INSTITUTIONAL REVIEW BOARD

MODIFICATION REVIEW

Date of Review:	July 9, 2024	Protocol Number: NHRC.2015.0019
Protocol Title:	Millennium Cohort Family Study: A Sub-study of the Millennium Cohort Study	
Principal Investigator:	Hope McMaster, PhD	
Project ID/WBS:	Family Cohort, N1240/1ZH8VA	

The principal investigator submitted a modification application for a protocol that was previously classified as minimal risk. With funding from Military Operational Medicine Research Program (MOMRP) (JPC-5) and Research Development Testing and Evaluation (RDT&E) funds, the primary objectives of this study are to: (1) 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; (2) assess the impact of military service and deployment on the quality of the relationships between Service members, spouses, and their children; (3) examine the association between family member outcomes and Service member outcomes; (4) identify vulnerability and resilience factors for deployment stress-related outcomes for spouses and children of deployed Service members; (5) operationalize and validate predictors of military family resilience and readiness based on revised DoD definitions of those constructs; (6) assess unique challenges faced by diverse and potentially vulnerable subgroups within the military community, including single parents, same-sex couples, dual-military couples, and female-sponsored military families; and (7) study the long-term adjustment of military families and the interdependence of family health and well-being over the course of separation from military service and transition to civilian life. An additional 30-60 active-duty military spouses will be recruited to complete an anonymous survey to beta test the proposed additions to the 2023 follow-up survey. These respondents will be a separate group from those enrolled in the Family Study and will not be included in the 47,400 total number of subjects previously outlined in the protocol.

The modification requests to:

(1) Add Yohannes Haile (Leidos, Inc.) to our protocol as Key Support assisting with database management and data request tracking
(2) Implement an addendum to the informed consent (noting a PI change)
(3) Administrative updates to the approved Single Parent and Panel 2 Consent forms (correct the running head, Family Study email address, and the IRB phone number, and add survey approval numbers and expiration dates)
(4) Administrative updates to Section 5.3 of the protocol (personnel updates)
(5) Update the protocol at Section 13.1 (note consent addendum re: PI change)
(6) Update the protocol at Section 13.2 (outline the plan to provide a $5 digital Amazon gift codes as a pre-incentive to specific sub-groups of interest to encourage follow-up participation)

(7) Update the protocol at Section 13.4 (noting that the participant also has the option to select a button instead of providing a signature on the informed consent)
(8) Contacts for the 2024-2025 survey cycle submitted for approval include:
   a. 2024 Targeted Letter for Widows
   b. 2024 Family Study Newsletter
   c. 2024 Newsletter Email
   d. 2024 Pre-incentive Notecard
   e. 2024 Pre-incentive Notecard Email
   f. 2024 Reminder Letter
   g. 2024 Reminder Letter Email
   h. 2024 Reminder Postcard
   i. 2024 Reminder Postcard Email
   j. 2024 Infographic Mailing
   k. 2024 Infographic Email
   l. 2024 Month of the Military Family Postcard
   m. 2024 Month of the Military Family Email
   n. 2024 Reminder Letter_2
   o. 2024 Monthly reminder Emails

The Principal Investigator is informed that any personnel changes approved via this modification submission will not display on this version of the study protocol. This is due to a glitch in the eIRB system and eIRB system administrators are currently working on a solution to mitigate the problem. The next approved submission will create a new version of the protocol that reflects these personnel changes. This outcome letter will serve as official documentation that the personnel changes requested on this modification submission have been approved by the NHRC IRB.

The IRB Vice-Chair has determined that already-enrolled subjects do not need to be informed of the changes to the revised consent form and/or re-undergo the consent process with the revised consent form, with the opportunity to withdraw from participation. Currently enrolled subjects will not be affected by the requested changes and the changes will not affect the safety, rights, or welfare of subjects.

A Waiver or alteration of informed consent has been granted for this study in accordance with 32 CFR§219.116(f) in that this study is classified as minimal risk; the requirement to obtain informed consent from the record holders is impractical in that the patients are numerous and geographically dispersed; and the decision to waive informed consent will not adversely affect the rights and welfare of the record holders of this study population.

The Principal Investigator is informed that any research personnel engaged in human subject research on this protocol with missing or expired required training certificates are not authorized to work on this study until the NHRC HRPP Office receives their current training certificates for file.

The NHRC IRB Vice-Chair reviewed this submission under the expedited review authority and permitted under 32 CFR §219.110(b)(2). The 32 CFR §219.111 criteria for the approval of research have been met. The NHRC Vice-Chair approves this protocol modification.

The research is expected to end on September 30, 2042.

In accordance with 32 CFR § 219.109(f), the Revised Common Rule, continuing review of this protocol is no longer required. All other reporting requirements remain in effect. The NHRC IRB Vice-Chair approves this research.

ADITYA PRASAD, MSC
Vice-Chair, Institutional Review Board (IRB)

EIRB Modification Form (Version 19.1)

1.0 Study and PI Info

1.1 Principal Investigator:

Name:

Hope Montgomery Mcmaster, PhD

Email:

hope.mcmaster@gmail.com

PH #:

1.2 Study Information:

Study Title:

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

Study Number:

Family Study NHRC.2015.0019

Expiration Date:

Protocol Abstract/Summary:
Summarize the proposed study in 500 words or less, to include the purpose, the subject population, the study's design type, and procedures

The Millennium Cohort Program (MCP) comprises the Millennium Cohort Study (Millennium Cohort) and the Millennium Cohort Family Study (Family Study). The overarching objective of this program of research is to evaluate the impact of military service, including deployments a nd other occupational exposures, on the long-term health of service members, veterans and family members. Both the Millennium Cohort and the Family Study are large-scale, longitudinal occupational cohorts, followed from the beginning stage of their affiliation with the military community, to understand the long-term impact of military occupational stress on service members and families.

Millennium Cohort first enrolled participants in 2001, however, the program first enrolled spouses from 2011-2013 in conjunction with the 4th panel of service members to join the program. Married spouses of newly enrolled service members with 2-5 years of service were recruited into the Family Survey at that time. Spouses complete online or paper self-report surveys and further consent to allow the study team to link their self-report data with a range of archival data resources, including DoD medical and personnel records to create a comprehensive datbase. Once enrolled spouses are surveyed approximately every three years—both during and after service separation for up to 21 years. The Family Study links the responses of married service members and spouses facilitating dyadic analysis, tracking multiple mental, behavioral, and physical health morbidities and disease trajectories over time, as well as family and couple relationship adjustment and child outcomes. Participants include active duty, Reserve/Guard, and veteran populations.

1.3 Study Status:

Study is open to accrual:

- [ ] No participants have been enrolled
- [x] No additional risks have been identified
- [ ] Participants are currently receiving study intervention
- [x] Participants have been enrolled but none are currently receiving study intervention
- [x] Ongoing data/medical record review/biological specimen collection

Study is closed to accrual:

- ○ Some participants are still receiving study intervention
- ○ Study intervention is complete for all participants; research-related diagnostic tests or follow-up clinic visits are continuing
- ○ Study intervention is complete or there was no intervention and there is ongoing research-related follow-up contact with participants via questionnaires, phones calls, interviews or mailings
- ○ Study intervention is complete or there was no intervention and follow-up is limited to review of medical records or other records (no ongoing contact)
- ○ Study is in data analysis phase only

2.0 Modifications

2.1 Type of modification:

- ☑ Personnel changes
- ☑ Administrative changes
- ☑ Minor Modification – a non-administrative change that does not affect the rights, safety, or welfare of the subjects
- ☐ Major Modification – a change that does affect the rights, safety, or welfare of the subjects
- ☐ Convert to multi-site

2.2 This modification requires changes to (check all that apply):

- ☑ Protocol (This must be selected if making changes to the PI or if making changes to personnel without an EIRB account)
- ☑ Consent documents or Waiver/Modification of Consent (revising or adding new documents)
- ☐ HIPAA Authorization/Waiver
- ☑ Recruitment/Advertising documents
- ☑ Other study documents (revising or adding new documents)

2.3 Has any component of this modification already been implemented?

○ Yes ◉ No

2.4 Does the modification impact study design in such a manner that requires scientific review?

○ Yes ◉ No

2.5 Does this modification impact any Investigators' Conflict of Interest Disclosure form?

○ Yes ◉ No

If yes please explain:

2.6 This modification includes a change to enrollment targets:

○ Yes ◉ No

2.7 * Please describe all changes that are being requested in this submission.

1. We request approval of updates to section 5.3 of the active protocol.

2. We request approval of updates to section 13.2 of the active protocol.

3. We request review of several participant contacts, including both postal mailings and emails that will span period of 6-8 months of the upcoming survey cycle.

4. We request approval of updates to section 13.1 of the active protocol.

5. We request approval of revisions to the previously approved Single Parent Consent Form and the Panel 2 Consent Form.

6. We request approval of updates to section 13.4 of the active protocol.

7. As requested by the IRB we updated the category in eIRB for a participant postcard and email reminder.

2.8 * Explain why these modifications are being made:

1. Section 5.3 of the active protocol has been updated to add Yohannes Haile to our protocol as Key Support Personnel. He will be assisting with database management and data request tracking.

2. Section 13.2 of the active protocol has been updated to outline the plan to provide $5 digital Amazon gift codes as pre-incentives to specific sub-groups of interest in order to encourage follow-up participation.

3. We request review of several participant contacts, including both postal mailings and emails that will span period of 6-8 months of the upcoming survey cycle. In order to encourage follow-up participation, we have developed monthly postal mailings and emails to send to our follow-up participants. Additionally, monthly reminder emails will be sent to all non-responders and partial completers for both the Family Study and Single Parent Module follow-up participants.
These contacts include:

(1) Targeted Letter for Widows
(2) Family Study Newsletter
(3) Newsletter Email
(4) Pre-incentive Notecard
(5) Pre-incentive Email
(6) Reminder Letter
(7) Reminder Letter Email
(8) Reminder postcard
(9) Reminder postcard Email
(10) Infographic Mailing
(11) Infographic Email
(12) Month of the Military Family postcard
(13) Month of the Military Family Email
(14) Reminder Letter
(15) Monthly reminder emails

4. Section 13.1 of the active protocol has been updated to note the changes to the Informed Consent Addendum and the reasoning for the change.

5. The previously approved Single Parent and Panel 2 Consent forms have been updated to reflect the new header requirements, the updated Family Study email address and the updated IRB phone number.

6. Section 13.4 of the active protocol has been updated to note the changes to the consent /consent addendum process for the Family Study surveys.

7. As requested, the category for the 2022 Millennium Cohort Family Study Military Spouse Appreciation Day Postcard was corrected in eIRB from "Consent" to "Other". In addition, the same correction was done for the July 2022 Millennium Cohort Family Study Email Reminder.

2.9 This modification is being submitted as a result of an adverse event (AE) report, protocol violation or incident report, unanticipated problem involving risks to subjects or others (UPIRTSO), or publication of a new Investigator's Brochure (IB) or other safety data:

○ Yes ◉ No

○ UPIRTSO Adverse event report
○ Protocol violation or incident report
○ New Investigator's Brochure
○ Other safety data

Was this event previously reported?

○ Yes ○ No

2.10 Have the risks to subjects changed (i.e. increased or decreased) by the modification?

○ Yes ◉ No

If yes, describe how the modification will affect the risk/benefit ratio for the subjects:

3.0 Personnel Modification

3.1 Please identify any change in personnel:

Added to study:

If applicable, please add the new Principal Investigator for the Protocol:

If applicable, please select the new Research Staff personnel:

A) Additional Investigators

B) Research Staff

If applicable, please add any new Study Contact:

The Project Contact(s) will receive all important system notifications along with the Principal Investigator. (e.g. The project contact(s) are typically either the Study Coordinator or the Principal Investigator themselves).

If applicable, please select any existing Personnel you wish to remove:

4.0 Revisions to the Protocol

4.1 Make revisions to the protocol template form as necessary:

If making changes to the PI, or to personnel without an EIRB account, changes to the Personnel Details (5.0) section are required.

Edit/ View	Version	Title
	1.39	EIRB Protocol Template (Version 1.39) - Attached

4.2 Do you plan to notify currently or previously-enrolled subjects of these changes?

- ○ Yes – all subjects
- ○ Yes – currently-enrolled subjects only
- ◉ No

If no, why not (e.g., Correcting typos or administrative changes that do not affect subjects' decision to participate?)

These are administrative changes that do not affect the subject's decision to participate.

If yes, describe the process for informing subjects (e.g., re-consent, letter sent to subjects, etc.)

5.0 Consent change notification

5.1 Consent modification:

- ☐ Full Revised Consent Document
- ☑ Consent Addendum

6.0 Consent documents

Indicate which types of documents you are attaching:

- ☐ Revisions to approved consent documents
- ☑ New consent documents

Attach revisions to existing consent documents or add new ones here:
(When possible, attach Word documents instead of PDFs.)

Version	Title	Category	Language	Expiration Date	Consent Outcome	Checked Out	View Document
1.1	Addendum to Informed Consent	Consent	English		Approved		436.70 KB

7.0 Other Study Documents

7.1 Attach Other Study Documents (revised documents or new documents)

Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
1.0	Response - Pre-Review AM38 #1	Other				11.56 MB

1.0	Investigators Compliance Attestation - Haile	Other				90.70 KB
1.0	2024 Monthly Reminder Emails	Other		Approved		447.92 KB
1.0	2024 Month of the Military Family Email	Other		Approved		440.08 KB
1.0	2024 Month of the Military Family Postcard	Other		Approved		1.98 MB
1.0	2024 Infographic Email	Other		Approved		441.47 KB
1.0	2024 Reminder Postcard Email	Other		Approved		439.18 KB
1.0	2024 Reminder Postcard	Other		Approved		3.60 MB
1.0	2024 Reminder Letter Email	Other		Approved		438.25 KB
1.0	2024 Pre-incentive Notecard Email	Other		Approved		438.76 KB
1.0	2024 Newsletter Email	Other		Approved		440.06 KB
1.0	2024 Family Study Newsletter	Other		Approved		3.40 MB
1.1	2024 Reminder Letter_2	Other		Approved		440.77 KB
1.1	2024 Infographic Mailing	Other		Approved		843.18 KB
1.1	2024 Reminder Letter	Other		Approved		438.48 KB
1.1	2024 Pre-incentive Notecard	Other		Approved		443.21 KB
1.1	2024 Targeted Letter for Widows	Other		Approved		440.81 KB

8.0 Updated Conflict of Interest Disclosure

8.1 Are there any changes in any financial interests related to this study or in any conflicts of interest of the PI or any other investigator?	
○ Yes ◉ No	

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 3900.39E CH-1 (Human Research Protection Program),
- OPNAV Instruction 5300.8C (Personnel Surveys),
- NAVHLTHRSCHCEN Instruction 3900.2K (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)

HAILE.YOHANNES.GEBREMEDHIN.1551864533 Digitally signed by HAILE.YOHANNES.GEBREMEDHIN.1551864533 Date: 2024.06.26 13:45:50 -07'00'

26 / 06 / 24

Yohannes Haile
Key Personnel
Naval Health Research Center (NHRC)
Leidos

EIRB Protocol Template (Version 1.39)

1.0 General Information

***Please enter the full title of your study:**

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

***Please enter the Protocol Number you would like to use to reference the protocol:**

Family Study NHRC.2015.0019
* This field allows you to enter an abbreviated version of the Protocol Title to quickly identify this protocol.

Is this a multi-site study (i.e. Each site has their own Principal Investigator)?

No

Does this protocol involve the use of animals?

○ Yes ◉ No

2.0 Add Site(s)

2.1 List sites associated with this study:

Primary Dept?	Department Name
◆	**Navy** - Naval Health Research Center (NHRC)

3.0 Assign project personnel access to the project

3.1 *Please add a Principal Investigator for the study:

Mcmaster, Hope Montgomery, PhD

Select if applicable

☐ Student ☐ Site Chair
☐ Resident ☐ Fellow

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

Carnes, Nathan Christopher
Co-Investigator
Rull, Rudolph P
Co-Investigator

Stander, Valerie A, Ph.D.
Co-Investigator
Trone, Daniel W, Ph.D.
Co-Investigator
Walter, Kristen Hanzak, Ph.D.
Co-Investigator

B) Research Support Staff

Altarejos, Isabel Velasco, MPH
Team Member
BRAMER, BRITTANY ANN
Research Coordinator
Bauer, Lauren Marie
Research Coordinator
Birenbaum, Beth
Research Coordinator
Carey, Felicia R
Team Member
Carinio, Sarah Rebecca
Team Member
Castaneda, Sheila Faye, PhD
Team Member
Lovec-Jenkins, Denise Elaine
Research Coordinator
Mcmaster, Hope Montgomery, PhD
Team Member
Sharifian, Neika, PhD
Team Member
Sheppard, Beverly DESIREE
Team Member
Tannenbaum, Karen, PhD
Team Member
Walstrom, Jennifer Lee
Team Member

3.3 *Please add a Protocol Contact:

Altarejos, Isabel Velasco, MPH
BRAMER, BRITTANY ANN
Bauer, Lauren Marie
Lovec-Jenkins, Denise Elaine
Mcmaster, Hope Montgomery, PhD
Stander, Valerie A, Ph.D.

The Protocol Contact(s) will receive all important system notifications along with the Principal Investigator. (i.e. The protocol contact(s) are typically either the Protocol Coordinator or the Principal Investigator themselves).

3.4 If applicable, please select the Designated Site Approval(s):

Add the name of the individual authorized to approve and sign off on this protocol from your Site (e.g. the Site Chair).

4.0 Project Information

4.1 * What department(s) will be associated with this protocol?

Psychology

4.2 * Is the IRB of record for this study an IRB/HRPP that does NOT use EIRB? If Yes, complete the application according to the IRB/HRPP Determination.

If your Projects or Protocols are under the oversight of another IRB that does use EIRB, stop this submission and contact the core site and request an invitation as a performing site.

If your Project or Protocol is now being submitted for the first time to an IRB that does use EIRB, continue with this application and answer the questions to be reviewed by the IRB.

Answering yes means the board of record is an IRB that does NOT use EIRB.

- ○ Yes
- ◉ No

4.3 * Is this protocol research, expanded access, or humanitarian use device?

- ◉ Yes
- ○ No

4.4 * What type of protocol is this?

- ☑ Behavioral Research
- ☐ Biomedical Research
- ☐ Clinical trial (FDA regulated)
- ☐ Educational Research
- ☐ Expanded Access
- ☐ Humanitarian Use Device (HUD)
- ☐ Psychosocial Research
- ☐ Oral History
- ☐ Other

4.5 Are you conducting this project in pursuit of a personal degree?

- ○ Yes
- ◉ No

4.7 * Is this human subjects research? (As defined by 32 CFR 219) Human subject means a living individual about whom an investigator (whether professional or student) conducting research:
(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
(ii) Obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens.

- ◉ Yes
- ○ No

4.8 * Do you believe this human subjects research is exempt from IRB review?

○ Yes ◉ No

5.0 Personnel Details

5.1 Does the Principal Investigator have a Permanent Change of Station (PCS) Date or Estimated Institutional Departure Date (EIDD)?

○ Yes ◉ No

5.2 List any Research Team members without EIRB access that are not previously entered in the protocol:

Name: (Last, First, M.I.)	Phone Number:	Email Address:	Associated Institution:
Stander, Valerie , A Role on Protocol: Co-Investigator, engaged in HSR	(619) 553-7174	valerie.a.stander.civ@health.mil	NHRC, MPH, CIV
McMaster, Hope, M Role on Protocol: Principal Investigator; engaged in HSR		hope.m.mcmaster.civ@health.mil	NHRC, MPH, CIV
Rull, Rudolph, P Role on Protocol: Co-investigator, engaged in HSR	(619) 553-9267	rudolph.p.rull2.civ@health.mil	NHRC, MPH, CIV
Trone, Daniel, W Role on Protocol: Co-investigator, engaged in HSR	(619) 767-4567	daniel.w.trone.civ@health.mil	NHRC, MPH, CIV
Walter, Kristen, H			

Role on Protocol: Co-investigator, engaged in HSR	(619) 553-0546	kristen.h.walter.civ@health.mil	NHRC, MPH, CIV
Name: (Last, First, M.I.) Castaneda, Sheila, F Role on Protocol: Co-investigator, engaged in HSR	Phone Number:	Email Address: sheila.f.castaneda.civ@health.mil	Associated Institution: NHRC, MPH, CIV
Name: (Last, First, M.I.) Carnes, Nathan, C. Role on Protocol: Co-investigator, engaged in HSR	Phone Number: 619-553-4363	Email Address: nathan.c.carnes.mil@health.mil	Associated Institution: NHRC, USN
Name: (Last, First, M.I.) Carey, Felicia R Role on Protocol: Key Support, engaged in HSR	Phone Number: (619) 767-4905	Email Address: felicia.r.carey.ctr@health.mil	Associated Institution: NHRC, MPH, CIV

5.3 Are any Contractors or Subcontractors involved in this study? If yes, please list them and describe their role.

(•) Yes ( ) No

Name: (Last, First, M.I.) Roesch, Scott Role on Protocol: Key Support, engaged in HSR	Phone Number:	Email Address: scott.c.roesch.ctr@health.mil	Associated Institution: NHRC, MPH, Leidos; IAIR executed
Name: (Last, First, M.I.) Moreno Ignacio, David Role on Protocol: Key Support, engaged in HSR	Phone Number:	Email Address: david.morenoignacio.ctr@health.mil	Associated Institution: NHRC, MPH, Leidos; IAIR executed

Name: (Last, First, M.I.) Ray, Travis N Role on Protocol: Key Support, engaged in HSR	Phone Number:	Email Address: travis.n.ray2.ctr@health.mil	Associated Institution: NHRC, MPH, Leidos (Remote - Tennessee); IAIR executed
Name: (Last, First, M.I.) Barkho, Wisam Z Role on Protocol: Key Support, engaged in HSR	Phone Number: (619) 553-9337	Email Address: wisam.z.barkho.ctr@health.mil	Associated Institution: NHRC, MPH, Leidos; IAIR executed
Name: (Last, First, M.I.) Dorrell, Michael Role on Protocol: Key Support, engaged in HSR	Phone Number: (619) 553-7522	Email Address: michael.s.dorrell2.ctr@health.mil	Associated Institution: NHRC, MPH, Leidos; IAIR executed
Name: (Last, First, M.I.) Boparai, Satbir K Role on Protocol: Key Support, engaged in HSR	Phone Number: (619) 553-7980	Email Address: satbir.k.boparai.ctr@health.mil	Associated Institution: NHRC, MPH, Leidos; IAIR executed
Name: (Last, First, M.I.) Bukowinski, Anna T Role on Protocol: Key Support, engaged in HSR	Phone Number: (619) 553-4690	Email Address: anna.t.bukowinski.ctr@health.mil	Associated Institution: NHRC, MPH, Leidos; IAIR executed
Name: (Last, First, M.I.) Esquivel, Alejandro P Role on Protocol: Key Support, engaged in HSR	Phone Number: (619) 767-4557	Email Address: alejandro.p.esquivel.ctr@health.mil	Associated Institution: NHRC, MPH, Leidos; IAIR executed

Name: (Last, First, M.I.) Woodall, Kelly A Role on Protocol: Key Support, engaged in HSR	Phone Number: (619) 553-4363	Email Address: kelly.a.woodall.ctr@health.mil	Associated Institution: NHRC, MPH, Leidos (Remote - Florida); IAIR executed
Name: (Last, First, M.I.) Geronimo-Hara, Toni Rose T Role on Protocol: Key Support, engaged in HSR	Phone Number: (619) 553-7938	Email Address: tonirose.t.geronimo-hara.ctr@health.mil	Associated Institution: NHRC, MPH, Leidos; IAIR executed
Name: (Last, First, M.I.) Kolaja, Claire A Role on Protocol: Key Support, engaged in HSR	Phone Number: (619) 553-7859	Email Address: claire.a.kolaja.ctr@health.mil	Associated Institution: NHRC, MPH, Leidos; IAIR executed
Name: (Last, First, M.I.) Rivera, Anna C Role on Protocol: Key Support, engaged in HSR	Phone Number: (619) 567-9025	Email Address: anna.c.rivera4.ctr@health.mil	Associated Institution: NHRC, MPH, Leidos (Remote - Washington); IAIR executed
Name: (Last, First, M.I.) Tu, Xin Role on Protocol: Key Support, engaged in HSR	Phone Number: (858) 246-1969	Email Address: x2tu@ucsd.edu	Associated Institution: NHRC, MPH, Innovative Employee Solutions; IIA executed
Name: (Last, First, M.I.) Jacobson, Isabel G Role on Protocol: Key Support, engaged in HSR	Phone Number: (619) 553-0684	Email Address: isabel.g.jacobson.ctr@health.mil	Associated Institution: NHRC, MPH, Leidos; IAIR executed
Name:			

(Last, First, M.I.) Richardson, Sabrina M Role on Protocol: Key Support, engaged in HSR	Phone Number: (619) 553-7598	Email Address: sabrina.m.richardson5.ctr@health.mil	Associated Institution: NHRC, MPH, Leidos; IAIR executed
Name: (Last, First, M.I.) Speigle, Steven J Role on Protocol: Key Support, engaged in HSR	Phone Number: (619) 553-8096	Email Address: steven.j.speigle.ctr@health.mil	Associated Institution: NHRC, MPH, Leidos; IAIR executed
Name: (Last, First, M.I.) LeardMann, Cynthia A Role on Protocol: Co-Investigator, engaged in HSR	Phone Number: (619) 553-8447	Email Address: cynthia.a.leardmann.ctr@health.mil	Associated Institution: NHRC, MPH, Leidos; IAIR executed
Name: (Last, First, M.I.) Altarejos, Isabel, V Role on Protocol: Key Support, engaged in HSR	Phone Number: (619) 507-0337	Email Address: isabel.v.altarejos.ctr@health.mil	Associated Institution: NHRC, MPH, Leidos; IAIR executed
Name: (Last, First, M.I.) Carinio, Sarah, R Role on Protocol: Key Support, engaged in HSR	Phone Number: (619) 767-4847	Email Address: sarah.r.carinio.ctr@health.mil	Associated Institution: NHRC, MPH, Leidos; IAIR executed
Name: (Last, First, M.I.) Tannenbaum, Karen Role on Protocol: Key Support, engaged in HSR	Phone Number:	Email Address: karen.tannenbaum.ctr@health.mil	Associated Institution: NHRC, MPH, Leidos (Remote - Washington); IAIR executed

Name: (Last, First, M.I.) Sheppard, Beverly, D Role on Protocol: Key Support, engaged in HSR	Phone Number:	Email Address: beverly.d.sheppard.ctr@health.mil	Associated Institution: NHRC, MPH, Leidos; IAIR executed
Name: (Last, First, M.I.) Walstrom, Jennifer, L Role on Protocol: Key Support, engaged in HSR	Phone Number: (619) 553-9145	Email Address: jennifer.l.walstrom.ctr@health.mil	Associated Institution: NHRC, MPH, Leidos; IAIR executed
Name: (Last, First, M.I.) Lovec-Jenkins, Denise, E Role on Protocol: Key Support, not engaged in HSR	Phone Number: (619) 553-7433	Email Address: denise.e.lovec-jenkins.ctr@health.mil	Associated Institution: NHRC, MPH, Leidos; IAIR executed
Name: (Last, First, M.I.) Bauer, Lauren, M Role on Protocol: Research Coordinator, engaged in HSR	Phone Number:	Email Address: lauren.m.bauer2.ctr@health.mil	Associated Institution: NHRC, MPH, Leidos (Remote - California); IAIR executed
Name: (Last, First, M.I.) Jamil, Ammar Role on Protocol: Key Support; engaged in HSR	Phone Number: (619)767-4719	Email Address: marc5477@gmail.com	Associated Institution: NHRC, MPH Leidos; IAIR executed
Name: (Last, First, M.I.) Sharifian, Neika Role on Protocol: Key Support; engaged in HSR	Phone Number: (619) 767-4590	Email Address: neika.sharifian.ctr@health.mil	Associated Institution: NHRC, MPH, Leidos; IAIR executed

Name: (Last, First, M.I.) Brown, Marvin Role on Protocol: Key Support; not engaged in HSR	Phone Number: (718) 644-6505	Email Address: marvinbrown563@gmail.com	Associated Institution: NHRC, MPH, Abbtech
Name: (Last, First, M.I.) Consigli, Rebecca Role on Protocol: Key Support; not engaged in HSR	Phone Number:	Email Address: rebecca.a.consigli.ctr@health.mil	Associated Institution: NHRC, MPH, Abbtech
Name: (Last, First, M.I.) Lewis, Crystal Role on Protocol: Key Support; engaged in HSR	Phone Number:	Email Address: crystal.l.lewis43.ctr@health.mil	Associated Institution: NHRC, MPH, Leidos; IAIR executed
Name: (Last, First, M.I.) Bramer, Brittany Role on Protocol: Key Support, not engaged in HSR	Phone Number:	Email Address: brittany.a.bramer.ctr@health.mil	Associated Institution: NHRC, MPH, Leidos; IAIR executed
Name: (Last, First, M.I.) Toma, Helen Role on Protocol: Key Support, engaged in HSR	Phone Number:	Email Address: helen.toma.ctr@health.mil	Associated Institution: NHRC; Leidos, Inc., IAIR executed
Name: (Last, First, M.I.) Haile, Yohannes Role on Protocol: Key Support, engaged in HSR	Phone Number: 619-767-4847	Email Address: yohannes.g.haile.ctr@health.mil	Associated Institution: NHRC; Leidos, Inc., IAIR executed

5.4

Will you have a Research Monitor for this study?

- ○ Yes
- ◉ No
- ○ N/A

6.0 Data/Specimens

6.1 Does the study involve the use of existing data or specimens only (no interaction with human subjects)?

◉ Yes ○ No

6.2 Sample Characteristics(s):

Specify the type of records or specimens used in this study

This study involves the collection of self-report data through both online survey and paper mail survey data collection methods. Participant data is further linked with archival electronic records from multiple sources as specified below in section 10.2.

6.3 Eligibility Criteria:

List the criteria for data/specimen collection (e.g., age, diagnoses, test limits, etc.)

Participants must be married spouses of active-duty, reserve-guard or coast-guard personnel with 1-5 years of service who have been invited to participate in the Millennium Cohort Study. Sampling frames for Millennium Cohort Program recruitment are randomly selected from DoD personnel records, obtained from the Defense ManPower Data Center. Spouses must be listed in the Defense Eligibility Enrollment Reporting System (DEERS), Defense Manpower Data Center (DMDC), or the Military Data Repository (MDR) as married to a military service sponsor eligible for Millennium Cohort in a selected sampling frame to be including in the Family Study sampling frame.

Additionally, beginning with Panel 5, all Millennium Cohort participants who report being single parents will be invited to participate in the Family Study and asked to complete a brief module regarding parenting and the well-being of their children.

6.4 Will the team have access to identifiable information?

- ○ NO, the study team will NOT have direct access to identifiable information
- ◉ YES, the study team will have direct access to identifiable information.

* If yes, waiver of informed consent or modification of consent must be included with this application, see the Recruitment and Consent section.

7.0 Funding and Disclosures

7.1 Source of Funding:

Funding Source	Funding Type	Amount

:	Military Operational Medicine Research Program (MOMRP) (JPC-5)

:	Research Development Testing and Evaluation (RDT&E) funds

Total amount of funding:

7.2 Do you or any other Investigator(s) have a disclosure of a personal interest or financial nature significant with sponsor(s), product(s), instrument(s) and/or company(ies) involved in this study?

○ Yes ◉ No

All personnel engaged in research must complete and attach a Conflict of Interest (COI) form.

8.0 Study Locations

8.1 Is this a collaborative or multi-site study? (e.g., are there any other institutions involved?)

○ Yes ◉ No

8.2 Study Facilities and Locations:

Institution	Site Name	Site Role	FWA or DoD Assurance Number	Assurance Expiration Date	Is there an agreement?	IRB Reviewing for Site
No records have been added						

Other:

Other Institution Site	Site Role	FWA or DoD Assurance Number	FWA or DoD Expiration Date	Is there an agreement?	IRB Reviewing for Site
No records have been added					

8.3 Are there international sites?

Attach international approval documents, if applicable, when prompted. Note: Ensure local research context has been considered

○ Yes ◉ No

8.4 Is this an OCONUS (Outside Continental United States) study?

○ Yes ◉ No

Select the area of responsibility:

Have you obtained permission from that area of responsibility? (This is a requirement prior to study approval)

○ Yes ○ No

9.0 Study Details

9.1 Key Words:

Provide up to 5 key words that identify the broad topic(s) of your study

family, spouse, child, health, longitudinal

9.2 Background and Significance:

Include a literature review that describes in detail the rationale for conducting the study. Include descriptions of any preliminary studies and findings that led to the development of the protocol. The background section should clearly support the choice of study variables and explain the basis for the research questions and/or study hypotheses. This section establishes the relevance of the study and explains the applicability of its findings

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 Family Cohort 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.

In 2018, the Department of Defense Office of Military Community and Family Policy (MC&FP) again called for assistance in understanding military family resilience and readiness (Thompson 2018). In order to inform military family policy and support programs across the Military Family Readiness System, MC&FP sponsored a National Academy of Sciences committee to review their current programs and policies. Among multiple recommendations, the committee highlighted the evolving nature of the DoD population, and the importance of broadening the definition of family in research and policy across the DoD (NAS, 2019). Furthermore, their report emphasized a critical knowledge gap in operationalizing and studying factors related to family resilience and readiness. In the context of an evolving military system and a changing demographic composition of the military family community, an ongoing study of the challenges families face within the military community and the ability of families to maintain resilience and readiness is critical.

9.3 Objectives/Specific Aims/Research Questions:

Describe the purpose and objective(s) of the study, specific aims, and/or research questions /hypotheses

As an integrated component of the Millennium Cohort Program, the Family Study has a broad overarching purpose to understand the nature, severity, and consequences of specific stressors inherent in military life for service members and their families. The DoD continually strives to take care of all members of the military community, both to preserve the readiness of the force and fulfill an ethical commitment to care for their own. Recently, the Office of the Under Secretary of Defense for Personnel and Readiness reconfirmed the importance of promoting family readiness as part of their strategic plan to enhance the lethality and readiness of the warfighter.5 In support of this, the Family Study, not only seeks to understand the impact of deployment and other military life experiences on the spouses and children of service members, but also the effects of family life and relationships on service member readiness and performance.

Currently, the Family Study and the Millennium Cohort Study are the largest and only long-term studies of health and well-being among service members and their families. Under the guidance of the Millennium Cohort Strategic Board, both have a mandate to assess the impacts of past, current, and future military conflicts on service members and their families, with a recommendation to enroll new panels of participants approximately every six years. This Millennium Cohort Program works to ensure the DoD will continue to have a valid baseline and long-term documentation of the health trajectories of service members and their families in response to evolving service-related stressors and exposures.

1. 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.
- To operationalize and validate predictors of military family resilience and readiness based on revised DoD definitions of those constructs.
- To assess unique challenges faced by diverse and potentially vulnerable subgroups within the military community, including single parents, same-sex couples, dual-military couples, and female-sponsored military families.
- To study the long-term adjustment of military families and the interdependence of family health and well-being over the course of separation from military service and transition to civilian life.

2. 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.
- Evaluate dyadic strategies to maximize participant response rates across both service member and spouse respondents in the context of dramatically declining survey response rates across the DoD and nationwide.

9.4 Study Design:

Describe study design in one to two sentences (e.g., prospective, use of existing records/data /specimens, observational, cross-sectional, interventional, randomized, placebo-controlled, cohort, etc.). Specify the phase – Phase I, II, III, or IV – for FDA-regulated investigational drug research

The Millennium Cohort Family Study is a longitudinal cohort study, collecting data using a self-report survey administered approximately every three years.

9.5 Target Population:

Describe the population to whom the study findings will be generalized

US service members from all US service branches and components, including the coast-guard and their spouses and children.

9.6 Benefit to the DoD:

State how this study will impact or be of benefit to the Department of Defense

The Millennium Cohort Family Study is the only DoD population-based research effort evaluating the physical and mental health of military-affiliated spouses and children. It is also the only current DoD-wide longitudinal study of the impact of past and future military operational exposures on the families of service personnel. As such, the results of this study are important to

multiple DoD stakeholders in understanding the needs of military families and better supporting them in the future. The Millennium Cohort has knowledge transition agreements in place with critical stakeholders who serve spouses and families to provide information about family well-being, including the DoD Office of Military Community and Family Policy Office providing oversite for programs such as family readiness, family service centers, and family advocacy, the DoD Sexual Assault Prevention and Response Office, and Human Military supporting TRICARE benefits for the Eastern U.S.

10.0 Study Procedures, Data Management, and Privacy

10.1 Study Procedures:

Describe step-by-step how the study will be conducted from beginning to end

PROPOSED DATES OF RESEARCH: 03 Mar 2015 to 30 Sep 2042
PROJECT TITLE AND ID#: Family Cohort N1240
WORK BREAKDOWN STRUCTURE (WBS) (OR JON, IF A LEGACY PROJECT): 1ZH8VA

Due to logistical reasons, the Family component of the Millennium Cohort Study was submitted to the Naval Health Research Center's Institutional Review Board as a standalone substudy 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 (Office of Management and Budget (OMB) Control Number 0703- 0064 Report Control Symbol (RCS): DD-NAVY(AR)2678 and System of Records Notices (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 substudy 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 third follow-up data collection cycle, revised survey documents and procedures that are developed for each new wave of data collection are being submitted to the IRB for approval as part of a modification to this protocol.

In conjunction with the recruitment of participants into Millennium Cohort Study Panel 5, military spouses will be recruited into a second participant panel for the Family Study. The sampling frame for Panel 2 will be composed of all married partners of eligible personnel included in the sampling frame for Panel 5. A random sampling frame of 600,000 personnel with 1-5 years of service from all DoD service branches and both active-duty, Reserve/Guard, and Coast Guard components will be provided to Millennium Cohort Program researchers by Defense Manpower Data Center (DMDC), with the objective of successfully contacting 500,000 with an invitation to participate in the service member study. The sampling frame will be stratified so that it comprises up to 35% married service members (N = 210,000). Across marital status, 80% will be male (~168,000 male, married) and 20% will be female (~42,000 female, married) service members. Furthermore, to maximize utility, a sample of service members with complete data for the following variables has been requested: component, Basic Active Service Date (BASD), Pay Entry Base Date (PEBD), date of birth, Fname, Lname, race/ethnicity, pay grade, marital status, sex, social security number, and service branch. Last, any service members included in previously requested sampling frames for Millennium Cohort Survey Panels 1-4 also will be excluded.

The sampling frame for the Family Study will be developed by matching the social security numbers (SSN) of all 500,000 service members in the final Millennium Cohort Panel 5 sampling frame with records designating them as the sponsors for military beneficiary spouses in the

Military Health System's Data Repository (MDR) Master Person Index (MPI) or Defense Manpower Data Center (DMDC). If multiple spouses are matched to the same military sponsor, MDR's VM6 Beneficiary Level (VM6BEN) dataset will be used to confirm the correct spouse. Additional information regarding the data management procedures and variables extracted for the sampling frame are described in section 10.14. Participant recruitment for Panel 2 is detailed further in section 13.1.

Subjects will participate in the study online, using a weblink and random study ID provided to them in each participant contact they receive. Study invitations will direct potential volunteers to an NHRC study website where they will each use their random study ID to login securely. Informed consent information will be available to participants in the opening screens of the survey. Additional information regarding participant consent can be found in section 13.4. Once they have acknowledged consent, the online interface will guide participants through the survey, ensuring appropriate skip patterns are followed and providing additional clarification and definitions of terms in key locations in order to reduce participant burden. Completing the survey will take approximately 45 minutes. However, participants will be able to save their work and logout at any time. They can login again later to answer further questions as many times as they choose until they complete the survey. The online survey will not include any requests for personal identifying information. The data will be entered in limited deidentifeid fashion and will be linked with personal identifiers at NHRC later, using the assigned random study IDs.

When they have finished answering all relevant questions, or whenever they choose to be done, participants can click a button at the end of the survey to submit it. Once submitted, the survey will redirect participants to a site supported by a private, subcontracted company where they will be able to choose among options for a $10 post incentive. This site will ask them to provide their address so that their incentive can be mailed to them. However, this information will be collected independently of their survey responses, preserving the security of their data. Further information about the nature and procedures for the distribution of subject incentives is provided in section 13.2.

The Millennium Cohort Program plans to conduct an experiment to determine the impact of the timing of dyadic invitations to participate in the Family versus Service Member surveys, as well as the nature of specific incentives during the course of the Panel 2 recruitment cycle. A group of 2,000 dyads from the Family and Service Member sampling frames will be held out from the initial study invitations, and will be included in this experiment. The experiment will be initiated within two months of the initial launch of Panel 2 recruitment. Married dyads will be assigned to 1 of 5 experimental groups. Each experimental group will vary by combination of recruitment type and incentive type (see table below).

INCENTIVE TYPE	RECRUITMENT TYPE	
Single	**Dyadic**	
Post	Group 1	Group 3
Pre/Post	Group 2	Group 4
Bonus		Group 5

Service members assigned to Single Recruitment will be invited to participate in the Millennium Cohort Study 8 weeks prior to their spouses being invited to the Family Study. Couples assigned to Dyadic Recruitment will be invited simultaneously. Couples assigned to a Post-Incentive group will receive contacts explaining that they will receive a gift card for completion of the survey. Couples assigned to a Pre/Post Incentive group will receive a postal invitation that includes a magnetic picture frame, as well as messaging about the opportunity for a gift card after completing the survey. Couples assigned to the Bonus Incentive group will receive contacts explaining that they will receive a gift card for completing the survey, as well as a Bonus $10 gift card for the Family Study participant if both members of the couple complete their survey. When participants log into the study website survey portal, their survey experience will be the same as participants not included in the experiment.

Although Family Study primarily enrolls legally married partners of U.S. military personnel invited to enroll into the Millennium Cohort Study, this definition of "family" excludes some of the more vulnerable types of families in the military community, such as single-parent families. Since the Family Study is the only DoD-wide evaluation of mental and physical well-being of spouses and children, it is important to work to represent all military families more completely. In pursuit of this, during the 2020 data collection cycle, the Family Study team will recruit self-reported single parent service members-who submit an online Millennium Cohort Survey-to "dual enroll" in the Family Study. Those who agree to volunteer will only complete a short (approximately 10-minute) module extracted from the Family Survey on parenting and child well-being. Additional information about the recruitment, and consent of single parents can be found in sections 13.1 and 13.4.

Once enrolled in Panel 2, as for Panel 1, spouses will be resurveyed approximately every three years up to 7 times. Overall, participation will last approximately through the year 2032 for Panel

1 and the year 2042 for Panel 2. Follow-up surveys for Panel 1 and Panel 2 will be fielded together, with coordinated content. Each future follow-up survey will continue to be submitted to the IRB as a separate modification for approval prior to use. To facilitate these follow-up surveys, participants' contact information will be updated regularly through federal or civilian records including email, phone, or residential address. Furthermore, so that we can stay in communication with participants over the timeframe of this long-term study, we will communicate with participants semi-annually to verify the accuracy of their contact information, and thank them for their ongoing participation.

Bi-annual postal mailings (ex: postcards, letters, brochures, pamphlets, etc.) and/or emails will be sent to all participants during the Month of the Military Family (November), the Month of the Military Child (April), and/or Military Spouse Appreciation Day (May) in order to maintain a familiar rapport with our participants, keep our participants engaged in the Family Study, and receive updated contact information. All contacts will be submitted for IRB approval prior to contact prior to any participant contact.

Participants also will be able to receive updates regarding study results through the Millennium Cohort Family Study website (www.familycohort.org). This website will be regularly updated with published studies and release informational materials such as infographics for participants and the public.

We plan to conduct an experiment to determine the impact of a pre-cycle contact to participate in the 2023 Family Study survey cycle among Panel 2 participants who only completed a partial baseline survey. A group of 1,530 Panel 2 participants with a signed consent form, and a partially completed baseline survey will be randomly divided into two groups. The first group will receive a postal mailing and a $10 gift card to Amazon.com, while the second group will only receive a postal mailing. We will analyze response rates of the two groups to determine which method encouraged higher participation, as well as survey completion rates.

We plan to select a minimum of one artwork submission per year to highlight in a Family Study mailing and/or communication. As a token of appreciation, a $5 gift card and thank you letter will be sent to the Millennium Cohort Family Study participants whose child(ren)'s artwork submissions are selected.

10.2 Data Collection:

Describe all the data variables, information to be collected, the source of the data, and how the data will be operationally measured.

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 below).
Family Study Measures:

1. Physical health history (self-reported medical conditions)
2. General mental health and functional status (Short-Form 36 [SF36] Healthy Survey)
3. Mental disorder screening (Patient health Questionnaire [PHQ] measures for depression, somatization, panic disorder, anxiety, alcohol abuse/dependence, binge eating disorder, and bulimia nervosa)
4. Posttraumatic stress symptoms (Posttraumatic Stress Disorder Checklist-Civilian Version [PCL-C])
5. Adverse childhood events (modified ACE)
6. Alcohol use (CAGE)
7. Sleep quality (Insomnia Severity Index [ISI])
8. Child health (Centers for Disease Control National Survey of Children's Health)
9. Child functioning (Strengths and Difficulties Questionnaire [modified SDQ])
10. Family satisfaction (Family Adaptability and Cohesion Evaluation Scales 4th version [FACES-IV])
11. Family communication (FACES-IV)
12. Marital satisfaction (Quality of Marriage Index [modified QMI])
13. Spouse work and family conflict (Work-Family Conflict Scale [modified WFCS])
14. Single Parent Family & Co-parenting Structure (self-reported)

The single parent module will ask single parent service members questions from the Family Study survey about their family and child well-being, as well as module-specific questions about co-parenting relationship structure and support from the military. Copies of the Panel 2 Baseline survey and single parent survey module have been attached to this protocol including track changes documenting all revisions to the content of these surveys since they were initially approved in August 2018.

Demographic Data:

1. Date of birth (DMDC)
2. Marital status (DMDC)
3. DoD Identification Number (DMDC)
4. Electronic Data Interchange Personnel Identifier (DMDC)
5. Social Security Number (DMDC)
6. First name, Middle Initial, Last name (DMDC)

The Family Study team is requesting a one-time request from DMDC for the most current demographic data for the Panel 2 responders of the Millennium Cohort Family Study. These variables will only be used for identity verification and data cleaning purposes.

We are requesting to retain demographic and military specific data acquired from DMDC for the Millennium Cohort Study Panel 5 sampling frame for all non-responding Panel 5 individuals whose spouse completed a Millennium Cohort Family Study Panel 2 baseline survey. We would also like to request updated deployment data, death data and military separation data from DMDC for these individuals. We are requesting these data so that we may have information on both marital partners and therefore include these couples in dyadic analyses. While we have complete dyadic data for our Panel 1 participants, due to the change in enrollment methodology for Panel 2, we do not have complete data for both partners. By utilizing archival DMDC records, we will be able to include the majority of our Panel 2 responders in dyadic analyses along with our Panel 1 participants.

10.3 At any point in the study, will you request, use, or access health information in any form, including verbal, hard copy and electronic?

(•) Yes ( ) No

10.4 Review the definitions below and respond to the following two questions. If you are not sure of the answers, email DHA.PrivacyBoard@mail.mil for assistance. The *Military Health System (MHS)* is defined as all DoD health plans and DoD health care providers that are organized under the management authority of, or in the case of covered individual providers, assigned to or employed by, the Defense Health Agency (DHA), the Army, the Navy, or the Air Force *MHS workforce members* are employees, volunteers, trainees, and other persons whose conduct, in the performance of work for the MHS, is under the direct control of the MHS, whether or not they are paid by the MHS. *MHS business associates* are persons or entities that provide a service to the MHS and require protected health information (PHI) to provide the service.

Are you an MHS workforce member?

( ) Yes, I am an MHS workforce member
(•) No, I am not an MHS workforce member

10.5 Have you consulted with an MHS data expert to determine the data elements required for your study?

Consulting with a data expert often saves time later in the compliance process because the data expert can advise on the data available in the numerous MHS information systems, the quality of that data and the methods for encrypting and collapsing data. To schedule a consult with an MHS data expert, send an email to: (**DHA.PrivacyBoard@mail.mil**)

( ) Yes, then complete the questions below according to the data consult
(•) No, then complete the questions below according to the best of your knowledge

10.6 Indicate how you will request data from the MHS. Select all that apply.

- [ ] Talking with MHS health care providers or MHS health plans about specific research participants
- [ ] Obtaining MHS hard copy records specific to research participants
- [x] Obtaining data from an MHS information system(s)

10.7 If you are obtaining data from an MHS information system(s), indicate whether you plan to receive a data extract or whether you plan to access an MHS information system directly to create a data set.

A data extract is when the MHS or a contractor provides the data set directly to the researcher. When receiving a data set through data extract, the researcher may indicate whether the data elements should be provided as is, encrypted or collapsed. In contrast to a data extract, access to an information system means that the researcher may directly access an MHS information system and create a data set for the research study

- [x] Data Extract
- [x] Access

10.8 Do you intend to request de-identified data from the MHS in your research study?

There are different two methods for de-identifying data pursuant to HIPAA:
1) Safe Harbor Method: Removing all of the identifiers listed in Table 1 below, provided that the researcher does not have actual knowledge that the remaining data can be used alone or in combination with other information to identify the individual who is the subject of the information
2) Statistical Method: An expert, with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable, determines that the data is not individually identifiable

(•) Yes ( ) No

10.9 Indicate the MHS information system(s) from which you will seek to obtain data

If you do not know which system(s) contains the data elements you need, refer to the Guide for DoD Researchers on Using MHS Data or request guidance from an MHS data expert at: **DHA.PrivacyBoard@mail.mil**.

Below is a list of commonly used MHS systems. If the system from which you seek to obtain data is not listed below, list the name of the system in the "Other MHS Systems" category below
PHI Systems:

MHS Information System	Requesting Data
: MDR	: Yes
: DEERS	: Yes
: PDHRA	: Yes
: PDTS	: Yes
: CHCS	: Yes
: PHDA	: Yes
: TMDS	: Yes

PII-Only Systems:

MHS Information System	Requesting Data
MHS Genesis	: Yes

De-Identified Data & Other Systems:

Information System	Requesting Data
Other MHS System (May include PII and/or PHI) List other system here: AFMES	: Yes
Other MHS System (May include PII and/or PHI) List other system here: Ancillary	: Yes
Other MHS System (May include PII and/or PHI) List other system here: CAPER	: Yes
Other MHS System (May include PII and/or PHI) List other system here: DoDSER	: Yes
Other MHS System (May include PII and/or PHI) List other system here: HCSRN	: Yes
Other MHS System (May include PII and/or PHI) List other system here: HCSRI	: Yes
Other MHS System (May include PII and/or PHI) List other system here: NMOP	: Yes
Other MHS System (May include PII and/or PHI)	

List other system here: SIDR	: Yes
Other MHS System (May include PII and/or PHI) List other system here: TEDN	
Other MHS System (May include PII and/or PHI) List other system here: TEDNI	
Other MHS System (May include PII and/or PHI) List other system here: Death	
Other MHS System (May include PII and/or PHI) List other system here: DMDC	: Yes

10.10 Do you intend to merge or otherwise associate the requested data with data from any sources outside of the MHS, including other DoD systems that are not part of the MHS?

- (●) Yes, will merge data
- ( ) No, will not merge data

10.11 Indicate the data elements about research participants or relatives, employers, or household members of the research participants that you will request from MHS hard copies or from MHS information systems.
If you will merge data, also indicate non-MHS data elements about research participants or relatives, employers, or household members of the research participants that you will have access to in any form or medium.

Direct and Indirect Identifiable Data Elements	DHA Hard Copies	DHA Data Elements to be Accessed	DHA Data Elements Verbal	Extracted DHA Digital Data	Downloaded DHA Digital Data	Non-DHA Hard Copies or Digital
1. Names	☐	☑	☐	☑	☑	☑
2. Postal address with only town, city, state, and zip code	☐	☐	☐	☐	☐	☐

3. Postal address with all geographic subdivisions smaller than state, including street address, city, county, precinct, zip code and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of Census: 1) the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and 2) the initial three digits of a zip code from all such geographic units containing 20,000 or fewer people is changed to 000	☐	☑	☐	☑	☑	☑
4. Dates including all elements (except year) directly related to an individual, including birthdate, admission date, discharge date, and date of death	☐	☑	☐	☑	☑	☑
5. Ages over 89 and all elements of dates						

(including year) indicative of such age, unless you will only request a single category of "age 90 or older"	☐	☐	☐	☐	☐	☐
6. Telephone Numbers	☐	☑	☐	☑	☑	☑
7. Fax Numbers	☐	☐	☐	☐	☐	☐
8. Email Addresses	☐	☑	☐	☑	☑	☑
9. Social Security Numbers	☐	☑	☐	☑	☑	☑
10. Medical Record Numbers (MRN) (including record ID)	☐	☑	☐	☑	☑	☑
11. Health Plan Beneficiary Numbers (including DEERS ID, Electronic Data Interchange Personal Identifier (EDIPI) or Number (EDIPN))	☐	☑	☐	☑	☑	☑
12. Account Numbers	☐	☐	☐	☐	☐	☐
13. Certificate /License Numbers	☐	☐	☐	☐	☐	☐
14. Vehicle identifiers and serial numbers,						

including license plate numbers	☐	☐	☐	☐	☐	☐
15. Device identifiers and serial numbers	☐	☐	☐	☐	☐	☐
16. Web Universal Resource Locators (URLs)	☐	☐	☐	☐	☐	☐
17. Internet Protocol (IP) address numbers	☐	☐	☐	☐	☐	☐
18. Biometric identifiers, including finger and voice prints	☐	☐	☐	☐	☐	☐
19. Full-face photographic images and any comparable images	☐	☐	☐	☐	☐	☐
20. Any other unique identifying number, characteristic, or code (including non-military provider IDs)	☐	☑	☐	☑	☑	☑
21. Free Text Fields	☐	☑	☐	☑	☑	☑

If you are obtaining SSNs, provide a justification as to why and explain why a substitute cannot be used.

Due to guidelines stated within DoDI 1000.30, Reduction of SSN Use within DoD, the reduction or elimination of SSN usage must occur wherever possible. If SSNs are required to complete the project, the PI must provide a justification and explanation as to why a substitution cannot be used.
For example:

- If alternatives to SSN (e.g., EDIPNs or pseudo person IDs) are sufficient in other instances, will those alternatives to SSN usage be sufficient to respond to Congressional inquiries and /or Senior DoD stakeholders inquiries?
- Are alternatives to SSN used first?

• Are those alternatives to SSN insufficient to combine data from multiple data sources? Is the issue that some individuals do not possess alternatives ID numbers and SSN is the only way to identify them?

Continued use of the Social Security Number (SSN) is justified for this system in accordance with DODI Instruction 1000.30 (8): Computer Matching. Continued capture and use of SSNs is necessary for computer matching of electronic sponsor demographic and exposure data with archival data resources, not all of which can accurately be linked without the use of the SSN. The elimination of SSNs would prevent the ability to link sponsor demographic and exposure data from DoD electronic data sources to measures of health outcomes.

a. Will you receive or obtain health information?

Note: *If you indicate you are not receiving health information, the answer must be consistent with the DHA data source. For a non-health information data request, if you are a non-MHS employee or non-MHS business associate, you may not access an information system that has PHI or LDS. For both MHS and Non-MHS employees and MHS business associates, you may* ***NOT*** *include data elements in the above table on: 1) lines 10 or 11, 2) line 21 if the free text field comes from a PHI or LDS system, and 3) lines 12, 13, or 18 if the account numbers, certificate and license numbers, biometric data, or any other data elements are health information created or received by an MHS health care provider, health plan, or business associate in relation to the physical or mental health or condition of an individual or payment for health care.*

(•) Yes, I will receive or obtain health information
( ) No, I will not receive or obtain health information

b. If no data elements were checked in the above table, is it possible that the requested DHA data is or will be identifiable because of any unique data elements, triangulation, or small cell size?

☑ Data elements were checked in the above table, STOP HERE.

NOTE: *A unique data element includes any unique features that alone are not identifiable but that could be used to identify an individual within the context of other information, such as any type of code (such as diagnosis or procedural), rank of general or admiral, gender, or race. Triangulation means using different data elements that when combined can be used to identify an individual, such as including the above lists of unique data elements in a data set. Determining whether an individual is identifiable through triangulation requires consideration of all data elements in combination. Within the military, the use of rank and/or diagnosis code, procedural codes, or any other code that changes on a predictable basis, increases the possibility of identification. Small cell size means that there is only a small number of eligible individuals that satisfy the category description. Department of Defense Manual 6025.13, Medical Quality Assurance and Clinical Quality Management in the Military Health System MHS, provides that the threshold for de-identifying data within the MHS requires a cell size of three, but also states that the de-identification standards must meet the DoD implementation of the HIPAA Privacy Rule. Centers for Medicare and Medicaid also gives guidance on small cell size stating that no data cell less than 11 may be published or displayed. However, the Office for Civil Rights' OCR, which is the official regulatory office for the HIPAA Privacy Rule, provides that OCR does not designate a universal value for small cell size in accordance with the de-identification standard; instead, the cell size should be set at a level that is appropriate to mitigate risk of identification by the anticipated recipient of the data set. This means that a cell size of 3 or 11 may not meet the HIPAA Privacy Rule requirements if the cell size level does not appropriately mitigate risk of identification by the anticipated recipient of the data set.*

Note: If dates are altered as a means of de-identifying the data, diagnosis and procedural codes need to be rolled-up or collapsed. If dates are provided "as time between events," the roll-up is not necessary.

☐ Yes, the DHA data will become identifiable
☐ No, the DHA data will not become identifiable

10.12 Do you believe it is possible for the MHS data to become identifiable because of triangulation, a small cell size, or any unique data element(s)?

Triangulation means using different data elements that are not themselves identifiable but that when combined can be used to identify an individual. For example, triangulation would use rank and race together to determine the identity of an individual with a particular health condition.

Small cell size means that there is only a small number of eligible individuals that satisfy the category description. Guidance for acceptable cell size is available from the Centers for Medicare and Medicaid Services. For example, the rank category of four star generals with a particular diagnosis may be less than 30, so the rank category may need to be expanded to include lower ranks.

A unique data element includes any unique features that are not explicitly enumerated in the categories of data in rows 1 – 20 of the table above (in Section 10.10), but that could be used to identify an individual. Unique data elements include characteristics that are not themselves identifying, such as the rank of general or admiral, or a race or gender, but within the context of other information could be identifiable.

- ○ Yes, I believe there is a reasonable possibility the MHS data will become identifiable
- ◉ No, I believe there is no reasonable possibility the MHS data will become identifiable

10.13 Have you completed and uploaded an appropriate HIPAA document (i.e. HIPAA Authorization will be obtained or Waiver/alteration of HIPAA Authorization is being requested)?

- ◉ Yes
- ○ No
- ○ N/A

If yes, please check which one.

- ☐ HIPAA Authorization
- ☑ HIPAA Waiver (Full or Partial)
- ☐ Other (please provide copies when uploading Other Study Documents)

10.14 Managing Data (Data Management and/or Sharing Plan) and/or Human Biological Specimens for this Study:

Include in this section the plan for acquiring data (both electronic and hard copy), access during the study, data/specimen storage and length of time stored, shipment/transmission, and the plan for storage and final disposition at the conclusion of the study. Describe any data agreements in place for accessing data within and/or outside of your institution (e.g., Data Sharing Agreement, Data Use Agreement, Business Agreements, etc.)

All contacts mailed to the participants (Panels 1 and 2) 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.

Data for the Panel 2 sampling frame will be extracted from multiple MDR data files, including the MPI, VM6BEN, Address (restricted file), and Military Health System (MHS) Genesis. Researchers included on this protocol with approved access to the MDR system will match the Service member SSNs to records for their beneficiary spouses in the MPI and VM6BEN as described in section 10.1, and download identifiers, demographics, and contact information for each eligible spouse directly to a data file on secure NHRC servers. As identifiers, EDIPN, SSN, date of birth, and spouse name will be extracted from the MPI, while Social Security Numbers will be obtained from MHS Genesis. Contact information for participant recruitment will include addresses from the Address (restricted) file and emails obtained from MHS Genesis. A complete list of all variables to be extracted from specific MDR data files for the sampling frame is attached to this protocol.

Beginning with the 2019 data collection cycle, all follow-up survey data for all panels and baseline data submitted for Panel 2 will be collected via the online survey portal. No mailed paper surveys will be used. Participants' data are only identifiable to the study team using the randomly generated study ID participants are given for use in logging into the survey to complete it. The survey does not ask for identifying information and the demographic information collected does not include enough information to deduce individual identities based on an NHRC HIPAA Privacy review. This protects all data on the server in limited deidentified format. All information collected through the Millennium Cohort Family Study online questionnaire will be transferred to Naval Health Research Center servers using Secure Sockets Layer (SSL) data transmission lines. SSL encrypts, or scrambles, all questionnaire data sent over the Internet. Information will only be understandable when it reaches the investigator database.

In preparation of the 2023 Family Study survey cycle, we believe it is necessary to beta test the new questionnaire content. The goal is to assess the face and construct validity of the new items prior to including them in the 2023 survey. An online questionnaire has been developed that includes items assessing military family readiness for military-related separation and deployment. The questionnaire also includes other previously-approved survey measures such as demographics, military characteristics, social support, and well-being. The brief beta test is anonymous and designed to assess the face and construct validity of the newly developed items. The beta test will distribute the questionnaire and assess the constructs in a convenience sample of 30-60 military spouses. All beta test data will be stored securely, as described in the previous paragraph, and destroyed after initial analyses have been completed.

The Family Study links self-report survey data with multiple sources of archival information data based on the informed consent of study respondents during study enrollment. Permissions for archival data linkage occurring prior to the establishment of this protocol (NHRC.2015.0019) are documented in the Millennium Cohort Study protocol (NHRC.2000.0007). Additional data linkages requested since the approval of this protocol include the following.

Family Advocacy Data. 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 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. The specified variables are requested 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 was obtained from DoD FAP, as well as from the Defense Manpower Data Center (DMDC) which is the repository for the database. Once permission was obtained, NHRC provided DMDC with a list of the SSNs for family study participants. DMDC then provided NHRC with all matching records in the Central Registry for those SSNs. Data extracts have been approved every three years in conjunction with the Millennium Cohort Program (MCP) data collection cycles. All data transfers are made using encrypted files either using the DoD 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)

Census Bureau and IRS Data. 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 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.

National Student Clearinghouse. 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.

Social Security Administration. We attempted to obtain selected variables regarding mortality status from the Social Security Administration (SSA) Death Master File, however due to the cost of the desired records, negotiations have been abandoned.

My Career Advancement Account (MyCAA). We would like to obtain selected variables regarding military spouse workforce development and tuition assistance from the Spouse Education and Career Opportunities (SECO) - My Career Advancement Account (MyCAA) scholarship program, which is within the Department of Defense Military Community and Family Policy office. The MyCAA scholarship provides tuition assistance to eligible military spouses who need professional credentials (e.g., licenses, certifications) or associate degrees to meet their career goals. Military spouses eligible for the MyCAA scholarship must have successfully completed high school and are married to an active duty, Reserve or National Guard service member in pay grades E-1 to E-5, W-1 to W-2. and O-1 to O-2.
For Millennium Cohort Family Study participants, we will request the specified variables including: education and training, career level/goal/objectives, career experience, occupation, certifications and licenses, and skill type, with recurring data extracts at the conclusion of each 3-year survey cycle. A data sharing agreement to obtain these data has been established with the DoD, Military Community and Family Policy - SECO

Administrative Portal (SAP) which is the repository for the MyCAA data and a copy has been provided to the IRB. NHRC will provide the SAP office with a list of the EDIPNs for the Family Study participants. SAP will then provide NHRC with all matching records in the MyCAA data base for those EDIPNs. All data transfers will be made in encrypted files using the DoD Safe Site.
The requested variables include the following information for spouses of the Family Study:

EPIDN
Years as a military spouse
Lifestyle Stages
Job search range
Job preference
Sponsor's time in service
PCS move start date
PCS move end date
Summary
Highest Level of Education
Education and Training - Education Type
Education and Training - Degree Type
Education and Training - School
Education and Training - Field of Study
Education and Training - Activities and Societies
Education and Training - Additional Information
Education and Training - Start Date
Education and Training - End Date
Career Level
Experience - Experience Type
Experience - Salary Range
Experience - Company
Experience - Title
Experience - Location
Experience - Description
Experience - Start Date
Experience - End Date
Occupation - Industry
Occupation - Occupation
Career Goal - Summary
Career Goal - Objectives
Certifications & Licenses - Title
Certifications & Licenses - Authority
Certifications & Licenses - License Number
Certifications & Licenses - State Date
Certifications & Licenses - End Date
Skill
MyCAA Scholarship – Date applied for MyCAA
MyCAA Scholarship – Date awarded scholarship
MyCAA Scholarship – Application approved (yes/no/pending review)
MyCAA Scholarship – Date award expiration
MyCAA Scholarship – Completion status
MyCAA Scholarship – Amount awarded
MyCAA Scholarship – School Campus: Name of College/University/Tech school attending
MyCAA Scholarship – School: Type of College/University/Tech school attending (private/public)
MyCAA Scholarship – Name Degree/Certificate/License program
MyCAA Scholarship – Career field
MyCAA Scholarship – Course Code
MyCAA Scholarship – Course Title
MyCAA Scholarship – Course Start Date
MyCAA Scholarship – Course End Date
MyCAA Scholarship – Course Level
MyCAA Scholarship – Spouse Cost

MyCAA Scholarship – Government Cost
MyCAA Scholarship – Refund Total Course Cost
MyCAA Scholarship – Total FA Government Cost
MyCAA Scholarship – Grade
MyCAA Scholarship – Grade Last Updated By
MyCAA Scholarship – Grade Last Updated Date
MyCAA Scholarship – Education level at time of application
MyCAA Scholarship – Service member's paygrade
MyCAA Scholarship – Service member's branch
MyCAA Scholarship – Service member's component

Defense Manpower Data Center (DMDC). We would like to obtain the most current demographic data from DMDC for the Panel 2 responders of the Millennium Cohort Family Study. These variables will only be used for identity verification and data cleaning purposes. In order to verify the identity of our responders as the initially selected individual from our sampling frame, we will be requesting the following variables from DMDC:

Spouse EDIPN
Spouse SSN
Spouse First Name
Spouse Last Name
Spouse Middle Initial
Spouse Birthdate
Marriage date
Service member current marital status and date status became valid
Current Address and date address became valid
Service Member service separation date (if applicable)
Dual military status (if applicable)

Defense Manpower Data Center (DMDC). We would like to retain the demographic and military specific data previously acquired from DMDC for the Millennium Cohort Study Panel 5 sampling frame for all non-responding Panel 5 individuals whose spouse completed a Millennium Cohort Family Study Panel 2 baseline survey. We would also like to request updated deployment data, death data and military separation data. No PHI will be collected for these individuals. These data will be used to complete a dyadic Panel 2 Family Study dataset. The variables previously acquired for the Panel 5 sampling frame are listed below:

Member	Active duty roster member status
YOS	Years of service
ResGrp	Reserve group
SVCCOMP	DMDC created variable-combines service branch and component
Component	Uniformed service organization component code
AFQT	AFQT score at entry
BASD	Basic active service date
PEBD	Pay entry base data
DOE	Date of first enlistment
DOB	Date of birth
DOCC	Duty occupation
POCC	Primary occupation
Fname	First name
Mname	Middle name
Lname	Last name
Email address	Current email address
Current Home Street Address	Current street #, street name, apt or unit #
Current Home City, St., Country	Current city, state & country names
Current Home ZIP+	Current duty 5 + 4 zip code
Current Duty Street Address	Duty street #, street name, apt or unit #
Current Duty City, St., Country	Duty city, state & country names
Current Duty ZIP+	duty 5 + 4 zip code
HOR State	Home of record, state
HOR Country	Home of record, country
Ethnic	Ethnic group membership
Race	Race
Race/Ethnic	DMDC race and ethnicity combined variable

Grade	Member's pay grade
HYEC	Highest educational grade achieved
MAR	Marital status
DMM	Dual military marriage
SEX	Sex
SSN	Social security number
SVC	Service branch
UIC	Unit identification code
EOT	Date of end of recruit training
SOF_flag	Special operations force
SOF_type	Type of SOF position

GENESIS FILES(MDR). We would like to obtain data from multiple GENSIS files within the Medical Data Repository (MDR) for all Panel 1 and Panel 2 responders of the Millennium Cohort Family Study. We will be requesting the following data tables from MDR:

GENESIS Admission Table
GENESIS Appointment Table
GENESIS Basic Encounter Table
GENESIS Episodic Encounter Table
GENESIS Immunization Table
GENESIS Laboratory File
GENESIS Laboratory Results File
GENESIS Location Table
GENESIS Microbiology Results File
GENESIS Microbiology Susceptibility Results File
GENESIS Order File
GENESIS Personnel Table
GENESIS Person Table
GENESIS Pharmacy
GENESIS Radiology File
GENESIS Referral Table
GENESIS Surgery Table
GENESIS Vitals File

In preparation of the 2023 Family Study survey cycle, the team would like to develop a weighted scoring for military life stress content on the follow-up survey. The study team plans to enlist the subject matter expert (SME) assistance of a systematically diverse group of up to 60 senior military members and Reservists and their spouses. SMEs will rate the typical stressfulness of a list of common military life experiences for families. SMEs will not provide any information about their own personal experiences as part of this rating process, therefore, we are requesting a waiver of informed consent and a non-human subjects research determination for the weighted scoring process.

Each individual will be instructed to provide minimal demographic and military career-related background information on their rating form and will be reminded not to enter personally identifying information. They will then be asked for their SME assessment of the stressfulness of each military life experience listed irrespective of having personally experienced the event or not. Specifically, SMEs will be asked to rate "on average how stressful" each experience is "for military families." They will also be asked to rate their own familiarity with each experience based on either their own experience or their observation of the experience of others.

Rating forms will be programmed online and initially, all ratings will be collected in limited de-identified fashion. Confidentiality will be ensured by not collecting personal identifiers (i.e., name, unit/command, etc.) although sex, rank, years of service, branch, service component, and military community will be collected to identify the distribution of SMEs across target demographic groups. Furthermore, SME contact information will be deleted as described further below so that the SME ratings will be fully anonymous as soon as possible and prior to analysis.

Is this a data repository?

○ Yes ◉ No

10.15 Managing Data (Data Management and/or Sharing Plan) and/or Human Biological Specimens for Future Research:

If the study involves collecting, storing, or banking human specimens, data, or documents (either by the Investigator or through an established repository) for FUTURE research, address. How the specimens/data will be used, where and how data/specimens will be stored (including shipping procedures, storage plan, etc.), whether and how consent will be obtained, procedures that will fulfill subjects' request as stated in the consent, whether subjects may withdraw their data/specimens from storage, whether and how subjects may be recontacted for future research and given the option to decline, whether there will be genetic testing on the specimens, who will have access to the data/specimens, and the linkage, the length of time that data/specimens will be stored and conditions under which data/specimens will be destroyed.

Study data are maintained within project specific data folders on network drives located on NHRC servers. Access controls are in place to restrict, monitor, and protect data, thus ensuring data availability, integrity, and confidentiality. Briefly, the NHRC Information Technology (IT) Department securely stores the servers within a restricted access room in an access-controlled building located on the NHRC complex in a manner that meets or exceeds DoD requirements. The IT Department creates incremental backups of the data nightly, which are stored locally on site. Once weekly, backups are replicated to an off-site server located at a remote NHRC building for disaster recovery. Access to project specific data folders is controlled by the Deployment Health Research Department (DHRD) Data Management Team. The study team prepares a data access request outlining the planned analyses, the data sources, agreements in place to access source data, and the PHI/PII involved. Personnel seeking access are limited to those with a need to know, and data are limited to what is necessary to address the study objectives. The request is reviewed by the Study PI, NHRC Privacy Officer, DHRD Head, Regulatory Affairs Manager, and members of the Data Management team. If a positive endorsement is received from each reviewer, the Data Manager then grants access to the data outlined on the request to the individuals listed on the request. Failure to receive an endorsement from each reviewer means that the study team needs to revise the request until the concerns raised by reviewers are met. Each time data are accessed, the date, time, and name of individual accessing are logged. Although access is restricted, the Data Manager conducts weekly reviews of the logs to ensure only approved individuals have accessed the data. Identifiable data must be maintained within project specific data folders. The PI verifies that data are analyzed as specified in the study protocol, and the IRB and command conduct annual reviews to ensure study progress continues in alignment with the protocol. The Privacy Office and NHRC IT independently exercise the right to monitor other network drives and folders for PHI/PII. These reviews occur periodically and are unannounced.

Is this a data repository?

○ Yes ◉ No

11.0 Statistical/Data Analysis Plan

11.1 Data Analysis Plan and Statistical Considerations:

List the statistical methods to be used to address the primary and secondary objectives, specific aims, and/or research hypotheses. Explain how missing data and outliers will be handled in the analysis. The analysis plan should be consistent with the study objectives. Include any subgroup analyses (e.g., gender or age group). Specify statistical methods and variables for each analysis. Describe how confounding variables will be controlled in the data analysis.

The Millennium Cohort Panel 4 recruitment oversampled for married personnel and for female service members, in order to ensure a sufficient sampling frame for the Family Study and to facilitate recruitment of a large enough subgroup of female service members for comparative analyses based on gender. Additional subgroup comparisons also are conducted using Millennium Cohort Program data based on DoD written research requirements, stakeholder request, and the prioritization of emergent research gaps. Analytic plans are developed and approved for specific projects as described further in section 11.6 below.

Due to stratified oversampling in the recruitment of Panel 4, all statistical analyses conducted with Family Study data are weighted to adjust both for the initial Millennium Cohort Panel 4 sampling frame stratification and for non-response bias. Spouse response propensity was analyzed using a selected set of demographic, military, covariate, and outcome variables available for all married Panel 4 Millennium Cohort Study respondents. This set of variables was used in logistic regression to estimate response propensity among spouses; and to adjust the initial sample design weights to create a final normalized stage 2 response propensity weight.

Both the Family Study and the MCP have a broad mandate to assess the impacts of past, current, and future military conflicts and other types of operational stress on service members and their families. Multiple projects are initiated each year under this protocol within the scope of the overall study objectives, making use of a broad range of analytic strategies following state-of-the art scientific methods. As a requirement of the research sponsor, the MCP develops a plan annually defining research priorities in collaboration with the Millennium Cohort Strategic Board and chair of the DHA Joint Program Committee-5. Priorities are evaluated based on DoD written research requirements, stakeholder requests, and/or the identification of emergent research gaps with of high relevance to the health and well-being of service members and their families. Specific projects to be initiated under the MCP annual plan are further required to develop a detailed analysis plan to address the research questions defined for that project. Analysis plans are approved by either the Family Study or Millennium Cohort Science Review Committee. The members of each committee include both internal MCP research investigators, as well as external military population health research subject matter experts representing DoD, VA, and academic institutions. Statistical analyses conducted under approved analysis plans include, but are not limited to, logistic regression, linear regression, path analysis, and factor analysis.

11.2 Sample Size:

The Millennium Cohort Family Study team and collaborators enrolled 10,065 participants during the 2011-2013 Panel 1 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 subsequently followed longitudinally or 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.

Number of Subjects: 9,872
Number of Female Subjects: 8,600
Number of Male Subjects: 1,273
Number of Civilian Subjects: 8,107
Number of Active-Duty Subjects: 916

During the 2020-2021 Panel 2 baseline survey cycle, the Family Study expects a 12%-17% response rate, with a sampling frame of approximately 210,000 spouses. Therefore, we expect maximum target recruitment numbers for Panel 2 as follows:

Number of Subjects: 36,000
Number of Female Subjects: 31,320
Number of Male Subjects: 4,680
Number of Civilian Subjects: 29,520
Number of Active-Duty Subjects: 6,480

We estimate there will be approximately 6.5% of the total Sampling frame for Millennium Cohort that will be single parents. With an estimate response rate for Millennium Cohort of 12% and 17-34% for the subsequent family module we expect maximum participation in the Single parent module to be as follows:

Number of Subjects: 1,335
Number of Female Subjects: 267
Number of Male Subjects: 1,068
Number of Civilian Subjects: 0
Number of Active-Duty Subjects: 1,041

Prior to the launch of the 2023 Family Study survey cycle, 30-60 individuals will be recruited to

complete an anonymous survey to beta-test the newly added items to the 2023 Family Study follow-up survey.

11.3 Total number of subjects requested (including records and specimens):

47400

11.4 If you are recruiting by study arm, please identify the arms of the study and how many subjects will be enrolled in each arm

NA

11.5 Please provide a justification for your sample size

The initial statistical power estimates of this study were developed to ensure the Family Study would have sufficient power to analyze research hypothesis focused on the impact of military deployment-related separations on a range of mental and physical health conditions. Based on this initial focus, power 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 had already been enrolled in the Millennium Cohort Study and who had deployed in support of the wars in Iraq and Afghanistan, it was estimated that 30% to 50% of the Service members who were enrolled in the 2010 cohort already would have been deployed in support of the current conflicts. Further, it was estimated that the overall prevalence of mental health outcomes would be from 5% to 10% for spouses of nondeployed military Service members. The following formula estimated the necessary sample size:

$N = ((Z_{\alpha})\text{sqrt}(P(1-P)(1/q1 + 1/q2)) + (Z_{\beta})\text{sqrt}(P1(1-P1)(1/q1) + P2(1-P2)(1/q2)))^2 / \Delta^2$

Where:

- N = sample size required
- P_1 = proportion of outcome among group 1 (spouses of non-deployed)
- P_2 = proportion of outcome among group 2 (spouses of deployed)
- Zα = standardized normal deviate for a two-tailed probability of an α-error, set at α = 0.05
- Zβ = standardized normal deviate for a two-tailed probability of an β-error, set at β = 0.80 or 0.90
- q_1 = proportion of sample population in group 1
- q2 = proportion of sample population in group 2
- P = q1 P1 + q2 P2
- Δ = P1 - P2

A power analysis based on this equation indicated that 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. Therefore, 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.

In line with the objective of the Millennium Cohort to enroll a larger sample into Panel 5 compared to Panel 4, the targeted sample for Family Study Panel 2 will be larger for multiple reasons. First, in order to improve the representativeness of our spouse population and to accommodate declining response rates, the Family Study plans to begin directly recruiting all eligible spouses in the sampling frame immediately at the beginning of the survey cycle, instead of recruiting them on a rolling basis subsequent to the enrollment of their military partners. Analysis of response rates for Panel 1 suggests recruiting spouses may actually improve Service Member response and the team hopes to directly incentivize dyadic responding as described

further in section 13.2. Furthermore, the Family Study hopes to recruit larger subsamples of important and potentially vulnerable demographic groups underrepresented in military research, to include male spouses, dual-military, and same-sex couples. Finally, the Family Study has identified important research gaps related to additional outcomes, some of which are less prevalent than those targeted for Panel 1 (i.e., family violence, adverse childhood events), however, these are high profile issues and in some cases have been requested by knowledge transition partners.

12.0 Participant Information

12.1 Subject Population:

Family Study enrolls legally married partners of U.S. military personnel (all service branches, including the Coast Guard, and both active-duty and Reserve components) with 1-5 years of service invited to enroll into the Millennium Cohort Study. However, this definition of "family" excludes some of the more vulnerable types of families in the military community, such as single-parent families. Since the Family Study is the only DoD-wide evaluation of mental and physical well-being of spouses and children at the present time, it is important for the study to work to represent all military families more completely. In pursuit of this, during the 2020 data collection cycle, the Family Study team will recruit self-reported single parent service members--at the time they complete and submit an online Millennium Cohort Survey--to "dual enroll" in the Family Study. Those who agree to volunteer will only complete a short (approximately 10-minute) survey module on parenting and child well-being.

12.2 Age Range:

Check all the boxes that apply. if the age range of potential subjects (specimens, records) does not match the range(s) selected, please specify in the text box.

- [x] 0-17
- [x] 18-24
- [x] 25-34
- [x] 35-44
- [x] 45-54
- [x] 55-64
- [x] 65-74
- [x] 75+

12.3 Gender:

- [x] Male
- [x] Female
- [x] Other

12.4 Special categories, check all that apply

- [ ] Minors /Children
- [ ] Students
- [ ] Employees - Civilian
- [ ] Employees - Contractor
- [ ] Resident/trainee
- [ ] Cadets /Midshipmen
- [x] Active Duty Military Personnel
- [ ] Wounded Warriors
- [ ] Economically Disadvantaged Persons

- ☐ Educationally Disadvantaged Persons
- ☐ Physically Challenged (Physical challenges include visual and/or auditory impairment)
- ☐ Persons with Impaired Decisional Capacity
- ☐ Prisoners
- ☐ Pregnant Women, Fetuses, and Neonates
- ☐ Non-English Speakers
- ☐ International Research involving Foreign Nationals - Headquarters Review is necessary

You must also consider the requirements of DoDI 3216.02, Enclosure 3, paragraph 7.e.

12.5 Inclusion Criteria:

Order Number	Criteria
1	Legally married partners of military service personnel eligible to enroll in the concurrent panel of the Millennium Cohort Study
1	Single parents responding to the Millennium Cohort Study will be eligible to dual-enroll in the Family Study, and will respond to a single module of questions regarding parenting factors and child well-being.

12.6 Exclusion Criteria:

Order Number	Criteria
1	Military spouses who are not married to a service member selected as part of a Millennium Cohort Study random sampling frame are not eligible recruitment.
1	Unmarried partners of service personnel who are not eligible DoD beneficiaries and married spouses who are not listed in the Defense Eligibility Enrollment Reporting System (DEERS) or the Defense Manpower Data Center (DMDC) are not eligible.
1	Sample selection and recruitment criteria are further 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 prior to additional participant recruitment.
1	Married spouses who are not registered in the Defense Eligibility Enrollment Reporting System (DEERS) or the Defense Manpower Data Center (DMDC) personnel records.
1	Service members with SSNs listed as 000-00-0000 or 999-99-9999 and their spouses

13.0 Recruitment and Consent

13.1 Please describe the recruitment process, including how subjects will be identified and selected for the study.

Subjects are identified for the Millennium Cohort Family Study through DoD archival personnel records. A random sampling frame of military personnel for recruitment is drawn for the

Millennium Cohort Study by DMDC from archival personnel records (. Based on the Millennium Cohort sampling frame, the Family Study recruits married spouses of the eligible service personnel in that sampling frame. For further documentation of recruitment methods for Panel 1, see NHRC.2000.0007.

To recruit Panel 2 spouses, all but 2,000 of the eligible sampling frame will be sent a mailed invitation to participate in the study simultaneously at the beginning of the recruitment cycle (see attached text). Subsequent contacts will be developed based on empirical research regarding effective subject recruitment strategies (e.g., modified Dillman survey methodology). Both email and paper mail contacts will be utilized for participants where both are available. Each specific contact and the dates scheduled for the contact will be provided to the IRB for review and approval in further modifications to this protocol prior to their use. As in previous survey cycles and outlined under the primary protocol for the Millennium Cohort Study (NHRC. 2000.0007), upon IRB approval, all printed recruitment and marketing materials will be printed by a private, subcontracted company. All necessary art and data files will be transferred to the company via a secure FTP site, an encrypted email, or secure disk. All mail items will include a scannable barcode, which allows for tracking returned mail items. Returned mail items will be scanned and processed by the subcontracted company, and bad address information will be securely transferred to the Family Study team utilizing the same secure FTP site, an encrypted email, or secure disk.

The research team hopes to obtain emails for potential participants through DoD archival records as noted under section 10.14. Otherwise, married Millennium Cohort service members who submit their surveys prior to their spouse will be informed of the Family Study and asked if they are comfortable providing their partner's email at the end of their survey ("Because families serve too, the Millennium Cohort Program includes a study designed for military spouses – The Millennium Cohort Family Study. Spouses can complete a survey and receive a $10 gift card! Please provide an email so we can request their participation.). In cases where email contact is not possible, eligible members of the sampling frame will only receive mailed invitations. The initial participant mailing to be sent to all members of the sampling frame at the launch of the Panel 2 recruitment is attached to this protocol. Further participant contacts for Panel 2 recruitment will be provided to the IRB in future modifications prior to use.

Single parents from the Millennium Cohort Study Panel 5 are identified based on their self-reported marital status (single, divorced, or widowed) and number of children 17 years old or younger (one or more children). Single parents will receive an initial message at the end of their Millennium Cohort survey, telling them we have determined that they are eligible to complete an additional single parent survey module as part of the Millennium Cohort Family Study. The text of this message will state: "Introducing The Millennium Cohort Family Study -- Because families serve too, the Millennium Cohort Program includes a study designed for single parents in the military – The Millennium Cohort Family Study. Single parents can complete an additional set of questions that takes no more than 10 minutes to complete and receive a $10 gift card! You will be receiving an email shortly with additional details and instructions to complete your survey." Following this, the Family Study will email single parents an official invitation with a new Family Study ID and a weblink to complete the module and monthly reminder emails will be sent to those who have not yet responded or completed their survey (see attached text for these emails).

To recruit the 2,000 spouses reserved from the Panel 2 sampling frame for the Recruitment Experiment, Family Study contacts will be adapted to include or exclude certain elements. Experimental Groups 2 and 4 will receive a magnet pre-incentive with their initial invitation, and the timing of postal contacts will be weekly. The initial participant mailing to be sent to the experiment subsample is attached to this protocol. Further participant contacts for Panel 2 recruitment will be provided to the IRB in future modifications prior to use.

The Family Study team will be recruiting 30-60 active-duty military spouses to complete an anonymous survey to betatest the proposed additions to the 2023 follow-up survey. These respondents will be a separate group from those actually enrolled in the Family Study, and will not be included in the 47,400 total number of subjects previously outlined in our protocol. Active duty spouses will be recruited via online social media posts, which allow them to volunteer without being publicly singled out or identified. Shareable social media advertisements have been created for this purpose. Staff from the Millennium Cohort Program will voluntarily post the recruitment advertisement to their social media pages (e.g., Facebook, Instagram, Snapchat, Reddit, etc.), social networking groups, and other online public-facing platforms.

The Family Study will follow-up with all participants approximately every three years. All eligible participants will be contacted via postal mailings and emails throughout the survey cycle. Contacts will be sent to inform participants that the follow-up questionnaire is available online, and encourage their continued participation in the Family Study. Each specific contact will

be provided to the IRB for review and approval in further modifications to this protocol prior to their use. The final follow-up survey instrument will be submitted to the IRB for review and approval prior to each follow-up survey cycle.

To develop and evaluate a proposed weighted scoring for military life stress content on the Family Study survey, the study team plans to enlist the subject matter expert (SME) assistance of a systematically diverse group of senior military members and Reservists and their spouses. Rating forms will be programmed online (see attached forms), and initially, all ratings will be collected in limited de-identified fashion. We plan to recruit no more than 60 Active-Duty or Reserve Guard SMEs, representing all branches, enlisted and officers, and both genders.

To further obtain the expert perspective of experienced military spouses and to verify the consistency of SME ratings, we also plan to ask our volunteer SMEs to invite their spouses (up to N = 60) to complete a rating form (see attached forms). Furthermore, to cover all bases we intend to utilize a bidirectional recruitment approach between service members and spouses. In our strategy either the service member or spouse will be recruited first and subsequently will be asked to invite their married partner.
For recruitment, primarily we plan to use a word-of-mouth procedure; the study team will initiate this by reaching out to their personal contacts, who then subsequently will be asked to solicit additional military members and Reservists to volunteer from among their acquaintances. The service member or military spouse will be invited to assist via email invitation (see attachments). We also plan to solicit self-referrals for participation by posting a media invitation (see attached media invite) on social media sites (e.g., family readiness group sites/pages, non-profit military family organization social media posts, Facebook, etc.), which invites potential SMEs to contact us through the Family Study general email. Subsequently, potential volunteers who email the study team in response to media posts will be invited to complete a rating form through the same procedures used for those referred via word-of-mouth.

Beginning in the 2024-2025 survey cycle, the Family Study will present all follow-up participants with a consent addendum. The addendum will inform the participants of the change in Principal Investigator from Dr. Valerie Stander to Dr. Hope McMaster.

13.2 Compensation for Participation:

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 post-incentives have been offered to participants from Panel 1, such as the choice of a $10 gift card to Starbucks, Subway, Walmart, or Amazon.com. The same procedures and gift card options will be used for Panel 2. No gift cards are exchangeable for cash. Additional nominal pre-incentives have been sent to Panel 1 participants as part of the recruitment and initial follow-up data collections (e.g., small reusable lunch bag, magnetic picture frame, $2 bill). All original Overhead Direct Costs (ODCs) for the purchase of prior incentives have been submitted in the appendices of the pdf copy of the current NHRC approved protocol attached with this initial eIRB submission. The use of incentives by the Millennium Cohort Program was reviewed and approved by the Office of the General Counsel for Navy Medicine on February 5, 2018, OMB on August 24, 2018 and RCS on September 24, 2018. All external approvals have been submitted as part of this package in Appendix H saved under "Other Protocol Documents" section of this protocol. Any future use of incentives not previously approved will be provided to the IRB as part of a future modification of this protocol.

Through an existing sub-contract with Anderson Direct & Digital (AD&D), the Millennium Cohort Family Study will offer each participant who completes a baseline or follow-up web survey a $10 gift card to either Starbucks, Walmart, Amazon, or Subway. On the final page of the web survey, the participant will have the option to choose their gift by clicking a radio button. This radio button will redirect the participant to the AD&D secure gift fulfillment page. Here, the participant will choose their gift and provide AD&D with their current mailing address for fulfillment.

On the last page of the Millennium Cohort Family survey below the radio button the following message will appear:

> By clicking the button above, you understand that you are being re-directed to our gift card fulfillment partner, Anderson Direct & Digital. Please be assured that the

> Millennium Cohort Study and Anderson Direct & Digital treat your privacy very seriously. Your personal information will not be shared with any outside parties.

On the AD&D page the following message will appear:

> The Millennium Cohort Family Study has partnered with Anderson Direct & Digital to offer you a selection of gifts as a token of our appreciation. Please be assured that the Millennium Cohort Study and Anderson Direct & Digital treat your privacy very seriously. Your personal information will not be shared with any outside parties.

All specific contact text and procedures previously approved for use with Panel 1 up through April 24th 2015 will continue to be documented through the primary Millennium Cohort Study protocol. The exact nature, texts, and procedures for all future contacts from April 25th 2015 onward will be submitted under this sub-study. The first of these contacts were submitted for approval as detailed in Appendix G (saved under "Other Protocol Documents" section of this protocol) 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 did 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.

For Panel 2 recruitment, the study team plans to offer an additional $10 post-incentive to be given to the Family Study spouse upon completion of both the service member and spouse surveys by the dyad ($20 maximum Family Study post-incentive). The additional incentive offered will be a $10 Amazon gift card mailed directly to the spouse’s postal address. At present no pre-incentives are planned for Panel 2. However, if it becomes possible to offer pre-incentives for targeted subgroups in the future, an additional IRB modification will be submitted for their approval. Finally, participants will be informed that they may be invited to participate in other future studies because of their participation in the Millennium Cohort Program, and these other programs of research may offer their own compensation. However, participation in any of these future offers will not be contingent on their participation in the Millennium Cohort Family Study and will involve a separate informed consent enrollment procedure.

Single parents will receive a $5 give card for their Millennium Cohort Study participation, and they will receive an additional $10 gift card for completing the Family Study single parent module (total of $15). Compensation procedures for single parents will be similar to those followed for the rest of panel 2 (see section 13.2).

Participants in the Recruitment Experiment will receive the same opportunities for post-incentives as participants not included in the experiment. Individuals assigned to the Pre /Post-Incentive Group will receive a pre-incentive magnetic picture frame in addition to post-incentives.

Nominal pre- and post-incentives have been offered to Panel 1 and Panel 2 participants in the past to encourage participation and completion of surveys. We are now requesting to send gift cards to Panel 2 participants, who enrolled in the Millennium Cohort Family Study during our 2019-2021 survey cycle, but did not submit a fully complete survey. In order to ensure these participants understand that they are included in our cohort, and their continued participation is important, we would like to send a $10 gift card top Amazon.com to all participants with a signed consent form, who completed at least half of their baseline survey, but did not submit a fully completed

survey. These partial completers provided valuable information with their enrollment survey, and we would like to utilize an incentive to encourage their participation and hopefully more complete survey submission during the upcoming follow-up survey cycle.

As a token of appreciation, a $5 gift card will be sent to the Millennium Cohort Family Study participants whose child artwork submissions are selected for use in future Family Study mailings and communications.

In an effort to encourage the continued participation of specific target groups of interest (i.e., dyadic completers, male spouses, etc.), we will be sending a $5 digital Amazon gift code as a pre-incentive during the 2024-2025 survey cycle to specifically identified participants. This gift code will be printed on the Family Study notecard mailing for these participants, while the remaining follow-up participants will receive the notecard without a gift code.

13.3 Please describe the pre-screening process. If no pre-screening, enter Not Applicable in the text editor

NA

13.4 Consent Process: Revised Common Rule, Section 219.116: General requirements for informed consent, whether written or oral, are set forth in this paragraph and apply to consent obtained in accordance with the requirements set forth in paragraphs (b) through (d) of this section. Broad consent may be obtained in lieu of informed consent obtained in accordance with paragraphs (b) and (c) of this section only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens.

Are you requesting a waiver or alteration of informed consent?

(●) Yes ( ) No

What type?

☐ Waiver of documentation of informed consent
☑ Waiver or alteration of informed consent

Please explain why your study is eligible for the requested waiver

Family Study participants will enter a Study ID number and/or select a button instead of a signature on the informed consent document. This is an alteration of the informed consent because we are altering how the document is signed.

We are requesting a waiver of informed consent for Millennium Cohort Study Panel 5 non-responders with a Millennium Cohort Family Study Panel 2 responder spouse in order to access archival records from DMDC. No PHI will be collected for these individuals. We will only be utilizing demographic and military specific data to complete a dyadic dataset for Panel 2 analyses.

Please explain the consent process:

Informed consent has already been obtained from all Family Study Panel 1participants during the baseline enrollment process in the 2011-2013 data collection cycle. This process is documented in the IRB protocol for the primary Millennium Cohort Study (NHRC.2000.0007). An approved informed consent document, privacy act statement, and HIPPA authorization form to facilitate Panel 2 recruitment are further attached in the appendices of the final NHRC paper protocol pdf attached to this initial eIRB submission. Additional documentation of any changes from Panel 1 in the procedures for enrollment of new Family Study Panel 2 participants or for other future panels will be documented in future modifications to this protocol. All changes in methods of recruitment informed consent and enrollment will be documented and submitted as part of those modifications including the new baseline survey materials to be used in those data collection cycles.

Defense Health Agency and with new common rule requirements, the Panel 2 informed consent documents have been revised and updated versions have been attached to this protocol. The informed consent document is now accompanied by both the privacy act statement and a newly

required HIPAA release form. The consent process for Panel 2 will be conducted entirely online. Each recruitment contact participants receive will include a link to the study website, as well as a login study ID.

When participants initially log into the study website, they will be presented with the consent documents. Participants will review the informed consent information on their own and click a box at the end to indicate they are willing to participate. After indicating their willingness to volunteer on the informed consent form, participants will next see the privacy act statement and the HIPAA release form. A separate box will be available to acknowledge release on the HIPAA form. For this study, we are requesting a waiver of signed consent, because this study will be conducted completely online, and it will not be practicable to collect physical signatures. Also, this waiver will not infringe on any other protections to which participants are otherwise eligible. A PDF version of each of the consent documents will be available for download from the study website, and participants can log into the study website at any time after their participation to access these. Finally, contact information and a dedicated study email address will be provided to participants as part of the consent documents to allow them to ask any questions they may have. After clicking their consent to participate, volunteers will then be forwarded to the study survey to begin their participation.

The consent process for single parents will be similar in most respects to the rest of the Family Study Panel 2 participants. However, single parents will read a slightly altered version of the consent form tailored to context of their participation (see attached consent form). Upon being invited to the single parent survey module, they will be emailed a Family Study SID to use as their login for the module. In this way, single parent Millennium Cohort participants also become Family participants once they agree to participate.

13.5 DoDI 3216.02 requires an ombudsman to be present during recruitment briefings when research involves greater than minimal risk and recruitment of Service members occurs in a group setting. If applicable, you may nominate an individual to serve as the ombudsman.

- (•) N/A
- ( ) Propose ombudsman

13.6 Withdrawal from Study Participation:

Explain the process for withdrawal and specify whether or not the subjects will be given the opportunity to withdraw their data their data/specimens in the event they wish to withdraw from the study

Participants are given the opportunity to withdraw from the study. The process for withdrawal from the study begins with the participant contacting the study team through email or phone and requesting to be removed from the study. They have the option of withdrawing from the current survey cycle or from the entire study. The study team will verify the participant's identity, fulfill their request of withdrawal, and confirm with the participant that their request has been completed.

14.0 Risks and Benefits

14.1 Risks of Harm:

Identify all research-related risks of harm to which the subject will be exposed for each research procedure or intervention as a result of participation in this study. Consider the risks of breach of confidentiality, psychological, legal, social, and economic risks as well as physical risks. Do not describe risks from standard care procedures; only describe risks from procedures done for research purposes

This study poses no physical risk to the participant. The primary risk to participants is the potential for a breach of confidential data. Panel 2 participants will be informed that the main risks associated with their participation could be the inappropriate disclosure of data collected about them. Furthermore, if someone gained unauthorized access to their personal data in the Family Study database, there would be a chance it could impact their reputation, insurability, or employability. However, we also inform them that study researchers have collected similar information for multiple studies over many years without any cases of inappropriate disclosure.

There is also the risk of possible discomfort from answering some sensitive questions, but participants may skip any question(s) they are uncomfortable answering. If participants do experience discomfort of this nature, the Family Study Team cannot offer direct support. Rather participants are instructed that if they feel they need medical care or counseling they should make contact with their regular health care providers.

Personal identifiable health information is collected as part of the Family Study, and strict procedures will be followed to minimize any risk of exposure. The procedures for data storage and security for Panel 1 and Panel 2 will continue under this protocol as they were previously under the primary study protocol (NHRC.2000.0007). 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 access to investigators and key personnel listed on this protocol. Only personnel on this protocol who need to make use of specific data files will have access to them. All results will be reported as aggregate data without identifying any individuals.

14.2
Measures to Minimize Risks of Harm (Precautions, safeguards):

For each research procedure or intervention, describe all measures to minimize and/or eliminate risk of harms to subjects and study personnel

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:

Administrative

- 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.

Procedural

- Study staff will transport survey records, which contain PII and PHI, other paper records, and computer disks from one location to another securely per the approved transportation SOP in the attached pdf of the final NHRC template protocol (Please see "Other Study Documents" Appendix I). Study staff will store study files in locked metal file cabinets at NHRC. Paper records that are no longer needed will be shredded according to the dispositions instructions of the active SORN (Please see "Other Study Documents" Appendix H).
- New data collected for the ongoing survey follow-up cycle under the present protocol are all electronic. No new paper is currently collected. New 2019 follow-up data are collected in limited deidentified fashion, using only study IDs for identification, and are stored securely on dedicated Millennium Cohort servers. No transfer of data or changes in the storage process are necessary as part of the initiation of this new protocol.

Computer Security

- 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.

- Study staff will download archival study data from the Corporate Executive Information System (CEIS) and DEERS through secure data transmission links meeting standard DoD requirements. The database will be stored on existing NHRC information systems network. This system meets current DoD data security requirements.
- 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 archival 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 a pre-determined secondary login (such as the last four digits of their social security number, the last four digits of their military sponsor's social security number, or the participant's DoD ID number) to access the Family Study questionnaire. (Please see "Other Study Documents" Appendix J The Millennium Cohort Family Study Website Description and Security Procedures.)
- The study database will primarily reside within the NHRC network environment. Any external data shared with research collaborators 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, de-identified data.

14.3
Confidentiality Protections (for research records, data and/or specimens):

Describe in detail the plan to maintain confidentiality of the research data, specimens, and records throughout the study and at its conclusion (e.g., destruction, long term storage, or banking). Explain the plan for securing the data (e.g., use of passwords, encryption, secure servers, firewalls, and other appropriate methods). If data will be shared electronically with other team members/collaborators outside the institution, describe the method of transmission and safeguards to maintain confidentiality. Explain whether this study may collect information that State or Federal law requires to be reported to other officials or ethically requires action, e. g., child or spouse abuse

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. All Study staff will be trained in HIPPA privacy procedures and follow the security procedures described in section 14.2 above. 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.

A Data Use Agreement (DUA; Please see "Other Study Documents" Appendix F) between NHRC and Abt Associates and their subcontractors Center for Child and Family Health (CCFH) was previously established, supporting deiedentified data sharing for tasks completed under an independent contract from CY2015-2019. Subsequently, sharing deidentifeid data under contracts with Abt Associates and its subcontractors, as well as other collaborators approved for use of Millennium Cohort Study data following Millennium Cohort Program science review is facilitated through a project specific data sharing agreement approved through the NHRC HIPPA Privacy Officer. All 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. External affiliates will 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 external collaborators is restricted to the minimum necessary to complete approved projects.

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 sections 10.14 and 14.5.

To further protect both follow-up and baseline data, beginning with the 2019 data collection cycle the Family Study has a Department of Health and Human Services (DHHS) Certificate of Confidentiality in place. This certificate protects participant privacy from being disclosed in the event of any civil, criminal, administrative, legislative or other proceedings, whether at the federal, state or local level. The Certificate cannot and will not be used to avoid providing information to personnel from the U.S. Government for auditing or evaluation. Furthermore, although the survey does not ask about reportable events such as this, the certification would not prevent the team from disclosing or reporting matters such as family abuse, sexual assault, reportable communicable diseases, a participant's threatened violence to self or others, or as military regulations may require should a participant voluntarily disclose such information to any member of the team.

14.4 Potential Benefits:

Describe any real and potential benefits of the research to the subject and any potential benefits to a specific community or society

If the individuals in the research are considered experimental subjects (per 10 USC 980), and they cannot provide their own consent, the protocol must describe the intent to directly benefit all subjects

Participants are not expected to receive any potential benefits from their participation in this research, beyond the satisfaction of knowing that they may be helping The DoD to understand the needs of military personnel and their families and to support the needs of military populations better in the future.

14.5 Privacy for Subjects:

Describe the measures to protect subject's privacy during recruitment, the consent process, and all research activities, etc.

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.

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.

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 personnel on this protocol and the principal investigator.

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.

14.6 Incidental or Unexpected Findings:

Describe the plan to address incidental findings and unexpected findings about individuals from screening to the end of the subject's participation in the research. In cases where the subject could possibly benefit medically or otherwise from the information, state whether or not the results of screening, research participation, research tests, etc., will be shared with subjects or their primary care provider. State whether the researcher is obligated or mandated to report results to appropriate military or civilian authorities and explain the potential impact on the subject

The Family Study survey content does not include any questions or response options that would require the reporting of unexpected findings. Some sensitive questions have been included on the survey regarding the experience of family conflict and potential risk for intimate partner violence. Under the direction of the DoD Family Advocacy Program, responses to these questions are not required to be reported. Furthermore, the Family Study has obtained a Certificate of Confidentiality from the National Institutes of Health to facilitate maintaining the privacy of participants' responses.

15.0 Study Monitoring

15.1 Your study requires either Data and Safety Monitoring Plan (DSMP) or a Data and Safety Monitoring Board (DSMB).

- (●) DSMP
- ( ) DSMB
- ( ) Both
- ( ) Not Applicable

A DSMP should describe the plan to monitor the data to verify that the data are collected and analyzed as specified in the protocol. Include who will conduct the monitoring, what will be monitored, and the frequency of monitoring. It should also include the plan to ensure the safety of subjects

Study data are maintained within project specific data folders on network drives located on NHRC servers.
Access controls are in place to restrict, monitor, and protect data, thus ensuring data availability, integrity, and
confidentiality.

The NHRC Information Technology (IT) Department securely stores the servers within a restricted access room in an access-controlled building located on the NHRC complex in a manner that meets or exceeds
DoD requirements. The IT Department creates incremental backups of the data nightly, which are stored locally
on site. Once weekly, backups are replicated to an off-site server located at a remote NHRC building for disaster

recovery. Access to project specific data folders is controlled by the DHRD Data Management Team. The study
team prepares a data access request outlining the planned analyses, the data sources, agreements in place to
access source data, and the PHI/PII involved. Personnel seeking access are limited to those with a need to know,
and data are limited to what is necessary to address the study objectives. The request is reviewed by the Study
PI, NHRC Privacy Officer, DHRD Head, Regulatory Affairs Manager, and members of the Data Management
team. If a positive endorsement is received from each reviewer, the Data Manager then grants access to the data
outlined on the request to the individuals listed on the request. Failure to receive an endorsement from each
reviewer means that the study team needs to revise the request until the concerns raised by reviewers are met.
Each time data are accessed, the date, time, and name of individual accessing are logged. Although access is
restricted, the Data Manager conducts weekly reviews of the logs to ensure only approved individuals have
accessed the data. Identifiable data must be maintained within project specific data folders. The PI verifies that
data are analyzed as specified in the study protocol, and the IRB and command conduct annual reviews to ensure
study progress continues in alignment with the protocol. The Privacy Office and NHRC IT independently
exercises the right to monitor other network drives and folders for PHI/PII. These reviews occur periodically and
are unannounced.

16.0 Reportable Events

16.1 Reportable Events: Consult with the research office at your institution to ensure requirements are met. Describe plans for reporting unexpected adverse events and unanticipated problems. Address how unexpected adverse events will be identified, who will report, how often adverse events and unanticipated problems will be reviewed to determine if any changes to the protocol or consent form are needed and the scale that will be used to grade the severity of the adverse event.

Consult with the research office at your institution to ensure requirements are met

• Describe plans for reporting expected adverse events. Identify what the expected adverse events will be for this study, describe the likelihood (frequency, severity, reversibility, short-term management and any long-term implications of each expected event)

• Describe plans for reporting unexpected adverse events and unanticipated problems. Address how unexpected adverse events will be identified, who will report, how often adverse events and unanticipated problems will be reviewed to determine if any changes to the research protocol or consent form are needed and the scale that will be used to grade the severity of the adverse event

Protocol deviation(s)/violation(s) or other issues of noncompliance with the protocol will be reported within 5 business days from the date of discovery.

17.0 Equipment/non-FDA Regulated Devices

17.1 Does the study involve the use of any unique non-medical devices/equipment?

○ Yes ◉ No

18.0 FDA-Regulated Products

18.1 Will any drugs, dietary supplements, biologics, or devices be utilized in this study?

- [ ] Drugs
- [ ] Dietary Supplements
- [ ] Biologics
- [ ] Devices
- [x] N/A

18.5 Sponsor (organization/institution/company):

- [ ] N/A

If applicable, provide sponsor contact information:

Congressionally Directed Medical Research Program
Defense Health Program, Defense Health Agency, Joint Program Committee-5

19.0 Research Registration Requirements

19.1 ClinicalTrials.gov Registration:

- (•) Registration is not required
- ( ) Registration pending
- ( ) Registration complete

19.2 Defense Technical Information Center Registration (Optional):

- (•) Registration is not required
- ( ) Registration pending
- ( ) Registration complete

20.0 References and Glossary

20.1 References:

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5. Azar, B. Online experiments: ethically fair or foul? Monitor on psychology 2000; 31: retrieved September 12, 2000 from the World Wide Web: http://www.apa.org/monitor/apr00/fairorfoul.html

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20.2 Abbreviations and Acronyms:

- Defense Eligibility Enrollment Reporting System (DEERS)
- Defense Manpower Data Center (DMDC)
- Military Data Repository (MDR)

Naval Health Research Center
CONSENT TO PARTICIPATE IN RESEARCH
Millennium Cohort Family Study
Principal Investigator: Valerie Stander, PhD

You have been selected to take part in this research study. This form gives you important information about the study.

Please take time to carefully review this information. You should reach out to research staff at usn.point-loma.navhlthrschcensan.mbx.family-cohort@health.mil and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or your personal physician) about your potential participation in this research study. You do not have to take part in this study. Participation is voluntary. You may also leave the research study at any time without penalization.

1. KEY INFORMATION:

This study includes the use of information collection tools (e.g., surveys, questionnaires):
OMB Control Number: 0703-0064 (expiration date: 28 FEB 2025)

RCS Approval Number: DD-NAVY (AR)2678 (expiration date: 28 FEB 2025)

You are being asked to volunteer in a longitudinal research study called "The Millennium Cohort Family Study" conducted by the US Department of Defense (DoD). The purpose of this study is to assess the interrelated health effects of military life on service members, spouses and their children. You were selected to be a part of this study because you were identified as a spouse of a service member eligible to volunteer for the Millennium Cohort Study. For more information on the Millennium Cohort Study, please visit www.MillenniumCohort.org. Participation is completely voluntary. Participation in this study will help us evaluate the availability of resources and the level of support that is needed in the lives of military service members and their families. You can still take part in this study even if your spouse is not currently living in the same home with you. Since this study observes how families change and grow over time in the context of military service and beyond, you will be asked to complete an online follow-up survey every three years. The follow-up surveys will ask questions about the health and well-being of you and your family. You can choose each time whether you would like to participate.

Potential risks may include inappropriate disclosure of reportable information or discomfort in answering study questions.

For your time, you will be compensated with a $10 gift card. While there is no direct benefit to you, your participation will help determine the long-term effects of military life on families and define family support policy for future generations of service members and their families, and guide prevention and treatment programs for years to come.

2. WHAT IS THE PURPOSE AND DURATION OF THIS RESEARCH AND WHO WILL TAKE PART?

The purpose of this research is to determine the impact of military service, including deployments and other occupational exposures, on the long-term physical, mental, and behavioral health of US service members, spouses and their children. The ultimate goal is to understand the needs of military families, and guide family support policy, prevention, and treatment programs for years to come.

If you participate, you will be 1 of approximately 37,400 who will take part in this study. Study participants are asked to remain involved long-term, even if their marital status or connection to the military changes over time. Participants will be invited to complete a total of 7 follow-up surveys, with 1 survey approximately every 3 years.

The results of this research will be available to you on the Millennium Cohort Family Study website (www.familycohort.org). We regularly update our website with published studies and release informational materials such as infographics for others to learn about the health and well-being of military children and families. Please check the website for routine updates on our research findings.

3. WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH?

You are being asked to do the following:

Complete an online survey today. You are also being asked to complete up to 7 follow-up surveys, over a period of approximately 21 years. Filling out the survey will take about 45 minutes each time you complete it. The surveys contain questions on a broad range of health, medical, and behavioral issues concerning yourself, your spouse, and your children (if you have any). Some of the questions are of a sensitive nature.

We will connect your survey data with other databases, medical records, surveys, or biological specimens collected or maintained by the Department of Defense, Department of Veterans Affairs, federal or state agencies, or nongovernmental organizations such as the National Student Clearinghouse.

So that we can stay in communication with you over the timeframe of this 21-year study, we will communicate with you semi-annually to verify your contact information, and we also may update your contact information through federal or civilian records including email, phone, or residential address.

If you choose to participate, in the future you may be invited to participate in other substudies relevant to your military life experience. However, your choice to participate in this study is completely independent of your choice to accept or reject any future research invitations.

4. WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS RESEARCH?

The main risks to you are those associated with the inappropriate disclosure of data that we collect from or about you. Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you. While inappropriate disclosure has the potential to impact your reputation, insurability, or employability, it is important for you to understand that this research group has collected similar information from numerous studies over many years without any cases of inappropriate disclosure.

There is also the risk of possible discomfort from answering some sensitive questions, but you may skip any question(s) that make you uncomfortable. As a strictly research-based project, we cannot offer direct support; therefore, if you feel that you might need medical care or counseling, you should make contact with your appropriate health care personnel.

5. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?

While your participation in this study will not directly benefit you, your participation is a critical step in developing programs and interventions to increase the well-being of service members and their families.

6. WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH?

Your alternative is not to participate in this research.

7. IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?

Yes, for completing your survey online, you may receive a gift card as a token of appreciation in value up to $10. Gift cards will be mailed to you within 6 weeks of survey completion. Additionally, since your service member spouse has been invited to participate in the Millennium Cohort Survey, you may be eligible for an additional $10 gift card if both you and your partner choose to participate in this research program.

8. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

No, there are no costs to you for taking part in this research study.

9. PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study):

Valerie Stander, PhD

10. STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data):

As the sponsor of this research, the Department of Defense may audit your research data in accordance with DoDI 3216.02. These records may be looked at by DoD staff as part of their duties. These duties include making sure that the research participants are protected.

11. SOURCE OF FUNDING:

The study is funded by the Defense Health Agency.

12. LOCATION OF THE RESEARCH:

Naval Health Research Center, San Diego, CA.

13. WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE PROTECTED (CONFIDENTIALITY)?

Records of your participation in this research study may only be disclosed in accordance with state and federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations.

The research team will secure your research records. These records may be looked at by staff from the Naval Health Research Center, the Institutional Review Board (IRB), and the DoD Higher Level Review as part of their duties. These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

Procedures to protect the confidentiality of the data in this study include but are not limited to:

When you complete your internet survey, you will not be asked for any identifying information. The information you submit will only be tracked using the special identification number provided to you for use in logging into the survey. All information collected through the Millennium Cohort Family Study Internet questionnaire will be transferred to Naval Health Research Center servers using Secure Sockets Layer (SSL) data transmission lines. SSL encrypts, or scrambles, all questionnaire data sent over the Internet. Information will only be understandable when it reaches the investigator database. The same methods of protection listed above will then be followed to further protect your information.

Once at Naval Health Research Center, to minimize the risk of any inappropriate access of your data, all files will be maintained on DoD computers protected by all the measures required by DoD computer security regulations. All members of the research team with access to data files will be trained in DoD computer security procedures specifically designed to protect sensitive data. Reports of the study findings will contain only grouped data, so that no individual study participant can be identified. Similar procedures have been used to protect data in previous studies conducted within this research center.

According to the DoD Policy "Interim Regulations to Improve Privacy Protections for DoD Medical Records" dated October 31, 2000, the information you provide is for research

purposes only and may not be disclosed except for specifically authorized purposes or with the consent of the individual about whom the information pertains. Uses and disclosures of this information shall comply with provisions of the Privacy Act and implementing regulations.

For this research study, a Department of Health and Human Services (DHHS) Certificate of Confidentiality is in place to protect your privacy such as your name or other identifying information from being disclosed in any civil, criminal, administrative, legislative or other proceedings, whether at the federal, state or local level. The Certificate cannot be used to resist a demand for information from personnel of the U.S. Government that is used for auditing or evaluation of Federally-funded projects or for information that must be disclosed in order to meet the requirements of the Food and Drug Administration (FDA). Further, the researcher is not prevented from disclosure for reporting matters such as family abuse, sexual assault, reportable communicable diseases, a participant's threatened violence to self or others, or as military regulations may require. You should understand that the Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. Insurers, employers, or other persons will not receive your research information, unless they obtain your written consent to do so.

The Millennium Cohort Family Study Principal Investigator, study coordinators, and research team described in the Informed Consent, and others with authority to oversee the conduct of the research agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law.

Information gained from your participation in this research study may be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified when your information is shared in these ways; all information will de-identified and combined with other participant study data.

14. VOLUNTARY PARTICIPATION:

The decision to take part in this research study is completely voluntary on your part which means you do not have to take part if you do not want to. You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty or loss of benefits to which you are otherwise entitled.

15. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

If you decide to participate, you can stop at any time you wish or skip any question you choose. If you choose not to participate or to discontinue your participation, you will not lose any benefit to which you are otherwise entitled. You may change your mind and revoke your permission to further collect or use your health information at any time. If you revoke your permission, no new health information about you will be gathered after that date. However, unless specified otherwise, information that has already been gathered may still be

used for analyses. Collected data will be maintained until all research questions are answered. To end participation, contact the principal investigator at usn.point-loma.navhlthrschcensan.mbx.family-cohort@health.mil

Please note that withdrawing your consent to participate in this research does not fully revoke your HIPAA Authorization Form to use/disclose your protected health information. To make that revocation, please send a letter to the principal investigator as discussed in the HIPAA Authorization Form.

The principal investigator of this research study may terminate your participation in this research study at any time if she determines this to be in your best interest, if you are unable to comply with the procedures required, or if you no longer meet eligibility criteria.

16. CONTACT INFORMATION:

Principal Investigator (PI)
The Principal Investigator or a member of the research staff will be available to answer any questions throughout this study.

Principal Investigator: Valerie Stander, PhD
Phone: (619) 553-7465
Email: usn.point-loma.navhlthrschcensan.mbx.family-cohort@health.mil

Institutional Review Board (IRB) Office
If you have any questions about your rights as a research participant or if you have concerns or complaints about the research study, please contact the IRB Chair by phone, 619-553-8424 or email usn.nhrc.irb@health.mil.

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, YOU SHOULD REACH OUT TO RESEARCH STAFF AT USN.POINT-LOMA.NAVHLTHRSCHCENSAN.MBX.FAMILY-COHORT@HEALTH.MIL AND ASK THE INVESTIGATORS BEFORE SIGNING.

Click here to download a copy of this consent for your records.

SIGNATURE OF PARTICIPANT

By entering your subject ID and clicking the Yes, I agree button below, you agree that you have read the information in this consent form. You have been given an opportunity to ask questions about this study and its procedures and risks, as well as any of the other information contained in this consent form. All of your questions have been answered to your satisfaction. You understand that this is research. You freely give your consent to be in this research study as it has been explained to you. You authorize the use and disclosure of your health information to the persons listed in the consent form for the purposes described above.

By entering my subject ID and clicking the Yes, I agree button below, I have not given up any of my legal rights as a research participant.

Type Your Subject ID: _____

Yes, I agree	No, I do not agree

Naval Health Research Center
CONSENT TO PARTICIPATE IN RESEARCH
Millennium Cohort Family Study
Principal Investigator: Valerie Stander, PhD

You have been selected to take part in this research study. This form gives you important information about the study.

Please take time to carefully review this information. You should reach out to research staff at usn.point-loma.navhlthrschcensan.mbx.family-cohort@health.mil and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or your personal physician) about your potential participation in this research study. You do not have to take part in this study. Participation is voluntary. You may also leave the research study at any time without penalization.

1. KEY INFORMATION:

This study includes the use of information collection tools (e.g., surveys, questionnaires):
OMB Control Number: 0703-0064 (expiration date: 28 FEB 2025)

RCS Approval Number: DD-NAVY (AR)2678 (expiration date: 28 FEB 2025)

You are being asked to volunteer in a longitudinal research study called "The Millennium Cohort Family Study" conducted by the US Department of Defense (DoD). The purpose of this study is to assess the interrelated health effects of military life on service members, spouses and their children. You were selected to be a part of this study as a service member participating in the Millennium Cohort Study who is a parent of one or more children under the age of 18. Your participation is completely voluntary. Participation in this study will help us evaluate the availability of resources and the types of support needed in the lives of military service members and their families. Your help is still needed even if your children are not currently living in the same home with you. Since this study observes how children change and grow over time in the context of military service and beyond, you will be asked to complete a brief survey module approximately every three years. The brief module will ask about parenting, your child's development and any family support services you may be using. You can choose each time whether you would like to participate.

Potential risks may include inappropriate disclosure of reportable information or discomfort in answering study questions.

For your time, you will be compensated with a $10 gift card. While there is no direct benefit to you, your participation will help determine the long-term health effects of military life on parents and children, define family support policy for future generations of service members and their families, and guide prevention and treatment programs for years to come.

2. WHAT IS THE PURPOSE AND DURATION OF THIS RESEARCH AND WHO WILL TAKE PART?

You are being asked to take part in this research study because you noted on the Millennium Cohort Survey that you were an unmarried parent of a minor child. The purpose of this research study is to learn about the interrelated health effects of military service on service members and their children. The ultimate goal is to understand the needs of military families and guide family support policy, prevention, and treatment programs for years to come.

If you participate, you will be 1 of approximately 37,400 who will take part in this study. Study participants are asked to remain involved long-term, even if their marital status or connection to the military changes over time. Participants will be invited to complete a total of 7 follow-up surveys, with 1 survey approximately every 3 years.

The results of this research will be available to you on the Millennium Cohort Family Study website (www.familycohort.org). We regularly update our website with published studies and release informational materials such as infographics for others to learn about the health and well-being of military children and families. Please check the website for routine updates on our research findings.

3. WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH?

If you volunteer, you will complete an additional brief Family Study child survey module that will augment the survey you have already completed about your military service and health. The brief Family Study child survey will ask questions about the current life circumstances of you and your children. You will be asked to complete 7 Family Study follow-up survey modules over approximately 21 years, with 1 survey to complete every 3 years, as part of your participation in the Millennium Cohort Research Program. The child survey module will take about 10 minutes to complete each time. The survey modules contain questions on a broad range of child well-being, health, and parenting issues concerning yourself, any romantic partner/parenting partners, and your children. Some of the questions are of a sensitive nature to allow us to more fully understand the dynamics of childhood in the military community and the diverse health care needs faced by all types of military families. You may skip any question(s) that make you uncomfortable.

We will also connect your survey data with other databases, medical records, surveys, or biological specimens collected or maintained by the Department of Defense, Department of Veterans Affairs, federal or state agencies, or nongovernmental organizations such as the National Student Clearinghouse.

So that we can stay in communication with you over the timeframe of this 21-year study, we will communicate with you semi-annually to verify your contact information, and we also may update your contact information through federal or civilian records including email, phone, or residential address.

If you choose to participate, in the future you may be invited to participate in other substudies relevant to your military life experience. However, your choice to participate in this study is completely independent of your choice to accept or reject any future research invitations.

4. WHAT ARE THE RISKS OR DISCOMFORTS FROM BEING IN THIS RESEARCH?

If you choose to take part in this study, the main risks to you are those associated with the inappropriate disclosure of data that we collect from or about you. Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you. While inappropriate disclosure has the potential to impact your reputation, insurability, or employability, it is important for you to understand that this research group has collected similar information from numerous studies over many years without any cases of inappropriate disclosure.

There is also the risk of possible discomfort from answering some sensitive questions, but you may skip any question(s) that make you uncomfortable. As a strictly research-based project, we cannot offer direct support; therefore, if you feel that you might need medical care or counseling, you should make contact with your appropriate health care personnel.

5. WHAT ARE THE POSSIBLE BENEFITS FROM THIS RESEARCH?

While your participation in this study will not directly benefit you, your participation is a critical step in developing programs and interventions to increase the well-being of service members and their families.

6. WHAT ARE THE ALTERNATIVES TO TAKING PART IN THIS RESEARCH?

Your alternative is not to participate in this research.

7. IS THERE COMPENSATION FOR YOUR PARTICIPATION IN THIS RESEARCH?

Yes, for your participation, you will receive a $10 gift card. Gift cards will be mailed to you within 6 weeks of survey completion.

8. ARE THERE COSTS FOR PARTICIPATING IN THIS RESEARCH?

No, there are no costs to you for taking part in this research study.

9. PRINCIPAL INVESTIGATOR (the person(s) responsible for the scientific and technical direction of the study):

Valerie Stander, PhD

10. STUDY SPONSOR (the organizations or persons who oversee the study and are responsible for analyzing the study data):

As the sponsor of this research, the Department of Defense may audit your research data in accordance with DoDI 3216.02. These records may be looked at by DoD staff as part of their duties. These duties include making sure that the research participants are protected.

11. SOURCE OF FUNDING:

The study is funded by the Defense Health Agency.

12. LOCATION OF THE RESEARCH:

Naval Health Research Center, San Diego, CA.

13. WHO WILL SEE MY INFORMATION (PRIVACY) AND HOW WILL IT BE PROTECTED (CONFIDENTIALITY)?

Records of your participation in this research study may only be disclosed in accordance with state and federal law, including the Federal Privacy Act, 5 U.S.C.552a, and its implementing regulations.

The research team will secure your research records. These records may be looked at by staff from the Naval Health Research Center, the Institutional Review Board (IRB), and the DoD Higher Level Review as part of their duties. These duties include making sure that the research participants are protected. Confidentiality of your records will be protected to the extent possible under existing regulations and laws but cannot be guaranteed.

Procedures to protect the confidentiality of the data in this study include but are not limited to:

When you complete your internet survey, you will not be asked for any identifying information. The information you submit will only be tracked using the special identification number provided to you for use in logging into the survey. All information collected through the Millennium Cohort Family Study Internet questionnaire will be transferred to Naval Health Research Center servers using Secure Sockets Layer (SSL) data transmission lines. SSL encrypts, or scrambles, all questionnaire data sent over the Internet. Information will only be understandable when it reaches the investigator database. The same methods of protection listed above will then be followed to further protect your information.

Once at Naval Health Research Center, to minimize the risk of any inappropriate access of your data, all files will be maintained on DoD computers protected by all the measures required by DoD computer security regulations. All members of the research team with access to data files will be trained in DoD computer security procedures specifically designed to protect sensitive data. Reports of the study findings will contain only grouped data, so that

no individual study participant can be identified. Similar procedures have been used to protect data in previous studies conducted within this research center.

According to the DoD Policy "Interim Regulations to Improve Privacy Protections for DoD Medical Records" dated October 31, 2000, the information you provide is for research purposes only and may not be disclosed except for specifically authorized purposes or with the consent of the individual about whom the information pertains. Uses and disclosures of this information shall comply with provisions of the Privacy Act and implementing regulations.

For this research study, a Department of Health and Human Services (DHHS) Certificate of Confidentiality is in place to protect your privacy such as your name or other identifying information from being disclosed in any civil, criminal, administrative, legislative or other proceedings, whether at the federal, state or local level. The Certificate cannot be used to resist a demand for information from personnel of the U.S. Government that is used for auditing or evaluation of Federally-funded projects or for information that must be disclosed in order to meet the requirements of the Food and Drug Administration (FDA). Further, the researcher is not prevented from disclosure for reporting matters such as family abuse, sexual assault, reportable communicable diseases, a participant's threatened violence to self or others, or as military regulations may require. You should understand that the Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. Insurers, employers, or other persons will not receive your research information, unless they obtain your written consent to do so.

The Millennium Cohort Family Study Principal Investigator, study coordinators, and research team described in the Informed Consent, and others with authority to oversee the conduct of the research agree to safeguard your protected health information by using and disclosing it only as permitted by you in this consent or as directed by state and federal law.

Information gained from your participation in this research study may be published in literature, discussed for educational purposes, and used generally to further science. You will not be personally identified when your information is shared in these ways; all information will de-identified and combined with other participant study data.

14. VOLUNTARY PARTICIPATION:

The decision to take part in this research study is completely voluntary on your part which means you do not have to take part if you do not want to. You may also leave the research study at any time. If you choose not to take part in this research study or if you leave the study before it is finished, there will be no penalty or loss of benefits to which you are otherwise entitled.

15. WHAT HAPPENS IF I WITHDRAW FROM THIS RESEARCH?

If you decide to participate, you can stop at any time you wish or skip any question you choose. If you choose not to participate or to discontinue your participation, you will not lose any benefit to which you are otherwise entitled. You may change your mind and revoke your permission to further collect or use your health information at any time. If you revoke your permission, no new health information about you will be gathered after that date. However, unless specified otherwise, information that has already been gathered may still be used for analyses. Collected data will be maintained until all research questions are answered. To end participation, contact the principal investigator at usn.point-loma.navhlthrschcensan.mbx.family-cohort@health.mil.

Please note that withdrawing your consent to participate in this research does not fully revoke your HIPAA Authorization Form to use/disclose your protected health information. To make that revocation, please send a letter to the principal investigator as discussed in the HIPAA Authorization Form.

The principal investigator of this research study may terminate your participation in this research study at any time if she determines this to be in your best interest, if you are unable to comply with the procedures required, or if you no longer meet eligibility criteria.

16. CONTACT INFORMATION:

Principal Investigator (PI)
The Principal Investigator or a member of the research staff will be available to answer any questions throughout this study.

Principal Investigator: Valerie Stander, PhD
Phone: (619) 553-7465
Email: usn.point-loma.navhlthrschcensan.mbx.family-cohort@health.mil

Institutional Review Board (IRB) Office
If you have any questions about your rights as a research participant or if you have concerns or complaints about the research study, please contact the IRB Chair by phone, 619-553-8424 or email usn.nhrc.irb@health.mil.

IF THERE IS ANY PORTION OF THIS DOCUMENT THAT YOU DO NOT UNDERSTAND, YOU SHOULD REACH OUT TO RESEARCH STAFF AT USN.POINT-LOMA.NAVHLTHRSCHCENSAN.MBX.FAMILY-COHORT@HEALTH.MIL AND ASK THE INVESTIGATORS BEFORE SIGNING.

Click here to download a copy of this consent for your records.

SIGNATURE OF PARTICIPANT

By entering your subject ID and clicking the Yes, I agree button below, you agree that you have read the information in this consent form. You have been given an opportunity to ask questions about this study and its procedures and risks, as well as any of the other information contained in this consent form. All of your questions have been answered to your satisfaction. You understand that this is research. You freely give your consent to be in this research study as it has been explained to you. You authorize the use and disclosure of your health information to the persons listed in the consent form for the purposes described above.

By entering my subject ID and clicking the Yes, I agree button below, I have not given up any of my legal rights as a research participant.

Type Your Subject ID: _____

Yes, I agree | No, I do not agree

MILLENNIUM COHORT FAMILY STUDY

ADDENDUM TO CONSENT TO PARTICIPATE IN A RESEARCH STUDY

1. KEY INFORMATION

This study includes the use of information collection tools (e.g., surveys, questionnaires):

OMB Control Number: 0703-0064 (expiration date: 28 FEB 2025)

RCS Approval Number: DD-NAVY (AR)2678 (expiration date: 28 FEB 2025)

The following information should be read as an addition to the original Consent form that you read and signed at the beginning of the study. Unless specifically stated otherwise in the following paragraphs, all information contained in that original Consent form is still true and remains in effect. Your participation continues to be voluntary. You may refuse to participate or may withdraw your consent to participate at any time, and for any reason.

Changes including the following:

- The Principal Investigator, the person responsible for the conduct of the study has changed from Valerie Stander, PhD to Hope McMaster, PhD. Dr. McMaster or a member of the research staff will be available to answer any questions throughout this study.
  Phone: (800) 571-9248
  Email: usn.point-loma.navhlthrschcensan.mbx.family-cohort@health.mil

By completing and returning the attached survey, you agree that you have read this addendum. You have been given an opportunity to ask questions about this study and its procedures and risks, as well as any of the other information contained in this addendum. All of your questions have been answered to your satisfaction. You understand that this is research. You freely give your consent to be in this research study as it has been explained to you.

Additionally, you may be asked to participate in other research studies that are outside the scope of the study. In the event that you agree to participate in such a study, a separate informed consent and HIPAA Authorization will be requested from you.

If you would like to receive a copy of your original consent form, please contact the study team at usn.point-loma.navhlthrschcensan.mbx.family-cohort@health.mil or (800) 571-9248.

If you have any questions about your rights as a research participant or if you have any concerns or complaints about the research study, please contact the IRB Chair by phone, 619-553-8424 or email usn.nhrc.irb@health.mil.

Continue to Survey

In recognition of Military Spouse Appreciation Day, the Millennium Cohort Family Study team would like to honor the resilience and strength of all military spouses. You play a crucial role supporting your spouse and families. Our nation is indebted to all of you, because families serve too!

We want to remind you that your children have the opportunity to contribute artwork for the 2023 Family Study calendar and future participant mailings. 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 part of a historic research effort to improve the lives of current and future military families. Thank you for your service and 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.

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 2023 Family Study Calendar and online gallery!

To review the submission guidelines, please visit http://www.familycohort.org/calendar.

As a reminder, your Subject ID is ######. We are excited to see your child(ren)'s artwork

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.

Reminder Letter: Follow-Up Non-responders
Mail Date: TBD
Dear NAME,

I understand that finding time to complete the Family Study follow-up survey is not easy. You may be wondering if the Family Study really matters and if it is different from other surveys. I want to assure you that it is! One of the reasons that the Family Study matters and is different from other surveys is the SCIENCE behind what we do.

When you joined the Family Study, you began a journey with a select group of spouses that we have the privilege to hear from every three years. There are no other DoD studies that are as large and long-term as the Family Study. We want to understand your experiences while your family is connected to the military, as well as after service! We want to hear from spouses who don't have children, as well as those that choose to have children! We want to hear from spouses even when their marital status changes! We care about you and want to make sure that military life is beneficial to you and your family.

This is why we work closely with Military Community and Family Policy, the White House, and numerous other advocacy and policy groups to make sure that your experiences as a military spouse are communicated to decision makers that can improve policy and programs.

We understand that families change over time and have tried our best to tailor our survey to address your specific situation. By sharing your perspective and experiences, you will help to fill in the gaps of how military life impacts service members, spouses, and children.

Please complete your survey today by visiting **www.familycohort.org**, clicking "**Start Survey"**, and entering your **Subject ID: XXXXXXX**. At the end of your survey, you will have the opportunity to select a $10 **Amazon digital gift code**, as a token of appreciation for your time.

Thank you for your continued support of this important research effort.

Very sincerely,

Hope McMaster, PhD
Principal Investigator
Millennium Cohort Family Study

The Millennium Cohort Family Study is a Department of Defense project at the Deployment Health Research Department, located at the Naval Health Research Center, in San Diego, California. OMB Control #: 0703-0064, RCS: DD-NAVY(AR)2678, and Primary Institutional Review Board Protocol # NHRC.2015.019

Dear NAME,

As a member of the Millennium Cohort Family Study, you are part of one of the most important research initiatives designed to understand the impact of military life on families over time. By gathering the perspectives and experiences of nearly 30,000 participants, our study team can better understand the challenges families, like yours, face every day.

We recognize that military spouses face unique stressors including frequent moves, disruptions in education and career progression, and separation from spouses during deployments, trainings, and unaccompanied tours. We know that these stressors can impact marriages and relationship well-being.

In the included infographic, we have highlighted findings from a study examining how different strengths can help couples overcome the challenges they face. When the study was launched in 2011, more than half of Family Study participants felt they had strong marriages. More than a decade later, it is important to understand what factors may have protected your marriage or put it at risk. Knowledge of risk and protective factors help the DoD understand how to support military families so they can stay healthy and happy.

Our research is only possible by hearing from our participants every three years. If you have not had a chance to complete your 2024-2025 follow-up survey yet, please consider doing so today.

Please complete your survey by going to www.familycohort.org, clicking on Start Survey, and entering your Subject ID: XXXXXXX. At the end of your survey, you will have the opportunity to select a digital $10 Amazon gift code that you can use immediately!

Thank you for your time and continued support of this research effort.

Very sincerely,

Hope McMaster, PhD
Principal Investigator
Millennium Cohort Family Study

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The Millennium Cohort Family Study

WHAT STRENGTHS ARE YOU BUILDING IN YOUR MARRIAGE?

Military life can be stressful for couples. Building these strengths can help during challenging times:

Personal Beliefs

Sense of control over your life • Positive outlook about the future • Spirituality, faith, and compassion

Family Communication Skills

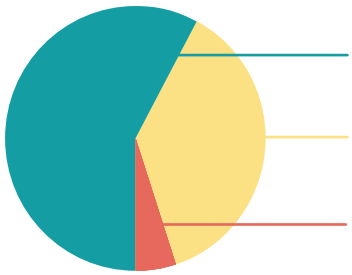
Ability to listen and empathize • Discuss ideas calmly • Solve problems effectively • Express feelings openly and honestly

Access to Social Support

Family and friends you can turn to for help • Others who care for you and make you feel loved

How do military couples view their strengths?

Most service members and their spouses report high levels of the above strengths in their marriage.



58% of couples reported the highest levels across all strengths.

37% of couples reported moderate levels of strengths.

Only **5%** of couples reported the lowest levels across all strengths.
Without important strengths, life stress may take a greater toll on couples.

Couples with the lowest levels of strengths experienced:

Worse mental health

Lower marital relationship quality

Less satisfaction with the military

Ways to build strengths in your marriage

Take an inventory of your personal beliefs:

- Participate in a survey of your character strengths
- Get involved in spiritual or charitable activities
- Seek out help from a professional when you need it

Work on improving communication in your family:

- Make a plan for staying connected when family members are apart
- Contact your local family service center to participate in a communication skills workshop
- Check out Military OneSource and sign up for a marriage enrichment weekend

Build your social support network:

- Make a list of family and friends you can turn to for support
- Communicate regularly with your most important friends and family
- Seek out opportunities to connect with others in your community

VIA Institute on Character. (2020). The VIA Character Strengths Survey. Retrieved from https://www.viacharacter.org/survey/account/register
Pflieger, J. C., Porter, B., Carballo, C. E., Stander, V. A., & Corry, N. H. (2020). Patterns of strengths in U.S. military couples. *Journal of Child and Family Studies*, 29, 1249–1263. https://doi.org/10.1007/s10826-019-01593-4

Research Center
NHRC.2015.0019
AL DATE: 07/09/2024

For more information, go to **http://www.familycohort.org**

The Millennium Cohort Family Study follows nearly 10,000 spouses of junior military personnel for 21 years to help the Department of Defense understand the needs of families and provide better support.

Reminder Letter - August

Dear NAME,

As one of nearly 30,000 members of the Millennium Cohort Family Study, you have a unique opportunity to inform policy and shape the lives of current and future military families. We hope you continue your involvement in this important research effort by taking some time out of your day to complete your 2024-2025 follow-up survey.

We know families change over time; even if your marital status has changed or your service member is no longer in the military, we want to hear from you! Your perspective and well-being matter, and we truly value your input.

We have put a lot of effort into modifying our survey questions to make the Family Study survey as relevant as possible to all of our participants. We hope this year's follow-up survey addresses issues that you consider important.

Please complete your survey by going to **www.familycohort.org**, clicking on **"Start Survey"**, and entering your **Subject ID: XXXXXXX**. At the end of your survey, you will have the opportunity to select a digital $10 **Amazon gift code** that you can use immediately!

Thank you for your time and continued support of this research effort.

Very sincerely,

Hope McMaster, PhD
Principal Investigator
Millennium Cohort Family Study

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Pre-incentive Notecard: Gift Version

Dear NAME,

As a member of the Millennium Cohort Family Study, you have the unique opportunity to share your experiences regarding how military life impacts your family. Because relationships and families change over time, this study is designed to reach out to you every few years so that you can share your experiences since the last survey.

This year's follow-up survey includes new questions to evaluate both the short- and long-term impact of military service on families. Even if your marital status has changed or you are no longer a part of the military community, your perspective matters! It is only through your continued dedication to this important research program that we can make an impactful difference in the lives of current and future military families.

Please complete your survey by going to **WWW.FAMILYCOHORT.ORG**, click on **START SURVEY**, and enter your Subject ID: XXXXXXX.

In recognition of your commitment to the Family Study, we are enclosing a $5 digital Amazon gift code as a small token of our appreciation. We truly value your input, and hope you spend some of your day completing your follow-up survey.

Very sincerely,

Hope McMaster, PhD
Principal Investigator
Millennium Cohort Family Study

The Millennium Cohort Family Study is a Department of Defense project at the Deployment Health Research Department, located at the Naval Health Research Center, in San Diego, California. OMB Control #: 0703-0064, RCS: DD-NAVY(AR)2678, and Primary Institutional Review Board Protocol # NHRC.2015.0019

Pre-incentive Notecard: No Gift Version

Dear NAME,

As a member of the Millennium Cohort Family Study, you have the unique opportunity to share your experiences regarding how military life impacts your family. Because relationships and families change over time, this study is designed to reach out to you every few years so that you can share your experiences since the last survey.

This year's follow-up survey includes new questions to evaluate both the short- and long-term impact of military service on families. Even if your marital status has changed or you are no longer a part of the military community, your perspective matters! It is only through your continued dedication to this important research program that we can make an impactful difference in the lives of current and future military families.

Please complete your survey by going to **WWW.FAMILYCOHORT.ORG**, click on **START SURVEY**, and enter your Subject ID: XXXXXXX.

We truly value your input, and hope you spend some of your day completing your follow-up survey.

Very sincerely,

Hope McMaster, PhD
Principal Investigator
Millennium Cohort Family Study

The Millennium Cohort Family Study is a Department of Defense project at the Deployment Health Research Department, located at the Naval Health Research Center, in San Diego, California. OMB Control #: 0703-0064, RCS: DD-NAVY(AR)2678, and Primary Institutional Review Board Protocol # NHRC.2015.0019

Targeted Letter for Widows

Dear NAME,

I know your life has changed considerably since you joined the Family Study and completed your first survey. I can't imagine what you've been through, but you are important to our research team and to the study.

I am writing this letter to ask you for time that you probably have little of, in the hope that I can encourage you to stay connected with the Family Study. Your experiences with the military are unique and we think it is important that we continue to follow-up with you.

The Family Study was started in 2010 to understand how military life impacts families over time. We invited spouses from all branches of service, active-duty, Reserve and National Guard, and made sure to also include male spouses. We wanted to be representative of the entire military community and we made a commitment to come back every three years to find out how families were doing.

To be as comprehensive and inclusive as possible, our survey has been updated to ensure an understanding of the evolving situations and circumstances of military spouses over time. As such, the survey includes sections intended for participants with current or prior military service, with and without children, as well as those who are separated, divorced, or widowed.

We do this so we can provide our partners within the DoD, as well as advocacy groups outside of government, with information that provides insights to help improve policies and programs designed to serve military families. We regularly publish and present our findings, so we can help inform health care providers, military leaders, and policy makers about the challenges, concerns, and needs of military families.

To complete your survey, please visit the study website **www.familycohort.org**, click **"Start Survey"** and enter your **Subject ID: XXXXXXX**. At the end of your survey, you will have the opportunity to select a $10 **Amazon digital gift code**, as a token of appreciation for your time.

If you have any questions, would prefer to not be contacted, or would like to be removed from this study, please contact the Millennium Cohort Family Study team at our toll-free number: 1-800-571-9248 or email: usn.point-loma.navhlthrschcensan.mbx.family-cohort@health.mil.

Very sincerely,

Hope McMaster, PhD
Principal Investigator
Millennium Cohort Family Study

The Millennium Cohort Family Study is a Department of Defense project at the Deployment Health Research Department, located at the Naval Health Research Center, in San Diego, California. OMB Control #: 0703-0064, RCS: DD-NAVY(AR)2678, and Primary Institutional Review Board Protocol # NHRC.2015.0019

Monthly Reminder Email: Family Study Follow-Up Partial Responders

Subject Line: Please Complete your Survey

Dear NAME,

We greatly appreciate the time that you have already invested to begin your 2024-2025 Millennium Cohort Family Study survey. We hope you will consider spending part of your day completing this important military family survey.

To complete the remaining questions on your survey, please visit, **www.familycohort.org** click **Start Survey** and enter the following **Subject ID: xxxxxxx.** Don't forget to claim your $10 **Amazon digital gift code!**

We truly value your past and current participation in a study designed to help improve the lives of military families.

Very respectfully,

Dr. Hope McMaster
Principal Investigator
Millennium Cohort Family Study

The Millennium Cohort Family Study is an authorized Department of Defense project. Note Report Control Symbol # DD-NAVY(AR)2678, Office of Management and Budget Approval #0703-0064, and Primary Institutional Review Board Protocol #NHRC.2015.0019

Monthly Reminder Email: Family Study Follow-Up Non-Responders

Subject Line: Take Your Family Study Survey Today

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 this important research thus far 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 2024-2025 follow-up survey today.

To complete your survey, please visit, **www.familycohort.org** click **Start Survey** and enter the following **Subject ID: xxxxxxx.** Upon completion you will be able to claim a $10 Amazon digital gift code!

We truly value your support of this historic research effort!

Very respectfully,

Dr. Hope McMaster
Principal Investigator
Millennium Cohort Family Study

The Millennium Cohort Family Study is an authorized Department of Defense project. Note Report Control Symbol # DD-NAVY(AR)2678, Office of Management and Budget Approval #0703-0064, and Primary Institutional Review Board Protocol #NHRC.2015.0019

Single Parent Non-responder Monthly Email

Subject line: Make an Impact on Military Families

Dear [FIRST NAME AND LAST NAME],

You are invited to join the Millennium Cohort Family Study because you indicated that you are a **parent** on the Millennium Cohort Study survey. The Family Study includes military families of all types, and we feel strongly that parents in the military should have their voices heard. Your experiences as a service member and parent are important for guiding decisions made by military and civilian leadership, support providers, policy makers, and clinicians.

As a token of our appreciation for your participation in this short 10-minute survey, you will have the opportunity to download a $10 digital Amazon gift code upon completion of the survey. We truly value your participation in a study designed to help improve the lives of your fellow service members and military families.

To complete the online survey now, log in to our secure website:
https://www.familycohort.org, click **Start Survey**, and enter your **Subject ID: XXXXXX**

Thank you for your service and your participation in DoD research.

Very sincerely,

Dr. Hope McMaster
Principal Investigator
Millennium Cohort Family Study

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Single Parent Partial Completer Monthly Email

Subject line: Please Complete Your Parent Survey

Dear [FIRST NAME AND LAST NAME],

We greatly appreciate the time that you have already invested to begin your Millennium Cohort Family Study survey. The Family Study includes families of all types, and we feel strongly that parents in the military should have their voices heard. We hope you will consider spending part of your day completing this important military family survey.

To complete the remaining questions on your survey, please visit **https://www.familycohort.org**, click **Start Survey**, and enter your **Subject ID: XXXXXX**

As a token of our appreciation for your participation in this short 10-minute survey, you will have the opportunity to download a $10 digital Amazon gift code upon completion of the survey. We truly value your participation in a study designed to help improve the lives of your fellow service members and military families.

Very sincerely,

Dr. Hope McMaster
Principal Investigator
Millennium Cohort Family Study

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Month of the Military Family Email: Follow-Up Non-Responders

Subject Line: Because Families Serve Too

Dear NAME,

During National Military Family Month, we want to thank you for your resilience and sacrifices made in support of our nation. We honor the important role you play and recognize that families serve too!

Unlike other studies, the Family Study is designed to follow you over time as you experience the unique challenges associated with military life (e.g., relocation, separation and deployment). Even if your spouse is no longer in the service, or if you have separated or divorced, we would still like to hear from you. Your perspective and experiences help to create the full picture of how military life impacts families.

We hope you take some time out of your day to complete your follow-up survey by visiting **www.familycohort.org**, clicking **"Start Survey"** and entering your **Subject ID: XXXXXXX**. At the end of your survey, you will be provided a $10 **Amazon digital gift code**!

Thank you for your time and sacrifices for our country.

Very respectfully,

Dr. Hope McMaster
Principal Investigator
Millennium Cohort Family Study

The Millennium Cohort Family Study is an authorized Department of Defense project. Note Report Control Symbol # DD-NAVY(AR)2678, Office of Management and Budget Approval #0703-0064, and Primary Institutional Review Board Protocol #NHRC.2015.0019

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Dear NAME,

During National Military Families Month, we acknowledge and honor the strength and sacrifices of our service members, veterans, and their families. Spouses and families serve as the backbone of our armed forces, and their strength is unparalleled. The Millennium Cohort Family Study team pays tribute to their unwavering dedication and invaluable contributions to our nation.

We would also like to take this opportunity to thank you for your contribution to the Family Study. Your continued participation is vital to this unique research effort. If you have not had a chance to complete your follow- up survey, please visit www.familycohort.org, click "Start Survey" and enter your Subject ID: XXXXXXX.

We hope to hear from you because families serve too!

Very respectfully,

Dr. Hope McMaster
Principal Investigator of the Millennium Cohort Family Study

The Millennium Cohort Family Study is an authorized Department of Defense project. Note Report Note Report Control Symbol #DD-HA(AR)2106, Office of Management and [illegible] approval # 0720-0029, and Primary Institutional Review Board Protocol # NHRC.2015.0019.

Naval Health Research Center
IRB NUMBER: NHRC.2015.0019
IRB APPROVAL DATE: 07/09/2024

Reminder Email #3: Follow-Up Non-Responders

Subject Line: Military Spouses Matter!

Dear NAME,

I hope you received our mailing recently with findings from the Family Study about Building Strengths in Marriages. We work with Military Community and Family Policy (MC&FP) to share our findings and help shape policy and programs.

Did you know that MC&FP is directly responsible for programs and policies that establish and support community quality of life programs for Service members and their families worldwide? These include childcare, youth programs, military spouse programs, family advocacy, support during mobilization and deployment, and confidential non-medical counseling through Military and Family Life Counselors (MFLCs) and Military OneSource!

We appreciate your participation thus far in the Family Study and ask for your continued support of this important research by completing your follow-up survey today!

Please complete your follow-up survey by visiting **www.familycohort.org**, clicking **"Start Survey"** and entering your **Subject ID: XXXXXXX**. Once your survey is completed you will be provided a $10 **Amazon digital gift code!**

Thanks again for being a part of this unique network of military spouses!

Very respectfully,

Dr. Hope McMaster
Principal Investigator
Millennium Cohort Family Study

The Millennium Cohort Family Study is an authorized Department of Defense project. Note Report Control Symbol # DD-NAVY(AR)2678, Office of Management and Budget Approval #0703-0064, and Primary Institutional Review Board Protocol #NHRC.2015.0019

Reminder Email #2: Follow-Up Non-Responders

Subject Line: Your cohort

Dear NAME,

We hope you will consider spending a part of your day completing your follow-up survey. By being part of a cohort of spouses that we hear from every three years, your experiences are amplified! The Family Study only contacts members of the study that joined in 2011 or in 2020, so you are part of a very important group of military spouses.

Every survey counts, which is why it is essential to stay involved with the Family Study even if your relationship status has changed or you are no longer connected to the military.

Please complete your survey today by visiting **www.familycohort.org**, clicking **Start Survey** and entering your **Subject ID: XXXXXXX**. As a token of appreciation for your time, you will receive a $10 **Amazon digital gift code** upon completion of your survey.

As always, thank you for your time, participation, and service.

Very respectfully,

Dr. Hope McMaster
Principal Investigator
Millennium Cohort Family Study

The Millennium Cohort Family Study is an authorized Department of Defense project. Note Report Control Symbol # DD-NAVY(AR)2678, Office of Management and Budget Approval #0703-0064, and Primary Institutional Review Board Protocol #NHRC.2015.0019

just a friendly reminder...

Millennium Cohort
Family Study

Naval Health Research Center
IRB NUMBER: NHRC.2015.0019
IRB APPROVAL DATE: 07/09/2024

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Please accept our small gift of recognition when you complete your follow-up survey.

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 on the lives of military spouses and children. Even if you are no longer connected to the military or married to your service member spouse, your perspective matters! We hope you continue your involvement in this important research effort by taking some time out of your day to complete your 2024-2025 follow-up survey.

To complete your survey, visit **www.familycohort.org**, click on "Start Survey" and enter your **Subject ID XXXXXXX**. At the end of your survey, you will receive a $10 digital Amazon gift code that can be used immediately!

Thank you for your time and continued support of this research effort.

Hope McMaster

Dr. Hope McMaster
Principal Investigator
Millennium Cohort Family Study

Millennium Cohort
Family Study

Postcard artwork provided by the child of a Millennium Cohort Family Study participant.

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Naval Health Research Center
IRB NUMBER: NHRC.2015.0019
IRB APPROVAL DATE: 07/09/2024

Reminder Email #1: Follow-Up Non-Responders

Subject Line: You are Important

Dear NAME,

As a member of the Millennium Cohort Family Study, you have the unique opportunity to represent all current and future military spouses. Even if you are no longer connected to the military or married to your service member spouse, your perspective matters! The study is designed to follow you, and we hope this year's follow-up survey addresses issues that you feel are important.

Please complete your follow-up survey today by visiting **www.familycohort.org**, clicking **"Start Survey"** and entering your **Subject ID: XXXXXXX**. At the end of your survey, you will receive a $10 digital **Amazon gift code** that can be used immediately!

Very respectfully,

Dr. Hope McMaster
Principal Investigator
Millennium Cohort Family Study

The Millennium Cohort Family Study is an authorized Department of Defense project. Note Report Control Symbol # DD-NAVY(AR)2678, Office of Management and Budget Approval #0703-0064, and Primary Institutional Review Board Protocol #NHRC.2015.0019

Pre-Incentive Notecard Email: Follow-Up Non-Responders

Subject Line: Take Your Survey Today

Dear NAME,

We are reaching out to let you know that the 2024-2025 Family Study survey is available online. Your participation thus far has made a true impact, and only by continuing to hear from you will we be able to better understand how military life changes over time.

Our study team mailed invitation cards last week; if you did not receive one, please consider updating your contact information on the Family Study website so you can stay up to date with all of our study findings and contacts.

Complete your follow-up survey today by visiting **www.familycohort.org**, clicking **"Start Survey"** and entering your **Subject ID: XXXXXXX**. Once your survey is completed you will receive a $10 **digital Amazon gift code** that can be used immediately!

Very respectfully,

Dr. Hope McMaster
Principal Investigator
Millennium Cohort Family Study

The Millennium Cohort Family Study is an authorized Department of Defense project. Note Report Control Symbol # DD-NAVY(AR)2678, Office of Management and Budget Approval #0703-0064, and Primary Institutional Review Board Protocol #NHRC.2015.0019

Bi-Fold Newsletter Email: Follow-Up Non-Responders

Subject Line: Gift card to say thank you

Dear NAME,

Because of being a military spouse myself, I understand that finding time to complete the Family Study follow-up survey is not easy. You may be wondering if the Family Study really matters and if it is different from other surveys. I want to assure you that it is! One of the reasons that the Family Study matters and is different from other surveys is the SCIENCE behind what we do.

When you joined the Family Study, you began a journey with a select group of spouses that we have the privilege to hear from every three years. There are no other DoD studies that are as large and long-term as the Family Study. We want to understand your experiences while your family is connected to the military and after service! We want to hear from spouses who don't have children as well as those that choose to have children! We want to hear from spouses even when their marital status changes! We care about you and want to make sure that military life is beneficial to you and your family.

This is why we work closely with Military Community and Family Policy, the White House, and numerous other advocacy and policy groups to make sure that your experiences as a military spouse are communicated to decision makers that can improve policy and programs.

Please complete your follow-up survey today by visiting **www.familycohort.org**, clicking **"Start Survey"** and entering your **Subject ID: XXXXXXX**. Once your survey is completed you will receive a $10 **digital Amazon gift code** that can be used immediately!

As always, thank you for your participation and your service. Because families serve too!

Very respectfully,

Dr. Hope McMaster
Principal Investigator
Millennium Cohort Family Study

The Millennium Cohort Family Study is an authorized Department of Defense project. Note Report Control Symbol # DD-NAVY(AR)2678, Office of Management and Budget Approval #0703-0064, and Primary Institutional Review Board Protocol #NHRC.2015.0019

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COMPLETE YOUR FOLLOW-UP SURVEY TODAY!

The 2024–2025 Family Study follow-up survey is available.

Complete it today and receive a $10 Amazon gift code!

The Millennium Cohort Family Study is an authorized Department of Defense project. Note Report Control Symbol #DD-NAVY(AR) 2678, Office of Management and Budget Approval #0703-0064, and Primary Institutional Review Board Protocol #NHRC.2015.0019

BECAUSE FAMILIES SERVE TOO!

Dear Participant,

On behalf of the Millennium Cohort Family Study team, I want to thank you for your commitment to this critically important research. It has been my privilege to serve on the Family Study team since it was launched in 2011. As we begin our fourth survey cycle, we are reaching out to almost 30,000 spouses that have already enrolled in the Family Study – representing spouses from all military branches, spouses of Reserve and National Guard, spouses of Veterans, male spouses, spouses that have served in the military, and spouses whose marital status has changed, but have military-connected kids! We are the only study that can examine the impact of military life over time and we are honored that you have chosen to join us on this journey. The Family Study is a key resource for decisions that are being made to protect and support military families both during and after service. Your continued participation is vital!

Please consider completing your 2024–2025 follow-up survey today!

Very respectfully,

Hope McMaster

Hope McMaster, PhD
Principal Investigator, Millennium Cohort Family Study

Naval Health Research Center
IRB NUMBER: NHRC.2015.0019
IRB APPROVAL DATE: 07/09/2024

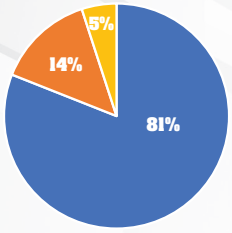
CHARACTERISTICS OF THE COHORT

11% Male

89% Female

70% have some college education

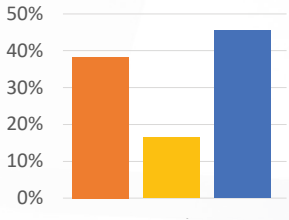
13,623 children are represented in the Family Study



5% are separated from the military

14% are Reserve/Guard families

81% are Active duty families



39% work full time

15% work part time

46% are not employed outside of the home

45% are Army families

15% are Navy families

10% are Marine Corps families

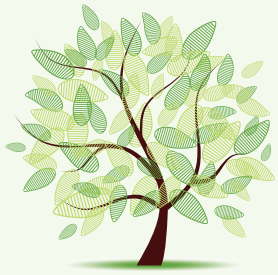
27% are Air Force families

3% are Coast Guard families

14% are currently serving or have served in the military

7500 Spouses in the study have experienced over 7,500 deployments

PARTICIPATION



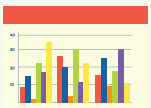
As a member of the Millennium Cohort Family Study, we ask that you take 45 minutes out of your day to complete your online follow-up survey.

COMPLETION GIFT

As a token of our appreciation for your participation in the 2024-2025 Family Study survey cycle, you will receive a $10 digital Amazon gift code at the end of your survey that can be used immediately!"

HOW YOUR PARTICIPATION HELPS MILITARY FAMILIES

Data from participants are collected, combined, and analyzed together. Individual information and data are not shared outside of the study team.



The study team analyzes data from all participants to better understand how military experiences impact families.

The study team writes reports, publishes articles and provide briefs to decision makers. Through partnerships with advocacy groups, support programs and military leadership, study findings help to inform policy and programs for current and future military families.

Naval Health Research Center
IRB NUMBER: NHRC.2015.0019
IRB APPROVAL DATE: 07/09/2024