



INSTITUTIONAL REVIEW BOARD RECOMMENDATION

CONTINUING REVIEW

Date of Review: 12 March 2018 Protocol Number: NHRC.2015.0019

Protocol Title: Millennium Cohort Family Study: A Sub-study of the Millennium Cohort Study

Principal Investigator: Valerie Stander, Ph.D.

Work Unit title/#/ION: Family Study, N1240; ION: 8LH3HA

The Principal Investigator submitted a continuing review request for a protocol that was previously classified as minimal risk. In order to assess the interrelated health effects of military service and deployment on service members, spouses, and their children a Family Cohort sub-study was added to the Millennium Cohort study (protocol #NHRC.2000.0007), in August 2009. All approvals for the Family Cohort sub-study have been obtained as a part of the main Millennium Cohort study. Any future approvals required for this sub-study will be submitted separately. A separate website www.familycohort.org for the sub-study was established earlier under Millennium Cohort study and is linked directly to www.millenniumcohort.org. The baseline enrollment for the Family Study began in June 2011 and ended in August of 2013. The first follow-up survey of Family Study participants launched October 1, 2014 and closed February 9, 2016. No new study participants were recruited during the 2014 survey cycle. To date, 9,872 subjects have been enrolled in the study and 6,625 follow-up surveys have been completed. Data collection is ongoing. A data use agreement is pending approval for permission to obtain census data as well as National Student Clearinghouse data and death records via the Social Security Administration.

The continuing review submission requests to: 1) add Alexis Takata (HJF), Deanne Millard (HJF), and Felicia Carey (HJF) as key support and 2) remove Christopher Lo from the protocol. The submission also included 2019 Family Study Calendar emails (March 2018, July 2018, and September 2018) for review and approval. No adverse events have been reported. The principal investigator indicated compliance with all relevant human subject protection regulations.

The NHRC IRB Chair reviewed this continuing review submission under the expedited review authority and permitted under 32 CFR § 219.110(b)(1), Federal Register expedited review category 7. 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 23 March 2019.

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



Signature



Date



DETERMINATION OF APPROVING AUTHORITY

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

Next review is required no later than: 23 March 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

 03/22/18

**HUMAN USE PROTOCOL
ROUTING SLIP**

FROM (Principal Investigator):

Valerie Stander, PhD



(PI SIGNATURE)

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

TITLE OF PROTOCOL: Millennium Cohort Family Study: A Sub-study of the Millennium Cohort Study

ABBREVIATED TITLE: Family Study

PROPOSED DATES OF RESEARCH: 2015/04/25 to 2032/09/30

FUNDING SOURCE: Congressional Mandate Research (CORE funding) USAMRMC (MOMRP) and Defense Health Agency (DHA)

WORK UNIT TITLE AND NUMBER: Family Study N1240

JON FUNDING THE PROTOCOL: 8LH3HA

SUBMISSION (CHECK ONE):

- INITIAL SUBMISSION
- MODIFICATION OF PREVIOUS SUBMISSION
- CONTINUING/ANNUAL REVIEW

PROTOCOL OBJECTIVE (Brief sentence or two): The primary objective is to compare the adjusted probabilities of new onset diseases and conditions among military spouses and children.

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.2015.0019

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	28 Feb 2018		SE	SE	
2	DIRECTOR*				N/A	
3	SCIENCE DIRECTOR*				N/A	
4	IRB ADMINISTRATOR	MAR 01 2018	N/A	Jy	N/A	

27 February 2018

From: Valerie Stander, Principal Investigator

To: Chair, Institutional Review Board, Naval Health Research Center, San Diego, CA

Subj: CONTINUING REVIEW OF PROTOCOL # NHRC.2015.0019, "Millennium Cohort Family Study: A Sub-study of the Millennium Cohort Study"

Ref: (a) NAVHLTHRSCHCENINST 3900.2G

Encl: (1) Continuing Review Summary for Protocol # NHRC.2015.0019
(2) Investigator Compliance Attestation (Alexis Takata, Deanne Millard, Felicia Carey)
(3) List of all current Study Personnel
(4) Full Current Protocol (clean and tracked-changes)
(5) **For Re-stamping:**
2019 Family Study Calendar emails (March 2018, July 2018, and September 2018)

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 Dr. Valerie Stander at 553-7174, valerie.a.stander.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 the proposed changes.



Valerie Stander, PhD
PI Signature and Date

Continuing Review Summary of Protocol Number NHRC.2015.0019
Title: Millennium Cohort Family Study: A Sub-study of the Millennium Cohort Study
Principal Investigator: Valerie Stander, PhD

Family relationships play an important role in the functioning and well-being of US military service members. In recent decades, mental health and related outcomes for US military service members following deployment have been well documented. Much less attention, however, has been paid to deployment-related outcomes for spouses and other family members of those deployed. The Millennium Cohort Family Study was added to the Millennium Cohort Program of research in 2011 in order to better assess the well-being of military spouses and children.

Objectives: The purpose of the family component is to compare the adjusted probabilities of new onset diseases and conditions among military spouses and children, and to assess the importance of family support and other factors on health and well-being outcomes.

Research Methods: The spouses of the Millennium Cohort Study participants that completed a baseline survey in the 2011-13 survey cycle were invited to the Family Study. Family study participants consent to be surveyed 7 times over the next 21 years, with repeat surveys at 3-year intervals. The spouse assessment survey consists of physical health, psychological well-being, health-related behaviors, access to and use of psychological support services, coping behaviors, military life stressors, marital relationship quality, deployment and reunion experiences, alcohol and tobacco use, military specific questions, as well as, parent reported child health and behavior. Data will be linked to personnel data, and medical records as well as state and federal agency program databases. These data will be collected and maintained by the Department of Defense. In addition, if the spouse is an active duty member and retires or separates from military service and utilizes the Department of Veterans Affairs for medical services, we may also link to those medical and personnel data.

Risks: The primary risks are those associated with inappropriate disclosure of sensitive information, including identifiable 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 baseline enrollment for the Family Study began in June 2011 and ended in August of 2013. The first follow-up survey of Family Study participants launched October 1, 2014 and closed February 9, 2016. No new study participants were recruited during the 2014 survey cycle.

CONTINUING REVIEW FOR IRB PROTOCOL NUMBER NHRC.2015.0019

1. **PROTOCOL NUMBER:** NHRC.2015.0019
2. **PROTOCOL TITLE:** Millennium Cohort Family Study: A Sub-study of the Millennium Cohort Study
3. **WORK UNIT TITLE AND NUMBER:** Family Study, N1240
4. **PRINCIPAL INVESTIGATOR(S):** Valerie Stander, 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**

Under this continuing review report, we respectfully request to modify the study protocol to remove Christopher Lo as he is no longer at NHRC and to add Alexis Takata, Deanne Millard and Felicia Carey, PhD 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.

Felicia Carey, 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.

The training certificates of those listed above (HIPAA, CITI basic and RCR) are already on file with the IRB.

7. **SUBJECTS**

Upon completion of the 2011-2013 survey cycle, there were 10,065 Family Study respondents. During the data cleaning phase between baseline and this continuing review, 193 participants were removed from the study sample and were not included in analyses. The reasons for exclusion were because a few questionnaires were submitted without a signed consent form, multiple surveys were submitted by the same individual, or several surveys were completed by an incorrect individual. Therefore, to date, there are 9,872 participants enrolled in the Millennium Cohort Family Study. The first follow-up survey cycle was launched on October 1, 2014, and this cycle closed on February 9, 2016. The follow-up response rate is 67.4% with 6,625 completed surveys.

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 at baseline are stored on-site electronically and/or in paper files by the Millennium Cohort Family Study team. The 2014-2016 Millennium Cohort Family survey cycles did not elicit a new panel 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. There are no research findings to report at this time.

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

There are no new collaborators with the study to report.



Valerie Stander, PhD
PI Signature and Date

**TASK AREA M APPROVED
MILLENNIUM FAMILY COHORT PROJECTS
(MARCH 2017 – FEBRUARY 2018)**

Internal Projects

These are three internally lead papers/projects that have been approved through Task Area M (TAM) since our last CR. All analyses for these projects will be done onsite, and therefore do not require DUAs.

Risks, assets and timing: The impact of deployment characteristics on military spouses
Sabrina Richardson, Jackie Pflieger, Kelly Woodall, Valerie Stander

The impact of military operational stressors and protective factors on the marital stability of military couples
Jackie Pflieger, Sabrina Richardson, Valerie Stander

The impact of family well-being on the service member's reasons for leaving the military
Kelly Woodall, Teresa Powell, Valerie Stander

External Projects

These are the TAM approved projects since our last Continuing Review that have or will involve data being transferred externally

An Examination of Parental Mental Health and Family Functioning: Impact on Child Psychosocial Outcomes among Military Families
John Fairbank, Ernestine Briggs-King, Ellen Gerrity, Robert Lee, Nida Corry, Jacqueline Pflieger, Angela Tunno, Robert Murphy
Data transfer supported by ABT agreement

Separation from the Military and Spousal Well-being
Nida Corry, Sharmini Radakrishnan, Chris Spera, Elle Gault
Data transfer supported by ABT agreement

Influence of Military and Family Life Stressors on the Readiness of Service Members
Towanda Street, Amy Lewin, Marie Thoma, Meredith Kleykamp, Kelly Woodall
Data transfer supported by University of Maryland DUA through NHRC Privacy Officer

Long-term and High-risk Opioid Use among Military Spouses
Douglas McDonald, Sharmini Radakrishnan, Nida Corry, Alicia Sparks, Carlos Carballo, Valerie Stander
Data transfer supported by ABT agreement

Deployment Factors Contributing to Partner Personal Growth
Sybil Mallonee, David Riggs, Valerie Stander
Data transfer pending approval of DUA
DUA in support of this project submitted to NHRC's Privacy Officer 26FEB2018

INVESTIGATOR COMPLIANCE ATTESTATION

As a researcher or team member responsible for performing and monitoring the research under the protocol titled "Millennium Cohort Family Study: A Sub-study of 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) Instruction 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 3900.2G (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)



Alexis Takata, BS
Naval Health Research Center
Henry M. Jackson Foundation, Inc.

2 / 28 / 18



Deanne Millard, BS
Naval Health Research Center
Henry M. Jackson Foundation, Inc.

2 / 28 / 18



Felicia Carey, PhD
Naval Health Research Center
Henry M. Jackson Foundation, Inc.

2 / 28 / 18

I. COVER PAGE(S)

1. Protocol Number: NHRC.2015.0019
2. Title: Millennium Cohort Family Study: A Sub-study of the Millennium Cohort Study
3. Date of Submission: 20 April 2015
Approved Work Unit Title Family Study and Full Work Unit Number: N1240
4. Approximate Dates of Research: 2015MAR03 to 2032SEP30
5. Principal Investigator: Valerie Stander, PhD
Behavioral Science and Epidemiology; Military Population Health
Naval Health Research Center, San Diego, CA
6. Co-Investigator(s): Hope McMaster, PhD
NHRC, San Diego, CA
Henry M. Jackson Foundation, Inc.

Cynthia LeardMann, MPH
NHRC, San Diego, CA
Henry M. Jackson Foundation, Inc.
7. Key Support
Denise Lovec-Jenkins
NHRC, San Diego, CA
Henry M. Jackson Foundation, Inc.

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

Evelyn Sun, MPH
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
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Anet Petrosyan
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Alexis Takata
NHRC, San Diego, CA
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Deanne Millard
NHRC, San Diego, CA
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Steven Speigle
NHRC, San Diego, CA
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William Lee
NHRC, San Diego, CA
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Daniel Vaughan
NHRC, San Diego, CA
Henry M. Jackson Foundation, Inc.

Gordon Lynch
NHRC, San Diego, CA
Henry M. Jackson Foundation, Inc.

Jacqueline Pflieger, PhD
NHRC, San Diego, CA
Henry M. Jackson Foundation, Inc.

Sabrina Richardson, PhD
NHRC, San Diego, CA
Henry M. Jackson Foundation, Inc.

Kristen Walters, PhD
NHRC, San Diego, CA
Leidos, Inc.

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

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

Teresa Powell, MS
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Richard Armenta, PhD, MPH
NHRC, San Diego, CA
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Daniel Trone, PhD
NHRC, San Diego, CA

Rudolph Rull, PhD, MPH
NHRC, San Diego, CA

Felicia Carey, PhD
NHRC, San Diego
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Anna Rivera, MPH
NHRC, San Diego, CA
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Claire Kolaja, MPH
NHRC, San Diego, CA
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Carlos Carballo, MS
NHRC, San Diego, CA
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Toni Geronimo, MPH
NHRC, San Diego, CA
Henry M. Jackson Foundation, Inc.

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

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

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

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

8. Identification of Medical Monitor: Not applicable
9. Primary Performing Institution(s):
Deployment Health Research Department,
Naval Health Research Center, San Diego, CA
10. Collaborating Institution(s):
 - The Millennium Cohort Family team provides de-identified datasets per a data use agreement and a funding contract established with Abt Associates and Center for Child and Family Health (CCFH).
 - Additional institutions may be identified for future unfunded collaborations. These institutions will be added to this protocol through future modifications specifying the nature of their role.
11. Funding Source: Congressional Mandate Research (CORE funding) and Defense Health Agency (DHA)
12. Subjects:
 - a. Number of Subjects: 9,928
 - b. Number of Female Subjects: 8,625
 - c. Number of Male Subjects: 1,303
 - d. Number of Civilian Subjects: 9,269
 - e. Number of Active-Duty Subjects: 659
13. Is an IAIR/IIRR needed? Not applicable

II. SIGNATURE PAGE

1. Principal Investigator

Valerie Stander, PhD
Behavioral Science and Epidemiology;
Military Population Health
Naval Health Research Center, San Diego, CA

2. Directorate Head/Dept Head

Natalie Wells MD, MPH
CDR, MC, USN
Directorate Head;
NHRC, San Diego, CA

Susan Farrish, MD, MPH
LtCol, USAF, MC
Department Head,
NHRC, San Diego, CA

3. Principal Director of Research

Kenneth Earhart, MD
NHRC, San Diego, CA

4. Ombudsman (if applicable)

N/A

5. Medical Monitor (if applicable)

N/A

6. Commanding Officer:

M. R. MONTEVILLE, CAPT, MCS, USN

III. RECORD OF CHANGES TO THE PROTOCOL

FEBRUARY 2018 CONTINUING REVIEW – STAFF UPDATE

Under this continuing review report, we respectfully request to modify the study protocol to remove Christopher Lo as he is no longer at NHRC and to add Alexis Takata, Deanne Millard and Felicia Carey, PhD as key personnel. They will be located at the Naval Health Research Center. Alexis Takata and Deanne Millard will serve as key support staff as research assistants. Dr. Carey, will serve as key support staff as an epidemiologist.

NOVEMBER 2017 STAFF UPDATE AND 2018 MILLENNIUM COHORT FAMILY STUDY CALENDAR

1. Revise the role of Alejandro Esquivel, MPH from Research Assistant to Data Analyst.
2. We are also submitting to the IRB for review and approval the 2018 Millennium Cohort Family Study calendar and cover letter, which will be sent to all current Family Study participants.

OCTOBER 2017 STAFF UPDATE AND SSA DATA

We respectfully request IRB approval to:

1. Add, Christopher Lo, BS and Daniel Vaughan, BS as key personnel. In addition, due to the recent Change of Command from CAPT Simmons to CAPT Monteville we have updated the CO signature line to CAPT Monteville. Also CDR Faix has received new orders and will be leaving NHRC; therefore, we have removed him as a co-investigator. In line with the above-mentioned update, we have updated the Directorate Head from CDR Faix to CDR Wells. Along with these updates we have removed Danielle Mitchell and Kyna Long due to their recent resignations.
2. Also, we would like to request permission to transfer social security numbers of study members, names, and dates of birth, along with some information about those study members from the family study survey and other DoD administrative sources, to the Social Security Administration (SSA) for matching against SSA records on annual earnings subject to Social Security and Medicare taxes, on social security retirement and survivor benefits, on Supplemental Security Income (SSI) benefit payments, and on Social Security Disability Insurance (SSDI) benefit payments.
3. We are also submitting to the IRB for review and approval the text for the annual Month of the Military Family postcard, which will be sent to all current Family Study participants.

FEBRUARY 2017 CONTINUING REVIEW MODIFICATION—STAFF UPDATE

We would like to notify the IRB that Toni Geronimo's position changed from Research Assistant to Data Analyst.

DECEMBER 2016 MODIFICATION—STAFF UPDATE 2017 MAILINGS

We respectfully request the following modifications to the protocol:

1. We are submitting to the IRB for review and approval three emails to be sent to Family Study participants in February 2017, July 2017 and October 2017. These emails will serve as reminders to submit their children's artwork for the 2018 Family Study calendar.
2. We are submitting to the IRB for review and approval the text for the annual Month of the Military Child postcard, which will be sent to all current Family Study participants.

3. We are submitting to the IRB for review and approval the text for birthday cards we will be sending to all current Family Study participants at the beginning of their birth month.
4. This protocol has undergone a change of staff; therefore, we request approval to remove Carrie Donoho, PhD; Christopher O'Malley, MPH; Gia Gumbs, MPH; Toni Geronimo, Dennis Hernando and Kathleen Gunn as they are no longer affiliated with the study. Additionally, we request to add Alejandro Esquivel to the protocol as key personnel. His training certificates (HIPAA and CITI) are included with this submission and his duties are provided below:

Alejandro Esquivel will be located at the Naval Health Research Center and will serve as key support staff as a Research Assistant. As a research assistant he will collect and organize survey data and forms for research projects. In addition, his duties as an assistant are to scan and verify survey data, perform data entry, literature searches, and assist with maintenance of databases for research projects.

FEBRUARY 2017 EMAIL

Subject: Now accepting submissions for the 2018 calendar

We hope you received the 2017 Family Study calendar last month and are considering submitting some of your child(ren)'s artwork for the 2018 calendar! Perhaps you have a beautiful winter mural hanging on your refrigerator or a decorative Valentine's Day drawing sitting on your kitchen counter that would make a great addition to the calendar.

To review the contest guidelines and make a submission, please visit <http://www.familycohort.org/calendar>. As a reminder, your Subject ID is #####. We are excited to see your child(ren)'s artistic creations!

Very respectfully,

Dr. Valerie Stander

Principal Investigator of the Millennium Cohort Family Study

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.2015.0019.

JULY 2017 EMAIL

Subject: Have your child's artwork featured in the Family Study Calendar

Happy 4th of July from the Millennium Cohort Family Study Team! We thank you and your family for your past, present, and future contributions in preserving our nation's independence. We hope you take this opportunity to submit your child(ren)'s artistic depiction of 4th of July fireworks and summer festivities! Their drawing could be featured in our 2018 Family Study Calendar and online gallery!

To review the contest guidelines and make a submission, please visit <http://www.familycohort.org/calendar>. As a reminder, your Subject ID is #####. We are excited to see your child(ren)'s artistic creations!

Very respectfully,

Dr. Valerie Stander

Principal Investigator of the Millennium Cohort Family Study

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.2015.0019.

OCTOBER 2017 EMAIL

Subject: Last chance to submit your child's artwork

Have you submitted your child(ren)'s artwork for the 2018 Family Study Calendar contest yet? The deadline is quickly approaching! We hope you consider submitting your child(ren)'s fall and pumpkin-themed drawings by Monday, October 17, to be considered for the 2018 Calendar that will be mailed to nearly 10,000 of your fellow Family Study participants!

To review the contest guidelines and make a submission, please visit <http://www.familycohort.org/calendar>. As a reminder, your Subject ID is #####. We are excited to see your child(ren)'s artistic creations!

Very respectfully,

Dr. Valerie Stander

Principal Investigator of the Millennium Cohort Family Study

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.2015.0019.

MONTH OF THE MILITARY CHILD POSTCARD TEXT

Dear Name,

During the Month of the Military Child, the Millennium Cohort Family Study Team recognizes the strength and resilience of all military families. We join the nation in honoring military children and families for their contributions to our country.

We want to remind you that your children have the opportunity to contribute artwork for the 2018 Family Study calendar, which will be sent to nearly 10,000 households. Please visit <http://www.familycohort.org/calendar> for more details and instructions to submit your child's artwork!

As a member of the Millennium Cohort Family Study, you are contributing to an effort of profound importance. Please know that you are making a difference in the lives of current and future generations of military families by remaining engaged in this important study.

Thank you for your continued participation!

Very respectfully,

Dr. Valerie Stander

Principal Investigator of the Millennium Cohort Family Study

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.2015.0019.

BIRTHDAY CARD TEXT

Dear Name,

On behalf of the Millennium Cohort Family Study team, I would like to wish you a very Happy Birthday!!!

I would also like to tell you how much I personally appreciate your commitment and thoughtfulness as a participant in this study. It's an honor for our team to be a small part of your life and the life of your family.

May this next year bring you great health and happiness!

Very respectfully,

Dr. Valerie Stander

Principal Investigator of the Millennium Cohort Family Study

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.2015.0019.

NOVEMBER 2016 MODIFICATION—CALENDAR

We respectfully request the following modification to the protocol:

We are submitting to the IRB for review and approval the 2017 Family Study calendar and cover letter which will be sent to all Family Study participants. This calendar contains artwork of the children of Family Study participants. All submitted artwork required a signed release form from the child's parent/legal guardian.

COVER LETTER

Dear NAME,

Happy holidays to you and your family from the Millennium Cohort Family Study team!

As a member of the Family Study, the information you provide makes it possible to understand the health and well-being of military families over time. Even though our study is currently off cycle, we would like to extend a token of our appreciation for your continued involvement, and have enclosed a 2017 Family Study calendar, featuring the artwork made by the children of your fellow Family Study participants.

Beginning January 1, 2017, once again we will be accepting submissions of artwork created by the children of study participants throughout the year, and posting as many as possible to our online art gallery on the Family Study website. At the end of the year, 12 submissions will be selected to be included in the 2018 calendar. To review the submission guidelines and upload your child's drawing or painting, please visit www.familycohort.org/calendar.

Thanks again to all of you for being a part of this program of research and part of the Millennium Cohort Family Study community! We wish you all the best for a happy holiday season and healthy New Year!



Dr. Valerie Stander

Principal Investigator of the Millennium Cohort Family Study

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.2015.0019.



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Document

SEPTEMBER 2016 MODIFICATION (ANNUAL MONTH OF THE MILITARY FAMILY)

We are submitting to the IRB for review and approval the text for the annual Month of the Military Family postcard, which will be sent to all current Family Study participants.

Incorporate a staff change to include Dr. Sabrina Richardson as key personnel. Her required training certificates (HIPAA, CITI and Research Integrity and Responsible Conduct) are included with this submission. Her duties and responsibilities are provided below:

Dr. Sabrina Richardson will be located at the Naval Health Research Center and will serve as key support staff as a 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.

Month of the Military Family Postcard – 2017

During National Military Family Month, the Millennium Cohort Family Study Team would like to thank you for your commitment and support of our military. We honor the dedication, strength and sacrifices made by the families of our nation's Service members.

We appreciate your participation in the 2014-2015 Family Study follow-up survey. Your continued involvement in this important study makes it possible for the Family Study to provide instrumental information to policymakers and military leaders to make a positive difference for all military families.

Very respectfully,

Dr. Valerie Stander,
Principal Investigator of the Millennium Cohort Family Study

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SEPTEMBER 2016 MODIFICATION—*APPROVED FEBRUARY 28, 2017*

We respectfully request IRB approval to:

1. We would like to request permission to obtain selected variables regarding employment from individual level income and earnings data from tax returns filed with the Internal Revenue Service (IRS) as well as linked data from the U.S. Census Bureau. To do so, we plan to work with the U.S. Census Bureau's Center for Administrative Records and Research (CARRA) to obtain permission from the IRS to access these tax records, as well as obtaining the necessary

permission to access Census data from the Census itself. CARRA has experience in obtaining such access and has been successful in doing so for the purposes of program evaluation and research.

The IRS tax data include, for each individual, wage information from W-2 forms, self-employment income from 1099 forms, and much additional information from the full tax forms on both earned and unearned income. It also has self-reported occupational information and industry sector information for each employer. The data is longitudinal, so it can be obtained for a sequence of consecutive years. Thus it can provide a great deal of information about the employment outcomes of study members before, during, and after the relevant period of military service.

This data can also be linked to Census data from various sources. We propose using data from the American Community Survey and/or other census databases as appropriate to create a comparison group of individuals from the general U.S. non-military-affiliated population similar to the military spouses on available characteristics such as gender, race and ethnicity, residence, and educational level. We would also pull data from IRS records on this comparison group to compare the employment outcomes of our study group with the comparison group,

Once permission to access has been obtained from IRS and Census, NHRC will provide the Census with a list of family study participant names, SSNs, and DOBs so that Census can match cases with IRS and Census data. This file will also contain an ID unique to the family study. We will also send to Census a set of variables from the family cohort study survey which will be used for analysis and for the construction of a comparison group, along with this same unique family study ID.

After matching has occurred, Census will assign each case a Protected Identity Key (PIK) and will remove all identifiers (SSN, name, DOB), creating a de-identified dataset for transfer to a Census Research Data Center (RDC), of which there are several around the county. Due to the sensitive and confidential nature of the data involved, Census and IRS require that the data be accessed at an RDC and that no microdata leave the RDC. Our analytic dataset containing family study data will also be transferred to the RDC.

At that point, after undergoing a rigorous Census background check, a Family Study research member will travel to one of the RDCs to access and analyze the de-identified data. All analytic results will be reviewed for data disclosure by the Census Bureau staff to ensure that no identifiable data about any individuals leaves the RDC. *Only* aggregate data results are released. Information that is based on an individual respondent, on a small sample, or on a highly concentrated cell will not be released. All family study data stored at the RDC will be erased from Census's computers after we complete our work at the RDC.

2. We would like to request permission to obtain selected variables regarding education from the National Student Clearinghouse. The NSC is a non-profit organization that collects data on student enrollment, degree earned, and other credential completion from most institutions of higher education in the country. The NSC has the most extensive database of enrollments and credentials available. Over 3,600 colleges and universities, enrolling 98 percent of all students in public and private institutions, provide data to the clearinghouse. NSC provides educational history information that confirms an individual's degrees, academic credentials, and enrollment status.

The relevant NSC database for Family Study analytic purposes is called StudentTracker. It includes both enrollment and credential data. StudentTracker can be queried in one of two ways, either by using a combination of name and date-of-birth, or by using Social Security Number (SSN). The NSC requires student consent in order to match on SSN, but NOT to

match on name and date-of-birth. We propose a non-consent-based data match which will not require the transfer of SSNs to NSC; rather, the data match will be performed using names and dates of birth as personally-identifiable information.

3. We would like to request permission to obtain selected variables regarding mortality status from the Social Security Administration (SSA) Death Master File. The SSA collects death information in order to implement their programs. The SSA receives death reports from many sources, including funeral directors, family members, financial institutions, and state and federal agencies. The data is then compiled into one file, the Death Master File. While this file does not capture all deaths in the United States, previous studies have found it captures between 83-95% of the deaths.

There are two primary reasons for obtaining mortality data from the SSA. First, the mortality data will be used to remove participants from mailing lists so to not inadvertently contact next of kin. The death data from the SSA will be received on a monthly basis, with minimal lag time between the date of death and receipt of the data to endure minimal burden on next of kin. Secondly, this data will be part of an algorithm to verify identity and mortality status of Family participants in conjunction with mortality data obtained through the National Death Index. This algorithm relies on using multiple data sources to verify mortality status and its accuracy will be comprised if SSA mortality data is not included.

Once permission to access the Death Master File has been obtained from the SSA, NHRC will provide the SSA with the list of Family study participants' SSN, full name, date of birth, and gender for matching purposes. The Army Safe Site (AMRDEC) will be use to transfer the encrypted data.

JULY 2016 MODIFICATION

We respectfully request the IRB approval to:

1. Incorporate a staff change to include Kelly Woodall, MPH as key personnel. Ms. Woodall a former employee is scheduled to rejoin the team 15AUG2016. Her required training certificates (HIPAA, CITI and Research Integrity and Responsible Conduct) will be submitted upon her arrival and before she begins working with any human subjects data. Her duties and responsibilities are provided below:

Kelly Woodall, MPH will be located at the Naval Health Research Center and will serve as key support staff as a Data Analyst. 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.

2. Remove Hector Lemus, PhD from the protocol as he is no longer affiliated with the Deployment Health Research at the Naval Health Research Center, San Diego.

JUNE 2016 MODIFICATION

We respectfully request the IRB approval to:

1. Incorporate a staff change to include Satbir Boparai as key personnel. Her training certificates (HIPAA and CITI) are included with this submission and her duties and responsibilities are provided below:

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.

2. Incorporate the two emails that will be sent out to all of the participants as reminders to submit their children's artwork for the 2017 Family Calendar.
3. Remove Serguey Parkhomovosky and Kristen Motylinski from the protocol as they have resigned and they are no longer affiliated with the Deployment Health Research at the Naval Health Research Center, San Diego.

July 2016 email Subject: Have your child's artwork featured in the Family Study Calendar

Happy 4th of July from the Millennium Cohort Family Study Team! We thank you and your family for your past, present, and future contributions in preserving our nation's independence.

We hope you are enjoying your summer and would like to remind you to submit your child's artwork for our 2017 calendar. Your child's drawing could be featured in our 2017 Family Study Calendar and online gallery!

To review the contest guidelines and submit your child's artwork, please visit <http://www.familycohort.org/calendar>

Very respectfully,

Dr. Valerie Stander
Principal Investigator of the Millennium Cohort Family Study

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October 2016 email

Subject: Last chance to submit your child's artwork

Have you submitted your child's artwork for the 2017 Family Study Calendar contest yet? The deadline is quickly approaching! Submit your child's drawing by Tuesday, November 1, to be considered for the 2017 Calendar that will be mailed to nearly 10,000 of your fellow Family Study participants!

Simply visit <http://www.familycohort.org/calendar> for the contest guidelines and online gallery. We can't wait to see your child's masterpiece!

Very respectfully,

Dr. Valerie Stander
Principal Investigator of the Millennium Cohort Family Study

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MARCH 2016 CONTINUING REVIEW

Under this continuing review submission we have included for IRB review and approval the following three participant contacts:

Millennium Cohort Family Study Month of the Military Child Postcard
Millennium Cohort Family Study Calendar Artwork Reminder Email (July 2016)
Millennium Cohort Family Study Calendar Artwork Reminder Email (October 2016)

In addition, we respectfully request permission to add Carlos Carballo. Mr. Carballo will be located at the Naval Health Research Center and serve as key support staff as a Data Analysts. 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 recent resignation we are removing her from the protocol.

DECEMBER 2015

We have included for IRB review and approval the calendar submission website for Family Study participants to submit their children's artwork for possible inclusion in the 2017 Family Study calendar and online gallery. The submission page includes the media release form, which was drafted by NHRC PAO Regena Kowitz, who received guidance from the NMRC PAO, Doris Ryan.

The screenshot shows the website header with a tree logo, the text "Millennium Cohort Family Study", and the tagline "Because Families Serve Too". The navigation menu includes: Home, Start Survey, About the Study, FAQ, Resources - Research -, Update Contact Info, and Contact Us.

What is the Millennium Cohort Family Study Calendar?

As a token of our gratitude for your continued involvement in this important study, you should have received the 2016 Family Study Calendar in the mail, which features artwork by our Family Study Team members' children.

Throughout the year, you will have the opportunity to submit your child(ren)'s artwork for possible inclusion in the 2017 Family Study Calendar and online gallery!

Artwork submission instructions:

- All submissions should be on 8.5"x11" white paper in landscape orientation.
- There are no strict guidelines for the artwork content, but we encourage the artwork to reflect your family and your relationship with the military.
- Please ensure that your child(ren)'s artwork does not contain any personally identifiable information such as names, addresses, etc.
- The deadline for artwork submission is **November 1, 2016**.
- To ensure the artwork file is suitable for printing in **high resolution**, please follow these recommendations:
 1. Scan the artwork using a scanner set at 300dpi resolution or higher.
 - OR
 2. In a setting with good lighting, take a picture of the artwork using a camera with 5 megapixels or more.
- To upload the artwork file, please complete the form below, attach your child(ren)'s artwork, and click submit.

Examples

2017 Family Calendar Artwork Submission Form

Please fill out the following consent form, and then proceed to the next page where you will be allowed to upload your child's artwork.



Naval Health Research Center
140 Sylvester Road
San Diego CA 92106-3521

Naval Health Research Center (NHRC) Media Consent Form

NHRC publishes information through various media forms—print (newsletters, magazines, reports, brochures, news releases, and feature articles), electronic (web site) and audio and video productions. The purpose of this media release form is to obtain permission for NHRC to use images or original artwork submitted to the Millennium Cohort Family Study.


By signing below, I give consent for NHRC to edit, use and reuse my child's drawing/original artwork for Millennium Cohort Family Study publications and marketing materials.

Minor child's first name <input type="text"/>	Minor child's last name <input type="text"/>	
Parent/guardian first name <input type="text"/>	Parent/guardian last name <input type="text"/>	Date <input type="text" value="2015/12/22"/>
Email <input type="text"/>		

This personal information will not be shared outside of NHRC.

If you have questions about the Millennium Cohort Family Study, please contact Dr. Valerie Stander at (800) 571-9248 or DOD.FamilyStudyPI@mail.mil

If you have questions about this form, please contact NHRC's Public Affairs Officer, Regena Kowitz at (619) 553-0548.

I'm not a robot 

[Next](#)

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Millennium Cohort
Family Study

Because Families Serve Too

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 [Start Survey](#)
 [About the Study](#)
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 [Resources](#) -
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2017 Family Calendar Artwork Submission Form (Part 2)

You're almost done! Please complete this form to finish uploading your child's artwork.

Child's Age <input type="text"/>	Family Study Subject ID <input type="text"/>
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Please tell us about your family's current or past affiliation with the military (Maximum of 300 characters):
(Examples: Husband is currently serving in the Navy; Wife served for 8 years in the Army; Husband and I are both serving in the Air Force)

Military affiliation (Maximum 300 characters)

Family Cohort Logo.JPG

Please upload your image file in JPEG, TIFF, or PNG format. Maximum file size is 15MB.

[Submit](#)

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NOVEMBER 2015

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 Family Advocacy Program (FAP) Central Registry Database. 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 Family Study research participants, with recurring data extracts at the conclusion of each cycle of data collection.

Permission to receive these data will be obtained from DoD FAP, as well as from the Defense Manpower Data Center (DMDC) which is the repository for the database. Once permission has been obtained, NHRC will provide DMDC with a list of the SSNs for family study participants. DMDC will then provide NHRC with all matching records in the Central Registry for those SSNs. 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 and spouses in the Family 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)

We have included for IRB review and approval the 2016 Family Study calendar and cover letter which will be sent to all Family Study participants. This calendar will serve as an example for the calendar we are planning to send in 2017. Over the next year, participants will be able to submit their child(ren)'s artwork to be posted on the Family Study website. At the end of the year, 12 images will be selected to be featured as the monthly artwork in the 2017 calendar. The Family Study Team is currently in the process of working with BUMED to create an appropriate release form for participants to sign prior to submitting their child(ren)'s artwork. Once finalized, this release form and the submission website will be submitted for review at a later time.

OCTOBER 2015

Submitting under this modification for IRB for review and approval is the Cover Letter for the Millennium Cohort Family Study Shortened Survey Mailing #2 that is within the permissible number of contacts.

In addition a change of staff request to remove Dr. David Luxton, Laura Tobin, and Madeline Cross as 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 a 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.

Millennium Cohort Family Study Shortened Survey Mailing #2 – Cover Letter

Dear NAME,

During National Military Family Month, the Millennium Cohort Family Study Team would like to thank you for the many contributions you make every day in support of the military and our nation. We join the country in celebration of the Military Family and honor the commitment and sacrifices made by the families of our nation's Service members.

Through your continued involvement, the Family Study will be able to provide vital information to military leaders and policymakers working to support families like yours. We value your participation, even if your marital status has changed or your spouse is no longer in the military. We know your time is valuable, so we have created a shortened paper version of our 2014 online survey with carefully selected questions. Please consider taking 5 minutes to complete this 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.familycohort.org, click "Start Survey," and enter your Subject ID: XXXXXXXX.

Thank you for your continued commitment to current, former, and future military families.

Very respectfully,

Dr. Valerie Stander
Principal Investigator of the Millennium Cohort Family Study

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JUNE 2015

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.

APRIL 2015

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

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.

Kristen Walter, Ph.D., will be located at the Naval Health Research Center and will serve as key support staff as subject matter expert in Depression and PTSD comorbidity. Her duties will include assisting in data analytic design and the development of research questions regarding depression among military spouse. Dr. Walters will assist in reviewing literature and writing research reports on this topic.

Also, included for IRB review and approval is the Memorial Day postcard and the Memorial Day follow-up email. These mailings are within the permissible number of contacts.

Subject: Last Chance to Participate

[NAME],

As we remember the sacrifices made by our Service members and their families, we ask that you consider representing current and future military spouses by completing your follow-up Family Study survey. The Millennium Cohort Family Study Team recognizes the importance of your contribution to protecting America's freedom, and our goal is to understand the unique effects of military life on the health and well-being of military families.

Your opportunity to be a part of this important study will be ending very soon, so don't delay in sharing your unique thoughts and experiences.

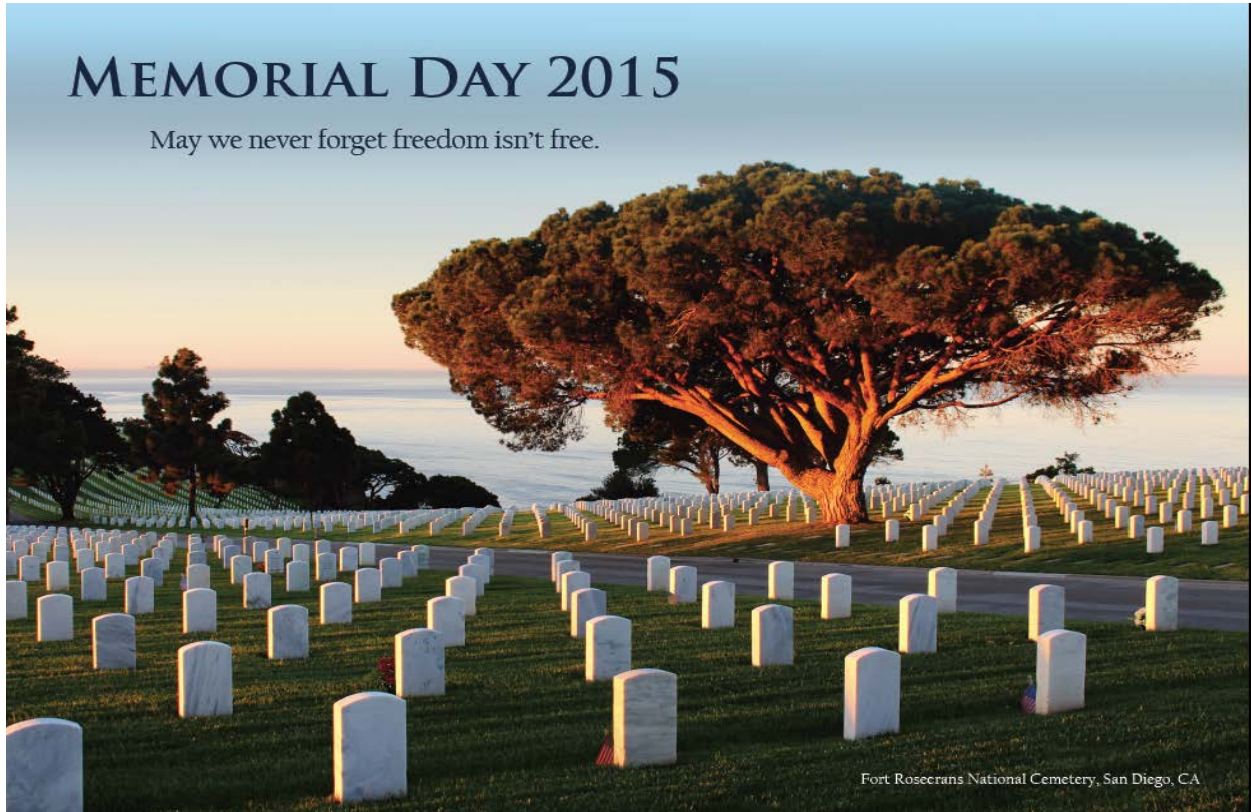
To complete your survey, please visit the following link: www.familycohort.org.

Your Subject ID is: XXXXXXXX

Thank you so much for your participation.

Very Respectfully,
Carrie Donoho, PhD
Captain, MS, USA
Spouse of a Veteran and Active Duty Family Study researcher

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Department of Defense
 Deployment Health Research Department
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Dear <NAME>,

On this Memorial Day, the Millennium Cohort Family Study Team remembers those who sacrificed their lives for our nation, and we thank you for your family's contribution to protecting America's freedom.

The Family Study Team is dedicated to improving the lives of Service members and their families. Your participation in this study helps provide valuable information to healthcare providers and military leaders about the short and long-term concerns of military families.

If you have not completed your online survey, please visit www.familycohort.org, click "Start Survey", and enter your Subject ID: **XXXXXXXX**. We truly value your time and participation in this important study. Please know that your continued involvement in the Family Study will make a difference in the lives of military 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.2015.0019

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V. SCIENTIFIC BACKGROUND AND OBJECTIVES

1. **Background**

In recent decades, mental health and related outcomes for US military Service members following war zone deployment(s) 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(s) 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(s) 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 FamilyCohort sub-study 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.

2. **Primary 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

3. **Secondary Objectives**

- 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.

VI. EXPERIMENTAL METHODS

1. Experimental Procedures and Rationale

A. Subjects

In order to assess the interrelated health effects of military service and deployment on Service members, spouses, and their children a Family Cohort sub-study was added to the main study (The Millennium Cohort Study) in August 2009 under protocol #NHRC.2000-0007. The

Millennium Cohort Family Study team and collaborators enrolled 10,065 participants during the 2011-2013 baseline survey cycle. During the data cleaning phase between baseline and the 2014-2015 follow-up survey cycle, 137 participants were removed from the study sample and were not included in analyses. The reasons for exclusion were questionnaires submitted without a signed consent form, multiple questionnaires submitted by the same participant, and submitted questionnaires that were found to be completed by the incorrect individual. During additional data cleaning in 2016, an additional 49 surveys were removed from the study sample, because it was discovered that the 49 Family participants had completed both Millennium Cohort and Family Cohort surveys. Therefore, to date, there are 9,872 participants enrolled in the Millennium Cohort Family Study. The first follow-up survey cycle was launched on October 1, 2014 and closed on February 9, 2016. The follow-up response rate is 67.4% with 6,625 completed surveys.

B. Methods and Informed Consent Plan

Due to logistical reasons, the Family component of the Millennium Cohort study is now submitted to the Naval Health Research Center's Institutional Review Board as a standalone sub-study as of April 25, 2015. Previously all approvals for this project were included under the primary protocol for the Millennium Cohort Study (NHRC.2000.0007). For all background and historical information prior to the standalone sub-study start date, please refer to the Millennium Cohort Study protocol. 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 this protocol. A separate website (www.familycohort.org) for this sub-study has been established under the main study (Millennium Cohort; NHRC.2000.0007), and is linked directly to the Millennium Cohort Study website, www.millenniumcohort.org.

As described in the Primary Millennium Cohort Study protocol, baseline data for Family Study were collected beginning in 2011. Furthermore, the first follow-up wave collected data from October 2014 to February 2016 and utilized a secure online data collection survey method previously approved and documented in the primary protocol. Over the course of this longitudinal study, spouses will be asked to complete a total of 7 follow-up surveys over 21 years, with one survey to be completed approximately every 3 years. These survey cycles will be conducted at the same time as the Millennium Cohort Study data collection cycle in order to maintain methodological consistency and to ensure that both the Family Study spouse participants and their Millennium Cohort Study military marital partners complete their surveys within a close time frame. Starting with the 2017 data collection cycle, revised survey documents and procedures that are developed for each new wave of data collection will be submitted to the IRB for approval as part of a modification to this new protocol.

Informed consent has already been obtained from all current study participants during the baseline enrollment process in the 2011 data collection cycle. This process is documented in the IRB protocol for the primary Millennium Cohort Study. At present, no additional participants will be enrolled in the Family study. Additional participants may be enrolled in a future wave of data collection. However, if that opportunity arises, all methods for informed consent and enrollment will be documented and submitted along with the modification including the new survey materials to be used in that data collection cycle.

Survey data collection methods have been developed based on empirical research regarding effective subject recruitment strategies (e.g., modified Dillman survey methodology). Multiple modes of contact will continue to be utilized, including email and mail. For those who provided phone information to the study team for contact purposes, phone calls may also be used. Nominal incentives will be offered to participants for completing the survey, such as the choice of a \$10 gift card to the military exchange (AAFES/NEX gift card), Starbucks, or Amazon.com. No gift

cards are exchangeable for cash. Additional nominal pre-incentives may be sent to participants as part of the recruitment process (e.g., small reusable lunch bag, magnetic picture frame, \$2 bill). All specific contact scripts and procedures previously approved up through April 24th 2015 will continue to be documented through the primary Millennium Cohort Study protocol. The exact nature, scripts, and procedures for all future contacts from April 25th 2015 onward will be submitted under this sub-study. The first of these contacts are submitted for approval as detailed in Appendix G that are within the number of contracts previously approved by the IRB under the Millennium Cohort Study (primary study). Any other future contacts will be submitted to the IRB for approval as modifications to this protocol.

During the 2014-2016 follow-up survey cycle, the type of contact and incentive offered alternated in order to ensure they do not become redundant or repetitive for participants. Furthermore, participants did not receive more than two email contacts in any individual month or more than twelve postal contacts total during the duration of the follow-up survey cycle. During the follow-up survey cycle, we sent recruitment solicitations to participants until (a) we received a completed survey from them, (b) they explicitly declined to participate, or (c) the survey cycle completion timeframe ended. Participants receive occasional contacts during off-cycle timeframes in order to update them about the progress of the study, to obtain updated contact information from them, and to maintain a relationship with them during the long off-cycle periods.

Family Component Domains and Measures. Based on our conceptual model and the existing literature, the previously approved Family Study surveys documented in the primary protocol assess 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 (See Table 1).

Table 1. 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

2. Sample Size Determination With Statistical Power Calculation

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. Based on the percent of Service members who have already been enrolled in the Millennium Cohort Study and who have deployed in support of the wars in Iraq and Afghanistan, it is estimated that 30% to 50% of the Service members who were enrolled in the 2010 cohort already will have been deployed in support of the current conflicts. Further, it was estimated that the overall prevalence of mental health outcomes will be from 5% to 10% for spouses of non-deployed military Service members. 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

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 detectible across the expected range of service members deployed.

Table 2. 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

Based on these analyses, 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 began baseline enrollment with a probability sample of personnel 250,000 Service members who were invited to participate in the 2010 cohort. Based on previous cohorts of the Millennium Cohort Study a response rate of 25% (62,500 enrolled service members) was expected. Of those, we estimated that 35% (21,875) would be married, and that 75% (16,407) of married Service members would refer their spouses for enrollment in the Family Study. We further estimated 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.

3. Justification for Exclusion of Specific Groups

Sample selection and recruitment criteria were documented in the original Millennium Cohort Study protocol. No additional subject recruitment will be conducted under this protocol without a specific modification and further review by the IRB. Selection and exclusion criteria for future subject enrollment will be provided in such potential future modifications.

4. Required Equipment and Supplies

Supplies needed for this protocol will include mailing supplies, participant incentives, and other standard office supplies. Computer equipment and support as provided through the Naval Health Research Center will facilitate data management and security as discussed further below.

VII. ORGANIZATION OF RESEARCH EFFORT

1. Duties and Responsibilities

Valerie Stander, PhD, will serve as a Principal Investigator for this study. She will be responsible for the implementation of and compliance with this protocol. She will have primary responsibility for supervising study enrollments, data collection and analyses and protection of human subjects. She will also be responsible for ensuring that all NHRC personnel involved with this protocol are properly trained and qualified. She is responsible for assisting with the design of the study and will be involved with data interpretation and publication.

Hope McMaster, PhD, will be located at the Naval Health Research Center and will serve as a co-investigator Research Psychologist. 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 will be located at the Naval Health Research Center and serve as a co-investigator 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.

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.

Lauren Bauer, MPH, will serve as key support staff as Study Coordinator. 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.

Evelyn Sun, MPH 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.

Beverly Sheppard, Study Coordinator for the Millennium Cohort Study and **Jennifer Walstrom** study will serve as key support staff and will work with the Millennium Cohort Family study team with coordinating the Millennium Cohort study and sub-study data as well as web site and survey testing.

Alexis Takata, Deanne Milliard and Anet Petroysan will be located at the Naval Health Research Center and will serve as key support staff as Research Assistants. As a Research Assistant, they will collect and organize survey data and forms for research projects. In addition, their duties will include scanning and verifying survey data, performing data entry and literature searches, and assisting with the maintenance of databases for research projects. .

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

William Lee has extensive knowledge in computer and internet technology, website maintenance and development. He will work with Mr. Speigle to ensure data security and integrity, as well as designing, creating, modifying, and updating web pages. He will also be responsible for building and maintaining the web-based component of the survey along with Mr. Speigle 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 a web designer. As the web designer Mr. Lynch will work with Mr. Speigle and Lee in creating and maintaining the study website.

Jacqueline Pflieger, PhD, and Sabrina Richardson, PhD, will be located at the Naval Health Research Center and will serve as key support Research Psychologists. Their 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.

Kristen Walter, PhD, will be located at the Naval Health Research Center and will serve as key support staff as subject matter expert in Depression and PTSD comorbidity. Her duties will include assisting in data analytic design and the development of research questions regarding depression among military spouse. Dr. Walter will assist in reviewing literature and writing research reports on this topic.

Christopher Phillips, MD, MPH, is a Senior Epidemiologist at the Naval Health Research Center in San Diego, CA. Dr. Phillips has spent many years working in both the military and civilian sectors of healthcare, as an active duty provider, bioinformaticist, and epidemiologist.

Dr. Phillips will be responsible for conducting the statistical analyses for the project. In addition, he will be responsible for assisting with the writing of the methods for this project and will assist with scientific manuscript preparation.

Ben Porter, PhD, Teresa Powell, MS and Richard Armenta, PhD, MPH 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.

Rudolph Rull, PhD, Daniel Trone, PhD and Felicia Carey, will be located at the Naval Health Research Center and 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 Rivera, MPH, Claire Kolaja, MPH, Carlos Carballo, MS, Toni Geronimo, MPH, Kelly Woodall, MPH and Alejandro Esquivel, MPH will be located at the Naval Health Research Center and serve as key support staff as Data Analysts. 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.

2. Chain of Command

All the co-investigators, key-personnel and consultants will report directly to the principal investigator, who will be responsible to the Commanding Officer of Naval Health Research Center, through the usual chain of command.

VIII. RISKS AND DISCOMFORTS TO RESEARCH VOLUNTEERS

1. Risk to the Volunteer and Means of Mitigation

The procedures for data storage and security will continue under this protocol as they were previously under the primary study protocol. This research study will collect data using a self-report survey. Study staff will store all identified data in secure server locations at the Naval Health Research Center and maintain limited password access. Only personnel on this protocol who need to make use of specific data files will have access. All results will be reported as aggregate data without identifying any individuals. Thus, this study poses no physical risk to the participant. The primary risk to participants is the potential for a breach of confidential data. Personal identifiable health information is collected, and strict procedures will be followed to minimize any risk of exposure.

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

- All study staff will receive training in confidentiality protection procedures.
- Supervisors will monitor staff to ensure that they follow proper confidentiality procedures.
- If study staff resign or otherwise leave the program, they will no longer have any access to any stored data. However, they will still remain under obligation indefinitely to keep any information confidential that they may have learned about individual participants.

- Based on previous agreements in the Primary study protocol, study staff will store study paper records in locked metal cabinets at NHRC. Paper records that are no longer needed will be shredded.
- New data collected for the ongoing survey cycle under the present protocol are all electronic. No new paper is currently collected. All new data are stored securely on the dedicated Millennium Cohort Survey server at the Naval Health Research Center. No transfer of data or changes in the storage process are necessary as part of the initiation of this new protocol.
- To gain entry into the study database, staff will be required to have a military CAC card and pin.
- The NHRC network fire wall is in place to deter unauthorized access to these files.
- Participant identifiers and study data are linked with a nonidentifying study number and are stored separately. Only study personnel on this protocol with authorized access will link personal identifiers with the data in order to match multiple data files including different waves of data and military personnel records. Identifiers will again be stripped following the match for analyses.
- For online data collection purposes, participant survey information transmitted over the Internet will be done using SSL-encrypted transmission lines. Further, participants will have to enter their unique study ID number and last four digits of their social security number to send completed questionnaires securely.
- The study database will primarily reside within the NHRC network environment. Any external data transfers will be limited to deidentified data and will be dependent on formal data use agreements established with NHRC and external partners. Only secure FTP will be used to transfer encrypted, deidentified data.

2. Special Risks to Pregnant Women

This study does not pose any specific risks to pregnant women.

3. Safety Precautions and Emergency Procedures

This study is an observational epidemiologic study and does not involve the administration of any medications or therapeutics. Participants participate remotely and will not have direct contact with study staff.

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. However, in the event of potential data compromise, action will be taken in compliance with NAVMED Policy 09-016.

5. Qualification of Medical Monitor and Medical Support Personnel

NA

IX. DESCRIPTION OF THE SYSTEM FOR MAINTENANCE OF RECORD

1. Experimental Data

All study data, including previously collected baseline paper questionnaires, will be managed by the principal investigator and stored in locked rooms at NHRC. Computerized Privacy Act data will be handled in a confidential, controlled access fashion in compliance with

NAVHLTHRESCENINST 3900.2F and NAVHLTHRESCENINST 6500.1A.

A Data Use Agreement (DUA; Appendix F) between NHRC and Abt Associates and their subcontractors Center for Child and Family Health (CCFH) has been established. These external collaborators will not have any contact with research participants and will only have access to deidentified data under the terms of an existing DUA. Abt associates and their affiliates will only maintain deidentified data on secure servers at their institutions for the duration of specific tasks they are contracted to perform. At the conclusion of said projects, those data files will be returned or deleted. Deidentified data may include demographics, health conditions and symptoms, functional health, habits (e.g., smoking, alcohol use, exercise, and diet), family relationship quality, parenting and child-related data, as well as military history information. Relative dates of events may be shared with Abt Associates for specific analyses; these dates will be coded as time (days) since an agreed upon baseline reference point. No specific dates will be shared with external collaborators.

Data transfers will only occur using password-protected encrypted files transferred through a secure FTP process employing an additional layer of password protection. The data provided by NHRC to the Abt Associates team is restricted to the minimum necessary to complete approved Elected variables regarding military assessment and treatment provision, as well as other medical care referral from the Department of Defense Family Advocacy Program (FAP) Central Registry Database will be obtained. 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 Family Study research participants, with recurring data extracts at the conclusion of each cycle of data collection.

Permission to receive these data will be obtained from DoD FAP, as well as from the Defense Manpower Data Center (DMDC) which is the repository for the database. Once permission has been obtained, NHRC will provide DMDC with a list of the SSNs for family study participants. DMDC will then provide NHRC with all matching records in the Central Registry for those SSNs. 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 and spouses in the Family 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)

We plan to work with the U.S. Census Bureau's Center for Administrative Records and Research (CARRA) to obtain permission from the IRS to access these tax records, as well as obtaining the necessary permission to access Census data from the Census itself. CARRA has experience in obtaining such access and has been successful in doing so for the purposes of program evaluation and research.

The IRS tax data include, for each individual, wage information from W-2 forms, self-employment income from 1099 forms, and much additional information from the full tax forms on both earned and unearned income. It also has self-reported occupational information and industry sector information for each employer. The data is longitudinal, so it can be obtained for a sequence of consecutive years. Thus it can provide a great deal of information about the employment outcomes of study members before, during, and after the relevant period of military service.

This data can also be linked to Census data from various sources. We propose using data from the American Community Survey and/or other census databases as appropriate to create a comparison group of individuals from the general U.S. non-military-affiliated population similar to the military spouses on available characteristics such as gender, race and ethnicity, residence, and educational level. We would also pull data from IRS records on this comparison group to compare the employment outcomes of our study group with the comparison group,

NHRC will provide the Census with a list of family study participant names, SSNs, and DOBs so that Census can match cases with IRS and Census data. This file will also contain an ID unique to the family study. We will also send to Census a set of variables from the family cohort study survey which will be used for analysis and for the construction of a comparison group, along with this same unique family study ID.

After matching has occurred, Census will assign each case a Protected Identity Key (PIK) and will remove all identifiers (SSN, name, DOB), creating a de-identified dataset for transfer to a Census Research Data Center (RDC), of which there are several around the county. Due to the sensitive and confidential nature of the data involved, Census and IRS require that the data be accessed at an RDC and that no microdata leave the RDC. Our analytic dataset containing family study data will also be transferred to the RDC.

At that point, after undergoing a rigorous Census background check, a Family Study research member will travel to one of the RDCs to access and analyze the de-identified data. All analytic results will be reviewed for data disclosure by the Census Bureau staff to ensure that no identifiable data about any individuals leaves the RDC. *Only* aggregate data results are released. Information that is based on an individual respondent, on a small sample, or on a highly concentrated cell will not be released. All family study data stored at the RDC will be erased from Census's computers after we complete our work at the RDC.

We would like to obtain selected variables regarding education from the National Student Clearinghouse. The NSC is a non-profit organization that collects data on student enrollment, degree earned, and other credential completion from most institutions of higher education in the country. The NSC has the most extensive database of enrollments and credentials available. Over 3,600 colleges and universities, enrolling 98 percent of all students in public and private institutions, provide data to the clearinghouse. NSC provides educational history information that confirms an *individual's degrees, academic credentials, and enrollment status*.

The relevant NSC database for Family Study analytic purposes is called StudentTracker. It includes both enrollment and credential data. StudentTracker can be queried in one of two ways, either by using a combination of name and date-of-birth, or by using Social Security Number (SSN). The NSC requires student consent in order to match on SSN, but NOT to match on name and date-of-birth. We propose a non-consent-based data match which will *not require the transfer of SSNs to NSC*; rather, the data match will be performed using names and dates of birth as personally-identifiable information.

We would like to obtain selected variables regarding mortality status from the Social Security Administration (SSA) Death Master File. The SSA collects death information in order to implement their programs. The SSA receives death reports from many sources, including funeral

directors, family members, financial institutions, and state and federal agencies. The data is then compiled into one file, the Death Master File. While this file does not capture all deaths in the United States, previous studies have found it captures between 83-95% of the deaths.

There are two primary reasons for obtaining mortality data from the SSA. First, the mortality data will be used to remove participants from mailing lists so to not inadvertently contact next of kin. The death data from the SSA will be received on a monthly basis, with minimal lag time between the date of death and receipt of the data to endure minimal burden on next of kin. Secondly, this data will be part of an algorithm to verify identity and mortality status of Family participants in conjunction with mortality data obtained through the National Death Index. This algorithm relies on using multiple data sources to verify mortality status and its accuracy will be comprised if SSA mortality data is not included.

NHRC will provide the SSA with the list of Family study participants' SSN, full name, date of birth, and gender for matching purposes. The Army Safe Site (AMRDEC) will be use to transfer the encrypted data.

Family Study tasks and access to these data will be limited to a minimum number of individuals necessary at each institution to achieve the required 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".

All contacts mailed to the participants 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 identification information 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. Currently, all data collection is conducted through an online survey portal. However, we plan that any possible future paper questionnaires that may be submitted for approval through the IRB will have the SID bar coded onto them when they are mailed to the participant so that can be scanned for identification purposes once returned.

The second database created will contain participant questionnaire responses along with corresponding information linked by SID only 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 longitudinal 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 longitudinal data collection and final study dataset completion, all identifying information will be destroyed. Prior to study completion, for back-up purposes, a list pairing the SID with the last 4-digits of the social security number will be created and stored separately by the Principal Investigator in a locked file cabinet.

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

Based on procedures approved previously in the primary Millennium Cohort Study protocol, 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 and the principal investigator.

4. Conflict of Interest

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

X. APPENDICES

APPENDIX A: Consent Documents

Current Informed Consent Form and survey instrument are approved under the main study (Millennium Cohort Study NHRC.2000.0007). The survey instrument for the survey cycle to begin in 2017 will be submitted to the IRB for review and approval prior to implementation and when all regulatory approvals such as OMB, RCS and SORN have been received.

B. INVESTIGATOR COMPLIANCE ATTESTATION

INVESTIGATOR COMPLIANCE ATTESTATION

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Signatures and dates:

(DD/MM/YY)

 Valerie Stander, PhD
 Principal Investigator

_____/_____/_____

 David D. Luxton, PhD, MS
 Co-Investigator

_____/_____/_____

 Dennis Faix, MD, MPH
 CDR, MC, USN
 Co-Investigator

_____/_____/_____

 Lauren Bauer, MPH
 Key Personnel

_____/_____/_____

 Hector Lemus, DrPh
 Key Personnel

_____/_____/_____

 Christopher Phillips, MD, MPH
 Key Personnel

_____/_____/_____

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Signatures and dates:

(DD/MM/YY)

Carrie Donoho, PhD
Co-Investigator

_____/_____/_____

Hope McMaster, PhD
Co-Investigator

_____/_____/_____

Ben Porter, PhD
Key Personnel

_____/_____/_____

Rudolph Rull, PhD
Key Personnel

_____/_____/_____

Daniel Trone, PhD
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_____/_____/_____

Lauren Kearney, MPH
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_____/_____/_____

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Signatures and dates:

(DD/MM/YY)

 Christopher O'Malley, MPH
 Key Personnel

_____/_____/____

 Cynthia LeardMann, MPH
 Co-Investigator

_____/_____/____

 Teresa Powell, MS
 Key Personnel

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 Gia Gumbs, MPH
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 Jennifer Walstrom
 Key Personnel

_____/_____/____

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Signatures and dates:

(DD/MM/YY)

 Evelyn Sun
 Key Personnel

____/____/____

 Danielle Mitchell
 Key Personnel

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 Dennis Hernando
 Key Personnel

____/____/____

 Anet Petroysan
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 Anna Bukowinski
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 Andrew Lin
 Key Personnel

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Signatures and dates:

(DD/MM/YY)

 William Lee
 Key Personnel

____/____/____

 Steven Speigle
 Key Personnel

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 Serguey Parkhomovsky
 Key Personnel

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 Gordon Lynch
 Key Personnel

____/____/____

 Kari Sausedo, MA
 Key Personnel

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 Denise Lovec-Jenkins
 Key Personnel

____/____/____

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Signatures and dates:

(DD/MM/YY)

Laura Tobin
Key Personnel

_____/_____/____

Madeline Cross
Key Personnel

_____/_____/____

Kathleen Gunn
Key Personnel

_____/_____/____

Kristin Motylinski
Key Personnel

_____/_____/____

Anna Nagel
Key Personnel

_____/_____/____

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Signatures and dates:

(DD/MM/YY)

Valerie Stander, PhD
Principal Investigator
Naval Health Research Center, San Diego, CA

_____/_____/_____

Toni Geronimo
Key Personnel

_____/_____/_____

Richard Armenta
Key Personnel

_____/_____/_____

Kristen Walters
Key Personnel

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Signatures and dates:

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Valerie Stander, PhD
Principal Investigator
Naval Health Research Center, San Diego, CA

_____/_____/_____

Jacqueline Pflieger
Key Personnel

_____/_____/_____

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Signatures and dates:

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Valerie Stander, PhD
Principal Investigator
Naval Health Research Center, San Diego, CA

_____/_____/_____

Claire Kolaja, MPH
Key Personnel, Henry M. Jackson Foundation

_____/_____/_____

Kyna Long
Key Personnel, Henry M. Jackson Foundation

_____/_____/_____

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Signatures and dates:

(DD/MM/YY)

Valerie Stander, PhD
Principal Investigator
Naval Health Research Center, San Diego, CA

_____/_____/_____

Carlos Carballo, MS
Key Personnel, Henry M. Jackson Foundation

_____/_____/_____

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Signatures and dates:

(DD/MM/YY)

Valerie Stander, PhD
Principal Investigator
Naval Health Research Center, San Diego, CA

_____/_____/_____

Satbir Boparai, MBA
Key Personnel, Henry M. Jackson Foundation

_____/_____/_____

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Signatures and dates:

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Valerie Stander, PhD
Principal Investigator
Naval Health Research Center, San Diego, CA

_____/_____/_____

Kelly Woodall, MPH
Key Personnel, Henry M. Jackson Foundation

_____/_____/_____

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Signatures and dates:

(DD/MM/YY)

Valerie Stander, PhD
Principal Investigator
Naval Health Research Center, San Diego, CA

_____/_____/_____

Sabrina Richardson, PhD
Key Personnel, Henry M. Jackson Foundation

_____/_____/_____

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Valerie Stander, PhD
Principal Investigator
Naval Health Research Center, San Diego, CA

_____/_____/_____

Alejandro Esquivel
Key Personnel, Henry M. Jackson Foundation

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Signatures and dates:

(DD/MM/YY)

Christopher Lo, BS
Key Personnel, Henry M. Jackson Foundation, Inc.

_____/_____/_____

Daniel Vaughan, BS
Key Personnel, Henry M. Jackson Foundation, Inc.

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Signatures and dates:

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Valerie Stander, PhD
Principal Investigator
Naval Health Research Center, San Diego, CA

_____/_____/_____

Alexis Takata, BS
Naval Health Research Center
Henry M. Jackson Foundation, Inc.

_____/_____/_____

Deanne Millard, BS
Naval Health Research Center
Henry M. Jackson Foundation, Inc.

_____/_____/_____

Felicia Carey, PhD
Naval Health Research Center

_____/_____/_____

Henry M. Jackson Foundation, Inc.C. REFERENCES

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10. United States General Accounting Office. Foreign Assistance: Contributions to Child Survival Are Significant, But Challenges Remain. Washington, DC: US General Accounting Office, 1996.
11. United States General Accounting Office. Defense Health Care: Medical Surveillance Improved Since Gulf War, But Mixed Results in Bosnia. Washington, DC: United States General Accounting Office, 1997.
12. United States General Accounting Office. Gulf War Illnesses: Improved Monitoring of Clinical Progress and Reexamination of Research Emphasis Are Needed. Washington, DC: United States General Accounting Office, 1997.
13. United States General Accounting Office. Operation Desert Storm: Evaluation of the Air Campaign. Washington, DC: United States General Accounting Office, 1997.

D. SUPPLEMENTAL DOCUMENTS

1. Other Documentation (as required)
 - a. For Research involving Children—Parental Permission and Child Assent
 - b. Recruitment materials (advertisements/flyers, email solicitations, telephone screen, scripts, recruitment briefing scripts and/or Power Point presentations).
 - c. Instruments, Data Collection Forms and Case Report Forms—including surveys, questionnaires, subject diaries, subject correspondence (letters, emails, postcards, etc.)
 - d. Product package or Label Sample
 - e. For FDA-Regulated Studies and/or studies using drugs, biologics or devices
 - i. For Investigational Drug, Biologics and Devices:
 1. FDA Letter for Investigational New Drug application (IND) or Investigational Device Exemption (IDE) application
 2. FDA Form 1571 and FDA Form 1572
 3. Investigator Brochure
 - ii. For Approved Drug, Biologics and Devices:
 1. FDA letter of approved IND or IDE
 2. Package Insert or User's Manual
 - f. Survey/OPNAV Approval (if required for questionnaire survey)
[Usually obtained after IRB approval].
 - g. Foreign Country Host Government Approval (if research is performed abroad) and foreign language translations of consent and survey instruments)
2. Collaborative Studies (as required)
 - a. Collaborating Institution's Federalwide Assurance or DoD Assurance and/or DON Assurance Addendum
 - b. Institutional Agreement for IRB Review (IAIR)
 - c. Institution and Investigator Roles and Responsibilities (IIRR) form
 - d. Documentation of review and action taken by all collaborating institution(s)
 - i. Acceptable results of review are: approval, exemption from review, joint review, or other formal review agreement
 - ii. Certification by the principal investigator that protocol submitted for review is the same final copy approved or under simultaneous review by collaborating institution(s)
3. Minutes of the Meeting of the IRB (to be added by IRB)
4. Command Recruitment Endorsements (to be obtained post-IRB approval)

E. SUPPLEMENTAL DOCUMENTS—ABT COLLABORATION PROTOCOL



Signed_FamilyCollab
orationProtocol_2014

F. SUPPLEMENTAL DOCUMENTS—ABT DATA USE AGREEMENT



NMR-4171 BUMED
APPROVED DUA btw l

G. SUPPLEMENTAL DOCUMENTS—FAMILY MAILINGS

Results of the 2015 Nonresponder Family Study Phone Call Pilot Test

The pilot test phone calls submitted in a previous IRB modification, which was approved on March 5, 2015 were conducted Tuesday, March 10 2015 through Friday, March 13 2015. We attempted to contact a total of 38 Millennium Cohort Family Study participants who had yet to complete their follow-up survey by calling phone numbers provided by the participant on their baseline survey as a means to remain in contact. All participants were called between the hours of 8am and 7pm within their respective time zones. No participant received more than three phone calls, and no phone messages were left for any participant. A copy of the call log has been included in this submission for reference.

We attempted to call 13 participants lacking a correct mailing address and a correct email address. Of this group, 3 participants (23.1%) provided updated contact information, 6 participants (46.2%) were unable to be reached, 3 phone numbers (23.1%) were found to be incorrect or no longer in service, and 1 participant (7.6%) asked to be removed from this wave of contacts, but would like to be contacted again for future follow-ups.

We attempted to call 11 participants lacking a correct mailing address. Of this group, 4 participants (36.4%) provided updated contact information, 4 participants (36.4%) were unable to be reached, 1 phone number (9.1%) was found to be incorrect or no longer in service, and 2 participants (18.1%) asked to be removed from the study.

We attempted to call 14 participants lacking a correct email address. Within this group, 2 participants (14.3%) provided updated contact information, 6 participants (42.9%) were unable to be reached, 5 phone numbers (35.7%) were found to be incorrect or no longer in service, and 1 participant (7.1%) was removed from this wave of contacts since they are currently incarcerated and unable to complete the survey.

In summary, 9 participants (23.7%) provided updated contact information, 16 participants (42.1%) were called, but we only reached their voicemails, 9 (23.7%) of the dialed phone numbers were no longer current phone numbers for the intended participant, 2 participants (5.3%) asked to be removed from this wave of contacts, and 2 participants (5.3%) asked to be removed from the study.

Overall, findings from this pilot test resulted in the retrieval of updated contact information and positive feedback from the majority of reached participants. Due to these results, we would like to request to call the remaining 860 Family Study participants who have not completed a follow-up survey and provided a phone number on their baseline survey as a means to remain in contact. Subjects will be contacted via telephone Monday through Friday between the hours of 8am and 7pm within their time zone. A maximum of three phone call attempts will be made per subject and a log of every attempt will be kept. If a specific participant is not able to be reached, a message will be left for the participant on the third call attempt.

Calls will be made by a third-party company hired for the sole purpose of this phone call outreach task. The company hired will sign a confidentiality agreement, and will return all data and call logs upon completion of the calls. All callers will be provided the below script, and trained by the Millennium Cohort Family Study Coordinator prior to contacting any participants.

2015 Nonresponder Family Study Phone Call Script

Phase II 2015: Contact by Phone

Subjects will be contacted via telephone 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. For participants contacted during the pilot study we request to attempt one more call in order to leave them a message this time if they do not answer the phone. In total, we will attempt to contact a total of N = 860 participants who provided phone numbers to the study team at baseline.

Script

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

[When participant is clearly not the one answering]

My name is (insert name) and I'm calling on behalf of the Department of Defense Family Study. May I speak with (insert participant name).

❖ [If not available] Is there a better time for me to call to reach (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 and your spouse participated in a very important and unique Department of Defense study designed to follow military families over time in an effort to understand the impact of military life on the health and well-being of spouses, service members, and children. We have been trying to reach you over the last several months to ask for your continued participation in the Millennium Cohort Family Study survey, and to provide you with a small token of our appreciation.

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

[If Yes or No]

We have also sent Postal mailings that have included a lunch bag, a sample survey, and a \$5 gift card. Have you received these mailings?

[If Participant has received both Emails and Postal mailings]

Great! We are glad you are receiving information about the study.

❖ Do you currently plan on completing your online follow-up survey?

- **[If Yes]** That's wonderful to hear. 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 military families. An email will arrive in a few days that includes a link to the survey to make completing the survey easier. Thank you for participation. Have a nice day!
- **[If No/Not sure]** Did you know that the Family Study is unique from other surveys you may be asked to complete? It is the only study that follows military families from all branches of the military, including Reserve and National Guard, over time. **Even if your marital status has changed or if your spouse has separated from the military, your participation is still vital!** This year's survey has been modified to make the questions as relevant as possible to our 10,000 members. In addition, we tailor every survey to the unique circumstances of the person completing it, so we don't waste your time with questions that don't apply to you.
 - Would you like to speak to a member of the Family 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 Family Study and your participation. Have a nice day.
 - ◆ **[If No]** Would you like the website address? It provides contact information, study background, a link to the survey, and other useful information.
 - **[If Yes]** www.familycohort.org
 - 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. We will also send you an email in a few days with a link to the survey to make completing it easier. Thank you for your time, have a nice day.
 - **[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 online follow-up survey. Thank you for your time, have a nice day.

[If Participant has not received one or both methods of contact]

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.familycohort.org and select “Update Contact Information.” We will be sending you an email in a few days that includes a link to the survey to make completing the survey easier. 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 military families. Thank you for your participation in the Family 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 only military family study that follows families over time, and includes families from all branches of the military, including Reserve and National Guard. **Even if your marital status has changed or if your spouse has separated from the military, your participation is still vital!** This year’s survey has been modified to make the questions as relevant as possible to our 10,000 members. In addition, we tailor every survey to the unique circumstances of the person completing it, so we don’t waste your time with questions that don’t apply to you.
 - Would you like to speak to a member of the Family 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 Family 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.familycohort.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. We will also send you an email in a few days with a link to the survey to make completing it easier.
 - **[If No]** Would you like us to stop contacting you?
 - **[If Yes]** We respect your decision. You will be removed from all future contacts. Thank you for your past participation. Have a nice day.

- **[If No]** We hope you choose to complete your online 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 Family Study. We want to let you know that we have been trying to contact you via postal mail and email over the last few months. A few years ago you and your spouse participated in a very important and unique Department of Defense study designed to follow military families over time called the Millennium Cohort Family Study. The Family Study is part of a strategic plan to understand the impact of military life on the health and well-being of spouses, service members, and children. We hope you have heard from us and received your gifts of appreciation. We have sent you a lunch bag, a sample survey, and a \$5 gift card, in addition to post cards, and study updates with the hope that you will complete your online follow-up survey. The information you provide is completely confidential and provides the Department of Defense with vital information about military families. You are one of only 10,000 people chosen to represent military families 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 military families. We hope you choose to complete this year's survey by visiting our study website www.familycohort.org. We will send you an email in the next few days with a link to the survey to make completing it easier. Thank you for your past participation and for your service as a military spouse.

Phone Call Follow-Up Email

This email will be sent to all participants who were included in the call outreach and received a phone call or voice message during the two previous weeks (n=860)

Subject line: Following Up

Dear **NAME**,

Over the last two weeks, we have had the privilege to speak to several hundred of our valued Family Study participants. We appreciated the opportunity to personally emphasize how your input and participation in the Family Study will make a difference in the lives of military families. Please consider sharing your unique perspective by completing your follow-up survey today.

To login to your survey, please visit www.familycohort.org, click **Start Survey** and enter your **Subject ID: XXXXXXXX**.

Thank you for your dedication to our Service members and their families.

Very Respectfully,

Carrie Donoho, PhD
Captain, MS, USA
Spouse of a Veteran and Active Duty Family Study researcher

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.

April Reminder Email

This email will be sent to all partial survey completers who were not included in the phone call outreach method

Subject line: Don't forget to complete your survey

Dear **NAME**,

Thank you for the time you have already dedicated to start your follow-up Family Study survey. As a valued member of this important Department of Defense study, your participation is critical to better understand the strengths and needs of military families. In order to ensure your input is included in future study results, please log back in to complete the remaining questions on your survey.

To login to your survey, please visit www.familycohort.org, click **Start Survey** and enter your **Subject ID: XXXXXXXX**.

Thank you for your dedication to our Service members and their families.

Very Respectfully,

Carrie Donoho, PhD
Captain, MS, USA
Spouse of a Veteran and Active Duty Family Study researcher

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April Non-Responder Email

This email will be sent to all Non-responders who were not included in the call outreach method

Subject line: Make an Impact on Military Family Health

Dear **NAME**,

As a member of the Millennium Cohort Family Study, you are part of a select group of individuals with the unique opportunity to make a lasting impact in the lives of millions of military spouses and children.

Your participation in the initial 2011-2013 survey helped to create a preliminary understanding of the challenges and opportunities uniquely associated with military life, but there is still so much to learn. Help us build a better understanding of military families by completing your follow-up survey today.

To complete your survey, please visit the study website www.familycohort.org, click **Start Survey** and enter your **Subject ID: XXXXXXXX**.

Thank you for helping us fill in the gaps.

Very Respectfully,

Carrie Donoho, PhD
Captain, MS, USA
Spouse of a Veteran and Active Duty Family Study researcher

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May Pre-Incentive Mailing– Card Text

This card will be sent to all Non-responders and Partial completers. Mailing will include a 5X7 Family Study note card, a \$2 bill and will be sent via FedEx or a special envelope/box.

Paragraph for the bold comment on the top half of the card:

As a member of the Family Study, you are sending a strong message that you care about the health and well-being of Service members and families, and that you are committed to scientific research efforts dedicated to this mission!

Card Body:

Dear Name,

We want to take this opportunity to thank you for your past participation in the Millennium Cohort Family Study and for your support of military family research! Please accept this token of our appreciation.

The Family Study team is comprised of active duty Service members, military spouses, and civilian scientists committed to understanding the impact of military life on Service members and their families. Your dedication to the Family Study makes it possible to provide evidence-based policy recommendations to military and civilian leaders, and to develop interventions informed by your survey responses.

Even if your marital status has changed or if your spouse has separated from the military, your participation is still vital! This year's survey has been modified to make the questions as relevant as possible to our 10,000 members. In addition, we tailor every survey to the unique circumstances of the person completing it, so we don't waste your time with questions that don't apply to you.

We hope you decide to complete your Family Study follow-up survey in the near future. Simply go to WWW.FAMILYCOHORT.ORG and click on 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

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Pre-Incentive Email

This email will be sent to all Non-responders and Partial completers.

Subject Line: Proudly participate in the Family Study

Dear **NAME**,

We hope you received our card last week with a small token of our appreciation for your continued involvement as a valued member of the Millennium Cohort Family Study.

By sharing your personal experiences with us, you are helping to shape the future health and well-being of military couples and families. We hope that you realize how valuable your continued participation is, and are proud to play a part in such groundbreaking and impactful research.

Your past participation helped begin the process of identifying the unique characteristics that define a military family. In order to develop a deeper understanding of the evolving complexities of military life, we are asking for your continued participation in this important study.

To complete your survey, please visit the study website www.familycohort.org, click **Start Survey** and enter your **Subject ID: XXXXXXXX**.

Thank you for your important contribution to this significant research study.

Very Respectfully,

Carrie Donoho, PhD
Captain, MS, USA
Spouse of a Veteran and Active Duty Family Study researcher

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.

Subject: Last Chance to Participate

[NAME],

As we remember the sacrifices made by our Service members and their families, we ask that you consider representing current and future military spouses by completing your follow-up Family Study survey. The Millennium Cohort Family Study Team recognizes the importance of your contribution to protecting America's freedom, and our goal is to understand the unique effects of military life on the health and well-being of military families.

Your opportunity to be a part of this important study will be ending very soon, so don't delay in sharing your unique thoughts and experiences.

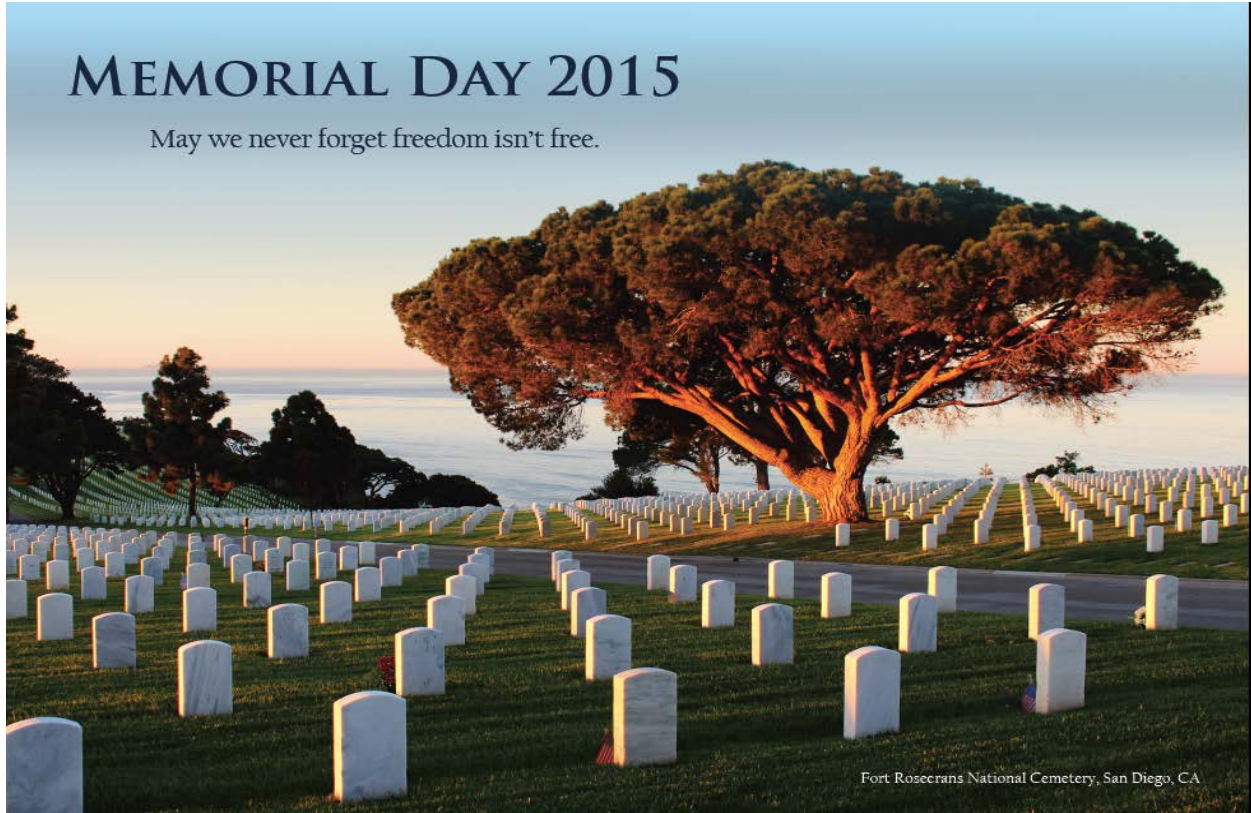
To complete your survey, please visit the following link: www.familycohort.org.

Your Subject ID is: XXXXXXXX

Thank you so much for your participation.

Very Respectfully,
Carrie Donoho, PhD
Captain, MS, USA
Spouse of a Veteran and Active Duty Family Study researcher

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.2015.0019.



Department of Defense
 Deployment Health Research Department
 c/o Naval Health Research Center
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Dear <NAME>,

On this Memorial Day, the Millennium Cohort Family Study Team remembers those who sacrificed their lives for our nation, and we thank you for your family's contribution to protecting America's freedom.

The Family Study Team is dedicated to improving the lives of Service members and their families. Your participation in this study helps provide valuable information to healthcare providers and military leaders about the short and long-term concerns of military families.

If you have not completed your online survey, please visit www.familycohort.org, click "Start Survey", and enter your Subject ID: XXXXXXX. We truly value your time and participation in this important study. Please know that your continued involvement in the Family Study will make a difference in the lives of military 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.2015.0019

Millennium Cohort Family Study Shortened Survey Mailing #2 – Cover Letter

Dear NAME,

During National Military Family Month, the Millennium Cohort Family Study Team would like to thank you for the many contributions you make every day in support of the military and our nation. We join the country in celebration of the Military Family and honor the commitment and sacrifices made by the families of our nation's Service members.

Through your continued involvement, the Family Study will be able to provide vital information to military leaders and policymakers working to support families like yours. We value your participation, even if your marital status has changed or your spouse is no longer in the military. We know your time is valuable, so we have created a shortened paper version of our 2014 online survey with carefully selected questions. Please consider taking 5 minutes to complete this 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.familycohort.org, click "Start Survey," and enter your Subject ID: XXXXXXXX.

Thank you for your continued commitment to current, former, and future military families.

Very respectfully,

Dr. Valerie Stander

Principal Investigator of the Millennium Cohort Family Study

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.2015.0019.



What is the Millennium Cohort Family Study Calendar?

As a token of our gratitude for your continued involvement in this important study, you should have received the 2016 Family Study Calendar in the mail, which features artwork by our Family Study Team members' children.

Throughout the year, you will have the opportunity to submit your child(ren)'s artwork for possible inclusion in the 2017 Family Study Calendar and online gallery!

Artwork submission instructions:

- All submissions should be on **8.5"x11" white paper** in **landscape orientation**.
- There are no strict guidelines for the artwork content, but we encourage the artwork to reflect your family and your relationship with the military.
- Please ensure that your child(ren)'s artwork does not contain any personally identifiable information such as names, addresses, etc.
- The deadline for artwork submission is **November 1, 2016**.
- To ensure the artwork file is suitable for printing in **high resolution**, please follow these recommendations:
 1. Scan the artwork using a scanner set at 300dpi resolution or higher.
 - OR
 2. In a setting with good lighting, take a picture of the artwork using a camera with 5 megapixels or more.
- To upload the artwork file, please complete the form below, attach your child(ren)'s artwork, and click submit.

Examples



2017 Family Calendar Artwork Submission Form

Please fill out the following consent form, and then proceed to the next page where you will be allowed to upload your child's artwork.



Naval Health Research Center
140 Sylvester Road
San Diego CA 92106-3521

Naval Health Research Center (NHRC) Media Consent Form

NHRC publishes information through various media forms—print (newsletters, magazines, reports, brochures, news releases, and feature articles), electronic (web site) and audio and video productions. The purpose of this media release form is to obtain permission for NHRC to use images or original artwork submitted to the Millennium Cohort Family Study.

By signing below, I give consent for NHRC to edit, use and reuse my child's drawing/original artwork for Millennium Cohort Family Study publications and marketing materials.

Minor child's first name Minor child's last name


Parent/guardian first name Parent/guardian last name Date

Email

This personal information will not be shared outside of NHRC.

If you have questions about the Millennium Cohort Family Study, please contact Dr. Valerie Stander at (800) 571-9248 or DOD.FamilyStudyPI@mail.mil

If you have questions about this form, please contact NHRC's Public Affairs Officer, Regena Kowitz at (619) 553-0548.

I'm not a robot 
[Privacy - Terms](#)

Next

The Millennium Cohort Family Study is a Department of Defense research project at the Deployment Health Research Department, located in San Diego, California. Note DMDC Reference Number 00-0019, RCS Number DD-HA(AR)2106, OMB Approval Number 0720-0028, ASD/HA/TMA Protocol Number CDO-06-206, and Primary IRB Protocol Number NHRC.2000.0007
[Privacy Policy](#)

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Contact Us

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- » Phone: (800) 571-9248





Millennium Cohort
Family Study

Because Families Serve Too

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2017 Family Calendar Artwork Submission Form (Part 2)

You're almost done! Please complete this form to finish uploading your child's artwork.

Child's Age Family Study Subject ID

Please tell us about your family's current or past affiliation with the military (Maximum of 300 characters):
(Examples: Husband is currently serving in the Navy; Wife served for 8 years in the Army; Husband and I are both serving in the Air Force)

Military affiliation (Maximum 300 characters)

Family Cohort Logo.JPG

Please upload your image file in JPEG, TIFF, or PNG format. Maximum file size is 15MB.

The Millennium Cohort Family Study is a Department of Defense research project at the Deployment Health Research Department, located in San Diego, California. Note DMDC Reference Number 00-0019, RCS Number DD-HA/ARJ2106, OMB Approval Number 0720-0029, ASD/HA/TMA Protocol Number CDO-06-206, and Primary IRB Protocol Number NHRC.2000.0007
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Contact Us

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- » Phone: (800) 571-9248

July 2016 email

Subject: Have your child's artwork featured in the Family Study Calendar

Happy 4th of July from the Millennium Cohort Family Study Team! We thank you and your family for your past, present, and future contributions in preserving our nation's independence.

We hope you are enjoying your summer and would like to remind you to submit your child's artwork for our 2017 calendar. Your child's drawing could be featured in our 2017 Family Study Calendar and online gallery!

To review the contest guidelines and submit your child's artwork, please visit

<http://www.familycohort.org/calendar>

Very respectfully,

Dr. Valerie Stander

Principal Investigator of the Millennium Cohort Family Study

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.2015.0019.

October 2016 email

Subject: Last chance to submit your child's artwork

Have you submitted your child's artwork for the 2017 Family Study Calendar contest yet? The deadline is quickly approaching! Submit your child's drawing by Tuesday, November 1, to be considered for the 2017 Calendar that will be mailed to nearly 10,000 of your fellow Family Study participants!

Simply visit <http://www.familycohort.org/calendar> for the contest guidelines and online gallery. We can't wait to see your child's masterpiece!

Very respectfully,

Dr. Valerie Stander

Principal Investigator of the Millennium Cohort Family Study

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.2015.0019.

Month of the Military Family Postcard – 2017

During National Military Family Month, the Millennium Cohort Family Study Team would like to thank you for your commitment and support of our military. We honor the dedication, strength and sacrifices made by the families of our nation's Service members.

We appreciate your participation in the 2014-2015 Family Study follow-up survey. Your continued involvement in this important study makes it possible for the Family Study to provide instrumental information to policymakers and military leaders to make a positive difference for all military families.

Very respectfully,

Dr. Valerie Stander,
Principal Investigator of the Millennium Cohort Family Study

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.2015.0019.

2017 CALENDAR-ARTWORK SOLICITATION

COVER LETTER

Dear NAME,

Happy holidays to you and your family from the Millennium Cohort Family Study team!

As a member of the Family Study, the information you provide makes it possible to understand the health and well-being of military families over time. Even though our study is currently off cycle, we would like to extend a token of our appreciation for your continued involvement, and have enclosed a 2017 Family Study calendar, featuring the artwork made by the children of your fellow Family Study participants.

Beginning January 1, 2017, once again we will be accepting submissions of artwork created by the children of study participants throughout the year, and posting as many as possible to our online art gallery on the Family Study website. At the end of the year, 12 submissions will be selected to be included in the 2018 calendar. To review the submission guidelines and upload your child's drawing or painting, please visit www.familycohort.org/calendar.

Thanks again to all of you for being a part of this program of research and part of the Millennium Cohort Family Study community! We wish you all the best for a happy holiday season and healthy New Year!



Dr. Valerie Stander
Principal Investigator of the Millennium Cohort Family Study

FEBRUARY 2017 EMAIL

Subject: Now accepting submissions for the 2018 calendar

We hope you received the 2017 Family Study calendar last month and are considering submitting some of your child(ren)'s artwork for the 2018 calendar! Perhaps you have a beautiful winter mural hanging on your refrigerator or a decorative Valentine's Day drawing sitting on your kitchen counter that would make a great addition to the calendar.

To review the contest guidelines and make a submission, please visit <http://www.familycohort.org/calendar>. As a reminder, your Subject ID is #####. We are excited to see your child(ren)'s artistic creations!

Very respectfully,

Dr. Valerie Stander

Principal Investigator of the Millennium Cohort Family Study

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.2015.0019.

JULY 2017 EMAIL

Subject: Have your child's artwork featured in the Family Study Calendar

Happy 4th of July from the Millennium Cohort Family Study Team! We thank you and your family for your past, present, and future contributions in preserving our nation's independence.

We hope you take this opportunity to submit your child(ren)'s artistic depiction of 4th of July fireworks and summer festivities! Their drawing could be featured in our 2018 Family Study Calendar and online gallery!

To review the contest guidelines and make a submission, please visit <http://www.familycohort.org/calendar>. As a reminder, your Subject ID is #####. We are excited to see your child(ren)'s artistic creations!

Very respectfully,

Dr. Valerie Stander

Principal Investigator of the Millennium Cohort Family Study

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OCTOBER 2017 EMAIL

Subject: Last chance to submit your child's artwork

Have you submitted your child(ren)'s artwork for the 2018 Family Study Calendar contest yet? The deadline is quickly approaching! We hope you consider submitting your child(ren)'s fall and pumpkin-themed drawings by Monday, October 17, to be considered for the 2018 Calendar that will be mailed to nearly 10,000 of your fellow Family Study participants!

To review the contest guidelines and make a submission, please visit <http://www.familycohort.org/calendar>. As a reminder, your Subject ID is #####. We are excited to see your child(ren)'s artistic creations!

Very respectfully,

Dr. Valerie Stander

Principal Investigator of the Millennium Cohort Family Study

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MONTH OF THE MILITARY CHILD POSTCARD TEXT

Dear Name,

During the Month of the Military Child, the Millennium Cohort Family Study Team recognizes the strength and resilience of all military families. We join the nation in honoring military children and families for their contributions to our country.

We want to remind you that your children have the opportunity to contribute artwork for the 2018 Family Study calendar, which will be sent to nearly 10,000 households. Please visit <http://www.familycohort.org/calendar> for more details and instructions to submit your child's artwork!

As a member of the Millennium Cohort Family Study, you are contributing to an effort of profound importance. Please know that you are making a difference in the lives of current and future generations of military families by remaining engaged in this important study.

Thank you for your continued participation!
Very respectfully,

Dr. Valerie Stander
Principal Investigator of the Millennium Cohort Family Study

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BIRTHDAY CARD TEXT

Dear Name,

On behalf of the Millennium Cohort Family Study team, I would like to wish you a very Happy Birthday!!!

I would also like to tell you how much I personally appreciate your commitment and thoughtfulness as a participant in this study. It's an honor for our team to be a small part of your life and the life of your family.

May this next year bring you great health and happiness!

Very respectfully,

Dr. Valerie Stander
Principal Investigator of the Millennium Cohort Family Study

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Month of the Military Family postcard

Postcard text:

During National Military Family Month, the Millennium Cohort Family Study Team honors the invaluable sacrifices of our military families, past and present. Along with all Americans, we recognize and thank you and your family for the important role you play in protecting our nation.

Additionally, we value your continued connection with the Family Study during our off-cycle. In 2018, we will launch our next follow-up survey and hope to have your support and participation. Your involvement in the study makes it possible to inform military leaders and policymakers of the experiences of military families and to improve measures that impact families like yours.

Very respectfully,

Dr. Valerie Stander

Principal Investigator of the Millennium Cohort Family Study

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2018 Calendar Cover Letter

Dear NAME,

Happy holidays to you and your family from the Millennium Cohort Family Study team!

As a member of the Family Study, the information you provide makes it possible to understand the health and well-being of military families over time. We would like to extend a token of our appreciation for your continued involvement, and have enclosed a 2018 Family Study calendar, featuring the artwork made by the children of your fellow Family Study participants.

Beginning January 1, 2018, once again we will be accepting submissions of artwork created by the children of study participants throughout the year, and posting as many as possible to our online art gallery on the Family Study website. Submissions will be accepted until October 14, 2018, at which point 12 submissions will be selected as monthly photos and 1 will be selected as the cover art for the 2019 calendar. To review the submission guidelines and upload your child's drawing or painting, please visit www.familycohort.org/calendar.

Thanks again for being a part of this program of research and part of the Millennium Cohort Family Study community! We wish you all the best for a happy holiday season and a healthy New Year!

Dr. Valerie Stander
Principal Investigator of the Millennium Cohort Family Study

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Family Calendar.pdf

March 2018 email

Subject: Your child's artwork in the 2019 Family Study calendar

[NAME],

The Millennium Cohort Family Study calendar has been our way of showcasing the military family community, past and present, and a gesture of our appreciation for your study participation.

We are currently accepting your children's artwork for our 2019 Family Study calendar contest. Please consider submitting your child's drawings of Valentine's Day, St. Patrick's Day, or springtime family events!

To review the contest guidelines and make a submission, please visit <http://www.familycohort.org/calendar>. As a reminder, your Subject ID is #####. We are excited to see your child's artistic creations!

Very respectfully,

Dr. Valerie Stander

Principal Investigator of the Millennium Cohort Family Study

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July 2018 email

Subject: Have your child's artwork featured in the Family Study calendar

[NAME],

Happy 4th of July from the Millennium Cohort Family Study team! We thank you and your family for your past, present, and future contributions in preserving our nation's independence.

We hope you take this opportunity to submit your child's artistic depiction of 4th of July fireworks and summer festivities! Their drawing could be featured in our 2019 Family Study Calendar and online gallery!

To review the contest guidelines and make a submission, please visit <http://www.familycohort.org/calendar>. As a reminder, your Subject ID is #####. We are excited to see your child(ren)'s artistic creations!

Very respectfully,

Dr. Valerie Stander

Principal Investigator of the Millennium Cohort Family Study

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September 2018 email

Subject: Last chance to submit your child's artwork

[NAME],

Have you submitted your child's artwork for the 2019 Family Study Calendar contest yet? The deadline is quickly approaching, and we are still searching for the perfect tree or family-themed drawing for our calendar cover!

We hope you consider submitting your child's fall, winter, and holiday drawings by Monday, October 15, to be considered for the 2019 Calendar that will be mailed to your fellow Millennium Cohort Family Study participants!

To review the contest guidelines and make a submission, please visit <http://www.familycohort.org/calendar>. As a reminder, your Subject ID is #####. We are excited to see your child(ren)'s artistic creations!

Very respectfully,

Dr. Valerie Stander

Principal Investigator of the Millennium Cohort Family Study

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