions.
 - Q29 (m-n) - Added “Ringing in the ears” and “Difficulty with balance.”
 - Informational blue box underneath Q30, added words “above on this page” for clarity.
 - Q41 – Added oral health question.
 - Q49 – Added question to measure support.
 - Q50 - Added a 3 item measure to determine resiliency.
 - Q56(o-q) – Added response options to include mental health care stereotypes.
 - Q78-81 - Added the Adverse Childhood Events (ACE) scale that was taken directly from the RAP survey instrument (Section 10 General History Q12-19).
 - Q117 – Added sleep question.
 - Q118(d) – Added ‘snoring’ to response options.
 - Q124 – Added question to determine if spouse has ‘ever’ served in the military.
 - Report Control Symbol approval has been obtained. DoD RCS#DD-HA(AR)2106 (expires 01/31/13). See attached renewal document, “Millennium Cohort Studies - RCS renewal DD-HA(AR)2106.pdf”
 - Office of Management and Budget (OMB) review and approval will be pursued once IRB approval is attained.

October 2009

- The following procedures are in place to ensure that confidential information will not be used or abused in ways that might directly or indirectly harm the individuals involved:
 - Administrative
 - All study staff will receive training in confidentiality protection procedures.

- Supervisors will monitor staff to ensure that they follow proper confidentiality procedures.
- An annual review of confidentiality procedures will be conducted.
- If study staff resign or otherwise leave the program, they will remain under obligation to protect the confidentiality of all data collected as part of the study.
- Procedural
 - The respective service survey approval managers will review the introductory letter and mail questionnaire. Their approval will be required before initiating the mailing.
 - Study staff will store study paper records in locked metal cabinets at NHRC. Paper records that are no longer needed will be shredded.
 - All data files will be destroyed when all research questions have been answered.
- Computer Security
 - To gain entry into the study database, staff will be required to enter their personal ID numbers and password.
 - Study staff will download study data through secure data transmission links meeting standard DoD requirements. The database will be stored on existing NHRC information systems network. This system meets current DoD data security requirements.
 - All identifiable data will be maintained at NHRC only and not further disclosed.
 - Supervisors will grant access to the confidential database only to those staff who require it.
 - The NHRC network fire wall is in place to deter unauthorized access to these files.
 - All data will be carefully guarded and used only to meet the stated study objectives.
 - Personal identifying information will be removed from the analytic database once the survey, medical facility use, and demographic information are linked and stored separately. Only the statistician, who is familiar with the database, will link personal identifiers with the data for the initial match or any subsequent matches, and the identifiers will again be stripped following the match.
 - The study database will reside within the NHRC network environment. Only IRB-approved NHRC researchers will have access to identifiable data.
 - Information transmitted over the Internet will be done so using SSL-encrypted transmission lines. Further, users will have to enter their unique study ID number and last four digits of their social security number to send completed questionnaires.
 - NHRC will periodically review the computer security procedures, including challenges to the security fire wall erected to assure its integrity.

October 2009

- Based on external consultant review and sponsor driven additions, the following changes have been made to the Panels 1, 2 and 3 “follow-up” questionnaires and the Panel 4 “new enrollee” questionnaire:
 - Women-only question set has been slightly modified to include a pregnancy and a gestational diabetes question. See Q12e&g (Follow-up) and Q13e&g (New Enrollee).

- 4 health conditions have been added to the general health condition list based on the most frequent diseases that were written in the “Other” open text field in past surveys, including ‘High cholesterol requiring medication,’ ‘Kidney stones,’ ‘Acid reflux/gastroesophageal reflux disease requiring medication,’ ‘Tinnitus/ringing of the ears,’ and ‘Infertility.’ Q13b,p,bb,ee,ss (Follow-up) and Q14b,p,bb,ee,ss (New Enrollee).
 - Dominant hand question has been added to evaluate the possible relationship between handedness and PTSD, Q26 (Follow-up) and Q27 (New Enrollee).
 - Infertility questions have been added for both men and women to answer, Q27-28 (Follow-up) and Q28-29 (New Enrollee).
 - Five questions have been added regarding sleep distribution from the Insomnia Severity Index standardized instrument, and one question was added regarding over the counter medicine use. Q33-38 (Follow-up) and Q34-39 (New Enrollee).
 - Added the NHANES’ standardized oral health measure. Q41 (Follow-up) and Q42 (New Enrollee).
 - Added a social support measure, which seems to be an important resilience factor for many of the mental health factors. Q56 (Follow-up) and Q57 (New Enrollee).
 - 4 complementary and alternative medicine treatments that the National Center for Complementary and Alternative Medicine found to have had significant increases from 2002-2007 have been added to the CAM question, including ‘Yoga,’ ‘Meditation,’ ‘Movement therapy,’ ‘Breathing techniques.’ Q57g,h,o,p (Follow-up) and Q58g,h,o,p (New Enrollee).
 - Expanded serious injury question set to include amount of time lost from work and specific associations for motor vehicle accidents/crashes. Q82, 84-85 (Follow-up) and Q84, 86-87 (New Enrollee).
 - Added an employment status question. Q89 (Follow-up) and Q91 (New Enrollee). In lieu of this addition, the question “Do you have a civilian job at this time? Answer choices: ‘Yes,’ ‘No civilian employment at this time,’ ‘Homemaker”” was removed.
 - Added a household income question. Q90 (Follow-up) and Q92 (New Enrollee).
 - With approximately 25% of Millennium Cohort participants now separated from the service, a couple of VA medical care use questions have been added, Q94-96 (Follow-up only). Also added a question to determine if a participant is employed by a US Federal agency or the US Federal government. Q97 (Follow-up only).
 - Added ‘exposure to smoke from burning trash and/or feces’ to the deployment exposure question. Q99n (Follow-up) and Q96 (New Enrollee).
 - Added the Posttraumatic Growth Inventory Short Form 10-item questions which measures resiliency after a traumatic event. Q102 (Follow-up) and Q97 (New Enrollee).
 - Please note, the PHQ (i) “Thoughts that you would be better off dead or hurting yourself in some way” has been removed from the PHQ standardized instrument.
- Office of Management and Budget (OMB) review and approval will be pursued once IRB approval is attained.
- Based on the success of the Starbucks gift card pilot study encouraging voluntary participation, we request permission to include a “Hallmark Reward Choice” \$5.00

rewards gift card as a cost-saving initiative for all online survey completers. As with past survey cycles, the Millennium Cohort Study hat and coin are the two other cost-saving initiatives that will be offered during the 2010-11 survey cycle for participating online.

- The “Hallmark Rewards Choice” certificate program offers a centralized mechanism for the Millennium Cohort Study to offer participants a selection of gift cards from 51 national merchants (i.e. Applebee’s, Target, Home Depot, etc.). From Hallmark, the Study would receive codes and/or URLs to their website to distribute to participants after completion of the online Millennium Cohort Study survey. This code will be emailed from the Millennium Cohort servers to the participant. In it will be a link that will direct them to the Hallmark Insights website, where they can select which retailer their gift card will be issued from. Hallmark only collects the minimum information necessary to deliver the card (name, address, and phone number), and does not require the participant to register for any sort of account before redemption. The information they do collect is only used for delivery purposes, although they may telephone the participant in case of an incorrect / undeliverable address. This information is not shared with any third party entities.
- The Hallmark Insights program is SAS70 Type II compliant (application pending at this date, expected to be completed by the end of 2009), and follows security measures compliant with the Payment Card Industries (PCI) best practices. This includes robust technical and physical security safeguards as well as regular auditing to prevent fraud. Additionally, regular security scans are performed by trusted 3rd party vendors to assess the technical security levels of the different components of their program. At no point during these scans are client data (i.e. any Millennium Cohort participant information) exposed to any outside entities.
- Expiration: The Hallmark Insights gift card does not expire nor does it decrease in value, and can't be exchanged for cash.

August 2009

- **Collaborating Institution(s):** Abt Associates, Inc., Cambridge, MS; New York University Langone Medical Center, New York, NY; Duke University Medical Center, Durham, NC
- **Millennium Cohort Family Collaborator(s):**
William Schlenger, PhD, Abt Associates, Inc, Cambridge, MS
Charles Marmar, MD, New York University Langone Medical Center, New York, NY,
John Fairbank, PhD, Duke University Medical Center, Durham, NC
- The collaborators listed above will provide expertise on family behavioral and mental health epidemiologic issues. They will assist in the study and survey instrument design, and collaborate and/or serve as their intuition’s liaison on research projects for the Millennium Cohort Family Study. All data exchanged which will include self-reported survey data as well as supportive military medical/personnel records, will be deidentified and will follow JRRRA/BAA/MOU guidance as directed by NHRC IRB.
 - Each collaborator is operating under a valid assurance to protect human subjects involved in research.
 - CVs for each collaborator are attached.
 - The Naval Health Research Center’s IRB will provide primary review over the Millennium Family Cohort Study necessary approvals.

- **Background**

- In recent decades, mental health and related outcomes for US military service members following deployment have been documented for multiple conflicts. Much less attention has been paid, however, to deployment-related outcomes for spouses and other family members of those deployed. Family member functioning can be degraded by separation and associated worries, and service member functioning can be degraded when concern over events at home reduces their ability to concentrate or to be attentive and vigilant. Additionally, war zone stress exposure has been shown to have substantial impact on service members after they return home, which can produce additional stressors for both the service member and their families when they are re-united.
- Family relationships play an important role in the functioning and well-being of US military service members. It has been suggested that family relationships can be an important source of support that bolsters force readiness, or alternatively, a stressor that depletes service members' resources and reduces readiness. Few epidemiologic studies have examined the impact of war zone deployment on family members and family functioning. The Millennium Cohort Study is strategically positioned to complete this research. This research will also facilitate identification of specific areas of intervention, such as deployment-related stress, family member resilience, family support dynamics, service member and family well-being, and force readiness.

- **Objectives**

- The primary Millennium Cohort Family Study objective is to compare the adjusted probabilities of new onset diseases and conditions among military spouses and children.
- The secondary Millennium Cohort Family Study objective is to assess the importance of family support and other factors on positive and negative health outcomes.

- **Hypothesis**

- Stressors associated with deployment (e.g. geographical separation, increased risk of being wounded or killed) are associated with adverse mental health and related outcomes for spouses and children of deployed service members.
- Strong family support is associated with positive mental health and related outcomes for spouses and children of deployed service members.

- **Procedures**

- Based on recommendations from sponsors and advisory committees, and the success of the Millennium Cohort, a fourth enrollment panel will be added to the next survey cycle beginning in 2010. The Millennium Cohort was originally designed to follow three panels of participants that enrolled in 2001, 2004, and 2007 through 2022. The team plans to invite approximately 250,000 individuals of active-duty, Reserve, or National Guard status, with 2-5 years military service experience, oversampling for women, Reserve/National Guard, and those with a deployment-related injury. Out of the 250,000, an estimated 62,500 new participants will enroll. This group will be consented to complete 7 follow-up surveys over 21 years, with one survey to complete every 3 years. The invited group will be a stratified random sample from

the Defense Manpower Data Center. The current total number enrolled is 151,597, so this new enrollment will bring the total number enrolled to approximately 214,000 individuals.

- In addition to Panel 4, a Family Cohort component will be added to the next survey cycle beginning in 2010. In order to assess the interrelated health effects of military service and deployment on service members, spouses, and co-resident children, the Millennium Cohort Study team and collaborators will survey the spouses of newly enrolled Panel 4 participants that consent to this assessment. The team estimates that about 10,000 spouses will enroll in the study, about half of whose service member will have been deployed to the conflicts in Iraq and Afghanistan at least once.
- Surrogate data on children health will be obtained from the spouse. The data collected on these children will be generalized. No child will be individually identified for the purposes of this study. Because families and family relationships change over time and to maintain methodological consistency with the Millennium Cohort Study, spouses will be asked to complete 7 follow-up surveys over 21 years, with one survey to complete every 3 years. Participants of the Family Cohort Study will only have the option of completing a web survey.
 - In October of 2009, 250,000 service members will be randomly selected from military rosters. These individuals will be invited to participate in the Millennium Cohort's fourth enrollment cycle once OMB and RCS approvals are in place. These participants will be referred to as Panel 4 participants/members. Out of these Panel 4 members, the married service members will view the following: the Millennium Cohort Family Study survey instrument, and the Panel 4 Millennium Cohort Family Study informed consent document and permission form. From this group of consenters, the first 100 spouses to consent to the study and complete their surveys will be included in a pilot sample. This group of 100 individuals will be treated the same as the large group of Millennium Cohort Family Study participants, however, the internal team of analysts will review their survey to ensure participants are understanding the survey questions. Based on survey research, missing data along with data completion rates will indicate how the survey is interpreted. Also, an open-ended question will be added to the end of the first 100 surveys, "Is there anything you didn't understand or would change in this survey?" This will provide us with information on how the questions were interpreted and understood. We will not be requesting further feedback from these participants.
 - Millennium Cohort Study contact methods will be employed, including the modified Dillman survey methodology. Complex algorithms will be developed for email, mail and response tracking.
 - A separate website will be built for this sub-study, but will link directly to the Millennium Cohort Study website, www.millenniumcohort.org. The URL will be www.familycohort.org
 - Like the Millennium Cohort Study, nominal incentives will be offered to participants that complete the survey online, participants will be offered the choice of a \$10 gift card to the following; military exchange (AAFES/NEX gift card), Starbucks, or Amazon.com. AAFES/NEX and Starbucks gift cards will be mailed to participants within 6 weeks of survey completion, and Amazon.com

electronic gift cards will be emailed within one week of survey completion. None of the gift cards are exchangeable for cash.

- **Data Analysis**

- The adjusted probabilities of new-onset diseases and conditions among military spouses will be conducted by examining self-reported data, and by validating these data with objective electronic medical data when possible. Spouse-reported data on children will be analyzed but not linked with objective data. Multivariable logistic regression modeling will be used for each outcome, and multivariable Cox proportional hazard modeling when possible. Similar to previous analyses conducted within the Millennium Cohort Study, covariate adjustment will include age, gender, occupation, marital status, race ethnicity, deployment status, branch of service, income, and length of service. SAS statistical analysis program software (SAS Institute, Inc., Cary, NC) will be used for the Millennium Cohort Family Study analyses.

- **Risks**

- The data collection procedures are not expected to involve any risk or discomfort for spouses or children. The only risks are those associated with the inappropriate disclosure of data provided. However, this research group has collected similar information from several studies over many years without any cases of inappropriate disclosure.

- **Data**

- We will link to Department of Defense personnel and medical records obtained from the following sources: DMDC (Data Manpower Data Center) and TMA (Tricare Management Activity). For mortality data only, we will link to AFIP (Armed Forces Institute of Pathology), NDI (National Death Index), and VA (US Dept of Veterans Affairs). In addition, if the spouse is an active duty member and retires or separates from military service and utilizes Department of Veterans Affairs for medical services, we will link to VA medical and personnel data as well as the DoD Joint Theater Trauma Registry and the Navy/Marine Corps Trauma Registry. These data will complement subjective measures with objective measures of exposures and health outcomes. These databases are accessed electronically through secure computers located at the Naval Health Research Center. Unique identifiers are used to link each participant with their electronic data. No data regarding a child and his/her health will be linked from any source for the purposes of this study.
- The term “Family” will be defined as: An individual(s) living in household for majority of the time who has an impact on the household environment. Co-residency is not a requirement for the spouse.
- The term “Sponsor” will be defined as the military service member who is a member of the Millennium Cohort Study and has named the invited participant as his/her spouse. The term "your sponsor" will be referred to as "your spouse" throughout the survey. Continued participation of a spouse regardless of relationship status is important since the aim of the study is to look at the long-term health effects. Therefore, co-residency of the spouse is not necessary since some spouses are non-

co-residents (i.e. military to military married who are in different services, and spouses that live with parents or other family members while military member is deployed or stationed overseas); however, co-residency of children will be a requirement. Following participants in the study long after they are divorced, separated, or no longer co-residing is still relevant, since such data will be used to assess the long-term health of family members. The relevancy of collected data on the sponsor may be diminished if contact with the ex-spouse becomes limited.

- Attached is the Panel 4 Millennium Family Cohort consent form. This web-based consent form is to be digitally signed by the Panel 4 Millennium Cohort member prior to his/her spouse being invited to participate in the Millennium Family Cohort Study. Prior to providing permission for the spouse to participate, there will be a link to the Millennium Family Cohort Study survey for review, and the Panel 4 participant will be able to print the consent form for his/her records. Once electronic consent has been obtained, the spouse of the Panel 4 member will be contacted and invited to participate in the Millennium Family Cohort Study.
- Confirmation of electronic consent will be recorded by each participant (both the Panel 4 member and spouse) typing out their full name and checking the “voluntary consent” box. All information collected through the Internet survey is done by Microsoft Sequel Server and is backed up daily by NHRC database systems.
- Note, we request a waiver of signed informed consent for both spousal informed consent and Panel 4 participant consent to be a secondary subject, as consenting will occur online.
- The Millennium Family Cohort Survey instrument and consent form are attached. The survey instrument uses a number of validated scales to assesses the following (sources listed on pg. 33 of Family Survey):
 - Demographic information
 - Relationship status
 - Child information
 - General health (including sleep)
 - Spouse, family, child, and service member stress
 - Impact of deployment
 - Impact of military service
 - Family cohesion, expressiveness and conflict
 - Child behavioral, developmental and health problems
 - Services received
 - Alcohol and tobacco use
 - Military specific questions for spouses serving in the military
- CAPT Margaret Ryan’s (Naval Hospital Camp Pendleton) status has changed from co-investigator to solely acting as the Millennium Cohort Study’s medical monitor.

April 2009

- This protocol has undergone a change of staff. Ms. Skye Endara and Ms. Lauren Zimmerman no longer work for the DoD Center for Deployment Health Research. Ms. Amber Seelig, Dr. Donald Sandweiss, , Ms. Kelly Jones, and Mr. Gordon Lynch have been added as new key support personnel.

February 2009

- To determine new techniques to better encourage participants in the future to continue to participate and to maintain interest in the study, we request approval to conduct a mock administration of the Millennium Cohort survey in order to get input from non-participants.
 - The purpose of the focus group testing session is to go over items in the approved survey (mock administration) and gain insights from non-participants about the instrument. Participants will be asked to address any aspect of the survey including clarity of approved subject materials, visual appeal of the approved materials, and thoughts about what might be done to increase respondent participation.
 - Focus groups will consist of 9 or less active duty service members, including Reserve/Guard status, with 1-3 years of service, per location.
 - Focus groups will last no longer than 60 minutes per session.
 - Each session will be audio recorded and have a note-taker separate from the moderator. Audio recordings will be destroyed once they are transcribed.
 - Participants will be asked to provide oral consent after reading “Information to Participants” form.
 - Millennium Cohort co-investigators will serve as the moderators and recruit individuals based on the composition goals. Each moderator will post a flyer for solicitation (see attached document).
 - Study will include 5 focus groups at the following locations: Camp Pendleton - CAPT Margaret Ryan, Wright-Patterson AFB - Col Tim Wells, Madigan Army Medical Center - COL Paul Amoroso, Veterans Affairs Puget Sound - Edward Boyko, MD, MPH, Uniformed Services University of the Health Sciences - Tomoko Hooper, MD, MPH, FACPM
 - Guidelines will be distributed to each moderator. Also, a packet of group materials (notepad, pen, cost-saving initiatives, and copies of a survey packet, postcard, and email) will be sent to each moderator to distribute to each individual. Moderators will provide a background of the Millennium Cohort Study and then begin an open discussion about current Millennium Cohort marketing techniques.
 - Moderators will provide a summary of the testing session that will be added to the Millennium Cohort Study Manual of Operations and will include: date and location of test session, number of participants, relevant demographic information on each, and response to screener questions, a summary of the discussion for each section of the moderator guidelines, and a summary conclusion of the findings and recommendations based on consensus reached at the focus group testing session. Identities of participants will not be recorded.
 - Small gifts of appreciation, such as a Millennium Cohort hat and coin, will be distributed to each focus group participant.
- The third Millennium Cohort Study enrollment cycle concluded 31 December 2008. Responses for the new Panel 3 enrollment group totaled 43,440. 198,275 individuals that were randomly selected through the Defense Manpower Data Center were contacted to participate in the Panel 3 enrollment group. The original IRB protocol estimated that 140,000 participants would be enrolled in the Cohort (Panels 1, 2, and 3). However, after the completion of the third enrollment cycle there are now 151,597 participants enrolled.

Due to the methodology of the research (mailed invitation to complete a self-administered survey), once invited, all surveys of participants contacted to complete the 2007-08 survey were accepted. This resulted in more participants enrolled than was anticipated when the original study protocol was created.

November 2008

- This amendment seeks to allow a bi-yearly data extract from the Joint Trauma Theater Registry (JTTR) so as to allow linkage of records that occur in both the JTTR and the Millennium Cohort data base. This linkage will allow researchers to classify the types and severity of injuries sustained during combat and to analyze the data together for long term psychological and functional health outcomes. Data transfer will be encrypted via password protected e-mail and all data will only reside on secured servers in password protected files after it arrives at NHRC.

The following variables will be requested from the JTTR: Admitting Service, Age, AIS, AIS Coder, Arrival-Ref Fac, ASCOT, Burn Type, Burn P, Cause-Level IV&V, Cause of Injury Specify, Causes-Level III, City-Injury Location, Classification of Injury, Conflict Related, Country-Injury Location, Date of Birth, Days in Sick Quarters, Days on Light Duty, Departure-Ref Fac, Discharge Condition, Discharged To, Disease Related, E-Code, Ethnicity, Extent of Body Surface Involved 948, Gender, GCS-Discharge Vitals, GCS-ED, GCS-Pre-Facility, GCS-Ref-Fac, GCS-Ref Fac(transport 1), GCS-Ref Fac(transport 2), Height/Units, ICD-9, Inhalation Injury, Injury Date and Time, ISS, ISS Body Region, Job Description, Mechanism-Level IV&V, Medication Given, Military Coding, Military Rank, NISS, Non-Trauma Diagnoses, Patient Military Service, Pre-Existing Conditions, Race, Revised Trauma Score, SSN, Time in ED, Total Days Hospitalized, Total Days ICU, Weight/Units-Discharge Vitals, Wounded By.

May 2008

- (Modification accepted) Dr. Tyler Smith's role changed from Co-Investigator to Principal Investigator. Dr. Tyler Smith replaced CAPT Margaret Ryan as Principal Investigator due to her permanent change of station to Naval Hospital, Camp Pendleton. CAPT Ryan will remain on the study as an external co-investigator. As an external co-investigator, CAPT Ryan will have no access to primary study data. Her role will be to assist in developing analysis plans, reviewing/interpreting results, and developing scientific manuscripts. The informed consent document for this study has been reviewed and remains accurate, indicating consistent general information for contact of the Principal Investigator.
- (Modification accepted) To increase response rate, we request permission to conduct a pilot study in which a designated group of participants are called with an automated tailored voice message. The pilot group will consist of Panel 1 and Panel 2 consented participants that have not completed the 2007 questionnaire and that have a phone number on record. The message will encourage participation, but state that this is a voluntary study. The provider uses a web-based auto dialer. The message will be left whether or not the call reaches a live person or an answering machine. Overseas phone numbers will not be included in this pilot study. See attached for a script of the message.
 - The system will dial each number up to 3 times to attempt to connect. Upon completion of each call the result will be logged into the software's database (i.e. human pick up, voice machine, busy, not in service). If a number is answered by a

- person or the answering machine picks up, the report will indicate a successful delivery, and the number will not be dialed again. If a number is not in service, does not answer, is invalid or hangs up after connection, the result is listed as a failed connection in the database, and the number will not be called again. If however, a number experiences a technical error, or is busy, the system will attempt 2 additional times (5 minutes apart) and then list the final status on the database report. Once the list has been executed a comma delimited text file will be exported and uploaded into our database. The data results file will be used to remove bad telephone numbers and identify successful call attempts.
- The provider has a technical support team in-house 24 hours a day to monitor the software and ensure there aren't any technical malfunctions, and to answer calls.
 - To ensure that auto dialing will only take place during reasonable hours telephone numbers will be categorized by time zone and the software will be set-up to call during mid-day in all time zones. If the list is not completed within the time limit that we specify for that day, the calls will be stopped and resumed the next day during the specified time frame.
- (Modification accepted) The 2005 Millennium Cohort Study: Telephone Study of 3,000 Non-Responders conducted by RTI for the Millennium Cohort suggested that some type of a cash incentive up front would increase and encourage participation. The 2007-08 Millennium Cohort questionnaire cycle launched on May 17, 2007 and will conclude in July 2008. To reach response rate goals, we request permission to conduct a pilot study in which a gift card incentive will be added to a designated group of Panel 1 and Panel 2 consented participants that have not completed the 2007-08 questionnaire.
 - The pilot group will consist of two groups of approximately 18,500 Panel 1 and Panel 2 consented participants that may be of active duty or separated status. One group will be the control and will not receive a gift card in their Certified mail packet, and the other group will receive a \$5 Starbucks coffee gift card. The current text on the outside questionnaire packet envelope that promotes a free gift after completing the questionnaire online will be revised to indicate the inclusion of a gift inside the envelope.
 - This protocol has undergone a change of staff. Mr. Robb Reed no longer works for the DoD Center for Deployment Health Research. Ms. Jamie McGrew, Ms. Molly Kelton, Mr. Martin White, Ms. Skye Endara, and Maj Nisara Granado have been added as new key support personnel.
 - CAPT Margaret Ryan will replace CDR Kevin Russell as the Medical Monitor of the Millennium Cohort Study.
 - Co-investigators Dr. Gregory Gray and Col (Ret) James Riddle have transitioned to consultants.

May 2007:

- This protocol has undergone a change of staff. Mr. Rob Shipps, Mr. Adam Richardson, Mr. Tony Russo, Ms. Christina Spooner, Ms. Katie Chapman, Ms. Laura Chu, and CDR Sylvia Young no longer work for the DoD Center for Deployment Health Research. Ms. Charlene Wong has been added as new key support personnel.
- Col Tim Wells and Dr. Tyler Smith changed roles from research support to Co-Investigators. They have been added to section VII.1 of the protocol, 'Organization Of

Research Effort/Duties and Responsibilities’ on page 29 and Appendix B: ‘Investigator Assurance Agreement.’ Signed Investigator Assurance Agreements are attached. Col Wells will help with interpretation of results and report writing only. Col Wells will not have access to any identifiable data in this capacity. Please note that “Co-investigators” with no access to identifiable study data (these include Col Wells, COL Amoroso, Dr. Gray, Dr. Boyko, Dr. Gackstetter, and Dr. Riddle) may be considered to work in an academic “Consultant” capacity.

- A Joint Research/Review Agreement has been established between the Naval Health Research Center and Uniformed Services University of the Health Sciences so co-investigator Dr. Tomoko Hooper can request de-identified data transfers of Millennium Cohort data. The Joint Research/Review Agreement is attached.
- USARIEM is no longer a collaborating institution due to co-investigator COL Paul Amoroso relocation to Madigan Army Medical Center. Memorandum for the Record attached. As above, COL Amoroso will help with interpretation of results and report writing only. COL Amoroso will not have access to any identifiable data in this capacity.
- There have been slight formatting changes made to the 2007 enrollment consent form since it was approved by the IRB in June 2006. The finalized informed consent form is attached.
- A Public Burden Statement has been added to the Privacy Act Statement. The updated Privacy Act Statement is attached.
- Letter of support from the Chairman of the Joint Chiefs of Staff, GEN Peter Pace, will be included in 2007 questionnaire packets to encourage participation. Copy is attached.
- Based on external consultant review, the following changes have been made to the Panels 1 and 2 follow-up questionnaires and Panel 3 new enrollee questionnaire:
 - Q4 on birth year has been added as an extra identifier for quality assurance reasons.
 - Women-only question set has been slightly modified to better assess menstrual periods. See Q12a-b (Panels 1&2) and Q13a-b (Panel 3).
 - Fibromyalgia has been added to the list of health conditions, Q13s (Panels 1&2) and Q14s (Panel 3).
 - The Atkins diet specific question has been removed from the questionnaire.
 - Complementary and Alternative Medicine (CAM) section of the survey has been expanded to include use of body building, energy and weight loss supplements, Q47a-c (Panels 1&2) and Q48a-c (Panel 3).
 - Questions on alcohol use have been slightly modified to better address binge drinking. See Q50-60 (Panels 1&2) and Q51-62 (Panel 3).
 - Additional life stressors have been added to Q67 (Panels 1&2) and Q69 (Panel 3).
 - Injuries are assessed through Q70-71 (Panels 1&2) and Q72-73 (Panel 3).
 - Occupational code 5H, Social Worker, has been added to the Officer or Warrant Officer Military Occupational Categories list.
 - Separation questions have been added to the survey. See Q76-78 (Panels 1&2) and Q78-79 (Panel 3).
 - The following country and sea locations have been added to the imminent danger pay,

- hardship duty pay, or combat zone tax exclusion list: Bosnia or Herzegovina, and the Adriatic Sea. Kuwait and Iraq have been separated into separate country codes.
- Additional deployment-specific exposures are assessed in Q82 (Panels 1&2) and Q83 (Panel 3). Several questions, including (m), "...being responsible for the death of a non-combatant," are recognized as potentially sensitive. Please note that these questions are a subset of the 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).
 - Office of Management and Budget (OMB) review and approval of survey instruments was completed in 2006; documentation attached.

June 2006:

- This protocol has undergone a change of staff. Mr. Nick Martin, Ms. Angelee Ferber, and Ms. Sheila Jackson no longer work for the Department of Defense Center for Deployment Health Research. Ms. Kari Welch, Ms. Laura Chu, Ms. Lacy Farnell, Ms. Carolyn Reed, and Ms. Kathy Snell have been added as new key support personnel.
- The consent form for the 2007 enrollment has been modified to include HIPAA language and minor technical changes. See Appendix A.

July 2005:

- This protocol has undergone a change of staff. Ms. Janette Astiazaran, Mr. Tom Corbeil, Ms. Doris Diehn, and Ms. Wendy Goldfinger no longer work for the Department of Defense Center for Deployment Health Research. Ms. Katharine Chapman, Ms. Angelee Ferber, Ms. Isabel Gomez, Ms. Cynthia Leard, and Ms. Christina Spooner have been added as new key support personnel. As of 13 June 2005, subjects who begin the survey online will no longer be asked, "Would you like to receive an email reminder?" Due to coding/script challenges, investigators have been unable to determine who specifically requested a reminder and who closed their browser without responding to the prompt. Per discussion with the IRB Chair and email approval dated 01 June 2005, email reminders will now be sent to all individuals who began the survey online but fail to complete/submit.**August 2004:**

- This protocol has undergone a change of staff. Ms. Suzanne Clark, Ms. Rebecca Gunnill, and Dr. Paul Sato no longer work for the Department of Defense Center for Deployment Health Research. Ms. Janette Astiazaran, Ms. Wendy Goldfinger, Mr. Travis Leleu, Mr. Nick Martin, Mr. Rob Shipps, Mr. Steven Speigle, LtCol Timothy Wells, and CDR Sylvia Young have been added as new key support personnel. CDR Kevin Russell has replaced Dr. Paul Sato as the Medical monitor for this study.
- The consent form has been modified for Panel 2 participants. Panel 2 participants were drawn from personnel serving as of October 2003 and they will be followed for 18 years. This change appears in yellow highlight on the consent form. The consent form also has been modified to clarify that survey data, if provided, will be linked to other military and medical databases. Consent form also modified to reflect that participation may be discontinued by investigators in the unlikely event that study ceases earlier than planned.
- Based on recommendations by the Millennium Cohort Scientific Steering and Advisory

Committee (SSAC), changes have been made to the Panel 1 follow-up survey and the Panel 2 enrollment survey. The changes are as follows:

- The previous survey instrument lacked self-reported information on hospitalization and illness that prevented work. To address this, Q10 and Q11 were added to the Panel 1 follow-up survey and the response options for Q8 were expanded to gather hospitalization information for specific conditions.
- Q19-22 and Q32-34 were added to the Panel 1 follow-up survey to better capture changes in weight over time, general dietary intake information, and physical activity levels.
- The Complementary and Alternative Medicine (CAM) section of the survey was expanded to include therapies that now constitute the accepted definition of CAM therapies. This change is evidenced in Q46 of the Panel 1 follow-up survey and Q38 of the Panel 2 enrollment survey.

- In response to the increased use of smallpox vaccine, participants are now asked if they have received the smallpox vaccine within the last 3 years. These are Q48 in the Panel 1 follow-up survey and Q40 in the Panel 2 new enrollee survey.
- To address challenges in deployment data, questions were added to both survey instruments. These are Q65-67 in the Panel 1 follow-up survey and Q60-62 in the Panel 2 follow-up survey.

We request permission to access existing data sources on prior healthcare utilization among non-responders. Data on these individuals are essential for exploring response bias and external validity of the findings of this study. Only de-identified demographic, administrative, and medical data for non-responders and decliners will be maintained to explore potential differences between survey participants and non-participants. Please see description and justification in protocol text, page 18.

June 2004:

- We have added an additional data source to the Supplemental Medical and Administrative Data section of the protocol. We will now also link to the Pre and Post-Deployment Health Assessments (DD2795 and DD2796) survey data. The addition is evidenced in yellow highlight on the page numbered 20 of the protocol.

9 Oct 03:

- In the recruitment letters, the clause “If you are willing to participate” has been added before “please review and sign the Consent Form...” as requested by the IRB.
- The phrasing on the consent form concerning potential benefits of the study has been changed as per IRB recommendation.
- As requested by the IRB, the email address for the IRB Chair has been added to the contacts section of the consent form.
- The bullet “Will you be provided medical care based on your responses?” and the corresponding response as outlined by the IRB has been added to the consent form document.

10 Sept 03:

- This protocol has undergone a change of staff. Some key support personnel, Ms. Jacqueline Valdes and Ms. Dinice Jimenez, no longer work for the Department of Defense Center for Deployment Health Research.

8 Nov 02:

- Consented participants will be contacted semi-annually to verify their current contact information. Semi-annual contact, in the form of a postcard or an email, will be a relatively simple means to maintain current mail and email addresses for study participants. This change is evidenced in Appendix
- Email invitations to complete the Millennium Cohort survey online were extended to invited participants for whom we had email addresses. Since that time, an additional incentive (phone card) has been added enabling participants to select one of two incentives (T-shirt or phone card). The participants we previously extended email invitations to did not have the opportunity to receive the new incentive. A final email invitation will be extended to these individuals so that they will have an opportunity to receive either incentive.
- This protocol has undergone a change of staff. Some key support personnel (Lacey Evans, James Ramage, and Karen Schlangen, MA) no longer work for the Department of Defense Center for Deployment Health Research. Ms. Jacqueline Valdes, Ms. Dinice Jimenez, and Mr. Thomas Corbeil have been added as new key support personnel.

4 Jun 02:

- Email addresses were obtained for study participants. Many email respondents have indicated that postal invitations were never received. Brief emails introducing the Millennium Cohort Study and inviting individuals to join the study have been sent to invited participants.

25 Mar 02:

- The consent form has been modified to reflect the transition from the Committee for the Protection of Human Subject to the Institutional Review Board and the appointment of Christopher G. Blood, JD, MA, as the Chair. This change is evidenced in Appendix A.

23 Jan 02:

- New duty addresses obtained from DMDC. Letter of endorsement from the Secretary of Defense will be sent to subjects in lieu of the third reminder postcard. An additional questionnaire packet will be sent to subjects following the endorsement letter. Official/duty e-mail addresses will be obtained and used for sending reminders to participants.
- There has been a change in staff. Gia Gumbs has replaced Karen Chesbrough as the study coordinator.

15 Oct 01:

- Added additional signatures for new personnel for Protocol Signature Pages and Appendix B. Investigator Assurance Agreements.
- Revised Cover Letter #2 to recognize 11 September 2001 terrorists' attacks.

01 Aug 01:

- Quality assurance revisions made to consent form, questionnaire, and cover letters to reflect program updates.

31 May 01:

- LCDR Ryan's role changed from Co-Investigator to Principal Investigator. LCDR Ryan replaced CAPT Gray as Principal Investigator due to his retirement. CAPT Gray will still remain on the study as a Co-Investigator.

APPENDIX F. MILLENNIUM COHORT PARTICIPANT CONTACT MATERIALS

Incomplete reminder

Subject: –DoD Health survey

Dear [Name],

Thank you for taking the time to start filling out your Millennium Cohort survey. We understand that your time is very valuable, but your participation in this landmark study is very important.

Please follow the link below to finish the remaining questions:

[link]

Your continued involvement in this important project makes it possible to inform policy makers regarding your experiences and to guide prevention measures that positively impact former, current, and future Service members.

Thank you in advance for completing this important DoD survey.

Very respectfully,

David D. Luxton
Principal Investigator and Military Veteran
DoD Center for Deployment Health Research
San Diego, CA
www.millenniumcohort.org

For any questions, please contact the Millennium Cohort Team at milcohortinfo@med.navy.mil or info@millenniumcohort.org. Or call toll free 1-888-942-5222 or DSN 553-7465, and reference your Subject Id: [SID]

The Millennium Cohort Study is an authorized Department of Defense project. Note Defense Manpower Data Center Reference # 00-0019, Report Control Symbol # DD-HA(AR)2106, Office of Management and Budget Approval # 0720-0029, Office of the Assistant Secretary of Defense (Health Affairs), TRICARE Management Activity Protocol # CDO-06-206, and Primary Institutional Review Board Protocol # NHRC.2000.0007.

If you would like this email address to be removed from our mailing list, [click here](#).

Millennium Cohort Study - Protecting Service Member Health

Graphic postcard Current Service Member Non-Responder

We greatly appreciate your past participation in the Millennium Cohort Study. Unlike other surveys you may receive, the Millennium Cohort Study is designed to follow you and other Service members over time as you experience the unique challenges of military life. This is why we are again asking for your help. Many of your fellow Service members have already completed their follow-up survey. But in order for us to fully understand how military service affects long-term health we need to hear from you.

You may complete the survey online at www.millenniumcohort.org. Just click **Start Survey** and enter your Subject ID located below the barcode.

The time that you take to respond to the survey will greatly help improve the understanding of how military service may affect the health and well-being of our Service members.

Thank you for considering our request and for your service.

Very respectfully,

David D. Luxton
Principal Investigator and Military Veteran
DoD Center for Deployment Health Research
San Diego, CA
www.millenniumcohort.org

Primary Institutional Review Board Protocol # NHRC.2000.0007.

Graphic postcard Veteran Non-Responder

We greatly appreciate your past participation in the Millennium Cohort Study. Unlike other surveys you may receive, the Millennium Cohort Study is designed to follow you and other Veterans over the years to understand how your time in service is impacting your health now. This is why we are again asking for your help. Many of your fellow Veterans have already completed their follow-up survey. But in order for us to fully understand how military service affects long-term health we need to hear from you.

You may complete the survey online at www.millenniumcohort.org. Just click **Start Survey** and enter your Subject ID located below the barcode.

The time that you take to respond to the survey will greatly help improve the understanding of how military service may affect the health and well-being of our Service members.

Thank you for considering our request and for your service.

Very respectfully,

David D. Luxton
Principal Investigator and Military Veteran
DoD Center for Deployment Health Research
San Diego, CA
www.millenniumcohort.org

Primary Institutional Review Board Protocol # NHRC.2000.0007

Graphic postcard Partial-Completer

We want to thank you for the time that you have already invested to begin the Millennium Cohort survey. Your participation goes a long way to helping current, former, and future Service members and Veterans, so we hope you will consider completing your survey.

Please visit, www.millenniumcohort.org to complete your survey. Just click **Start Survey** and enter your Subject ID located below the barcode.

The survey will continue at the point where you previously stopped, so you will be able to simply finish the incomplete sections.

The time that you take to respond to the survey will greatly help improve the understanding of how military service may affect the health and well-being of our Service members.

Thank you for considering our request and for your service.

Very respectfully,

David D. Luxton
Principal Investigator and Military Veteran
DoD Center for Deployment Health Research
San Diego, CA
www.millenniumcohort.org

Primary Institutional Review Board Protocol # NHRC.2000.0007

Email

Dear [\[name\]](#),

We have been writing to you these last few weeks because it is so important that we hear from you and want you to continue to be part of this important study. Some people have written and asked us, “How will my participation in this study make a difference?”

Simply stated, without your shared experiences, we will not be able to determine the potential impact of military service on the health and well-being of our Service members and Veterans. It is essential that we receive your information because you have been carefully selected to represent your fellow Soldiers, Sailors, Airmen, and Marines. There are a limited number of Service members and Veterans taking this survey, so every individual response is needed for this to be a successful study. Ultimately, the greatest benefits of this study will not be known for many years. This is why it is essential to stay involved with the study even after you are out of the service or if you are not currently having any health concerns.

We have not, to the best of our knowledge, received your completed survey. Therefore, we are sending this email to provide an electronic link, which we hope will make it easier for you to respond.

Please follow the link below to complete your survey:

[link]

Thank you again for working with us to make the Millennium Cohort Study a success in protecting the health of past, current, and future members of our military.

Very respectfully,

David D. Luxton
Principal Investigator and Military Veteran
DoD Center for Deployment Health Research
San Diego, CA
www.millenniumcohort.org

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Email (Panel 4 Married Version)

To be sent to the 2,396 Panel 4 non-responders whose Family Study spouse has completed their survey.

Subject Line: Please help military families

Dear [\[name\]](#),

Your spouse, <name>, has already completed the 2014-2015 Millennium Cohort Family Study survey and we hope that you will choose to complete the new Millennium Cohort Service member survey as well!

Your continued participation in the Millennium Cohort Study is especially important because you are one of nearly 10,000 Service members whose spouse is enrolled in the Family Study. The Millennium Cohort survey of Service members is designed to work in partnership with the Family Study to provide a more complete picture of military life.

Simply stated, without your shared experiences and that of other Service members, we will not be able to determine the potential impact of military service, both recent and in the past, on the health and well-being of our Service members, Veterans, and their families.

In order to complete your survey, please click on the following link:

[link]

Thank you again for working with us to make the Millennium Cohort Study and the Millennium Cohort Family Study successful in the DoD's effort to protect the health of current and future Service members and their families.

Very respectfully,

David D. Luxton, PhD
Principal Investigator and Military Veteran
DoD Center for Deployment Health Research
San Diego, CA
www.millenniumcohort.org

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Endorsement Letter

Dear [\[name\]](#),

We truly appreciate the support of [\[endorsement name\]](#) (please see enclosed letter) for our DoD study of the health and well-being of Service members and Veterans. We also appreciate your help with this important study.

The Millennium Cohort Study is the largest study in US history on the short- and long-term military effects on the health of Service members and Veterans. The valuable information that you and other Service members have previously provided has been utilized by DoD leaders and policymakers to implement strategies to protect the health and well-being of our Service members and Veterans. We hope you will continue to share your experiences by completing the newest version of the survey.

We've created an easy way for you to complete the survey. Just go to www.millenniumcohort.org and click **Start Survey** and enter your **Subject ID: xxxxxx**.

We really appreciate your effort to complete the survey online – completing it on the web saves DoD money and allows us to produce results more quickly.

Thanks so much for your time and sacrifices for our country.

Very respectfully,

David D. Luxton
Principal Investigator and Military Veteran
DoD Center for Deployment Health Research
San Diego, CA
www.millenniumcohort.org

The Millennium Cohort Study is an authorized Department of Defense project. Note Defense Manpower Data Center Reference # 00-0019, Report Control Symbol # DD-HA(AR)2106, Office of Management and Budget Approval # 0720-0029, Office of the Assistant Secretary of Defense (Health Affairs), TRICARE Management Activity Protocol # CDO-06-206, and Primary Institutional Review Board Protocol # NHRC.2000.0007



DEPARTMENT OF THE NAVY
OFFICE OF THE CHIEF OF NAVAL OPERATIONS
2226 NAVY PENTAGON
WASHINGTON, DC 20350-2000

July 31, 2017

MEMORANDUM FOR MILLENNIUM COHORT STUDY SERVICE MEMBER AND
VETERAN PARTICIPANTS

SUBJECT: Request for Continued Participation in Military Health Research

1. You have made an important decision to improve the health and well-being of your fellow Service members and Veterans by participating in the Millennium Cohort Study. I hope that you will continue to remain an active participant in this important Department of Defense study.
2. The Millennium Cohort is the largest study of health and well-being in military history. This study includes more than 200,000 members from all branches of the military and includes Active Duty, Reservists, and National Guardsmen. This study plans to follow participants for 67 years. In this way, researchers can identify how specific occupations, deployments, or other military exposures contribute to the long-term health and well-being of our Service members and Veterans. Identifying these factors is a key to the design and implementation of preventive measures and policies that can improve the health and quality of life of current, former, and future Service members.
3. As a participant, you have provided valuable information that will help the Millennium Cohort Study Team understand the health concerns and needs of military members. Therefore, your continued participation is critical, even if you are no longer serving in the military.
4. I encourage you to give your time to participate in this important study. I thank you for your time, dedication, and selfless service to your Nation.

A handwritten signature in black ink, appearing to read "M. I. Nathan".

M. I. NATHAN
Vice Admiral, Medical Corps
United States Navy
Surgeon General of the Navy



REPLY TO
ATTENTION OF

DASG-ZA

DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
7700 ARLINGTON BOULEVARD
FALLS CHURCH, VA 22042-5140

15 SEP 2014

MEMORANDUM FOR Millennium Cohort Study Service Member and Veterans
Participants

SUBJECT: Request for Participation in Military Health Research

1. You have been invited to participate in or continue your participation in the Department of Defense (DoD) Millennium Cohort Study. Your involvement represents a significant contribution to the largest study of health and well-being in military history. I am grateful for your decision, and hope you will continue to remain an active participant in this important study over the years to come.
2. The Millennium Cohort Study now includes more than 200,000 Active Duty, Reserve, and National Guard Service Members and Veterans from the Army, Navy, Marine Corps, Air Force, and Coast Guard. The goal is to follow these Service Members and Veterans throughout their lifetimes (up to 67 years) in order to identify the impact of specific occupations, deployments, and other military exposures on long-term health and well-being. Identifying and understanding these factors is key to designing and implementing preventive measures, healthcare interventions, and policies to improve the health and quality of life of current, former, and future Soldiers, Sailors, Marines, Airmen, and Coast Guardsmen.
3. As a participant, the valuable information you provide will help the Millennium Cohort Study Team, DoD, and Veterans Affairs understand the health concerns and needs of Service Members and Veterans. Your continued participation is critical, whether or not you are still serving in the military, and the information you provide will be confidential whether or not you are still serving.
4. I thank you for your time, dedication and selfless service to our Nation.

A handwritten signature in black ink, appearing to read "Patricia D. Horoho".

PATRICIA D. HOROHO
Lieutenant General
The Surgeon General and
Commanding General, USAMEDCOM

Millennium Cohort Veterans Day Postcard/Follow-up correspondence

Veterans Day Reminder PC /Email – Non-responder

Contents: 5x7 Postcard

Dear _[name]_,

On this Veterans Day, the Millennium Cohort Study Team thanks you for your service. We would not enjoy the daily freedoms we do without your selfless sacrifice.

Our team's primary goal is to improve the health of all Service members. In order to do so, we need your continued participation, even if you never deployed, or have left military service. Recording your experiences over time helps reveal important health issues and unique military exposures that affect Service members.

Please visit our website www.millenniumcohort.org to complete your survey.

Thank you again for your selfless service and dedication to our nation.

Very Respectfully,
Dr. David D. Luxton
Principal Investigator and Military Veteran

[Included in email]

For any questions, please contact the Millennium Cohort Team at milcohortinfo@med.navy.mil or info@millenniumcohort.org. Or call toll free 1-888-942-5222 or DSN 553-7465, and reference your Subject Id: 100003

The Millennium Cohort Study is an authorized Department of Defense project. Note Defense Manpower Data Center Reference # 00-0019, Report Control Symbol # DD-HA(AR)2106, Office of Management and Budget Approval # 0720-0029, Office of the Assistant Secretary of Defense (Health Affairs), TRICARE Management Activity Protocol # CDO-06-206, and Primary Institutional Review Board Protocol # Naval Health Research Center.2000.0007.

If you would like this email address to be removed from our email list, please visit [https://www.millenniumcohort.org/emailUnsubscribe.php?email=\(Beverly.Sheppard@med.navy.mil\)](https://www.millenniumcohort.org/emailUnsubscribe.php?email=(Beverly.Sheppard@med.navy.mil))

Millennium Cohort Study - Protecting Service Member Health

Contents:

➤ 5x7 Postcard



Veteran's Day PC/Email - Responder

Dear [\[name\]](#),

On this Veterans Day, the Millennium Cohort Study Team thanks you for your service. We would not enjoy the daily freedoms we do without your selfless sacrifice.

Our team's primary goal is to improve the health of all Service members. We would like to thank you for taking the time to complete your 2014 survey. Recording your experiences over time helps reveal important health issues and unique military exposures that affect Service members.

Thank you for your selfless service and dedication to this study and our nation.

Very Respectfully,
Dr. David D. Luxton
Principal Investigator and Military Veteran

[Included in email]

For any questions, please contact the Millennium Cohort Team at milcohortinfo@med.navy.mil or info@millenniumcohort.org. Or call toll free 1-888-942-5222 or DSN 553-7465, and reference your Subject Id: 100003

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Millennium Cohort Study - Protecting Service Member Health

Contents:

➤ 5x7 Postcard



Email

Dear [\[name\]](#),

We recently sent you a postcard to thank you for your service, and for your continued support of the Millennium Cohort Study.

This request was sent to you because you previously completed a survey. We are especially interested in your experiences and any changes in your health that may have occurred since we last heard from you. Even if you have never deployed or are no longer in the military, your response can provide greater insight into issues facing today's military Service members and Veterans. In order to gain a complete picture of military service and its effects on the health and well-being of Service members over time, we need to hear from you along with the other military Service members and Veterans selected to be in this study.

If you have already been able to go online and complete the questionnaire, thank you! If you have not yet had time to consider our request, we hope you will be able to do so soon.

To complete the survey, please go to the website, www.millenniumcohort.org, click **Start Survey**, and use the following **Subject ID: xxxxxx**.

Thanks so much for your consideration for completing this important study.

Very Respectfully,
Dr. David D. Luxton
Principal Investigator and Military Veteran

For any questions, please contact the Millennium Cohort Team at milcohortinfo@med.navy.mil or info@millenniumcohort.org. Or call toll free 1-888-942-5222 or DSN 553-7465, and reference your Subject Id: 100003

The Millennium Cohort Study is an authorized Department of Defense project. Note Defense Manpower Data Center Reference # 00-0019, Report Control Symbol # DD-HA(AR)2106, Office of Management and Budget Approval # 0720-0029, Office of the Assistant Secretary of Defense (Health Affairs), TRICARE Management Activity Protocol # CDO-06-206, and Primary Institutional Review Board Protocol # Naval Health Research Center.2000.0007.

If you would like this email address to be removed from our email list, please visit [https://www.millenniumcohort.org/emailUnsubscribe.php?email=\(Beverly.Sheppard@med.navy.mil\)](https://www.millenniumcohort.org/emailUnsubscribe.php?email=(Beverly.Sheppard@med.navy.mil))

Millennium Cohort Study - Protecting Service Member Health

Questionnaire 1 mailing

Dear [\[name\]](#),

During the last few weeks, we have requested your continued help with this long-term study of the health and well-being of Service members. It is the only prospective study that is able to evaluate the effects of military service on long-term health.

We have not, to the best of our knowledge, heard from you. We have enclosed a paper survey, hoping that this will make it easier for you to fill out and return.

As a member of this study, you are adding to the picture of the overall health of military Service members throughout their lives. Your past participation, and the participation of others like you, has already helped us to provide valuable information the health impacts of deployments and other military experiences. For example, we found that combat-related trauma and predeployment insomnia symptoms increased the risk for developing post-traumatic stress symptoms, depression, and anxiety following deployment. Findings from this study are intended to influence training, health care, and policies of Department of Defense as well as Department of Veterans Affairs related to serving in the U.S. military.

We thank you for completing the enclosed survey and returning it in the postage-paid envelope. Or, to complete the survey online, please go to the website:

<http://www.MillenniumCohort.org>

Enter your unique Subject ID: **xxxxxx**.

Be assured that this is an authorized study supported by the highest levels of the Department of Defense. Note DMDC Reference #00-0019; DoD RCS #DD-HA(AR)2106; OMB approval #0720-0029.

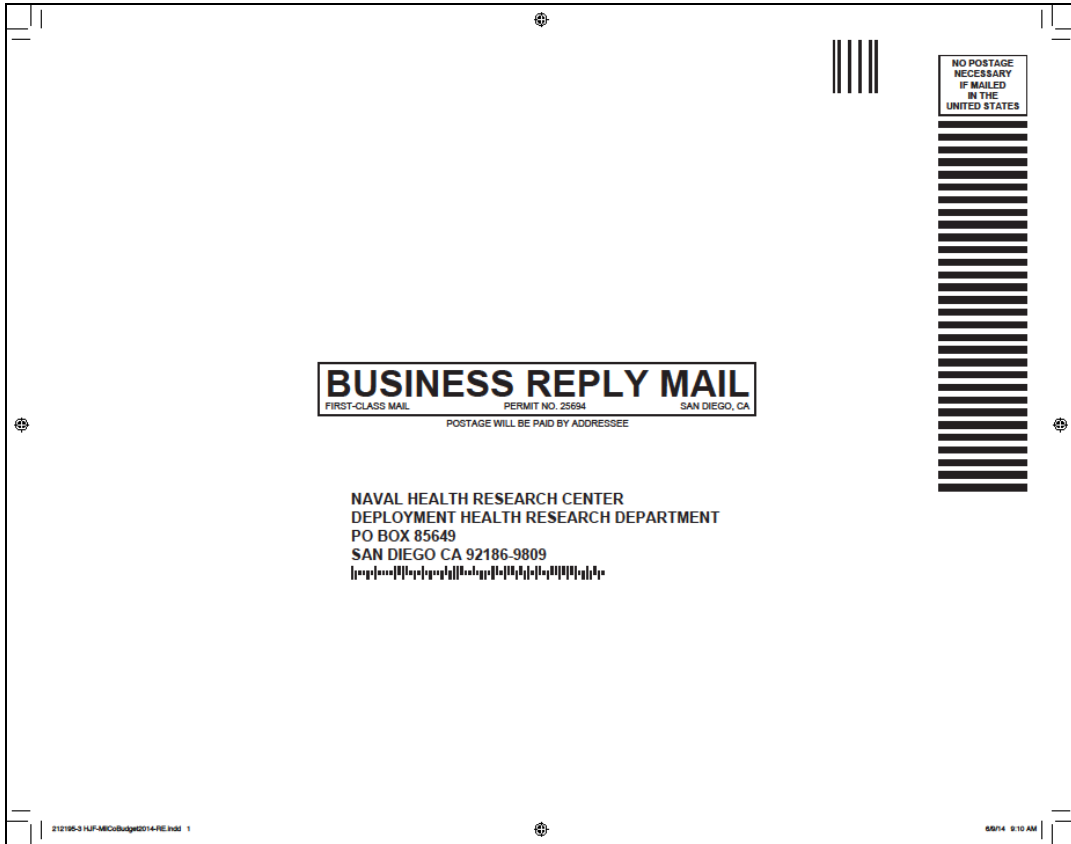
We look forward to hearing from you as one of our valued Millennium Cohort members!

[Insert Signature]

Very Respectfully,
Dr. David D. Luxton
Principal Investigator and Military Veteran

If you have any questions, please contact the Millennium Cohort team at our toll-free number, 1-888-942-5222, or DSN 553-7465, or email info@millenniumcohort.org.

10x13 Business Reply Envelope



Endorsement letter – 2 versions Army and Navy

Dear [\[name\]](#),

We truly appreciate the support of [\[LTG Patricia Horoho, or VADM Matthew Nathan\]](#) (please see enclosed letter) for our DoD study of the health and well-being of Service members. We also appreciate your help with this important study.

The valuable information that you and other Service members have previously provided have been utilized by DoD leaders and policymakers to implement strategies to protect the health and well-being of our Service members. We hope you will continue to share your experiences by going online and completing the newest version of the survey. Even if you have never deployed, have retired, or are no longer in the military, your participation is essential!

We have created an easy way for you to complete the survey. Just go to www.millenniumcohort.org, click **Start Survey** and enter your **Subject ID: xxxxxx**.

Be assured that this is an authorized study supported by the highest levels of the Department of Defense. Note DMDC Reference #00-0019; DoD RCS #DD-HA(AR)2106; OMB approval #0720-0029.

If you have already completed your survey, please accept my thanks and disregard this request.

We look forward to hearing from you as one of our valued Millennium Cohort members!

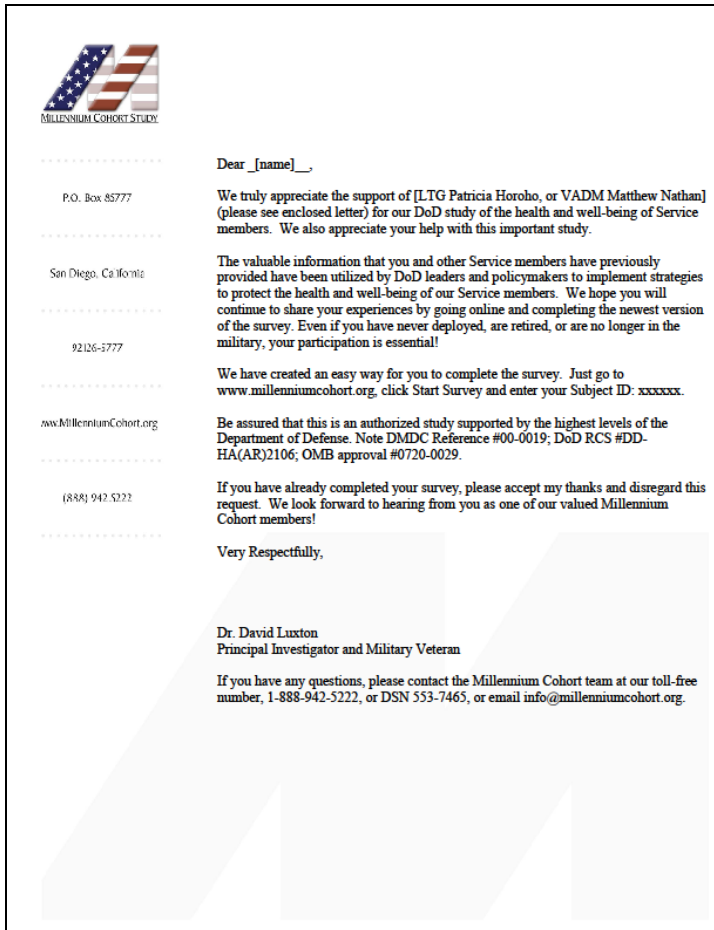
Very Respectfully,

Dr. David D. Luxton
Principal Investigator and Military Veteran

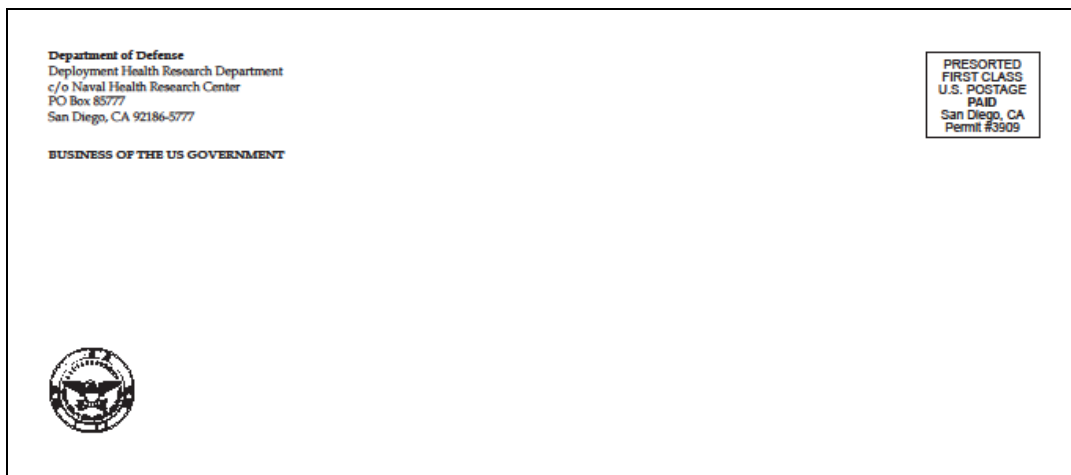
If you have any questions, please contact the Millennium Cohort team at our toll-free number, 1-888-942-5222, or DSN 553-7465, or email info@millenniumcohort.org.

Contents:

➤ Cover letter



➤ #10 envelope



➤ Endorsement letter



DEPARTMENT OF THE NAVY
OFFICE OF THE CHIEF OF NAVAL OPERATIONS
2000 NAVY PENTAGON
WASHINGTON, DC 20350-3000

July 31, 2014

MEMORANDUM FOR MILLENNIUM COHORT STUDY SERVICE MEMBER AND
VETERAN PARTICIPANTS

SUBJECT: Request for Continued Participation in Military Health Research

1. You have made an important decision to improve the health and well-being of your fellow Service members and Veterans by participating in the Millennium Cohort Study. I hope that you will continue to remain an active participant in this important Department of Defense study.
2. The Millennium Cohort is the largest study of health and well-being in military history. This study includes more than 200,000 members from all branches of the military and includes Active Duty, Reservists, and National Guardsman. This study plans to follow participants for 67 years. In this way, researchers can identify how specific occupations, deployments, or other military exposures contribute to the long-term health and well-being of our Service members and Veterans. Identifying these factors is a key to the design and implementation of preventive measures and policies that can improve the health and quality of life of current, former, and future Service members.
3. As a participant, you have provided valuable information that will help the Millennium Cohort Study Team understand the health concerns and needs of military members. Therefore, your continued participation is critical, even if you are no longer serving in the military.
4. I encourage you to give your time to participate in this important study. I thank you for your time, dedication, and selfless service to your Nation.

A handwritten signature in black ink, appearing to read "M. L. Nathan".

M. L. NATHAN
Vice Admiral, Medical Corps
United States Navy
Surgeon General of the Navy



REPLY TO
ATTENTION OF

DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
7700 ARLINGTON BOULEVARD
FALLS CHURCH, VA 22042-5140

15 SEP 2014

DASG-ZA

MEMORANDUM FOR Millennium Cohort Study Service Member and Veterans
Participants

SUBJECT: Request for Participation in Military Health Research

1. You have been invited to participate in or continue your participation in the Department of Defense (DoD) Millennium Cohort Study. Your involvement represents a significant contribution to the largest study of health and well-being in military history. I am grateful for your decision, and hope you will continue to remain an active participant in this important study over the years to come.
2. The Millennium Cohort Study now includes more than 200,000 Active Duty, Reserve, and National Guard Service Members and Veterans from the Army, Navy, Marine Corps, Air Force, and Coast Guard. The goal is to follow these Service Members and Veterans throughout their lifetimes (up to 67 years) in order to identify the impact of specific occupations, deployments, and other military exposures on long-term health and well-being. Identifying and understanding these factors is key to designing and implementing preventive measures, healthcare interventions, and policies to improve the health and quality of life of current, former, and future Soldiers, Sailors, Marines, Airmen, and Coast Guardsmen.
3. As a participant, the valuable information you provide will help the Millennium Cohort Study Team, DoD, and Veterans Affairs understand the health concerns and needs of Service Members and Veterans. Your continued participation is critical, whether or not you are still serving in the military, and the information you provide will be confidential whether or not you are still serving.
4. I thank you for your time, dedication and selfless service to our Nation.

PATRICIA D. HOROHO
Lieutenant General
The Surgeon General and
Commanding General, USAMEDCOM

PHASE 1: 2014

1a: Pre-notice letter – ACTIVE DUTY
Week 1 [Proposed start: June/July 2014]

Contents: cover letter, study results pamphlet, #10 business size envelope

Study results insert

Dear [name],

You are one of over 200,000 current and former Service members who completed an important DoD survey (the Millennium Cohort Study) aimed at understanding the possible effects of military service on long-term health. The last questionnaire you completed for the study was in (survey month/year).

We appreciate enormously your help with this Department of Defense study, and thought you might appreciate knowing about some of the results from this effort. The enclosed summary provides just a few of the results and how they are being used. Because of occasional follow-up questionnaires, we are able to understand how health circumstances change. Even in the short period since the beginning of this research, we have been able to observe changes in health-related situations and the reasons for these changes.

Those of you who have helped with this study come from all branches and components of the military. Some of you are no longer in the active military service, while others of you continue to serve. The breadth of this study, the largest of its kind ever conducted, is especially valuable because it allows for understanding if different kinds of military service and deployments result in no specific health symptoms or in the development of a health symptom or concern. Regardless of your specific situation, your information is critically important to this effort.

We hope you'll find these results of interest. More research findings will be posted to our website, www.millenniumcohort.org, as analyses are released and used.

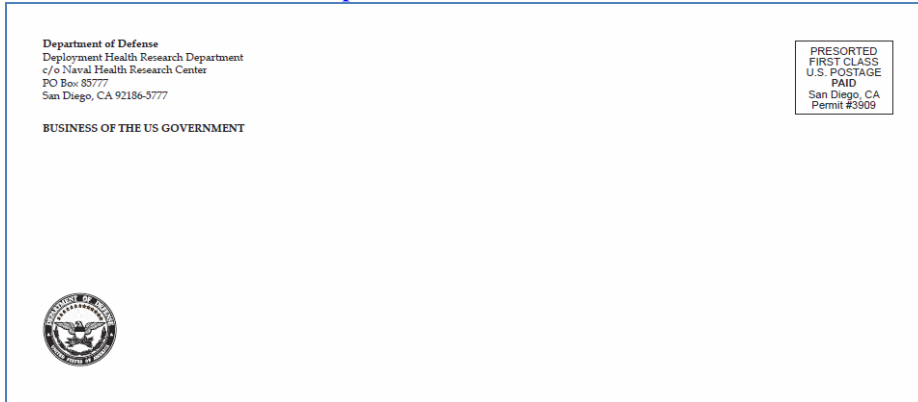
In a few weeks, we will be contacting you to learn about any changes that may have occurred in your health since we last heard from you. We are eager to learn more about how participants' lives may have been affected by military service, or whether there has been no specific effects from your military time – both are very important for understanding the ongoing health of Service members.

Thanks so much for your effort to help the U.S. military provide the best medical care to current and future members of the military.

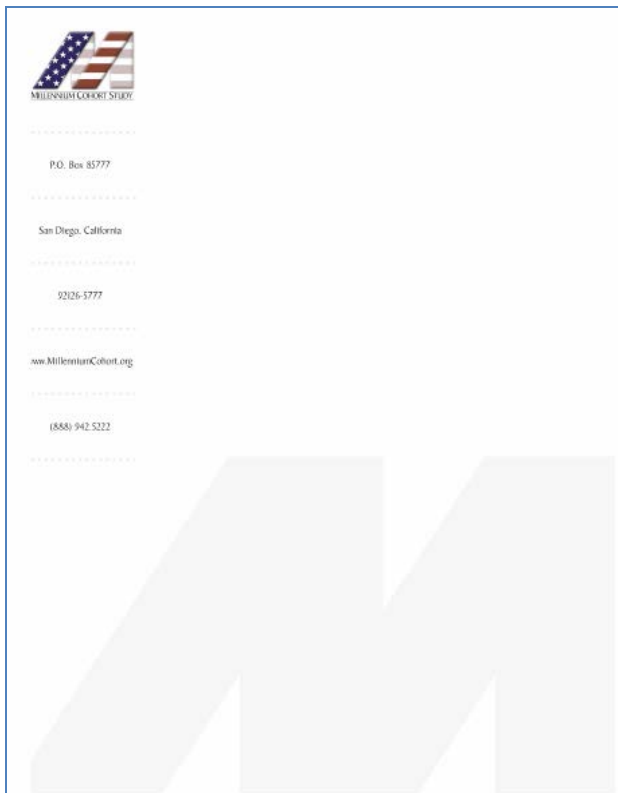
Very sincerely,
The Millennium Cohort Study Team

Contents:


➤ #10 business size envelope:



➤ Letterhead for cover letter:



➤ Active Duty Study Findings insert: (front)



What has the Millennium Cohort Study been up to...


What have we learned?

- Those who were *deployed* or had *returned from deployment* were more likely to report *trouble sleeping* compared to those who had not deployed
- *Deployment in general* did not result in post-deployment breathing issues
- Physical *activity* is associated with *decreased PTSD* symptoms


Deployment Experiences

Number of Deployments	
Two or more	31%
One	30%
None	39%


Number of Participants Deployed by Year



THE NUMBERS



61%
of the cohort have deployed in support of the recent operations in Iraq and Afghanistan



42%
of participants are veterans of military service

44%
of participants are Reserve/National Guard

31%
of participants are women

WWW.MILLENNIUMCOHORT.ORG

➤ Study Findings insert: (back)

Study Timeline

Group	Enrolled Participants	Wave 1	Wave 2	Wave 3	Wave 4	Wave 5
Group 1	77,047	2001	2004	2007	2011	2014
Group 2	31,110	2001	2004	2007	2011	-
Group 3	43,440	2001	2004	2007	-	-
Group 4	50,052	2001	2004	-	-	-

Study Facts

- Over **200,000** Service members have enrolled since 2001
- Participants are from all **five service branches** and include active duty, Reservists and National Guard members
- The Study is being conducted at the **Naval Health Research Center**, in San Diego, California
- The study follows each Service member over the course of their life **including after military separation**
- The Millennium Cohort Study is a **DoD sponsored** study with the backing of military leaders


The Cohort by Service Branch

Service Branch	Color
Air Force	Blue
Army	Green
Coast Guard	Light Blue
Marines	Red
Navy	Dark Blue

Please Keep Us Updated

Have you recently **moved** or **changed your email address**?

- Please visit our website and **log in** to **update** your information
- Use your **Subject ID**, located near the **barcode** on the address side of most correspondence we have sent you, to **log in** and **update** your personal information

 www.millenniumcohort.org ♦ (888) 942-5222 ♦ DSN 553-7465

This is only a small amount of information being learned from the Millennium Cohort Study. For more information, please visit MILLENNIUMCOHORT.ORG

1b: Pre-notice letter – SEPARATED/RETIRED

Week 1

Contents: cover letter, study results insert, #10 business size envelope

Dear [\[name\]](#),

You are one of 200,000 current and former service members who completed an important DoD survey (the Millennium Cohort Study) aimed at understanding the possible effects of military service on long-term health. The last questionnaire you completed for the study was in ([survey month/year](#)).

We appreciate enormously your help with this Department of Defense study, and thought you might appreciate knowing about some of the results from this effort. The enclosed summary provides just a few of the results and how they are being used. Because of occasional follow-up questionnaires, we are able to understand how health circumstances change. Even in the short period since the beginning of this research, we have been able to observe changes in health-related situations and reasons.

We understand that you are no longer in the active military service, but we still need your continued participation. Because former Service members and Veterans face unique challenges, sharing your experiences will help the DoD understand the impact of health and life situations of people even after they leave military service. This knowledge may eventually lead to better treatments and preventive measures for Veterans.

The breadth of this study, the largest of its kind ever conducted, is especially valuable because it allows for understanding if different kinds of military service and deployments have resulted in no specific health symptoms or in the development of a health symptom or concern. Regardless of your specific situation, your information is critically important to this effort.

We hope you'll find these results of interest. More research findings will be posted to our website, www.millenniumcohort.org, as analyses are released and used.

In a few weeks, we will be contacting you to learn about any changes that may have occurred in your health or life situation since we last heard from you.


Thanks so much for your effort to help provide the best medical care to former and current members of the military.

Very sincerely,
The Millennium Cohort Study Team

Contents:

- #10 business size envelope: same as 1a
- Letterhead for cover letter:: same as 1a

➤ Separated/ Retired Study Findings insert: (front)



MILLENNIUM COHORT STUDY

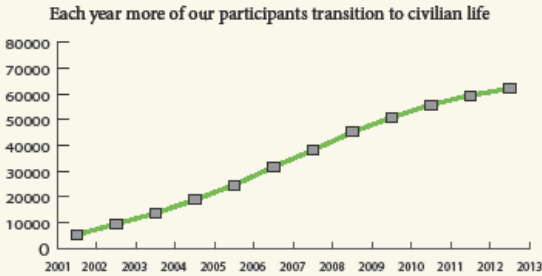
What has the Millennium Cohort Study been up to...

What have we learned?

- Deployment experiences and *PTSD* were *NOT associated with unemployment* among Veterans
- Veterans living in *rural* areas maintained the same *same quality of life* as those living in *urban* areas
- Those who were currently *deployed* or had *returned from deployment* were more likely to report *trouble sleeping* compared to those who had not deployed
- Physical *activity* was associated with *decreased PTSD* symptoms


Our Retired / Separated Participants


Each year more of our participants transition to civilian life



Year	Number of Participants
2001	10,000
2002	12,000
2003	15,000
2004	20,000
2005	25,000
2006	30,000
2007	35,000
2008	40,000
2009	45,000
2010	50,000
2011	55,000
2012	60,000
2013	65,000

THE NUMBERS

- 

61% of the cohort has deployed in support of the recent operations in Iraq and Afghanistan
- 

42% of participants have separated / retired from military service
- 36%** of participants are married
- 31%** of participants are women

WWW.MILLENNIUMCOHORT.ORG

➤ Separated/ Retired Study Findings insert: (back)

Study Timeline

Group	Enrolled Participants	Wave 1	Wave 2	Wave 3	Wave 4	Wave 5
Group 1	77,047	2001	2004	2007	2011	2014
Group 2	31,110	2001	2004	2007	2011	-
Group 3	43,440	2001	2004	2007	-	-
Group 4	50,052	2001	2004	-	-	-

Study Facts

- The study follows each Service member over the course of their life *including after military separation*
- The Millennium Cohort Study is a *DoD sponsored* study with the backing of military leaders
- Over *200,000* Service members have enrolled since 2001
- The Study is being conducted at the *Naval Health Research Center*, in San Diego, California

Please Keep Us Updated

Have you recently *moved* or *changed your email* address?

- Please visit our website and *log in* to *update* your information
- Use your *Subject ID*, located near the *barcode* on the address side of most correspondence we have sent you, to *log in* and *update* your personal information

www.millenniumcohort.org ♦ (888) 942-5222 ♦ DSN 553-7465

Separated by Service Branch

- Air Force
- Army
- Coast Guard
- Marines
- Navy

This is only a small amount of information being learned from the Millennium Cohort Study. For more information, please visit MILLENNIUMCOHORT.ORG

2: Pre-notice Email
Week 3

Subject Line: Preliminary results from your participation in research study

Dear [\[name\]](#),

We hope you recently received our letter in the mail which highlights the study progress of the Service member study since it began in 2001.

You are one of 200,000 current and former Service members who completed an important DoD survey aimed at understanding the possible effects of military service on long-term health. The last survey you completed for the study was in [\[survey month/year\]](#). We greatly appreciate you sharing your experiences, including those after you leave the military, to evaluate the potential long-term health effects of military service.

The study produces important results that inform DoD and VA leaders regarding the associations of military experiences on future health outcomes. Our recent postal letter to you highlighted some of this study's findings since 2001. If you did not receive our recent postal letter, we would appreciate you providing us a current postal address so that we can continue to keep you informed about results from this important national study.

In a few weeks, we will send you the new survey version, which has some important updates from the previous version. The 2014 survey also includes some questions that are similar to those which you have completed in the past so that we can track changes in experiences and health events since the previous survey.

To view our study progress and to also update your postal address, please visit our study website: [website address](#)

Meantime, as additional analyses are completed, we will post results on our website, and want to let you know that you may go there to see them.

Thanks so much for your effort to help the U.S. military provide the best medical care to current, former, and future members of the military, through your participation in this critical study.

Very sincerely,
The Millennium Cohort Study Team

Some people have multiple email addresses. If we've reached you at an inappropriate email address, please visit this web site: [\[add link\]](#)

3a: Card NOT LINKED to Family Study participant.
Week 8

Contents: Card, 5x7 business size envelope:

Dear [\[name\]](#),

A few years ago, you were very helpful in completing a survey for the Millennium Cohort Study which assesses the health and well-being of Service members over time. We are writing to ask for your continued help with the largest effort ever undertaken to understand if military service affects the health of military members during, as well as after, their military service is completed.

We appreciate greatly your previous help with this effort that involves all branches and components of the military. You may notice that this year's questionnaire has changed, removing some questions and adding others that seem to be helpful in understanding what happens over time with regard to health issues.

Please complete the survey by going to: **www.millenniumcohort.org**, where you should click on **Start Survey**, and enter your **Subject ID: xxxxxx**.

[text for card with incentive] In appreciation for your contribution to the Millennium Cohort Study, we are enclosing a [\$2 bill, gift card, magnet] as a small way of expressing our appreciation for your previous and continued efforts to make a difference in the lives of current and future military members.

[text for card without incentive] Thank you for your continued help in making this the largest and most important DoD study in US military history and working with us to protect the health of members of our military service.

[text for card with opportunity drawing] Upon receipt of your completed survey, your name will be entered into a drawing to win an i-Pad*

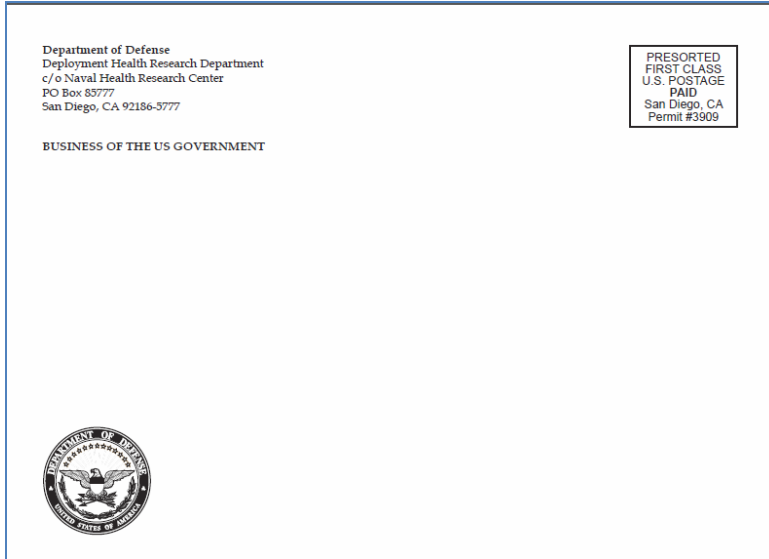
Thank you for your continued help in making this the largest and most important DoD study in US military history and working with us to protect the health of members of our military service.

Very sincerely,
The Millennium Cohort Study Team

*For every 500 survey respondents one name will be drawn. All surveys must be received by [date] in order to enter. The winners will be randomly selected and notified via email.

Contents:

➤ 5x7 envelope:



➤ 5x7 Card: (front)



5x7 Card: (back)



➤ Randomly assigned inserts:

- cash pre-incentive in the form a two dollar bill
- Magnet



- No pre-incentive
- \$5 Gift card
- Opportunity to win I-Pad

3b: Card LINKED to Family Study participant.

Week 8

Contents: Card, 5x7 business size envelope:

Dear [\[name\]](#),

A few years ago, you were very helpful in completing a survey for the Millennium Cohort Study which assesses the health and well-being of Service members over time. We are writing to ask for your continued help with the largest effort ever undertaken to understand if military service affects the health of military members during, as well as after, their military service is completed.

We appreciate greatly your previous help with this effort that involves all branches and components of the military. You may notice that this year's questionnaire has been changed, removing some questions and adding others that seem to be helpful in understanding what happens over time with regard to health issues.

Please complete the survey by going to: **www.millenniumcohort.org**, click on **Start Survey**, and enter your **Subject ID: xxxxxx**.

[text for card with incentive] In appreciation for your contribution to the Millennium Cohort Study, we are enclosing a [\$2 bill, gift card, magnet] as a small way of expressing our appreciation for your previous and continued efforts to make a difference in the lives of current and future military members.

[text for card without incentive] Thank you for your continued help in making this the largest and most important DoD study in US military history and working with us to protect the health of members of our military service.

[text for card with opportunity drawing] Upon receipt of your completed survey, your name will be entered into a drawing to win an i-Pad*

In addition, your spouse will also receive an invitation in the fall to complete his/her follow-up survey as part of the Family Study, which works in partnership with this Service member survey. These two studies are the only ones in history that follow the Service member and their family over time as they experience both the unique challenges and achievements associated with military life.

Thank you for your continued help in making this the largest and most important DoD study in US military history and working with us to protect the health of members of our military service.

Very sincerely,
The Millennium Cohort Study Team

*For every 500 survey respondents one name will be drawn. All surveys must be received by [date] in order to enter. The winners will be randomly selected and notified via email.

Contents:

- 5x7 envelope: same as 3a
- 5x7 Card: same as 3a
- Incentives same as 3a

4a: Email ACTIVE DUTY NOT LINKED to Family participant
Week 9

Subject Line: Appreciation for your past participation

Dear [\[name\]](#),

Last week you should have received a letter requesting your continuing participation in the largest effort ever undertaken to understand how military service may affect the health situation of military members during, as well as after, their military service is completed.

We are following up with this email to provide an electronic link, which we hope makes it easier for you to access and complete this follow-up survey. Please go to:
[\[link to survey\]](#)

Unlike many other surveys, this study is designed to follow you over time to understand any changes to your health and any concerns you may have. Even if you are no longer on active duty, or are not experiencing any health symptoms, your responses are still very valuable in understanding how specific military experiences do or do not affect the health of current and former Service members.

Thank you for working with thousands of other Service members and Veterans to protect the health of current and future members of our military service.

This survey is “Official Business”. Military members may complete this at their duty station, using government equipment. If you choose, you can also complete the survey at home or elsewhere.

If you did not receive our postal mailing, then we may not have your most updated information. You are a valued participant and we want to assure that we send it to the correct postal address. Please update your contact info at: [\[update contact info -website\]](#).

Very sincerely,
The Millennium Cohort Study Team

Some people have multiple email addresses. If we’ve reached you at an inappropriate address, please visit this web site to provide a preferred address for contacting you: [\[unsubscribe email link\]](#)

4b: Email SEPARATED/RETIRED NOT LINKED to Family participant
Week 9

Subject Line: Appreciation for your past participation

Dear [\[name\]](#),

Last week you should have received a letter requesting your continuing participation in the largest effort ever undertaken to understand how military service may affect the health situation of military members during, as well as after, their military service is completed.

We are following up with this email to provide an electronic link, which we hope makes it easier for you to access and complete this follow-up survey. Please go to:
[\[link to survey\]](#)

Some believe their continued participation in this study is no longer valuable because they have separated or retired from military service. However, the Millennium Cohort Study was designed to evaluate **long-term** health effects, so the continued participation of former Service members is essential to the project's success.

Thank you for working with thousands of other Service members and Veterans to protect the health of current and future members of our military service.

If you did not receive our postal mailing, then we may not have your most updated information. You are a valued participant and we want to assure that we send it to the correct postal address. Please update your contact info at: [\[update contact info -website\]](#).

Very sincerely,
The Millennium Cohort Study Team

Some people have multiple email addresses. If we've reached you at an inappropriate address, please visit this web site to provide a preferred address for contacting you: [\[unsubscribe email link\]](#)

4c: Email ACTIVE DUTY LINKED to Family Study participant.

Week 9

Purpose: reference recent postal contact. Continue to push for web completion.

Subject Line: Appreciation for your past participation

Dear [\[name\]](#),

Last week you should have received a letter requesting your continuing participation in the largest effort ever undertaken to understand how military service may affect the health situation of military members during, as well as after, their military service is completed.

We are following up with this email to provide an electronic link, which we hope makes it easier for you to access and complete this follow-up survey. Please go to:

[\[link to survey\]](#)

Unlike many other surveys, this study is designed to follow you over time to understand any changes to your health and any concerns you may have. Even if you are no longer on active duty, or are not experiencing any health symptoms, your responses are still very valuable in understanding how specific military experiences do or do not affect the health of current and former Service members.

In addition, your spouse will also receive an invitation in the fall to complete his/her follow-up survey as part of the Family Study, which works in partnership with this Service member survey. These two studies are the only ones in history that follow the Service member and their family over time as they experience both the unique challenges and achievements associated with military life.

Thank you for working with thousands of other Service members and Veterans to protect the health of current and future members of our military service.

This survey is “Official Business”. Military members may complete this at their duty station, using government equipment. If you choose, you can also complete the survey at home or elsewhere.

If you did not receive our postal mailing, then we may not have your most updated information. You are a valued participant and we want to assure that we send it to the correct postal address. Please update your contact info at: [\[update contact info -website\]](#).

Very sincerely,
The Millennium Cohort Study Team

Some people have multiple email addresses. If we've reached you at an inappropriate address, please visit this web site to provide a preferred address for contacting you: [\[unsubscribe email link\]](#)

4d: Email SEPARATED/RETIRED LINKED to Family participant
Week 9

Purpose: reference recent postal contact. Continue to push for web completion.

Subject Line: Appreciation for your past participation

Dear [\[name\]](#),

Last week you should have received a letter requesting your continuing participation in the largest effort ever undertaken to understand how military service may affect the health situation of military members during, as well as after, their military service is completed.

We are following up with this email to provide an electronic link, which we hope makes it easier for you to access and complete this follow-up survey. Please go to:
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In addition, your spouse will also receive an invitation in the fall to complete his/her follow-up survey as part of the Family Study, which works in partnership with this Service member survey. These two studies are the only ones in history that follow the Service member and their family over time as they experience both the unique challenges and achievements associated with military life.

Some believe their continued participation in this study is no longer valuable because they have separated or retired from military service. However, the Millennium Cohort Study was designed to evaluate **long-term** health effects, so the continued participation of former Service members is essential to the project's success.

Thank you for working with thousands of other Service members and Veterans to protect the health of current and future members of our military service.

If you did not receive our postal mailing, then we may not have your most updated information. You are a valued participant and we want to assure that we send it to the correct postal address. Please update your contact info at: [\[update contact info -website\]](#).

Very sincerely,
The Millennium Cohort Study Team

Some people have multiple email addresses. If we've reached you at an inappropriate address, please visit this web site to provide a preferred address for contacting you: [\[unsubscribe email link\]](#)

2014 Memorial Day Postcard
May 2014

Contents: 5x7 color postcard

Mail Date: 5/19/14

Message:

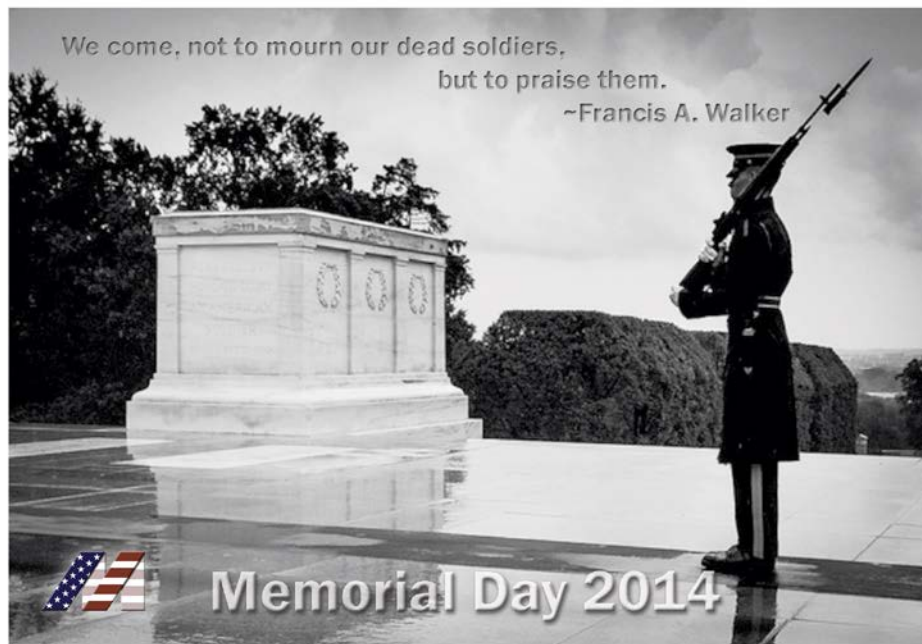
On this day, we remember those who gave their lives for our nation, and reflect on the sacrifices made by current and former service members. Your service, and that of each military member who lost their life defending our nation, is remembered and honored on this **Memorial Day**.

The next survey cycle will be starting soon, and your continued participation, even if you have left military service, is critically important to this study. Your continued involvement makes it possible to inform policy makers regarding your experiences and to guide prevention measures that positively impact former, current and future military members.

Very Sincerely,
The Millennium Cohort Study Team

Contents:

- 5x7 postcard image:



2014 Memorial Day Email
May 2014

Contents: 5x7 color postcard

Email Date: 5/19/14

Dear _____,

On this day, we remember those who gave their lives for our nation, and reflect on the sacrifices made by current and former service members. Your service, and that of each military member who lost their life defending our nation, is remembered and honored on this **Memorial Day**. You will receive a Memorial Day postcard in the mail from the Millennium Cohort Study team. You can also view it online at [[website](#)].

The next survey cycle will be starting soon, and your continued participation, even if you have left military service, is critically important to this study. Your continued involvement makes it possible to inform policy makers regarding your experiences and to guide prevention measures that positively impact former, current and future military members.

Very Sincerely,

The Millennium Cohort Study Team

For any questions, please contact the Millennium Cohort Team at milcohortinfo@med.navy.mil or info@millenniumcohort.org. Or call toll free 1-888-942-5222 or DSN 553-7465, and reference your Subject Id: [SID]

The Millennium Cohort Study is an authorized Department of Defense project. Note Defense Manpower Data Center Reference # 00-0019, Report Control Symbol # DD-HA(AR)2106, Office of Management and Budget Approval # 0720-0029, Office of the Assistant Secretary of Defense (Health Affairs), TRICARE Management Activity Protocol # CDO-06-206, and Primary Institutional Review Board Protocol # Naval Health Research Center.2000.0007.

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Millennium Cohort Study – Protecting Service Member Health

Veteran's Day 2013

The *Millennium Cohort* email will read as follows:

Veteran's Day 2013 Email

Dear {Name},

On this Veterans Day, the Millennium Cohort Study Team joins all Americans in honoring those who have served our nation as members of the Armed Forces. We thank all Service members, past and present, for their unyielding sacrifice and dedication to our great nation.

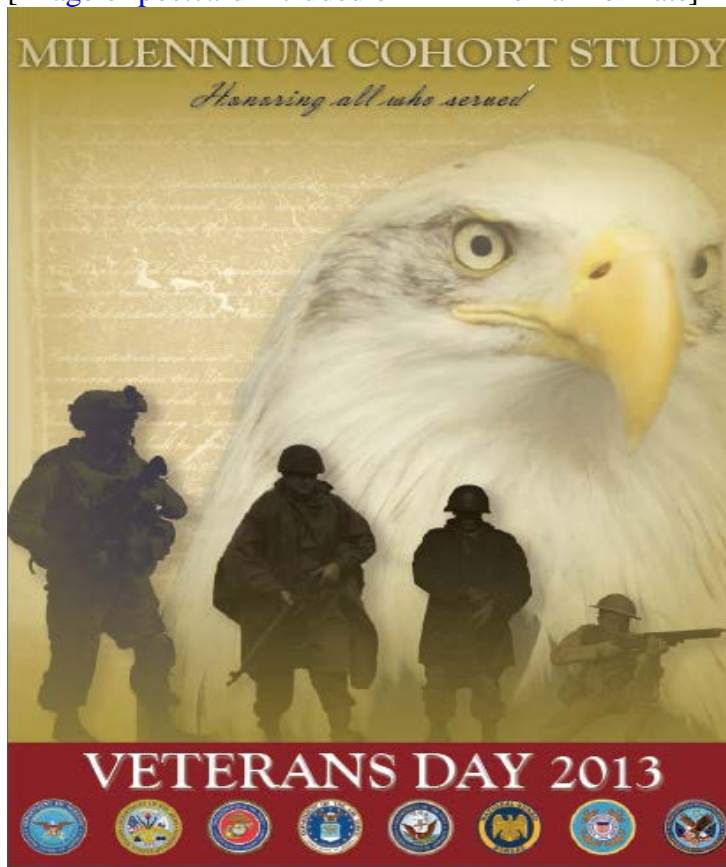
The Department of Defense launched the Millennium Cohort Study in 2001 to improve the health of Service members and Veterans. There are now over 200,000 participants enrolled in this landmark study, which is the largest of its kind working towards protecting the health of members of our military. We will touch base with you again in 2014 to learn about any changes that may have occurred with your health and well-being since we last heard from you.

Thank you again for your selfless service and your continued support of this important project!

Very Sincerely,

The Millennium Cohort Study Team

[[image of postcard included on HTML email formats](#)]



APPENDIX G. MILLENNIUM COHORT FAMILY HISTORICAL PROTOCOL SCIENTIFIC BACKGROUND

In recent decades, mental health and related outcomes for US military service members following war zone deployment have been documented empirically for multiple conflicts, beginning with Vietnam and continuing through the conflicts in Iraq and Afghanistan. Much less attention has been paid, however, to deployment-related outcomes for spouses and other family members (e.g., children, parents) of those deployed.

Stressors associated with service member deployment can have important consequences for their family members, particularly when tours are long and multiple deployments are required. Family member functioning can be degraded by separation and associated worries, and service member functioning is degraded when concern over events at home reduces their ability to concentrate or to be attentive and vigilant. Additionally, war zone stress exposure has been shown to have substantial impact on service members after they return home, which can produce additional stressors for both the service members and their families when they are re-united. Post-deployment stress also erodes readiness for future deployment.

In essence, the geographic separation and life threat that are inherent in war zone deployment open the door to anxiety and mood changes and alcohol abuse among service members and their families that can degrade the functioning of both in multiple ways, prior to (e.g., via anticipatory anxiety) and during deployment. Compounding the problem, family relationships and dynamics can be negatively affected when the service member returns home if s/he is among the estimated 20-30% of returning troops who suffer the negative mental health and related outcomes (e.g., PTSD, depression, substance use) associated with high levels of war zone stress exposure and/or has sustained significant physical injuries.

Prior research documents that military families are significantly affected by a service member's war-related mental health problems, as well as the chronic stress of multiple and extended wartime deployments characterized by diminished "dwell" time. Findings from the National Vietnam Veterans Readjustment Study indicated that children of veterans with PTSD had higher levels of behavioral and emotional problems than children of veterans without PTSD. Families of veterans with PTSD are also more likely to suffer domestic violence or intimate partner violence than families of veterans without PTSD. In the U.S. Army, younger couples, and those with a previous incident of domestic violence, are at greatest risk for an episode of domestic violence post-deployment.

Adverse childhood experiences (ACE), such as having a parent with a severe mental illness and exposure to domestic violence and child maltreatment have been found to contribute to negative adolescent trajectories, including early school drop-out, substance abuse, severe obesity and promiscuity. In addition, adverse childhood experiences contribute significantly to adverse adult outcomes, such as depression, PTSD, substance abuse, poorer medical health, and low occupational attainment. The Department of Defense Plan to Achieve the Vision of the DoD Task Force on Mental Health

(September, 2007) addressed these concerns directly by recommending the following actions to better understand the role that deployment stress and war-related PTSD has on military families:

- DoD should conduct research on the processes of post-deployment adjustment for family members
- DoD should conduct research on children who have been separated from their parents by deployment, including their access to support for psychological health issues

Although much of the existing research suggests that war-time stress and deployments are associated with a host of negative sequelae for both the service member and their family, the relationships are not linear, in that some service members and their families demonstrate resiliency in the face of adversity. Moreover, studies have demonstrated that other potential factors (e.g., social support, previous exposure to violence) may either moderate (i.e., reduce or exacerbate the impact of the stressor) or mediate this relationship suggesting alternate pathways and trajectories. To this end, the family component seeks to address both the risk and protective factors associated with the process of post-deployment adjustment for family members. This line of inquiry has significant implications for both early intervention efforts and future research, given the potential information gained on patterns of risk and resiliency, and targets for intervention, particularly for the families of deployed service members.

Systematic documentation of both negative and positive outcomes associated with deployment to Iraq and Afghanistan, along with detailed analysis of risk and resilience factors, will provide a scientifically sound foundation for understanding the relationships among multiple factors related to family member functioning and family dynamics. This information will facilitate identification of specific interventions aimed at: reducing deployment-related stress, increasing family member resilience, and increasing the capability of family members to support service members with negative outcomes resulting from war zone stressor exposures.

Objectives

- To assess the impact of military service and deployment on the physical and mental health and related outcomes of spouses and co-resident children of service members
- To assess the impact of military service and deployment on the quality of the relationships between service members, spouses and their children
- To examine the association between family member outcomes and service member outcomes
- To identify vulnerability and resilience factors for deployment stress-related outcomes for spouses and children of deployed service members

Through the Collaboration Protocol (Appendix J) already in place with Abt Associates the following objectives can be met. Therefore a Data Use Agreement (Appendix K) between NHRC and Abt Associates and their subcontractors Duke University (Duke) and New York University (NYU) has been established. The Principal Investigators and Co-Investigators from the NHRC and Abt Associates teams will meet to discuss and determine the priority of analyses to be conducted based on their scientific merit and

potential to impact force health protection (to prepare, protect, and treat the families of Service members):

- Explore the association between service member deployment (e.g. combat, duration, dwell time, and frequency) and the health and well-being of spouses and children.
- Explore the association between service member readjustment issues (e.g., PTSD, anxiety, depression, alcohol misuse/abuse) and the health and well-being of spouses and children.
- Examine factors related to resiliency and vulnerability that moderate the association between deployment experiences and service member readjustment issues, and the health and well-being of spouses and children.
- Examine factors related to marital quality and family function.
- Evaluate methodological approaches to ensure adequate representation of spouses from all service branches, Reserve and National Guard; and assess validity of assessment measures and instruments.
- Contribute data to the service member cohort study on spouse and child factors that are associated with service member health and well-being, as well as length of service.

Data, collected from spouses of service members, may include demographics, health conditions and symptoms, functional health, habits (e.g., smoking, alcohol use, exercise, and diet), family relationships and children-related data, and select information from the main study (the Millennium Cohort Study) including military-related data, such as deployment information. Additionally, dates of events may be shared with Abt Associates for specific analyses of the Family Study; these dates will be coded as time (days) since an agreed upon baseline date and no actual dates will be in the shared dataset. Survey data may be linked by NHRC to electronic health and administrative data from other sources as outlined in this protocol, and shared with Abt Associates for analyses requiring this information. NHRC will not transfer any data involving names, dates (including dates of birth), social security numbers, or any contact information to Abt Associates. Proposals will be written for each proposed analysis using the Family Study data containing a list of required data elements and investigators which will be provided to the IRB at the study's annual review or at the time of development should any data requirements and/or aims fall outside those presented under this modification.

Data transfers will only occur through secure means using password-protected encrypted files. The data provided by NHRC to the Abt Associates team is restricted to the minimum necessary to complete the approved Family sub-studies and access to these data will be limited to a minimum number of individuals necessary at each institution to achieve the purpose. Data will be stored in a manner consistent with Federal and DoD regulations and data security best practices as described under section IX "Description Of The System For Maintenance Of Records".

VI. EXPERIMENTAL METHODS

Methods

Based on recommendations from sponsors and advisory committees, and the success of the Millennium Cohort, a fourth enrollment panel will be added to the next survey cycle beginning in 2011. The Millennium Cohort was originally designed to follow three panels of participants that enrolled in 2001, 2004, and 2007 through 2022. The team plans to invite approximately 250,000 individuals of active-duty, Reserve, or National Guard status, with 2-5 years military service experience, oversampling for women and married personnel. Out of the 250,000, an estimated 62,500 new participants will enroll. This group will be consented to complete 7 follow-up surveys over 21 years, with one survey to complete every 3 years. The invited group will be a stratified random sample from the Defense Manpower Data Center. The current total number enrolled is 151,597, so this new enrollment will bring the total number enrolled to approximately 214,000 individuals.

In addition to Panel 4, a Family Cohort component will be added to the next survey cycle beginning in 2011. In order to assess the interrelated health effects of military service and deployment on service members, spouses, and co-resident children, the Millennium Cohort Study team and collaborators will survey the spouses of newly enrolled Panel 4 participants that consent to this assessment. The team estimates that about 10,000 spouses will enroll in the study, about half of whose service member will have been deployed to the conflicts in Iraq and Afghanistan at least once.

- Surrogate data on children health will be obtained from the spouse. The data collected on these children will be generalized. No child will be individually identified for the purposes of this study. Because families and family relationships change over time and to maintain methodological consistency with the Millennium Cohort Study, spouses will be asked to complete 7 follow-up surveys over 21 years, with one survey to complete every 3 years. Participants of the Family Cohort Study will only have the option of completing a web survey.
- In October of 2010, 250,000 service members were randomly selected from military rosters. These individuals will be invited to participate in the Millennium Cohort's fourth enrollment cycle once OMB and RCS approvals are in place. These participants will be referred to as Panel 4 participants/members. Out of these Panel 4 members, the married service members will view the following: the Millennium Cohort Family Study survey instrument, and the Panel 4 Millennium Cohort Family Study informed consent document and permission form. From this group of consenters, the first 100 spouses to consent to the study and complete their surveys will be included in a pilot sample. This group of 100 individuals will be treated the same as the large group of Millennium Cohort Family Study participants, however, the internal team of analysts will review their survey to ensure participants are understanding the survey questions. Based on survey research, missing data along with data completion rates will indicate how the survey is interpreted. Also, an open-ended question will be added to the end of the first 100 surveys, "Is there anything you didn't understand or would change in this

survey?" This will provide us with information on how the questions were interpreted and understood. We will not be requesting further feedback from these participants.

- Millennium Cohort Study contact methods will be employed, including the modified Dillman survey methodology. Complex algorithms will be developed for email, mail and response tracking.
- For the Millennium Cohort Family Study, we are seeking permission to call those participants who completed the paper survey, but failed to sign the informed consent form in the survey document. These phone calls will be the last contact attempt during the cycle in attempt to have the subject provide consent, and hence for the study team to utilize their survey data. Approximately 100 participants will be called. Those who did not sign the consent and who did not complete the majority of the survey will not be contacted, rather they will simply be excluded from the study.

Subjects will be contacted via telephone during Monday through Friday between the hours of 8 am to 8 pm within their time zone, and/or Saturday between 10 am to 6 pm in their time zone. No calls will be made on Sundays. A maximum of 10 phone call attempts will be made per subject and a log of every attempt will be kept. Staff making phone calls will not leave a voice message. A verbal "yes" or "no" reply will be accepted as the subject's consent and documented by caller who will be a member of the study team. If the subject responds with a "no", they will no longer be contacted and their survey data will not be utilized. Calls will end once the 10 call limit occurs or we are able to reach the participant in person, whichever occurs first. All participants who agree to consent to the study will be offered a copy of the consent form which will be mailed to them.

The script for the phone calls is as follows:

Hi (interviewee name):

My name is (caller name), and I am calling from the Naval Health Research Center. We appreciate the time you spent completing our survey on (Date) for the Family Study which is being conducted by the Department of Defense.

When we reviewed your survey, we noticed that you did not sign the consent form on the 2nd page of the survey. In order to use your data for our study, we would need to have your consent to participate in the study. Will you give your consent for participation?

If the subject responds yes:

Thank you. We will document your response. We know your time is valuable and we thank you for helping with this important project. We would be happy to send you a copy of the study's consent to your home address? Would you like a copy? If yes, (confirm address).

If the subject responds no:

Thank you. We will document your response. Unfortunately, we will not be able to use the information you gave us in the survey you completed. Thank you for your time.

- A separate website will be built for this sub-study, but will link directly to the Millennium Cohort Study website, www.millenniumcohort.org. The URL will be www.familycohort.org
- Like the Millennium Cohort Study, nominal incentives will be offered to participants that complete the survey online, participants will be offered the choice of a \$10 gift card to the following; military exchange (AAFES/NEX gift card), Starbucks, or Amazon.com. AAFES/NEX and Starbucks gift cards will be mailed to participants within 6 weeks of survey completion, and Amazon.com electronic gift cards will be emailed within one week of survey completion. None of the gift cards are exchangeable for cash.

Family Component Domains and Measures

Based on our conceptual model and the existing literature, we intend to focus the assessment on four broad domains: (1) spouse physical health; (2) spouse mental health and adjustment; (3) spouse's reports of their children's mental/physical health and functioning; and (4) family functioning and protective and vulnerability factors.

Family Component Domains and Measures		
Construct	Inventory	# Items
Physical Health History	Self-reported Medical Conditions	46
General Health and Functional Status	SF-36	36
Mental Disorder Screening (depression, somatization, panic disorder, anxiety, alcohol abuse/dependence, binge eating disorder, and bulimia nervosa)	PHQ	15-16
PTSD Symptoms	PCL-C	17
Adverse Childhood Events	ACE	8
Alcohol Use	CAGE	4
Sleep Quality	ISS	9
Child Health	CDC: National Survey of Children's Health	23
Child Functioning	Adapted Strengths and Difficulties Questionnaire	15
Family Satisfaction	FACES-IV	10
Family Communication	FACES-IV	10
Marital Satisfaction	Adapted Quality of Marriage Index	4
Spouse's Work and Family Conflict	Adapted Work-Family Conflict Scale	5

SF-36 = Short-Form 36 Health Survey; PHQ = Patient Health Questionnaire; PCL = PTSD check list; ACE = Adverse Childhood Events; ISS = Insomnia Severity Index; FACES-IV = Family Adaptability and Cohesion Evaluation Scale, fourth version

Family Study: Sample Size Determination

The sample size for the Family Assessment Component is based on the prevalence of mental health outcomes among spouses of US service members. As the US military and the Millennium Cohort are predominantly male populations, it is presumed that the sample of spouse responders will be predominantly female. Approximately 15% of the 2.2 million US military population in 2000 were female and close to 25% of the current Millennium Cohort Study members are female.²⁰ Therefore, prevalence estimates from the general US women population were used to represent the spouses of service members.

Using standardized self-reported instruments to identify individuals with certain mental health conditions, previous findings have found the weighted prevalence to be 18.3% for any mental disorder, 2.4% for PTSD, 3.2% for major depressive disorder, 1.0% for panic syndrome, 2.0% for other anxiety syndrome, and 12.6% for alcohol abuse among US military service members.²¹ Higher prevalence of mental disorders was found among 1991 Gulf War veterans and those deployed to the current wars in Iraq and Afghanistan with combat exposures.^{21, 22}

Among the general US women population, the prevalence of frequent mental distress, which included stress, depression, and problems with emotions, was 10.6% from 1993-2000.²³ Results from the National Comorbidity Survey showed lifetime prevalence of many mental health disorders to be approximately twice as high for women compared to men, with 5.0% for panic disorders and 6.6% for general anxiety disorder.²⁴ Additionally, the Epidemiological Catchment Area survey found that the 1-month prevalence of all anxiety disorders was twice as high in women (9.7%) than in men (4.7%).²⁵ Among women in the general US population, the prevalence of alcohol abuse was 11.5% with alcohol dependence at 8.0%.²⁶

Based on the percent of service members who have already been enrolled in the Millennium Cohort Study who have deployed in support of the wars in Iraq and Afghanistan, it is estimated that 30% to 50% of the service members who will be enrolled in the 2010 cohort will have already been deployed in support of the current conflicts. The statistical power of this study depends on the prevalence of the various mental health disorders and the percent of spouses married to service members with and without exposure to deployment. The following formula estimates the necessary sample size:

$$N = \frac{\left(Z_{\alpha} \sqrt{P(1-P)(1/q_1 + 1/q_2)} + Z_{\beta} \sqrt{P_1(1-P_1)(1/q_1) + P_2(1-P_2)(1/q_2)} \right)^2}{\Delta^2}$$

Where:

N = sample size required

P₁ = proportion of outcome among group 1 (spouses of non-deployed)

P₂ = proportion of outcome among group 2 (spouses of deployed)

Z_α = standardized normal deviate for a two-tailed probability of an α-error, set at α = 0.05

Z_β = standardized normal deviate for a two-tailed probability of an β-error, set at β = 0.80 or 0.90

q₁ = proportion of sample population in group 1

q₂ = proportion of sample population in group 2

P = q₁ P₁ + q₂ P₂

Δ = P₁ - P₂

For the sample size calculation, it is estimated that the overall prevalence of mental health outcomes will be from 5 to 10% for spouses of non-deployed military service members. The necessary study sample size for spouses of military service members to detect specified odds ratios with 80% and 90% power and the alpha error level set at <0.05 are shown in Table 1. With a study sample of 10,000 spouses, odds ratios of 1.3 and higher with 80% power will be detectable regardless of the percent of service members deployed.

Table 4. Sample Size Necessary at Different Levels of Statistical Power to Detect a Given Magnitude of Prevalence (as reflected by the Odds Ratio) for Spouses of Service Members

% Prevalence of Exposure (Deployment)	Detectable Odds Ratio	Low-End Estimate (5%)		High-End Estimate (10%)	
		N Required for 80% Power	N Required for 90% Power	N Required for 80% Power	N Required for 90% Power
30%	1.2	21,555	29,034	11,502	15,480
30%	1.3	9,999	13,504	5,363	7,234
30%	1.5	3,903	5,295	2,113	2,861
30%	2.0	1,167	1,596	645	879
40%	1.2	18,988	25,497	10,124	13,589
40%	1.3	8,836	11,880	4,733	6,360
40%	1.5	3,468	4,673	1,874	2,522
40%	2.0	1,049	1,418	578	779
50%	1.2	18,348	24,562	9,775	13,085
50%	1.3	8,563	11,462	4,581	6,132
50%	1.5	3,378	4,521	1,822	2,438
50%	2.0	1,031	1,379	566	756

The estimated sample size of spouses of military service members with adequate power to detect differences in mental health outcomes was determined to be approximately 10,000. To achieve this spouse sample size, we will begin with a probability sample of personnel 250,000 service members who will be invited to participate in the 2010 cohort. Based on Millennium Cohort Study experience to date, we expect a response rate of 25% (62,500 enrolled service members). Of those, we estimate that 35% (21,875) will be married, and that 75% (16,407) of married service members will consent to our contacting their spouses for enrollment. We further estimate

a spouse response rate of 60%, thus giving an estimated sample size of approximately 10,000 spouses of military service members for this study. Based on the above table, a sample size of 10,000 will provide adequate power to detect the targeted mental health outcomes among this population.

APPENDIX H. MILLENNIUM COHORT FAMILY PARTICIPANT CONTACT MATERIALS

Millennium Cohort Family Study Non-responder letter

Dear [\[name\]](#),

When you and your spouse joined the Family Study and the Millennium Cohort Study a few years ago, you became part of a special community of couples that inform leadership, guide interventions and shape support programs designed to target the specific needs of military couples and families. As a member of the Millennium Cohort Family Study, you have the opportunity to represent all military spouses. We are re-contacting you because your continued participation makes it possible to form a more complete picture of how military life influences family dynamics, structure and relationships. Whatever your circumstances and feelings, whether you have children or not, we would like to encourage you to provide your input by completing your Family Study follow-up survey.

We realize that relationships and families change over time, so we contacted you last year and asked you to share your experiences since the last survey. We have heard from a large number of the military spouses who participated in the initial 2011-2013 survey. However, the results of this important study will have the greatest impact if we can hear from you since your unique input will help make the Millennium Cohort Family Study a powerful resource for understanding the unique strengths and challenges experienced by current and former military couples.

In an effort to be as inclusive and comprehensive as possible, our survey has been updated to ensure an understanding of the evolving situations and circumstances of military spouses over time. As such, the survey includes sections intended for participants with current or prior military service, with and without children, as well as those who are separated, divorced, or widowed. Even if your spouse is no longer in the military or if your marital status has changed, your participation is critical to defining how military life affects families.

To complete your survey, please visit the study website www.familycohort.org, click **Start Survey** and enter your **Subject ID: XXXXXXXX**.

Very Respectfully,

Carrie Donoho, PhD
Captain, MS, USA
Spouse of a Veteran and Active Duty Family Study researcher

On behalf of the Millennium Cohort Family Study Team

If you have any questions, please contact the Millennium Cohort Family Study team at our toll-free number, 1-800-571-9248, or DSN 553-7465, or email info@familycohort.org.

The Millennium Cohort Family Study is an authorized Department of Defense project. Note Report Control Symbol #DD-HA(AR)2106, Office of Management and Budget Approval # 0720-0029, and Primary Institutional Review Board Protocol # NHRC.2000.0007

Millennium Cohort Family Study Non-responder with Panel 4 Responder letter

Dear [name],

When you and your spouse joined the Family Study and the Millennium Cohort Study a few years ago, you became part of a special community of couples that inform leadership, guide interventions and shape support programs designed to target the specific needs of military families. Your spouse has already completed their Millennium Cohort follow-up survey, but we have yet to hear from you. We are re-contacting you because your participation is critically important, even if you are no longer married. The participation of both you and your spouse makes it possible to form a more complete picture of the impact of military life, which is why we would like to encourage you to provide your input by completing your Family Study follow-up survey.

We realize that relationships and families change over time, so we contacted you last year and asked you to share your experiences since the last survey. We have heard from a large number of the military spouses who participated in the initial 2011-2013 survey. However, the results of this important study will have the greatest impact if we can hear from both you and your spouse since your combined participation is what makes the Millennium Cohort Family Study such a powerful resource for understanding the complexities of military life.

In an effort to be as inclusive and comprehensive as possible, our survey has been updated to ensure an understanding of the evolving situations and circumstances of military spouses over time. As such, the survey includes sections intended for participants with current or prior military service, with and without children, as well as those who are separated, divorced, or widowed. Even if your spouse is no longer in the military or if your marital status has changed, your participation is critical to defining how military life affects families.

To complete your survey, please visit the study website www.familycohort.org, click **Start Survey** and enter your **Subject ID: XXXXXXXX**.

Very Respectfully,

Carrie Donoho, PhD
Captain, MS, USA
Spouse of a Veteran and Active Duty Family Study researcher

On behalf of the Millennium Cohort Family Study Team

If you have any questions, please contact the Millennium Cohort Family Study team at our toll-free number, 1-800-571-9248, or DSN 553-7465, or email info@familycohort.org.

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Millennium Cohort Family Study Male Non-responder letter

Dear [name],

The well-being of military spouses and families has become a national priority; however, there is limited awareness of the unique needs and challenges experienced by male spouses. In 2011, there were approximately 100,000 male spouses of Service members, accounting for nearly 9% of all US military spouses. As a member of the Millennium Cohort Family Study, you have the unique opportunity to help represent all military husbands, even if you are part of a dual-military couple or have formerly served. We are re-contacting you because your participation is critically important. Your continued participation makes it possible to develop a more complete picture of the impact of military life, which is why we would like to encourage you to provide your input by completing your Family Study follow-up survey.

We realize that relationships and families change over time, so we contacted you last year and asked you to share your experiences since the last survey. We have heard from a large number of the military spouses who participated in the initial 2011-2013 survey. However, the results of this important study will have the greatest impact if we can hear from you since your unique input will help make the Millennium Cohort Family Study a powerful resource for understanding the unique strengths and challenges experienced by male spouses.

In an effort to be as inclusive and comprehensive as possible, our survey has been updated to ensure an understanding of the evolving situations and circumstances of military spouses over time. As such, the survey includes sections intended for participants with current or prior military service, with and without children, as well as those who are separated, divorced, or widowed. Even if your spouse is no longer in the military or if your marital status has changed, your participation is critical to defining how military life affects families.

To complete your survey, please visit the study website www.familycohort.org, click **Start Survey** and enter your **Subject ID: XXXXXXX**.

Very Respectfully,

Carrie Donoho, PhD
Captain, MS, USA
Spouse of a Veteran and Active Duty Family Study researcher

On behalf of the Millennium Cohort Family Study Team

If you have any questions, please contact the Millennium Cohort Family Study team at our toll-free number, 1-800-571-9248, or DSN 553-7465, or email info@familycohort.org.

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Millennium Cohort Family Study Dual-military Non-responder letter

Dear [name],

When you and your spouse joined the Family Study and the Millennium Cohort Study a few years ago, you became part of a special community of couples that inform leadership, guide interventions and shape support programs designed to target the specific needs of military families. As someone who is currently serving or has previously served in the military, you have a unique perspective of what it means to be part of a dual-military couple and family. We are re-contacting you because it is especially important that we hear from you, so that we can gain a better understanding of current and former dual-military couples. Your continued participation makes it possible to form a more complete picture of the impact of military life, which is why we would like to encourage you to provide your input by completing your Family Study follow-up survey.

We realize that relationships and families change over time, so we contacted you last year and asked you to share your experiences since the last survey. We have heard from a large number of the military spouses who participated in the initial 2011-2013 survey. However, the results of this important study will have the greatest impact if we can hear from you since your unique input will help make the Millennium Cohort Family Study a powerful resource for understanding the unique strengths and challenges experienced by current and former dual-military couples.

In an effort to be as inclusive and comprehensive as possible, our survey has been updated to ensure an understanding of the evolving situations and circumstances of military spouses over time. As such, the survey includes sections intended for participants with current or prior military service, with and without children, as well as those who are separated, divorced, or widowed. Even if your spouse is no longer in the military or if your marital status has changed, your participation is critical to defining how military life affects families.

To complete your survey, please visit the study website www.familycohort.org, click **Start Survey** and enter your **Subject ID: XXXXXXXX**.

Very Respectfully,

Carrie Donoho, PhD
Captain, MS, USA
Spouse of a Veteran and Active Duty Family Study researcher

On behalf of the Millennium Cohort Family Study Team

If you have any questions, please contact the Millennium Cohort Family Study team at our toll-free number, 1-800-571-9248, or DSN 553-7465, or email info@familycohort.org.

The Millennium Cohort Family Study is an authorized Department of Defense project. Note Report Control Symbol #DD-HA(AR)2106, Office of Management and Budget Approval # 0720-0029, and Primary Institutional Review Board Protocol # NHRC.2000.0007

Millennium Cohort Family Study Reserve/Guard Non-responder letter

Dear [name],

When you and your spouse joined the Family Study and the Millennium Cohort Study a few years ago, you became part of a special community of couples that inform leadership, guide interventions and shape support programs designed to target the specific needs of military couples and families. As the spouse of a Reserve or National Guard Service member, you have a unique perspective that is especially important. We are re-contacting you because it is critical that we hear from you, so that we can gain a better understanding of the experiences of Reserve and National Guard couples and families. Your continued participation makes it possible to form a more complete picture of the impact of military life, which is why we would like to encourage you to provide your input by completing your Family Study follow-up survey.

We realize that relationships and families change over time, so we contacted you last year and asked you to share your experiences since the last survey. We have heard from a large number of the military spouses who participated in the initial 2011-2013 survey. However, the results of this important study will have the greatest impact if we can hear from you since your unique input will help make the Millennium Cohort Family Study a powerful resource for understanding the unique strengths and challenges experienced by Reserve and National Guard families.

In an effort to be as inclusive and comprehensive as possible, our survey has been updated to ensure an understanding of the evolving situations and circumstances of military spouses over time. As such, the survey includes sections intended for participants with current or prior military service, with and without children, as well as those who are separated, divorced, or widowed. Even if your spouse is no longer in the military or if your marital status has changed, your participation is critical to defining how military life affects families.

To complete your survey, please visit the study website www.familycohort.org, click **Start Survey** and enter your **Subject ID: XXXXXXX**.

Very Respectfully,

Carrie Donoho, PhD
Captain, MS, USA
Spouse of a Veteran and Active Duty Family Study researcher

On behalf of the Millennium Cohort Family Study Team

If you have any questions, please contact the Millennium Cohort Family Study team at our toll-free number, 1-800-571-9248, or DSN 553-7465, or email info@familycohort.org.

The Millennium Cohort Family Study is an authorized Department of Defense project. Note Report Control Symbol #DD-HA(AR)2106, Office of Management and Budget Approval # 0720-0029, and Primary Institutional Review Board Protocol # NHRC.2000.0007

Millennium Cohort Family Study Non-responder with Children letter

Dear [name],

When you and your spouse joined the Family Study and the Millennium Cohort Study a few years ago, you became part of a special community of couples that inform leadership, guide interventions and shape support programs designed to target the specific needs of military families. As a parent raising children in a military family, you have the opportunity to provide critical information that will help inform health care providers, military leaders and policy makers about the challenges, concerns and needs of military families. We are re-contacting you because your continued participation makes it possible to form a more complete picture of the impact of military life on families with children. By sharing your personal perspective and experiences, your contribution will make a difference in the lives of current and future military spouses and children.

We realize that relationships and families change over time, so we contacted you last year and asked you to share your experiences since the last survey. We have heard from a large number of the military spouses who participated in the initial 2011-2013 survey. However, the results of this important study will have the greatest impact if we can hear from you; your unique input as a parent will help make the Millennium Cohort Family Study a powerful resource for understanding the unique strengths and challenges experienced by current and former military families.

In an effort to be as inclusive and comprehensive as possible, our survey has been updated to ensure an understanding of the evolving situations and circumstances of military families over time. As such, the survey includes sections intended for participants with current or prior military service, as well as those who are separated, divorced, or widowed. Even if your spouse is no longer in the military or if your marital status has changed, your participation is critical to defining how military life affects families.

To complete your survey, please visit the study website www.familycohort.org, click **Start Survey** and enter your **Subject ID: XXXXXXX**.

Very Respectfully,

Carrie Donoho, PhD
Captain, MS, USA
Spouse of a Veteran and Active Duty Family Study researcher

On behalf of the Millennium Cohort Family Study Team

If you have any questions, please contact the Millennium Cohort Family Study team at our toll-free number, 1-800-571-9248, or DSN 553-7465, or email info@familycohort.org.

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Millennium Cohort Family Study Widowed Non-responder letter

Dear [\[name\]](#),

As a member of the Family Study, you have the opportunity to provide critical information that will help inform health care providers, military leaders and policy makers about the challenges, concerns and needs of military families. We are re-contacting you because your continued participation makes it possible to form a more complete picture of the impact of military life. By sharing your personal perspective and experiences, your contribution will make a difference in the lives of current and future military spouses and children.

We realize that relationships and families change over time, so we contacted you last year and asked you to share your experiences since the last survey. We have heard from a large number of the military spouses who participated in the initial 2011-2013 survey. However, the results of this important study will have the greatest impact if we can hear from you since your unique input will help make the Millennium Cohort Family Study a powerful resource for understanding the strengths and challenges experienced by current and former military couples.

We honor the important role that you play in serving our country and supporting our troops. In an effort to be as comprehensive and inclusive as possible, our survey has been updated to ensure an understanding of the evolving situations and circumstances of military spouses over time. As such, the survey includes sections intended for participants with current or prior military service, with and without children, as well as those who are separated, widowed or divorced.

To complete your survey, please visit the study website www.familycohort.org, click **Start Survey** and enter your **Subject ID: XXXXXXXX**.

If you have any questions, would prefer to not be contacted, or would like to be removed from this study, please contact the Millennium Cohort Family Study team at our toll-free number, 1-800-571-9248, or DSN 553-7465, or email info@familycohort.org.

Very Respectfully,

Carrie Donoho, PhD
Captain, MS, USA
Spouse of a Veteran and Active Duty Family Study researcher

On behalf of the Millennium Cohort Family Study Team

If you have any questions, please contact the Millennium Cohort Family Study team at our toll-free number, 1-800-571-9248, or DSN 553-7465, or email info@familycohort.org.

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Millennium Cohort Family Study Non-responder Email

Subject: Help make an impact in the lives of military families!

Dear [\[name\]](#),

As an important member of the Millennium Cohort Family Study, you are one of a select group of individuals helping to inform military leaders and policy makers about the strengths and challenges associated with military life. In order to fully understand the impact of military service on spouses and families, it is important that we hear your unique perspective, which is why we are re-contacting you to complete your Family Study follow-up survey.

We value your continued participation even if your marital status has changed or your spouse is no longer in the military. As such, the survey includes sections intended for participants with current or prior military service, with and without children, as well as those who are separated, divorced, or widowed.

To complete your survey, please visit the study website www.familycohort.org, click **Start Survey** and enter your **Subject ID: XXXXXXXX**.

Very Respectfully,

Carrie Donoho, PhD
Captain, MS, USA
Spouse of a Veteran and Active Duty Family Study researcher

On behalf of the Millennium Cohort Family Study Team

If you have any questions, please contact the Millennium Cohort Family Study team at our toll-free number, 1-800-571-9248, or DSN 553-7465, or email info@familycohort.org.

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Millennium Cohort Family Study Non-responder with Panel 4 Responder Email

Subject: Help make an impact in the lives of military families!

Dear [\[name\]](#),

As important members of the Family Study and the Millennium Cohort Study, both you and your spouse are part of a select group of couples with the unique opportunity to help represent the experiences and needs of military families. Your spouse has already completed their follow-up survey, so we would greatly appreciate hearing from you too. In order to fully understand the impact of military service on couples and families, it is important that we hear from both you and your spouse, which is why we are re-contacting you to complete your Family Study follow-up survey.

We value your continued participation even if your marital status has changed or your spouse is no longer in the military. As such, the survey includes sections intended for participants with current or prior military service, with and without children, as well as those who are separated, divorced, or widowed.

To complete your survey, please visit the study website www.familycohort.org, click **Start Survey** and enter your **Subject ID: XXXXXXXX**.

Very Respectfully,

Carrie Donoho, PhD
Captain, MS, USA
Spouse of a Veteran and Active Duty Family Study researcher

On behalf of the Millennium Cohort Family Study Team

If you have any questions, please contact the Millennium Cohort Family Study team at our toll-free number, 1-800-571-9248, or DSN 553-7465, or email info@familycohort.org.

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Millennium Cohort Family Study Male Non-responder Email

Subject: Help make an impact in the lives of male spouses!

Dear [\[name\]](#),

As an important member of the Millennium Cohort Family Study, you are one of a select group of individuals that has the unique opportunity to help represent all military husbands. In order to fully understand the impact of military service on male spouses, it is important that we hear from you, which is why we are re-contacting you to complete your Family Study follow-up survey.

We value your continued participation even if your marital status has changed or your spouse is no longer in the military. As such, the survey includes sections intended for participants with current or prior military service, with and without children, as well as those who are separated, divorced, or widowed.

To complete your survey, please visit the study website www.familycohort.org, click **Start Survey** and enter your **Subject ID: XXXXXXX**.

Very Respectfully,

Carrie Donoho, PhD
Captain, MS, USA
Spouse of a Veteran and Active Duty Family Study researcher

On behalf of the Millennium Cohort Family Study Team

If you have any questions, please contact the Millennium Cohort Family Study team at our toll-free number, 1-800-571-9248, or DSN 553-7465, or email info@familycohort.org.

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Millennium Cohort Family Study Dual-military Non-responder Email

Subject: Help make an impact in the lives of dual-military families!

Dear [\[name\]](#),

As an important member of the Millennium Cohort Family Study, you are part of a select group of individuals that has the opportunity to represent dual-military spouses. In order to fully understand the impact of military service on current and former dual-military couples and families, it is important that we hear from you, which is why we are re-contacting you to complete your Family Study follow-up survey.

We value your continued participation even if your marital status has changed or your spouse is no longer in the military. As such, the survey includes sections intended for participants with current or prior military service, with and without children, as well as those who are separated, divorced, or widowed.

To complete your survey, please visit the study website www.familycohort.org, click **Start Survey** and enter your **Subject ID: XXXXXXXX**.

Very Respectfully,

Carrie Donoho, PhD
Captain, MS, USA
Spouse of a Veteran and Active Duty Family Study researcher

On behalf of the Millennium Cohort Family Study Team

If you have any questions, please contact the Millennium Cohort Family Study team at our toll-free number, 1-800-571-9248, or DSN 553-7465, or email info@familycohort.org.

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Millennium Cohort Family Study Reserve/Guard Non-responder Email

Subject: Help make an impact in the lives of Reserve and National Guard families!

Dear [\[name\]](#),

As an important member of the Millennium Cohort Family Study, you are one of a select group of individuals that has the unique opportunity to help represent Reserve and National Guard families. In order to fully understand the impact of military service on current and former Reserve and National Guard couples and families, it is important that we hear from you, which is why we are re-contacting you to complete your Family Study follow-up survey.

We value your continued participation even if your marital status has changed or your spouse is no longer in the military. As such, the survey includes sections intended for participants with current or prior military service, with and without children, as well as those who are separated, divorced, or widowed.

To complete your survey, please visit the study website www.familycohort.org, click **Start Survey** and enter your **Subject ID: XXXXXXXX**.

Very Respectfully,

Carrie Donoho, PhD
Captain, MS, USA
Spouse of a Veteran and Active Duty Family Study researcher

On behalf of the Millennium Cohort Family Study Team

If you have any questions, please contact the Millennium Cohort Family Study team at our toll-free number, 1-800-571-9248, or DSN 553-7465, or email info@familycohort.org.

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Millennium Cohort Family Study Non-responder with children Email

Subject: Help make an impact in the lives of military families!

Dear [\[name\]](#),

As an important member of the Family Study, you are part of a select group of individuals with the unique opportunity to help represent the experiences and needs of military parents. In order to fully understand the impact of military service on parents and families, it is important that we hear your unique perspective, which is why we are re-contacting you to complete your Family Study follow-up survey.

We value your continued participation even if your marital status has changed or your spouse is no longer in the military. As such, the survey includes sections intended for participants with current or prior military service, as well as those who are separated, divorced, or widowed.

To complete your survey, please visit the study website www.familycohort.org, click **Start Survey** and enter your **Subject ID: XXXXXXXX**.

Very Respectfully,

Carrie Donoho, PhD
Captain, MS, USA
Spouse of a Veteran and Active Duty Family Study researcher

On behalf of the Millennium Cohort Family Study Team

If you have any questions, please contact the Millennium Cohort Family Study team at our toll-free number, 1-800-571-9248, or DSN 553-7465, or email info@familycohort.org.

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Millennium Cohort Family Study Widowed Non-responder Email

Subject: Help make an impact in the lives of military families!

Dear [\[name\]](#),

As an important member of the Millennium Cohort Family Study you are one of a select group of individuals helping to inform military leaders and policy makers about the strengths and challenges associated with military life. In order to fully understand the impact of military service on spouses and families, it is important that we hear your unique perspective, which is why we are re-contacting you to complete your Family Study follow-up survey.

Our survey has been updated to ensure an understanding of the ever-changing circumstances of military spouses. As such, the survey includes sections intended for participants with current or prior military service, with and without children, as well as those who are separated, widowed or divorced.

To complete your survey, please visit the study website www.familycohort.org, click **Start Survey** and enter your **Subject ID: XXXXXXXX**.

Very Respectfully,

Carrie Donoho, PhD
Captain, MS, USA
Spouse of a Veteran and Active Duty Family Study researcher

On behalf of the Millennium Cohort Family Study Team

If you have any questions, please contact the Millennium Cohort Family Study team at our toll-free number, 1-800-571-9248, or DSN 553-7465, or email info@familycohort.org.

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Month of the Military Child Non-responder Postcard

Military children bloom everywhere the wind carries them. They are resilient and strong, cultivated deeply in the culture of the military, planted swiftly and surely. - anonymous

The Millennium Cohort Family Study Team joins the nation in celebrating April as the Month of the Military Child. We recognize the strength and service of all military families.

To complete your follow-up survey, please visit www.familycohort.org, click **Start Survey** and enter your **Subject ID XXXXXXX**. Your continued participation is what makes the Millennium Cohort Family Study such a powerful resource for understanding the short and long-term impact of military life. Please know that your contribution will make a difference and will benefit current and future generations of Service members and their families.

Very Respectfully,

Carrie Donoho, PhD
Captain, MS, USA
Spouse of a Veteran and Active Duty Family Study researcher

Primary Institutional Review Board Protocol # NHRC.2000.0007

Month of the Military Child Responder Postcard

Military children bloom everywhere the wind carries them. They are resilient and strong, cultivated deeply in the culture of the military, planted swiftly and surely. - anonymous

The Millennium Cohort Family Study Team joins the nation in celebrating April as the Month of the Military Child. We recognize the strength and service of all military families.

Thank you for completing your follow-up survey. Your continued participation is what makes the Millennium Cohort Family Study such a powerful resource for understanding the short and long-term impact of military life. Please know that your contribution makes a difference and will benefit current and future generations of Service members and their families.

Very Respectfully,

Carrie Donoho, PhD
Captain, MS, USA
Spouse of a Veteran and Active Duty Family Study researcher

Primary Institutional Review Board Protocol # NHRC.2000.0007

Month of the Military Child Non-responder Email

Subject: Celebrating Month of the Military Child

Dear name,

During the month of April, the Millennium Cohort Family Study Team joins the nation in celebrating the Month of the Military Child. We recognize and appreciate the sacrifices made by military spouses and families on a daily basis.

The Millennium Cohort Family Study was launched in 2011 to help ensure the health and well-being of military families. As a member of this important study, you are helping to inform leadership and guide resources designed to support the specific needs of current and future military couples and families.

To complete your follow-up survey, please visit www.familycohort.org, click **Start Survey** and enter your **Subject ID: XXXXXXXX**. Your continued participation is what makes the Millennium Cohort Family Study such a powerful tool for understanding the unique strengths and challenges of military life.

Very Respectfully,

Carrie Donoho, PhD
Captain, MS, USA
Spouse of a Veteran and Active Duty Family Study researcher

On behalf of the Millennium Cohort Family Study Team

If you have any questions, please contact the Millennium Cohort Family Study team at our toll-free number, 1-800-571-9248, or DSN 553-7465, or email info@familycohort.org.

The Millennium Cohort Family Study is an authorized Department of Defense project. Note Report Control Symbol #DD-HA(AR)2106, Office of Management and Budget Approval # 0720-0029, and Primary Institutional Review Board Protocol # NHRC.2000.0007



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Military children bloom everywhere the wind carries them. They are resilient and strong, cultivated deeply in the culture of the military, planted swiftly and surely. ~anonymous

The Millennium Cohort Family Study Team joins the nation in celebrating April as the Month of the Military Child. We recognize the strength and service of all military families.

Thank you for completing your follow-up survey. Your continued participation is what makes the Millennium Cohort Family Study such a powerful resource for understanding the short and long-term impact of military life. Please know that your contribution makes a difference and will benefit current and future generations of Service members and their families.

Very Respectfully,

Carrie Doesoho, PhD
 Captain, MS, USA
 Spouse of a Veteran and Active Duty Family Study researcher

Primary Institutional Review Board Protocol # 10-NHRC.2003.0007



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Deployment Health Research Department
c/o Naval Health Research Center
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ADDRESS SERVICE REQUESTED

Military children bloom everywhere the wind carries them. They are resilient and strong, cultivated deeply in the culture of the military, planted swiftly and surely. ~anonymous

The Millennium Cohort Family Study Team joins the nation in celebrating April as the Month of the Military Child. We recognize the strength and service of all military families.

To complete your follow-up survey, please visit www.familycohort.org, click Start Survey and enter your Subject ID XXXXXXXX. Your continued participation is what makes the Millennium Cohort Family Study such a powerful resource for understanding the short and long-term impact of military life. Please know that your contribution will make a difference and will benefit current and future generations of Service members and their families.

Very Respectfully,

Carrie Donoho, PhD
Captain, MS, USA
Spouse of a Veteran and Active Duty Family Study researcher

Primary Institutional Review Board Protocol # NHRC.2000.0007

Pilot Test Phone Call Procedures & Script
For IRB Submission

The Family Study is seeking permission to call a small number of participants who have not completed a follow-up survey as a pilot test to determine the efficacy of phone contact in participant retention and retrieval of updated contact information. We would only call those participants who provided a phone number on their baseline survey as a means to remain in contact. Approximately 37 participants will be called; all of whom have received limited contact from the Family Study during the current survey cycle due to the lack of a correct mailing address, email address or both.

Subjects will be contacted via telephone Monday through Friday between the hours of 8 am to 7 pm within their time zone. A maximum of 3 phone call attempts will be made per subject and a log of every attempt will be kept. For the purposes of this pilot, if we are not able to reach a specific participant within 3 attempts, we will replace their phone number in the pilot study call pool so that we can actually speak with up to 37 participants. Staff making phone calls will not leave a voice message for any participant.

A log of all of the phone calls will be kept and submitted for review.

The script for the phone calls is as follows:

Hello, my name is (caller name), and I am calling on behalf of the Department of Defense Millennium Cohort Family Study team. Am I speaking with (participant name)?

[If speaking to correct person]

I am calling because we have tried to contact you several times over the past few months to complete a Family Study follow-up survey, but some of our contacts have been returned to us as undeliverable. We would like to be able to send you a token of appreciation and keep you informed about the study, but we do not have your current contact information. Would you like to update your mailing address and email so that we can send you your gift and future study updates?

[If participant does not want to provide update information]

I understand. Do you wish to continue to participate in this study?

[If no]: We respect your decision. I will remove you from all future contacts. Thank you for your participation thus far. Have a nice day.

[If yes]: We appreciate your continued participation in this important study. In order to complete your follow-up survey please visit www.familycohort.org, click on Start Survey and enter your Subject ID. If you change your mind, and decide you would like to update your contact information, you can do so on our website.

[If participant provides updated information]

Thank you for providing your correct address and or email/address. We will send your gift and information about how to complete your follow-up survey within the next few days. We appreciate your continued participation in this important study. Have a nice day.

FAMILY CORRESPONDENCE

January Reminder email

Purpose: Reminder to log back in and complete the survey

Subject: Please help military families

Dear [name](#),

Happy New Year! We hope that you had a wonderful holiday season.

We want to thank you for the time that you have already invested to begin your Millennium Cohort Family Study survey. Your participation and survey responses go a long way toward helping military families, so we hope you will consider completing your survey.

Please visit, www.familycohort.org click **Start Survey** and enter the following **Subject ID: xxxxxxxx**.

Thank you for your past participation in this important Department of Defense survey, and for your continued participation. Together, we can make a difference in improving the lives of military families!

Very Respectfully,

The Millennium Cohort Family Study Team

The Millennium Cohort Family Study is an authorized Department of Defense project. Note Report Control Symbol # DD-HA(AR)2106, Office of Management and Budget Approval # 0720-0029, and Primary Institutional Review Board Protocol # NHRC.2000.0007.

February Reminder email #1

Purpose: Reminder to log back in and complete the survey

Subject: Please take some time to help military families

Dear [_name_](#),

Thank you for logging into the Millennium Cohort Family Study website and starting your survey. In order to make sure your participation has the greatest impact, we ask that you log back in and complete the remaining questions.

To complete the remainder of your survey, please visit, www.familycohort.org click **Start Survey** and enter the following **Subject ID: xxxxxxxx**.

The survey will continue at the point where you previously stopped, so you will be able to simply finish the incomplete sections.

By participating in this study, you are helping to determine the potential effects of military service on US military families.

Thank you for your continued participation in this important study!

Very Respectfully,

The Millennium Cohort Family Study Team

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February Reminder email #2

Purpose: Reminder to log back in and complete the survey

Subject: Please complete your Military Family survey

Dear [_name_](#),

We want to thank you for your past participation, and for the time you have already invested in the 2014-2015 follow-up survey.

Unlike other surveys you may be receiving, the Millennium Cohort Family Study is designed to follow your family over time as you experience the unique challenges associated with military life. This is why we are, again, asking for your help.

We understand the demands of military life and greatly appreciate the time that you have already invested to begin your Family Study survey. We hope you will consider spending part of your day completing this important military family survey.

To complete the remaining questions on your survey, please visit, www.familycohort.org click **Start Survey** and enter the following **Subject ID: xxxxxxxx**.

We truly appreciate your past and current participation in a study designed to help improve the lives of military families.

Very Respectfully,

The Millennium Cohort Family Study Team

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MILLENNIUM COHORT FAMILY HOLIDAY MAILING NOVEMBER 2014

Subject: Your response matters!

Dear name ,

Next week you will be receiving a holiday postcard, so keep an eye on your mailbox!

We realize that this time of year is very busy and that your time is limited, but we want to remind you that your perspective and experiences help to create the full picture of how military life impacts families.

We appreciate the time that you have already invested to begin your survey, and we hope that you take the time to complete the remaining questions. This way, all of your responses can be included in future analyses. To complete the remainder of your survey, please visit, www.familycohort.org click Start Survey and enter the following Subject ID: xxxxxxx.

We want to sincerely thank you for taking the time out of your busy schedule to complete the survey. Hearing from you is very important because families serve too!

Very Respectfully,

The Millennium Cohort Family Study Team

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Millennium Cohort Family Study

Thank you for completing the
Millennium Cohort Family Study survey.

Please accept this gift as a token of our
appreciation of your continued support.

For study updates or to change your contact information,
please visit our website at www.FamilyCohort.org
or contact us at 1-800-571-9248.

The Millennium Cohort Family Study is an authorized Department of Defense project. Note Report Control Symbol # DD-HA(AR)2106, Office of Management and Budget Approval # 0720-0029, and Primary Institutional Review Board Protocol # NHRC.2000.0007.



Dear [\[name\]](#),

The Millennium Cohort Family Study Team would like to wish you and your family a joyful holiday season.

As a member of the Family Study, the information provided by you and other participants will help provide critical information to health care providers and military leaders about the specific health and well-being concerns of military families.

We hope that you have been able to complete the survey online. If not, we want to encourage you to complete the survey soon because this will be one of your last opportunities to share your thoughts and experiences. To complete the survey, go to www.familycohort.org click 'Start Survey' and enter your Subject ID: xxxxxxxx.

We hope to hear from you as the opportunity to be a part of this important study will be ending at the end of this month.

Happy Holidays,

The Millennium Cohort Family Study Team

Primary Institutional Review Board Protocol # NHRC.2000.0007.

Subject: Last Chance to Take Part in an Important Military Family Health and Wellness Study

Dear [\[name\]](#),

We have contacted you many times over the past several months about the Family Study, and we are writing again because the opportunity to be part of this important study will be ending in a few short weeks.

This study was specifically designed to understand the impact of military experiences on the short and long-term health and well-being of military families. As such, it is essential that we continue to receive responses from all spouses who initially joined the study in order to determine how families, relationships and health change over time.

Even if your spouse is no longer in the service, or if your relationship status has changed, your participation is critical to form a complete picture of the impact of military life. Whatever your circumstances and feelings, we would like to encourage you to take a few minutes and provide your unique thoughts and experiences for this valuable study.

We appreciate your help and want to make it as easy to respond as possible. Simply go www.familycohort.org click Start Survey and enter your **Subject ID: xxxxxxxx**.

For any questions, please contact the Family Study Team at our toll-free number (800) 571-9248 or email us at familycohortinfo@med.navy.mil.

Thank you so much for considering this final opportunity to respond.

Very Respectfully,

The Millennium Cohort Family Study Team

We hope we've reached an appropriate email address. However, if you don't want us to use this address, please visit: [\[unsubscribe email link\]](#)

The Millennium Cohort Family Study is an authorized Department of Defense project. Note Report Control Symbol # DD-HA(AR)2106, Office of Management and Budget Approval # 0720-0029, and Primary Institutional Review Board Protocol # NHRC.2000.0007.

**MILLENNIUM COHORT FAMILY MONTH OF THE MILITARY FAMILY
MAILING OCTOBER 2014**

Month of the Military Family Cover Letter



Dear [NAME],

It is National Military Family Month and we want to thank you for your participation in the Millennium Cohort Family Study. The Department of Defense launched the Family Study, a long-term study of the impact of military service on families, as part of America's commitment to our Service members and their families. As a member of this important study, you are helping the U.S. military provide the best services possible to current and future military families.

If you have already been able to complete the Family Study follow-up questionnaire, we want to say thank you. If you have not yet had time to consider our request, we hope you will be able to do so soon. To complete the survey, visit www.familycohort.org click 'Start Survey' and enter the following Subject ID: XXXXXXX.

Please know that we honor the important role you have played in serving our country. With the hundreds of thousands of Service members who have deployed overseas in support of recent conflicts, recognizing our past and present military families is more important than ever.

We hope you will accept the enclosed gift along with our gratitude for your continued participation in the Family Study.

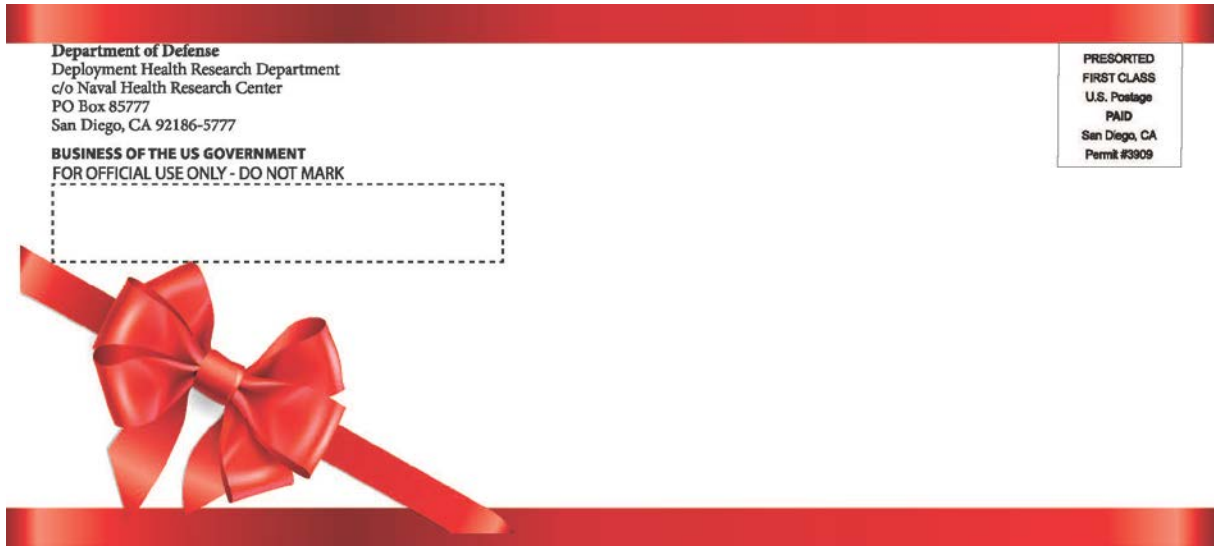
Very Respectfully

The Millennium Cohort Family Study Team

The Millennium Cohort Family Study is an authorized Department of Defense project. Note Report Control Symbol #DD-HA(AR)2106, Office of Management and Budget Approval # 0720-0029, and Primary Institutional Review Board Protocol # NHRC.2000.0007

PO Box 85777 San Diego, CA 92186-5777 www.familycohort.org 800-571-9248 familycohortinfo@med.navy.mil

Month of the Military Family Graphic Envelope



Month of the Military Family Priority Mail Envelope



Month of the Military Family E-mail

Subject: Celebrating National Military Family Month

Dear name,

You should have received a letter last week with an invitation to complete a Millennium Cohort Family Study follow-up survey and a small token of gratitude for your continued participation.

During National Military Family Month, we want to thank you for the sacrifices you have made in your unwavering support of our nation. We honor the important role you play in supporting our Service members and in serving our country. As a member of this important study, you are helping the U.S. military provide the best services possible to current and future military families. We want to hear your unique perspective on the health and well-being of military families, even if your spouse is no longer in the service or if you have separated or divorced.

If you have already been able to complete the Family Study follow-up questionnaire, we want to say thank you. If you have not yet had time to consider our request, we hope you will be able to do so soon. To complete your survey, visit www.familycohort.org click Start Survey and enter the following Subject ID: xxxxxxxx.

Thank you for your time and sacrifices for our country.

Very Respectfully,

The Millennium Cohort Family Study Team

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November Reminder E-mail

Subject: Don't Forget to Complete your Survey

Dear name ,

You should have received a letter last week reminding you to complete the Millennium Cohort Family Study follow-up survey you previously started, along with a small token of gratitude for your continued participation.

During National Military Family Month, we want to thank you for the sacrifices you have made in your unwavering support of our nation. We honor the important role you play in supporting our Service members, and serving our country.

Unlike other studies, the Family Study is designed to follow your family over time as you experience the unique challenges associated with military life (e.g., relocation, separation and deployment). Even if your spouse is no longer in the service, or if you have separated or divorced, we would still like to hear from you. Your perspective and experiences help to create the full picture of how military life impacts families.

We appreciate the time you have already invested to begin your survey and we hope you take the time to complete the remaining questions to assure that your responses can be included in future analyses. To complete the remainder of your survey, visit www.familycohort.org click Start Survey and enter the following Subject ID: xxxxxxxx.

Thank you for your time and sacrifices for our country.

Very Respectfully,

The Millennium Cohort Family Study Team

The Millennium Cohort Family Study is an authorized Department of Defense project. Note Report Control Symbol # DD-HA(AR)2106, Office of Management and Budget Approval # 0720-0029, and Primary Institutional Review Board Protocol # NHRC.2000.0007.

MILLENNIUM COHORT FAMILY MAILING JULY 2014

Sample Survey Cover Letter



Because Families Serve Too

Millennium Cohort
Family Study

Dear [NAME],

A few weeks ago, we wrote to you asking you to complete your follow-up Family Study survey. Your response is very important to ensure that we have complete responses from all spouses who initially completed the survey. Knowing your experiences as a current or former military spouse will be especially helpful in determining how military families are doing over time.

The Family Study works in partnership with the Millennium Cohort Study and is the only military family study that includes families from all branches and components of the military, including active duty, National Guard and Reserves. In addition, no other study surveys military families over time as they experience both the unique challenges and achievements associated with military life.

Some people have asked us what the study is about. Therefore, we are enclosing a sample of some of the questions included in the survey. You can see that the survey includes a wide variety of items on physical and emotional health, and life experiences. We have updated the questions to ensure an understanding of the changes and evolving concerns of military spouses over time. If you are separated or divorced from your Service member spouse, or widowed, we have created unique sections in the survey for you.

Just go to www.familycohort.org, click Start Survey and enter your Subject ID: XXXXXXX.

We believe this study will help inform decisions on how to provide the best health-related services possible for current and future military families.

Thank you so much for your time and sacrifices for our country.

Very Respectfully,

The Millennium Cohort Family Study Team

PO Box 85777 San Diego, CA 92186-5777 www.familycohort.org 800-571-9248 familycohortinfo@med.navy.mil

Sample Survey



Millennium Cohort
Family Study

Some examples of questions on the Family Study survey.

We thought you might like to see the kinds of questions that are asked before going online to complete this important survey about the health and well-being of the families of US military members. You may notice this year's questionnaire includes new questions that have been added to better understand how health issues, family dynamics and relationships change over time.

We hope you find these examples useful.

To complete the survey, visit

WWW.FAMILYCOHORT.ORG

click "Start Survey"

ENTER YOUR SUBJECT ID LOCATED ON THE ENCLOSED LETTER

PHYSICAL HEALTH

We would like to begin by asking you some questions about your physical health, how you feel, and how well you are able to do your usual activities. These items allow us to assess changes in your general health over time and if those changes may be related to other information you provide.

In general, would you say your health is:

- Excellent
 Very good
 Good
 Fair
 Poor

The following questions are about activities you might do during a **typical day**. Does your health now limit you in these activities? If so, how much?

- | | No, not limited at all | Yes, limited a little | Yes, limited a lot |
|--|------------------------|-----------------------|-----------------------|
| Vigorous activities , such as running, lifting heavy objects, or participating in strenuous sports? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| Moderate activities , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf? | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

In the **past 3 years**, where have you gone for medical care? Mark all that apply.

- Military Treatment Facility
 VA facility
 Civilian Provider
 Public health centers

During the **last 4 weeks**, how much have you been bothered by back pain?

- Not bothered
 Bothered a little
 Bothered a lot

SUPPORT AND RESILIENCE

Now, we will ask you about your available social support and how you cope with life's challenges.

Please indicate how you feel about each statement.

- | | Very strongly disagree | Strongly disagree | Mildly disagree | Neutral | Mildly agree | Strongly agree | Very strongly agree |
|--|------------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
| There is a special person who is around when I am in need | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| I get the emotional help and support I need from my family | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| I can count on my friends when things go wrong | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

Indicate the degree to which the following statements are true in your life.

- | | Not at all | To a very small degree | To a small degree | To a moderate degree | To a great degree | To a very great degree |
|--|-----------------------|------------------------|-----------------------|-----------------------|-----------------------|------------------------|
| I prioritize what is important in life | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| I have established a path for my life | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| I know that I can handle difficulties | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |
| I'm stronger than I thought I was | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> | <input type="radio"/> |

SURVEY QUESTION EXAMPLES
VISIT WWW.FAMILYCOHORT.ORG TO COMPLETE YOUR SURVEY

WELL-BEING

Now, we would like to ask you about your mental well-being. These questions are about how you feel and how things have been going over the last 4 weeks.

Over the **last 4 weeks**, how often have you been bothered by any of the following problems?

	Not at all	Several days	More than half the days
Feeling nervous, anxious, on edge, or worrying a lot about different things	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feeling restless so that it is hard to sit still	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Getting tired very easily	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

In the **last month**, how often have you...

	Never	One time	Two times	Three or four times	Five or more times
Felt that you were unable to control the important things in your life	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Felt confident about your ability to handle personal problems	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Felt that things were going your way	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Felt difficulties were piling up so high that you could not overcome them	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

LIFE EXPERIENCES

The following section concerns life experiences that have the potential to act as protective or risk factors. We are aware that many of these questions are quite personal, but we would appreciate your candid response. We want to assure you that all your answers are strictly confidential.

Please indicate your level of agreement with each item.

	Strongly disagree	Disagree	Slightly disagree	Neither agree or disagree	Slightly agree	Agree	Strongly agree
In most ways my life is close to my ideal	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
I am satisfied with my life	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
So far I have gotten the important things I want in life	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Have you had any of the following life events happen to you in the last 3 years?

If **Yes**, did this event occur in the last 12 months

You changed job, assignment, or career path involuntarily (for example, you lost a job, or you had to take a job you did not like)	<input type="radio"/> No	<input type="radio"/> Yes	→	<input type="radio"/> No	<input type="radio"/> Yes
Had a family member or loved one who became severely ill	<input type="radio"/> No	<input type="radio"/> Yes	→	<input type="radio"/> No	<input type="radio"/> Yes
Suffered a disabling illness or injury	<input type="radio"/> No	<input type="radio"/> Yes	→	<input type="radio"/> No	<input type="radio"/> Yes

SURVEY QUESTION EXAMPLES
VISIT WWW.FAMILYCOHORT.ORG TO COMPLETE YOUR SURVEY

DEPLOYMENT RETURN AND REUNION

The deployment return and reunion process can often be challenging, so our next questions are about that experience.

Following your spouse's **most recent** deployment, please rate the following statement. The process of reunion/reinterpretation with your spouse was stressful.

- Strongly disagree Disagree Neither agree nor disagree Agree Strongly agree

Please choose the best answer regarding your spouse's **most recent** return from deployment.

	Less than one month	1-2 months	3-5 months	6 months or more	Not yet adjusted
How long did it take for you to adjust to your spouse's return from being away from home?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How long did it take for your spouse to adjust to his/her return home?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How long did it take for your relationship to return to the way it was before he/she left home?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
How long did it take for your children to adjust to his/her return home? (If no children currently reside in your home, please skip this question)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

YOUR FAMILY

Now we would now like to ask about your family, including you, your spouse, and your children (if applicable).

How satisfied are you with:

	Very dissatisfied	Somewhat dissatisfied	Generally satisfied	Very satisfied	Extremely satisfied
The degree of closeness between family members	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Your family's ability to cope with stress	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Your family's ability to share positive experiences	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Your family's ability to resolve conflicts	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Do you have children with your spouse or from prior relationship(s)?

(Please include any biological or adopted children.)

- No Yes

(If YES)

For each of your children 3 to 17 years of age living at home, mark whether you have observed the following behaviors in the **past month**. Mark all that apply.

	Child 1	Child 2	Child 3	Child 4	Child 5	Child 6
Considerate of other people's feelings	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Restless, overactive, cannot stay still for long	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Often complains of headaches, stomach-aches, or sickness	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Generally liked by other children	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please indicate the degree to which your child was disturbed or upset by your spouse's most recent or current deployment or active duty assignment. (Note: Children ages 3-17)

- A lot More than just a moderate amount A moderate amount Only a little Not at all

SURVEY QUESTION EXAMPLES
VISIT WWW.FAMILYCOHORT.ORG TO COMPLETE YOUR SURVEY

MARITAL STATUS

In order to better understand how military life affects families, this next section asks you questions about your relationship with your spouse. Once again, we'd like to remind you that all your answers are strictly confidential and will not be shared with your spouse.

What is your current marital status with your spouse?

NOTE: Spouse refers to the military service member who is a member of the Millennium Cohort Study and to whom you were married in 2011/2012/2013.

- Currently married Separated Divorced Widowed

(IF MARRIED)

Taking all things together, how would you describe your marriage?

Very unhappy ←————→ Very happy

1 2 3 4 5 6 7

Please rate the following statements regarding your spouse's current job.

	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
The demands of my spouse's work interfere with <u>our</u> home and family life	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
My spouse's job produces stress/strain that makes it difficult for <u>him/her</u> to fulfill family responsibilities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
My spouse's job produces stress/strain that makes it difficult for <u>me</u> to fulfill family responsibilities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

(IF FULL-TIME WORK, PART-TIME WORK, OR HOMEMAKER)

How satisfying is your current employment?

Not satisfying ←————→ Extremely satisfying

1 2 3 4 5 6 7

(IF FULL-TIME OR PART-TIME WORK)

How long did it take you to find employment after your last permanent change of station (PCS)?

- Less than 1 month 1 to 4 months 5 to 8 months 9 months to 1 year More than 1 year

Do you feel that being a military spouse has hindered your career development (In other words, that you have not achieved in your career as much as you would have if you were not a military spouse)?

Not at all hindered ←————→ Extremely hindered

1 2 3 4 5 6 7

SURVEY QUESTION EXAMPLES
VISIT WWW.FAMILYCOHORT.ORG TO COMPLETE YOUR SURVEY

Sample Survey Email

F5: Email ALL NON-RESPONDERS

Purpose: Mention sample survey mailed previous week

Subject Line: Have you Completed Your Family Study Survey Yet?

Dear [NAME](#),

About a week ago we sent you a sample of questions to help you better understand the variety of topics included in the Millennium Cohort Family Study survey. We hope that it was helpful to see that the survey covers various experiences of military families, such as changes in relationships, the birth of children, new health concerns, relocations, and military separation.

The request to complete a follow-up survey was sent to you because you had previously completed a survey for the study in [\[survey month/year\]](#). We are especially interested in hearing about your most recent experiences because they will provide greater insight into the health and well-being of today's military families.

If you have already completed the online survey, we wish to thank you. If you have not yet had time to consider our request, we hope you will be able to do so soon. To complete it, simply visit the study website, www.familycohort.org, click Start Survey and enter your Subject ID: [XXXXXXX](#).

Thank you again for making the Family Study a success in improving the lives of military Service members and their families.

Very Respectfully,

The Millennium Cohort Family Study Team

For more information about the Millennium Cohort Family Study, please visit www.familycohort.org.

We hope we have reached an appropriate email address. However, if you would prefer we use a different email address or if you do not want to be contacted at this address, please visit: [\[unsubscribe link\]](#)

Page only seen if participant reported that their Panel 4 spouse is Active Duty on page 10 of survey



Privacy Act Statement

Survey

MILITARY LIFE

Now, we'd like to ask you some questions about the stress of military life and the military's efforts to help you and your family deal with those stressors.

On average, during the **past month**, or the most recent month Mr. Spouse was not deployed, how many hours did your spouse work per week (including weekends)?

hours per week

I don't know

On average, during the **past year**, how many days of leave from work did Mr. Spouse take?

days in the past year

I don't know

How many **total months** was Mr. Spouse away from home in the past year (including deployments, training, temporary duty-TDY/TAD)?

months in past year

I don't know



Previous

Save & Continue Later

Continue

The Millennium Cohort Family Study is a Department of Defense research project at the Deployment Health Research Department, located at the Naval Health Research Center, in San Diego, California. Note DMDC Reference Number 00-0019, RCS Number DD-HA(AR)2106, OMB Approval Number 0720-0029, ASD/HA/TMA Protocol Number CDO-06-206, and Primary IRB Protocol Number NHRC.2000.0007

Page seen by all participants except those who report being widowed on page 4 of the survey

 [Privacy Act Statement](#) [Survey](#) 

WORK LIFE

On average, during the **past month**, or the most recent month **Mr. Spouse** was not deployed, how many hours did your spouse work per week (including weekends)?

hours per week

I don't know

On average, during the **past year**, how many days of leave from work did **Mr. Spouse** take?

days in the past year

I don't know

How many **total months** was **Mr. Spouse** away from home in the past year (for example: work-related travel, deployments, training, temporary duty, TDY/TAD)?

months in past year

I don't know

[Previous](#)

[Save & Continue Later](#)

[Continue](#)

The Millennium Cohort Family Study is a Department of Defense research project at the Deployment Health Research Department, located at the Naval Health Research Center, in San Diego, California. Note DMDC Reference Number 00-0019, RCS Number DD-HA(AR)2106, OMB Approval Number 0720-0029, ASD/HA/TMA Protocol Number CDO-06-206, and Primary IRB Protocol Number NHRC.2000.0007

F2a: Study Findings Email: different versions for those with good or bad mailing addresses
(If F1 mailing returns as bad address, send this version of email)

Week 3

Purpose: 1st email connection. Mention unable to send F1 mailing because of bad address. Mention more results on website. Have a 'What's New' page on website.

Subject Line: Re-establishing Contact with You

Dear [\[name\]](#),

Two weeks ago we sent you a postal letter that was returned to us. You are one of an important group of military spouses who completed a DoD survey as a participant in the Millennium Cohort Family Study in ([survey month/year](#)). We are enormously grateful for your help with this unique study, which seeks to better understand health and wellness issues facing military families in all branches of the U.S. Armed Forces.

The reason we are contacting you is because we would like to share the progress of the Millennium Cohort Family Study. We would appreciate you providing us a current postal address so that we can continue to keep you informed about results from this important study, as well as to stay in touch so that you can participate in the future. To update your address, just click on this link ([ADD LINK](#)).

We are enormously grateful for your effort to help inform the U.S. military about how to provide the best health care and support programs possible to current and future military families through your participation in this critical Department of Defense study. We hope that you will participate again in the future.

Very sincerely,

The Family Study Team

Some people have multiple email addresses. If we've reached you at an inappropriate address, please visit this website to provide a preferred address for contacting you <change of address>.

F2b: Study Findings Email *(If F1 mailing is a good address, send this version of email)*
Week 3

Purpose: reconnect by email. Mention more results on website . Have a ‘What’s New’ page on website.

Subject Line: Preliminary Results from Your Participation

Dear [\[name\]](#),

We hope you recently received our letter in the mail which highlights the preliminary study findings of the DoD Millennium Cohort Family Study.

You are one of an important group of military spouses who completed this significant DoD survey aimed at understanding the impact of military service on families. You completed your first study questionnaire in ([survey month/year](#)). We greatly appreciate you sharing your thoughts and experiences because these will provide greater insight into issues facing today’s military families.

In a few weeks, we will send you information regarding the follow-up survey, which has some important new updates from the previous version. We know that families change over time and would greatly appreciate hearing how you are doing since the last survey. Even if you are no longer with your Service member spouse, or if your Service member is no longer in the military, we greatly value your continued participation and input.

Additionally, we would like to share with you some of our study updates:[[Web link to “What’s New” webpage](#)]

Thank you again for your help in completing the current survey and your commitment for protecting the health and wellness of current and future military families.

Very sincerely,

The Family Study Team

Some people have multiple email addresses. If we've reached you at an inappropriate address, please visit this website to provide a preferred address for contacting you <change of address>.

MILLENNIUM COHORT FAMILY MAILING JUNE 2014

**2014 Pre-notice letter with Key Study Findings insert
June 2014**

Contents: Cover letter, 6x9 Study Findings bi-fold insert, 6x9 envelope
Mail Date: June 2, 2014

Cover letter Message:

Dear [name],

You are one of 10,000 military spouses who completed a survey as part of an important DoD survey (the Family Study) initiated to understand the impact of military service on families. You completed your first study questionnaire in ([survey month/year](#)).

We greatly appreciate that you shared your experiences with us and thought you might appreciate knowing about some of the preliminary findings from this effort. The enclosed summary provides just a few of the initial results and how they will be used.

Those of you who helped with this study represent families from all branches and components of the military – active duty, Reserve, and National Guard. Some of your spouses are no longer serving in the military, while others continue to serve. Regardless of your specific situation, it is very important that we continue to hear from you. This study is designed to follow military families over time, including both during and after military service time.

We hope you'll take a few moments to review the findings that we've included in this mailing. More study information can be found on our website, www.familycohort.org.

In the fall, we will be contacting you to learn about any changes that may have occurred in your health and well-being since we last heard from you. We are eager to learn more about how participants' lives may have changed over time. By completing occasional follow-up questionnaires, we will be able to understand the unique challenges associated with military life (such as moves, separation from the military, and deployments).

Thanks so much for your effort to help the U.S. military provide the best services possible to current and future military families.

Very Sincerely on behalf of the Family Cohort Study Team,



Hope M. McMaster, PhD
Research Psychologist and Military Spouse

Study Findings content:

**IMPROVING THE LIVES
OF MILITARY MEMBERS
AND THEIR FAMILIES**

Value of the Study

The quality of life for military families is a growing national priority. As of 2012, there were approximately 3 million military family members, including over 2 million children. The influential role of military families and their sacrifices are starting to be recognized by policy makers, but little research has been conducted to fully understand the impact military service has on families. The Millennium Cohort Family Study is the first study to link spouse information with Service member's data to better understand the larger picture of military service and military families.

"One of the best ways to provide military leaders with a broad picture of how military families are coping is to follow them over time as they experience the unique challenges associated with military life."
-Debbie Dempsey, wife of General Martin E. Dempsey, Chairman of the Joint Chiefs of Staff



Endorsed by General Martin E. Dempsey, Chairman of the Joint Chiefs of Staff and his wife Debbie Dempsey

FAMILYCOHORT.ORG

Millennium Cohort

Family Study

A STUDY OF HOW MILITARY SERVICE MAY AFFECT THE HEALTH AND WELL-BEING OF MILITARY FAMILIES



Because families serve too



2011
Nearly 10,000
Participants Enrolled

2014

2017

2020

2023

2026

2029

2032

Participants are asked to complete one survey about every 3 years

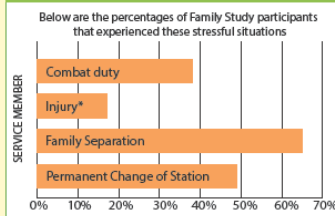
THE NUMBERS

Study Facts

- ♥ Approximately 10,000 spouses of military members have enrolled since 2011.
- ♥ Participants represent military families from all service branches, including active duty, Reserve, and National Guard families.
- ♥ The study follows each spouse over time regardless of any changes in marital status and even after military separation.
- ♥ The study also looks at the health and well-being of spouses in dual military families.
- ♥ Results from this study will help inform DoD leadership of the impact that military service has on families.
- ♥ This study works in partnership with the Millennium Cohort Study, the Service members study, to complete the picture of military family health and well-being.
- ♥ This study helps to understand how families affect the health of the Service member.

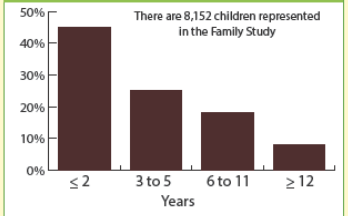
- 89% of participants are younger than 35 years old
- 12% of participants are male
- 71% of participants have been married 5 years or less
- 63% of participants have children
- 10% of participants are dual military families
- 74% of participants' spouses have deployed
- 3% of participants represent Reserve and National Guard families

Military Family Experiences



*Combat-related injury

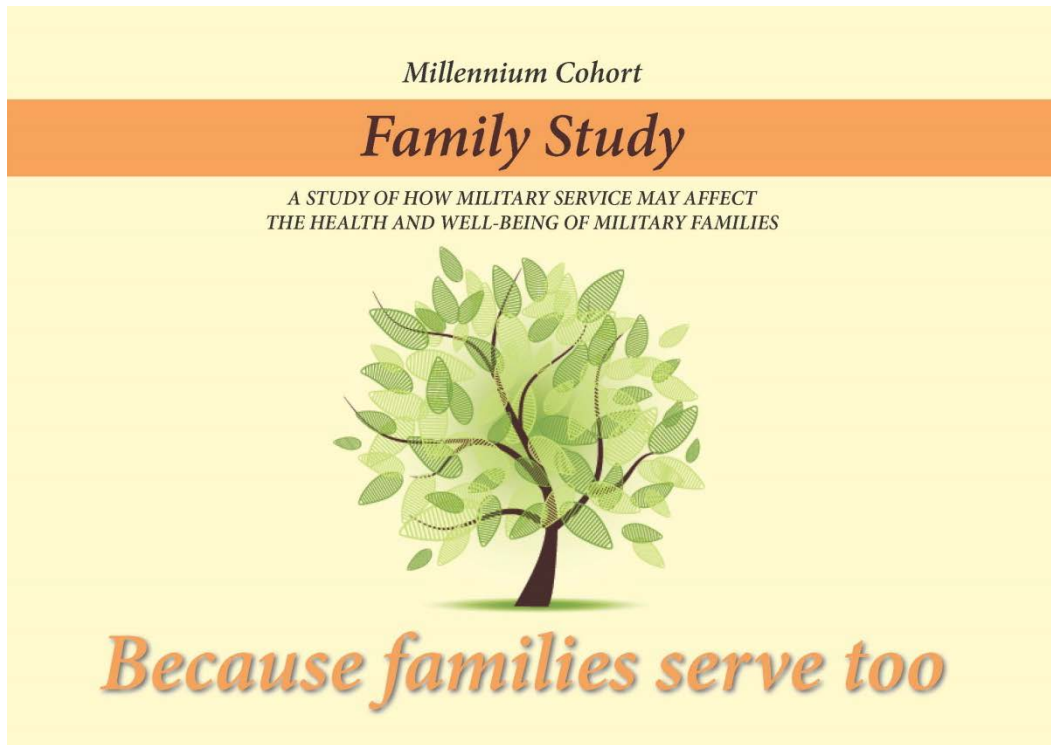
Reported Age of Children



This is only a small amount of information being learned from the Family Study. For more information, please visit

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Front Cover:



Inside Panel (left):

2011 Nearly 10,000 Participants Enrolled

2014

2017

2020 Participants are asked to co

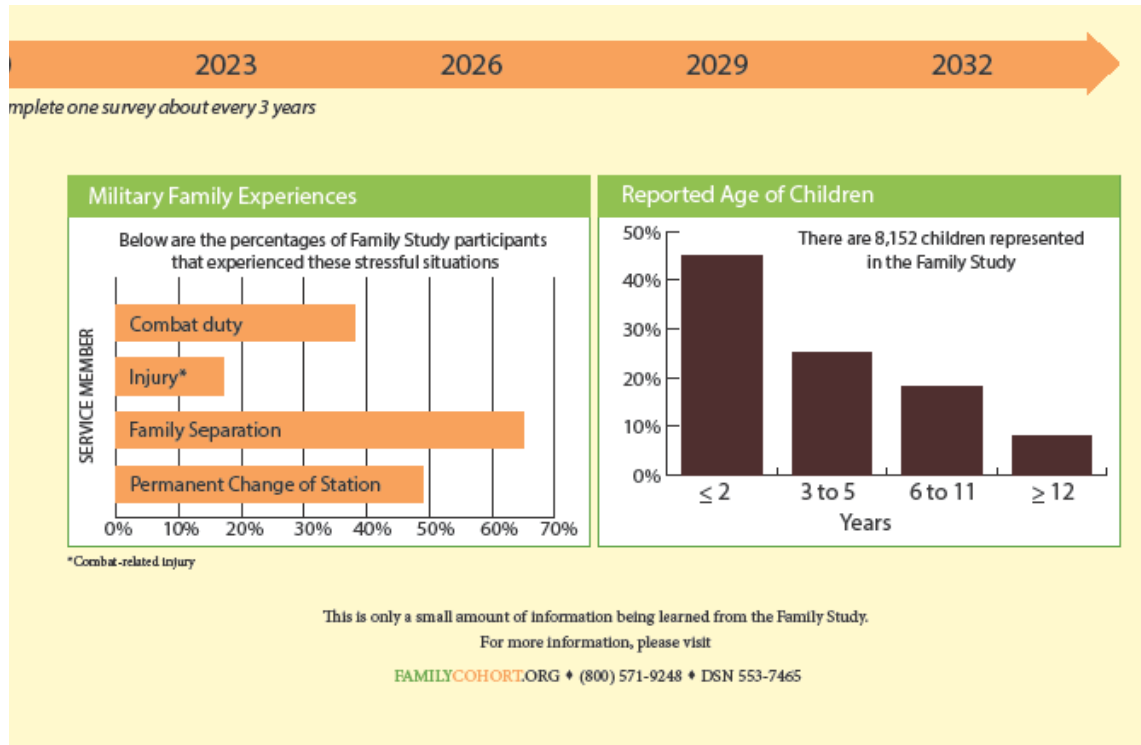
THE NUMBERS

Study Facts

- ♥ Approximately **10,000 spouses** of military members have enrolled since 2011.
- ♥ Participants represent military **families from all service branches**, including active duty, Reserve, and National Guard families.
- ♥ The study **follows each spouse over time** regardless of any changes in marital status and even after military separation.
- ♥ The study also looks at the health and well-being of spouses in **dual military families**.
- ♥ Results from this study will help **inform DoD leadership** of the impact that military service has on families.
- ♥ This study works in partnership with the Millennium Cohort Study, the Service members study, to **complete the picture of military family health and well-being**.
- ♥ This study helps to understand how families affect the **health of the Service member**.

- 89%** of participants are younger than 35 years old
- 12%** of participants are male
- 71%** of participants have been married 5 years or less
- 63%** of participants have children
- 10%** of participants are dual military families
- 74%** of participants' spouses have deployed
- 3%** of participants represent Reserve or National Guard families

Inside Panel (right):



Back Panel:

IMPROVING THE LIVES OF MILITARY MEMBERS AND THEIR FAMILIES

"One of the best ways to provide military leaders with a broad picture of how military families are coping is to follow them over time as they experience the unique challenges associated with military life."

*- Deanie Dempsey, wife of General Martin E. Dempsey,
Chairman of the Joint Chiefs of Staff*

Value of the Study

The quality of life for military families is a growing national priority. As of 2012, there were approximately 3 million military family members, including over 2 million children. The influential role of military families and their sacrifices are starting to be recognized by policy makers, but little research has been conducted to fully understand the impact military service has on families. The Millennium Cohort Family Study is the first study to link spouse information with Service member's data to better understand the larger picture of military service and military families.



*Endorsed by General Martin E. Dempsey, Chairman of the
Joint Chiefs of Staff and his wife Deanie Dempsey*

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National Military Family Month 2013

The following provides the *Family Cohort Study* email contents:

National Military Family Month 2013 Postcard Text

During **National Military Family Month**, we want to thank you for your daily sacrifices and steadfast support of our nation. We honor your strength, resilience, and the important role you play in protecting our nation. Military families often make many sacrifices as they support our men and women in uniform – sacrifices that are worthy of recognition.

As part of America's commitment to protect the well-being of the family members our military service men and women hold dear, the Department of Defense launched a long-term study in order to understand the impact of military service on families.

Thank you for completing your Family Study survey and contributing to this important study. Your participation makes it possible to inform policy makers regarding your experiences and to guide prevention measures that positively impact military families.

Very sincerely,

The Millennium Cohort Family Study Team
Department Head
DoD Center for Deployment Health Research
San Diego, CA

Appendix I. COLLABORATION PROTOCOLS



Signed_FamilyCollab
orationProtocol_2014

Appendix J. SERVICE AGREEMENTS



DUA ABT.pdf