INSTITUTIONAL REVIEW BOARD

MODIFICATION REVIEW

Date of Review:	August 14, 2024	Protocol Number: NHRC.2000.0007
Protocol Title:	Prospective Studies of U.S. Military Forces: The Millennium Cohort Study	
Principal Investigator:	Rudolph Rull, PhD	
Project ID/WBS:	Deployment Health Research, 60002/100001869677_007A	

The principal investigator submitted a modification request for a protocol that was previously classified as minimal risk. With funding from the Defense Health Agency administered Military Operational Medicine Research Program (JPC-5) and Department of Veterans Affairs (VA) Research Development Testing and Evaluation funds, the primary objective of this project is to evaluate the impact of military service, including deployments and other occupational exposures, on long-term mental, physical, and behavioral health. The goal is to provide evidence-based knowledge products to inform and improve interventions, guidelines, and policy of key stakeholders including DOD and VA leaders. The objective of this research is to examine any trends in the health of U.S. service members and their families over time. Toward that end, the health of a cohort of regular active-duty, National Guard, and Reserve military personnel will be followed for 67 years via surveys administered at three-year intervals. Participants are requested to complete questionnaires every 3 to 5 years. Participants are allowed to complete the questionnaire by paper-and-pencil or online. Individuals are tracked while serving, as they integrate into civilian life and beyond. Participant follow-up is planned through at least 2068. Survey information collected includes mental, physical, and behavioral health metrics as well as military and post-service experiences. These data are linked to enterprise databases, including military, healthcare utilization, and mortality records.

The modification requests to:

(1) Add two new participant contacts (to be included in Appendix G):
   a. A completion email for those that complete the web survey
   b. A thank-you card for responders that choose to receive the gift hat

(2) Revise Section 13.2 of the protocol to include:
   a. Update the date of the last Office of General Counsel approval
   b. Add a challenge coin thank-you gift option for participants that complete the web survey
   c. Indicate that instead of a gift card, the project will offer a gift code
   d. Remove listed vendors that the study team was unable to establish contracts
   e. Explain the process for providing participants with the gift code

A waiver of documentation of informed consent has been granted for this study under 32 CFR§219.116(f) in that the research involves no more than minimal risk, subjects' rights and

welfare would not be adversely affected, and the only record linking the subject to the study would be the signature on the consent form.

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 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 Chair approves this protocol modification.

The research is expected to end on September 30, 2068.

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 Chair approves this research.

PHI NGO, MA
Chair, Institutional Review Board (IRB)

EIRB Modification Form (Version 34.1)

1.0 Study and PI Info

1.1 Principal Investigator:

Name:

Rudolph P Rull

Email:

rudolph.p.rull2.civ@health.mil

PH #:

6195539267

1.2 Study Information:

Study Title:

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

Study Number:

The Millennium Cohort Study, NHRC.2000.0007

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

In the late 1990s, the US Department of Defense (DoD) and Congress identified the need for coordinated epidemiological research to determine how military occupational exposures, including deployment, affect long-term health. The Institute of Medicine more specifically defined the importance of a large, prospective study for evaluating exposures and a broad spectrum of important health outcomes. The Millennium Cohort Study was designed, in collaboration with all military services and the Department of Veterans Affairs (VA), to meet these research challenges.

Launched in 2001, the Millennium Cohort Study began by recruiting a representative sample of US military personnel, including both active duty and Reserve/ National Guard members. Currently, over 200,000 participants have been enrolled in the study. Participants are requested to complete questionnaires every 3 to 5 years. Individuals are tracked while serving, as they integrate into civilian life and beyond. Participant follow-up is planned through at least 2068. Survey information collected includes mental, physical, and behavioral health metrics as well as military and post-service experiences. These data are linked to enterprise databases, including military, healthcare utilization, and mortality records. The fifth follow-up survey is currently underway (2019-2020).

The primary objective of this project is to evaluate the impact of military service, including deployments and other occupational exposures, on long-term mental, physical, and behavioral health. The ultimate goal is to provide evidence-based knowledge products to inform and improve interventions, guidelines, and policy of key stakeholders including DoD and VA leaders.

As the largest and longest running cohort study in military history, the Millennium Cohort Study is uniquely positioned to follow the course of mental, physical, and behavioral health of service members, including the transition to civilian life. Veteran’s health and well-being have become growing priorities for our research portfolio as 70% of our participants have left active military service.

1.3 Study Status:

Study is open to accrual:

- [ ] No participants have been enrolled
- [ ] 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
- [x] Administrative changes
- [x] 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):

- [x] 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
- [x] 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.

The Millennium Cohort Study is submitting for review and approval:

1. Two (2) additional participant contacts added to Appendix G.
2. Updates to section 13.2 of the protocol.

2.8 * Explain why these modifications are being made:

1. Two (2) new contacts have been added to Appendix G.
2. Section 13.2 of the protocol has been modified to
    1. update the date of the last OGC approval
    2. add the challenge coin as a thank you gift option for participants that complete the web survey
    3. show that instead of a gift card, the project will offer a gift code
    4. remove vendors with whom we were not able to establish contracts
    5. explain the way with which we will provide the participant with the gift code, if selected.

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 Revisions to the Protocol

3.1 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
	1.46	EIRB Protocol Template (Version 1.46) - Attached

3.2 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?)

This modification does not change the risks of the study, therefore, the participants will not be notified.

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

4.0 Other Study Documents

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

Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
1.0	Completion Messages	Other				248.33 KB
1.42	APPENDIX G PARTICIPANT CONTACTS	Other				8.74 MB

5.0 Updated Conflict of Interest Disclosure

5.1 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

EIRB Protocol Template (Version 1.46)

1.0 General Information

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

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

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

The Millennium Cohort Study, NHRC.2000.0007
* 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:

Rull, Rudolph P

Select if applicable

☐ Student ☐ Site Chair
☐ Resident ☐ Fellow

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

Castaneda, Sheila Faye, PhD
Co-Investigator
Stander, Valerie A, Ph.D.
Co-Investigator

B) Research Support Staff

Altarejos, Isabel Velasco, MPH
Team Member
BRAMER, BRITTANY ANN
Research Coordinator
Carinio, Sarah Rebecca
Team Member
Gumbs, Gia R
Team Member
Lovec-Jenkins, Denise Elaine
Research Coordinator
Seay, Julia S, PhD
Team Member
Sheppard, Beverly DESIREE
Research Coordinator
Tannenbaum, Karen, PhD
Team Member
Walstrom, Jennifer Lee
Research Coordinator

3.3 *Please add a Protocol Contact:

BRAMER, BRITTANY ANN
Castaneda, Sheila Faye, PhD
Lovec-Jenkins, Denise Elaine
Rull, Rudolph P
Sheppard, Beverly DESIREE
Walstrom, Jennifer Lee

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?

	Other

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.) McMaster, Hope Role on Protocol: Key Support; engaged in HSR	Phone Number: 619-767-4624	Email Address: hope.m.mcmaster.civ@health.mil	Associated Institution: NHRC
Name: (Last, First, M.I.) Trone, Daniel Role on Protocol: Key Support; engaged in HSR	Phone Number: 619-767-4567	Email Address: daniel.w.trone.civ@health.mil	Associated Institution: NHRC
Name: (Last, First, M.I.) Carey, Felicia Role on Protocol: Key Support; engaged in HSR	Phone Number: 619-767-4905	Email Address: felicia.r.carey.civ@health.mil	Associated Institution: NHRC
Name: (Last, First, M.I.) Castaneda, Sheila Role on Protocol: Key Support; engaged in HSR	Phone Number: 619-553-8025	Email Address: sheila.f.castaneda.civ@health.mil	Associated Institution: NHRC
Name: (Last, First, M.I.) Belding, Jennifer Role on Protocol: Key Support; engaged in HSR	Phone Number: 619-553-6889	Email Address: jennifer.n.belding.civ@health.mil	Associated Institution: NHRC
Name: (Last, First, M.I.) Carnes, Nathan Role on Protocol: Key Support; engaged in HSR	Phone Number: 405-816-5079	Email Address: nathan.c.carnes.mil@health.mil	Associated Institution: NHRC
Name: (Last, First, M.I.)			

Stander, Valerie Role on Protocol: Co-Principal Investigator; engaged in HSR	Phone Number: 619-553-7174	Email Address: valerie.a.stander.civ@health.mil	Associated Institution: NHRC
Name: (Last, First, M.I.) Rull, Rudolph Role on Protocol: Principal Investigator; engaged in HSR	Phone Number: 619-553-9267	Email Address: rudolph.p.rull2.civ@health.mil	Associated Institution: NHRC
Name: (Last, First, M.I.) Peretti, Jacqueline Role on Protocol: Key Support; not engaged in HSR	Phone Number: 209-373-9646	Email Address: jacqueline.rine@gmail.com	Associated Institution: NHRC/UCSD-SDSU Preventive Medicine Residency, Naval Medical Center San Diego
Name: (Last, First, M.I.) Allos, Khider Role on Protocol: IT Specialist/Data Managment; engaged in HSR	Phone Number: (619) 553-6892	Email Address: khider.e.allos.civ@health.mil	Associated Institution: NHRC
Name: (Last, First, M.I.) Role on Protocol:	Phone Number:	Email Address:	Associated Institution:
Name: (Last, First, M.I.) Role on Protocol:	Phone Number:	Email Address:	Associated Institution:

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.) Bauer, Lauren Role on Protocol: Key Support; engaged in HSR	Phone Number: 619-767-4605	Email Address: lauren.m.bauer2.ctr@health.mil	Associated Institution: NHRC; Leidos, Inc., IAIR executed
Name: (Last, First, M.I.) Baccetti, Anna Role on Protocol: Key Support; engaged in HSR	Phone Number: 530-263-9567	Email Address: anna.l.baccetti.ctr@health.mil	Associated Institution: NHRC; Leidos, Inc., IAIR executed
Name: (Last, First, M.I.) Speigle, Steven Role on Protocol: Key Support; engaged in HSR	Phone Number: 619-553-8096	Email Address: steven.j.speigle.ctr@health.mil	Associated Institution: NHRC; Leidos, Inc., IAIR executed
Name: (Last, First, M.I.) Dorrell, Michael Role on Protocol: Key Support; engaged in HSR	Phone Number: 650-576-1171	Email Address: michael.s.dorrell2.ctr@health.mil	Associated Institution: NHRC; Leidos, Inc., IAIR executed
Name: (Last, First, M.I.) Richardson, Sabrina Role on Protocol: Key Support; engaged in HSR	Phone Number: 619-553-7598	Email Address: sabrina.m.richardson5.ctr@health.mil	Associated Institution: NHRC; Leidos, Inc., IAIR executed
Name: (Last, First, M.I.) Tu, Xin Role on Protocol: Key Support; engaged in HSR	Phone Number: (610) 724-6925	Email Address: x2tu@ucsd.edu	Associated Institution: NHRC; IES, IIA executed
Name: (Last, First, M.I.)			

LeardMann, Cynthia Role on Protocol: Key Support; engaged in HSR	Phone Number: 619-553-8447	Email Address: cynthia.a.leardmann.ctr@health.mil	Associated Institution: NHRC; Leidos, Inc., IAIR executed
Name: (Last, First, M.I.) Rivera, Anna Role on Protocol: Key Support; engaged in HSR	Phone Number: 619-567-9025	Email Address: anna.c.rivera4.ctr@health.mil	Associated Institution: NHRC; Leidos, Inc., IAIR executed
Name: (Last, First, M.I.) Jacobson, Isabel Role on Protocol: Key Support; engaged in HSR	Phone Number: 619-553-0684	Email Address: isabel.g.jacobson.ctr@health.mil	Associated Institution: NHRC; Leidos, Inc., IAIR executed
Name: (Last, First, M.I.) Hall, Clint Role on Protocol: Key Support; engaged in HSR	Phone Number: 619-767-4762	Email Address: clinton.j.hall15.ctr@health.mil	Associated Institution: NHRC; Leidos, Inc., IAIR executed
Name: (Last, First, M.I.) Bukowinski, Anna Role on Protocol: Key Support; engaged in HSR	Phone Number: 619-553-4690	Email Address: anna.t.bukowinski.ctr@health.mil	Associated Institution: NHRC; Leidos, Inc., IAIR executed
Name: (Last, First, M.I.) Boparai, Satbir Role on Protocol: Key Support; engaged in HSR	Phone Number: 619-553-7980	Email Address: satbir.k.boparai.ctr@health.mil	Associated Institution: NHRC; Leidos, Inc., IAIR executed
Name: (Last, First, M.I.) Geronimo-Hara, Toni	Phone Number:	Email Address:	Associated Institution:

Role on Protocol: Key Support; engaged in HSR	619-553-7938	tonirose.t.geronimo-hara.ctr@health.mil	NHRC; Leidos, Inc., IAIR executed
Name: (Last, First, M.I.) Kolaja, Claire Role on Protocol: Key Support; engaged in HSR	Phone Number: 619-553-7859	Email Address: claire.a.kolaja.ctr@health.mil	Associated Institution: NHRC; Leidos, Inc., IAIR executed
Name: (Last, First, M.I.) Esquivel, Alejandro Role on Protocol: Key Support; engaged in HSR	Phone Number: 619-767-4489	Email Address: alejandro.p.esquivel.ctr@health.mil	Associated Institution: NHRC; Leidos, Inc., IAIR executed
Name: (Last, First, M.I.) Woodall, Kelly Role on Protocol: Key Support; engaged in HSR	Phone Number: (562) 355-7387	Email Address: kelly.a.woodall.ctr@health.mil	Associated Institution: NHRC; Leidos, Inc., IAIR executed
Name: (Last, First, M.I.) Barkho, Wisam Role on Protocol: Key Support; engaged in HSR	Phone Number: 619-553-9337	Email Address: wisam.z.barkho@health.mil	Associated Institution: NHRC; Leidos, Inc., IAIR executed
Name: (Last, First, M.I.) Ray, Travis Role on Protocol: Key Support; engaged in HSR	Phone Number:	Email Address: travis.n.ray2.ctr@health.mil	Associated Institution: NHRC; Leidos, Inc., IAIR executed
Name: (Last, First, M.I.) Moreno Ignacio, David Role on Protocol:	Phone Number: 619-553-6892	Email Address: david.morenoignacio.	Associated Institution: NHRC; Leidos,

Key Support; engaged in HSR		ctr@health.mil	Inc., IAIR executed
Name: (Last, First, M.I.) Zhu, Yunnuo (Katie) Role on Protocol: Key Support; engaged in HSR	Phone Number: 858-531-6133	Email Address: yunnuo.zhu.ctr@health.mil	Associated Institution: NHRC; Leidos, Inc., IAIR executed
Name: (Last, First, M.I.) Sharifian, Neika Role on Protocol: Key Support; engaged in HSR	Phone Number: 919-271-7891	Email Address: neika.sharifian.ctr@health.mil	Associated Institution: NHRC; Leidos, Inc., IAIR executed
Name: (Last, First, M.I.) Villalobos, Jr., Javier Role on Protocol: Key Support; engaged in HSR	Phone Number: 559-974-1129	Email Address: javier.villalobos12.ctr@health.mil	Associated Institution: NHRC; Leidos, Inc., IAIR executed
Name: (Last, First, M.I.) Roesch, Scott Role on Protocol: Key Support; engaged in HSR	Phone Number:	Email Address: sroesch@sdsu.edu	Associated Institution: NHRC; Leidos, Inc., IAIR executed
Name: (Last, First, M.I.) Romano, Celeste Role on Protocol: Key Support; engaged in HSR	Phone Number: 619-553-9292	Email Address: celeste.j.romano.ctr@health.mil	Associated Institution: NHRC; Leidos, Inc., IAIR executed
Name: (Last, First, M.I.) Harbertson, Judith (Judy) Role on Protocol:	Phone Number: 619-553-9095	Email Address: judith.harbertson.ctr@health.mil	Associated Institution: NHRC; Leidos,

Key Support; engaged in HSR			Inc., IAIR executed
Name: (Last, First, M.I.) Jackson, Lauren Role on Protocol: Key Support; engaged in HSR	Phone Number: 619-553-7317	Email Address: lauren.e.jackson27.ctr@health.mil	Associated Institution: NHRC; Leidos, Inc., 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; Leidos, Inc., IAIR executed
Name: (Last, First, M.I.) Altarejos, Isabel Velasco Role on Protocol: Key Support; engaged in HSR	Phone Number: 619-507-0337	Email Address: isabel.v.altarejos.ctr@health.mil	Associated Institution: NHRC; Leidos, Inc., IAIR executed
Name: (Last, First, M.I.) Bramer, Brittany Role on Protocol: Key Support; engaged in HSR	Phone Number: 619-226-5059	Email Address: brittany.a.bramer.ctr@health.mil	Associated Institution: NHRC; Leidos, Inc., IAIR executed
Name: (Last, First, M.I.) Carinio, Sarah Role on Protocol: Key Support; engaged in HSR	Phone Number: 619-767-4847	Email Address: sarah.r.carinio.ctr@health.mil	Associated Institution: NHRC; Leidos, Inc., IAIR executed
Name: (Last, First, M.I.) Gumbs, Gia Role on Protocol: Key Support;	Phone Number: 619-813-8271	Email Address: gia.r.gumbs.ctr@health.mil	Associated Institution: NHRC; Leidos, Inc., IAIR executed

engaged in HSR			
Name: (Last, First, M.I.) Lovec-Jenkins, Denise Role on Protocol: Key Support; engaged in HSR	Phone Number: 619-553-7433	Email Address: denise.e.lovec-jenkins.ctr@health.mil	Associated Institution: NHRC; Leidos, Inc., IAIR executed
Name: (Last, First, M.I.) Sheppard, Beverly Role on Protocol: Key Support; engaged in HSR	Phone Number: 619-553-8750	Email Address: beverly.d.sheppard.ctr@health.mil	Associated Institution: NHRC; Leidos, Inc., 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; Leidos, Inc., IAIR executed
Name: (Last, First, M.I.) Walstrom, Jennifer Role on Protocol: Key Support; engaged in HSR	Phone Number: 619-553-9145	Email Address: jennifer.l.walstrom.ctr@health.mil	Associated Institution: NHRC; Leidos, Inc., IAIR executed
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; Leidos, Inc., IAIR executed
Name: (Last, First, M.I.) Richard, Erin Role on Protocol: Key Support; engaged in HSR	Phone Number:	Email Address: erin.l.richard.ctr@health.mil	Associated Institution: NHRC; Leidos, Inc., IAIR executed

Name: (Last, First, M.I.) Consigli, Rebecca Role on Protocol: Key Support; engaged in HSR	Phone Number: (661) 334-0837	Email Address: rebecca.a.consigli.ctr@health.mil	Associated Institution: NHRC; Abbtech, IIA 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
Name: (Last, First, M.I.) Burce, Cleo, M Role on Protocol: Key Support; engaged in HSR	Phone Number: (619) 553-7569	Email Address: cleomae.p.burce.ctr@health.mil	Associated Institution: NHRC; Leidos, Inc., IAIR executed
Name: (Last, First, M.I.) Woods, Kerris, J Role on Protocol: Key Support; engaged in HSR	Phone Number: (619) 553-7522	Email Address: kerris.j.woods.ctr@health.mil	Associated Institution: NHRC; Dan Sources, Inc., IIA 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

7.0 Funding and Disclosures

7.1 Source of Funding:

Funding Source	Funding Type	Amount
: Military Operational Medicine Research Program (MOMRP) (JPC-5) Defense Health Program	: Research Development Testing and Evaluation (RDT&E) funds	
: Other Department of Veterans Affairs	: 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

service members, longitudinal, mental health, physical health, behavioral health

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

Background

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

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

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

Expert External Review Panels

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

- Defense Science Board(1,10)
- Presidential Advisory Committee on Gulf War Veterans' Illnesses (2,5,11)
- Institute of Medicine(IOM) Committee on Measuring Health of Gulf War Veterans (3,4,12-16)
- General Accounting Office (17-29)
- Presidential Special Oversight Board for Department of Defense Investigations of Gulf War Chemical and Biological Incidents (30,31)

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

Health Registry Evaluations

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

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

Previous Gulf War Veteran Research

The investment in medical research concerning Gulf War veterans has resulted in numerous important findings. Research reports and manuscripts are best chronicled in the DVA Annual Report to Congress (8) and in a 4,462-citation Topical Bibliography of Published Works Regarding the Health of Veterans of the Persian Gulf War. (35)

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

- Studies of mortality-Several studies have examined deaths among Gulf War veterans, (36-38) and with the exception of increased deaths due to accidents, (38) found little evidence of unexplained deaths associated with service in the Gulf War.
- Studies of hospitalizations–Numerous comparisons of post-1991 hospitalizations of Gulf War veterans and those of other veterans of the same era have been published. (39-43) Data from DoD, VA, and California hospitals do not support arguments that Gulf War veterans are being hospitalized at a higher rate for Gulf War-related conditions.
- Studies of symptoms-Controlled studies of Gulf War veterans unanimously document that Gulf War veterans report more conditions and have evidence of more psychological morbidity. (44-48) However, investigators have not been able to implicate specific Gulf War exposures as causing these symptoms. While one team of scientists used factor analysis to suggest unique aggregations of symptoms among Gulf War veterans, (49) other investigators have found the same factor-analysis symptom aggregations among non-deployed veterans. (50-52)

- Studies of reproductive outcomes–While a number of news reports have suggested that Gulf War veterans are experiencing unusual reproductive outcomes, published research studies have not validated these reports. Thus far, researchers have not found increases in the number of birth defects among the offspring of Gulf War veteran families. (53-56)
- Etiologic exposures–A number of investigators have championed hypotheses concerning the cause of increased symptom reporting among Gulf War veterans. While often not in the mainstream of etiologic thinking, these hypotheses have influenced some investigative research. (4,15,57,58) These hypotheses have implicated:
    - Mycoplasma fermentans (59-61)
    - Pyridostigmine bromide (62,63)
    - Multiple chemical sensitivity (64)
    - Depleted uranium (65)
    - Sand exposure (66)
    - Deployment vaccinations (67)
    - Chemical agent resistant coating (CARC)
    - Oil well fires (17)
    - Nerve agents (42)

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

Data Limitations

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

Risk Management

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

Recommendations for the Longitudinal Study of Deployed Forces

The 1999 IOM Measuring Health Report (12) surmised that numerous investigations and research efforts have been undertaken because of concern about the impact of the Gulf War on the health of U.S. troops who served in that conflict. Some of these efforts addressed the federal government's preparedness to meet its obligations and responsibilities to protect U.S. military service members, veterans, and their families. Others attempted to determine what health effects might be attributed to service in the Gulf War. Still others have identified possible causes for the myriad reports of health problems among Gulf War veterans.

IOM also recognized that the continuing focus on the health problems of Gulf War veterans is attributable in no small part to the efforts of individual veterans and the organizations that represent them. They have tirelessly pressured policy officials and the Congress that more

needs to be done to help those Gulf War veterans who are experiencing health problems. In its report on measuring health, the IOM committee recommended implementation of a research portfolio centered on a prospective cohort study of deployed forces. The IOM committee maintained that establishing a prospective cohort study of deployed forces would lead to a greater understanding of the longer-term health effects of military service, including service in deployments such as the Gulf War.

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

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

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

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

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

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

Future Efforts

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

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

- Research on treatments for Gulf War veterans' illnesses
- Longitudinal follow-up of Gulf War veterans' illnesses

- Research on improved disease prevention, especially in the area of stress-related symptoms
- Research to improve environmental and occupational hazard identification and risk assessment

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

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

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

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

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

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

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

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

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

In order to determine those MCS participants who have already enrolled in MVP or refused to join MVP, MVP study staff will send to MCS encrypted social security numbers (SSNs) of those MCS participants. These data will be sent via the DoD Secure Access File Exchange (SAFE) site. Upon receipt of these data, MCS staff will remove these participants with matching SSNs from the list of MCS participants who have met the other eligibility criteria.

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

The above-mentioned high-level DoD and VA agreement (NMR-9558-Memorandum of Agreement Between Department of Defense, Naval Health Research Center and Department of Veterans Affairs, Office of Research and Development for Data Sharing- Millennium Cohort Study with Million Veteran Program) has been established. A copy of the established Agreement is located in Appendix J of this protocol.

Per this Agreement, the MCS will provide the MVP study with five data elements for all living Millennium Cohort participants: MVP study specific Study Identification Numbers (Dummy SIDs), last name, DOB, SSN, and postal address. Additionally, MCS will contact eligible active duty and Veteran MCS participants with information about enrolling in MVP. Only those MCS participants who meet the following criteria will be contacted:

MVP criteria

- Never enrolled in MVP
- Did not decline participation in the MVP
- Was not previously invited to join MVP

MCS Criteria

- Must have completed the MCS 2019-21 follow-up survey
- Did not refuse future contact or withdraw from the MCS
- Did not opt out from future contact during the previous 2017 MVP co-enrollment effort
- Have not answered NO to question #114 on the 2014 MCS follow-up survey.
- Not deceased
- Good quality mailing address with no returned mail

- Currently or previously on active duty service
- If no longer in active service, discharged or released under conditions other than dishonorable

In order to determine those MCS participants who have already enrolled in MVP, refused to join MVP, or who were previously invited to join MVP, MCS staff will send to MVP a list of encrypted social security numbers (SSNs) and dates of birth (DOB) that are linked to Dummy SIDs for all follow-up MCS participants. These data will be sent via the DoD Secure Access File Exchange (SAFE) site.

Upon receipt of these data, MVP staff will remove these participants with matching SSNs and/or DOB from the list of MCS participants and then return the filtered file to the MCS. MCS staff will then apply the MCS eligibility criteria from the above list. Additionally, from this list, MVP staff will flag approximately 20,000 MCS participants that were eligible to receive an invitation from the MVP during the previous effort, but were not contacted. The MCS will provide updated contact information for these participants during the final data transfer.

The remaining eligible participants will be sent one postal contact with information about enrolling in MVP along with the option to opt out from receiving any information. This letter includes information about the PMI. Those participants who do not wish to receive information and enrollment materials from MVP will be asked to tear off the bottom portion of the letter and return it to the Millennium Cohort Study in a provided postage paid envelope within 30 days of receipt of the letter. After 60 days of the expected receipt of the letter, MCS study staff will generate a list of eligible participants who did not return the bottom portion of the letter along with their respective current contact addresses and corresponding Dummy SID. MCS will also include the updated mailing address, if one exists, and Dummy SID for the 20,000 MCS participants mentioned above. This list will be encrypted and sent to MVP staff via the DoD SAFE site. The MVP will then send these individuals an invitation to enroll in the MVP study.

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

Background: Millennium Cohort Study Feedback Survey
Due to the ongoing decline in survey response not just to this study but all DoD studies, the Millennium Cohort Study (MCS) has designed a participant feedback survey that will help us gather crucial information about participant recruitment and study retention.

This feedback survey was developed to assess participant feedback on study marketing and branding methods, the effectiveness of the MCS survey design, identify any areas for improvement, provide participants with an opportunity to express their opinions about the study, and assess participant satisfaction and motivation to participate. These data will inform future participant communication and engagement efforts. Additionally, insights gained from this feedback survey can be used to inform future studies and improve the design, implementation, and participant experience. Finally, surveying participants about their experiences with the study can build trust and demonstrate the commitment of our researchers to transparency and participant-centered practices.

The MCS Feedback survey is low-burden way to obtain participant feedback on study methods and materials that are typically obtained via focus group methods. Given the large sample size in the MCS and the remote nature of the study (e.g., all participant contacts are via the web or via

postal mail), focus groups are not feasible. The MCS Feedback survey is estimated to take 8 minutes to complete.

The MCS Feedback Survey has been developed by MCS staff and reviewed and approved by the Office of Management and Budget (OMB Control # 0703-0064).

9.3 Objectives/Specific Aims/Research Questions:

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

The objectives the Millennium Cohort Study are to determine how the health of U.S. military veterans' changes over time.

A. Primary Objective:

- To compare the adjusted incidence of chronic disease between cohorts.

B. Secondary Objectives:

- To compare the adjusted change in health between cohorts by Short Form-36 Questions/Veterans (SF 36V) scores. (74)
- To compare the change in health between cohorts by Patient Health Questionnaire (PHQ) score diagnostics. (75)
- To serve as the foundation for a portfolio of future studies of the impact of military service, including anthrax vaccination, on the health of members of the armed forces.

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

Self-reported health information (e.g., mental, physical, and behavioral health metrics as well as military and post-service experiences) is collected from study participants through periodic surveys through the year 2068. These data are linked to enterprise databases, including military, healthcare utilization, and mortality records to create a total picture of health.

9.5 Target Population:

Describe the population to whom the study findings will be generalized

This prospective cohort study will follow regular active duty, National Guard, and reserve military personnel. For each new panel, a probability-based sample of service members is randomly drawn from the electronic rosters of active duty and reserve personnel at Defense Manpower Data Center (DMDC), Seaside, California. Individuals are tracked while serving, as they integrate into civilian life and beyond. Participant follow-up is planned through at least 2068. Given the longitudinal design and sampling frame of the study, findings from this research will be generalizable to service members as well as veterans.

9.6 Benefit to the DoD:

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

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

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: 01OCT2000 to 30SEP2068
PROJECT TITLE and ID#: The Millennium Cohort Study, 60002
WORK BREAKDOWN STRUCTURE (WBS) (or JON, if a legacy project): 100001869677_007A

This prospective cohort study will follow regular active duty, National Guard, and reserve military personnel through, at least, the year 2068.

The cohorts will be followed via serial postal surveys with on-line completion options. The sample will be drawn randomly from the electronic rosters of active-duty and reserve personnel at Defense Manpower Data Center (DMDC), California. The cohort will be selected as a probability sample, stratified for deployment vs. nondeployment, active duty vs. reserve, and male vs. female. Subjects will be contacted in five phases.

1. First Phase: 2001 Cohort (Millennium Cohort). Panel 1 members included regular active duty, National Guard, and Reserve U.S. military personnel. A probability-based sample of 256,400 active duty and reserve military personnel was randomly drawn from the electronic service member rosters at the Defense Manpower Data Center (DMDC), Seaside, California, as of October 1, 2000. Veterans who served in Southwest Asia, Bosnia, and Kosovo (after 1997) made up 18% of the military population at this time but were over-sampled such that 30% of the population was invited to participate. Females comprised 15% of the military population at this time but were over-sampled such that 24% of females were invited. The expected cohort response of 100,000 will represent approximately a 3.7% sample of the 2.7 million persons in uniform at that time.
2. Second Phase: 2004 Cohort. Panel 2 members included regular active duty, National Guard, and Reserve U.S. military personnel with 1 - 2 years of service. A probability-based sample of 150,000 service members was randomly drawn from the electronic rosters of active duty and reserve personnel as of October 1, 2003 at Defense Manpower Data Center (DMDC), Seaside, California. To achieve a higher proportion of Marines, the population was comprised of 20% Marines and 80% other service branches (Army, Navy, Air Force, and Coast Guard). Females were also over-sampled; the 80% non-Marine group was comprised of 70% males and 30% females with random distributions of all other variables.
3. Third Phase: 2007 Cohort. Panel 3 members included regular active duty, National Guard, and Reserve U.S. military personnel with 1-3 years of service. A probability-based sample of 250,000 service members was randomly drawn from the electronic rosters of active duty and reserve personnel as of October 1, 2007. To achieve a higher proportion of Marines, the population was comprised of 20% Marines and 80% other service branches (Army, Navy, Air Force, and Coast Guard). Females were also over-sampled; the 80% non-Marine group was comprised of 70% males and 30% females with random distributions of all other variables.
4. Fourth Phase: 2011 Cohort. Panel 4 members included regular active duty, National Guard, and Reserve U.S. military personnel with 2-5 (24-60 months) years of service. A

probability-based sample of 250,000 service members was randomly drawn from the electronic rosters of active duty and reserve personnel as of October 1, 2010 at Defense Manpower Data Center (DMDC), Seaside, California. To achieve a higher proportion of married participants, the population was comprised of 80% male and 20% female service members. For each gender, the sample was comprised of 50% married and 50% not married with random distributions of all other variables.

5. Fifth Phase: 2020 Cohort. Panel 5 members will include regular active duty, National Guard, and Reserve U.S. military personnel with 1-5 years (12-60 months) of service. A probability-based sample of 600,000 service members was randomly drawn from the electronic rosters of active duty and reserve personnel as of June 1, 2020 at Defense Manpower Data Center (DMDC), Seaside, California. To achieve a higher proportion of married participants, the population was comprised of 80% male and 20% female service members. For each gender, the sample was comprised of 35% married and 65% not married with random distributions of all other variables.

   In an effort to ensure the highest response rate possible, the study team will be contacting an initial 500,000 potential participants selected from the 600,000 DMDC sample while the remaining 100,000 are maintained as reserve pool. These initial 500,000 participants selected will include all service members whose DMDC records indicate they are married followed by a random sampling of the remaining service members. After 2 email contacts, all participants that have had an email contact bounce back, indicating that the email address on file is not usable, will have their email address marked as “do not use”. The team will not attempt to contact potential participants at this email address again. Additionally, all potential participants will be sent one postal mailing to the address received from DMDC. All participants that have their postal item returned to us due to the post office indicating it is a “bad address” will not be contacted at this postal address again.

These cohorts will be followed with repeat surveys at approximately 3-year intervals through, at least, the year 2068.

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

Those who did not sign the consent form on the baseline survey will be excluded from enrollment into the study.

Informed consent documents are updated just prior to periods of recruitment and enrollment. Therefore, the Millennium Cohort Study consent form will be updated every three to six years.

Supplemental Medical and Administrative Data

NHRC manages or has access to numerous established military data sets. Information from these data sources can be used to supplement the survey instruments and enhance the ability to track study outcomes. Data linkage for the Millennium and Family Cohort will be linked to Department of Defense personnel and medical records obtained from the following sources: DMDC (Data Manpower Data Center) and Defense Health Administration. For mortality data, we submit requests to Armed Forces Medical Examiner System (AFMES), Armed Forces Health Surveillance Branch (AFHSB), JPC (Joint Pathology Center), NDI (National Death Index), Defense Suicide Prevention Office (DSPO), DMDC and VA (US Department of Veterans Affairs). In addition, if the spouse is an active duty member and retires or separates from military service and utilizes Department of Veterans Affairs for medical services, we will

link to VA medical and personnel data as well as the DoD Joint Theater Trauma Registry and the Navy/Marine Corps Trauma Registry.

These data will complement subjective measures with objective measures of exposures and health outcomes. Access to additional datasets for linkage with survey data will be established using data use agreements.

Millennium Cohort Study Feedback Survey

Before the launch of the 2023-2024 survey cycle (pre-launch) and again near the end of the same survey cycle (post-launch), the Millennium Cohort Study will conduct the participant feedback survey among Panel 1-5 responders and non-responders. The survey will be bi-modal and was designed to assess a variety of factors including those that have motivated and/or discouraged Millennium Cohort participants to stay connected with the study. This survey will be sent to already enrolled and consented participants and falls under the scope of the original consent; therefore, we will not be re-consenting any participants for this project.

1. The pre-launch feedback survey will collect data from study participants for approximately 6 weeks. During the pre-launch feedback survey cycle all Panel 1-4 (Panel 5 will be excluded from the pre-launch survey cycle due to their limited involvement with the study at this time point) responders and non-responders will be contacted and asked to provide feedback. Initial contact method will be determined based on a participant's individual response to the 2019-2021 survey cycle (paper responder, web responder, non-responder). 8,500 paper responders and 8,500 non-responders will receive a postal letter invitation, paper survey, and pre-paid return envelope, while all other remaining participants will receive an email invitation with a link to the web version of the survey. Each participant will then be contacted for a maximum of two additional times until they provide a response, or the survey cycle closes. If the participant completes a survey, they will also receive a thank you email.
2. The post-launch feedback survey will be conducted among Panel 1-5 responders and non-responders to the 2023-2024 survey cycle. The methods for this data collection will be submitted for review and approval at a future date.

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.

Questionnaire Development

A questionnaire was developed specifically for this study and modeled after the DVA National Health Survey of Persian Gulf War Era Veterans that provides the framework to ask participants about current and historical medical conditions, health complaints and symptoms, military and personal experiences, and approaches to self-medication and self-care. The questionnaire is available to participants via physical copy sent through the postal service and on the Internet at www.millenniumcohort.org.

Survey measures

After providing informed consent and completing a baseline survey, participants are invited to complete follow-up surveys every 3 to 5 years through 2068. Study measures assessed over time utilize from validated measures or publicly available epidemiological survey sources. Although constructs assessed have largely remained consistent over time, certain measures have changed in response to developments in research priorities, military policy, stakeholder input, or scientific advances. A summary of the survey measures is described below and listed in **Table 1**.

Sociodemographic factors. Financial problems, marital status, occupation (military and civilian), and educational attainment have been consistently assessed over time. The survey has expanded to assess employment (e.g., unemployed, part-time, full-time), household income, homelessness, household composition, relationship quality, sexual orientation, and gender identity.

Military service characteristics. Service-related factors that have been consistently assessed over time include combat experiences, environmental exposures, deployments (e.g., locations and dates), military satisfaction, and reasons for separating from the military. Assessment of unit cohesion was recently added.

Stressful life events. Varying stressful events stemming from the Social Readjustment Rating Scale have been assessed over time. More recently, detailed assessments of sexual harassment and assault and additional life stressors, such as adverse childhood experiences, discrimination, bullying, harassment, and hazing experienced have been included.

Psychosocial factors. Posttraumatic stress disorder (PTSD) has been measured using the PTSD Checklist (PCL), originally with the PCL Civilian Version (PCL-C) and more recently with the PCL for DSM-5 (PCL-5). In addition, major depressive disorder has been measured using the Patient Health Questionnaire (PHQ)-9 or PHQ-8, with other anxiety syndrome, panic syndrome, and disordered eating measured using additional corresponding modules in the PHQ. Social support has been consistently measured using an item from the PHQ and a 6-item version of the Multidimensional Scale of Perceived Social Support (MSPSS) was added more recently. More recent psychosocial factors include anger measured by the Dimensions of Anger Reactions-5 (DAR-5), positive outlook measured by a modified "current standing" short form of the Posttraumatic Growth Inventory (PTGI), and self-mastery measured by the Perlin Mastery Scale.

Health-related behaviors. Tobacco use has been included since the Study's beginning (e.g., lifetime cigarette use, quit attempts, use of other tobacco products), with vaping and e-cigarette use recently added. Alcohol use (e.g., heavy weekly drinking, binge drinking, problem drinking, and potential alcohol dependence) has been assessed throughout the duration of the study. In addition, varying sleep measures have been included over time, including sleep duration and insomnia symptoms measured by the PHQ anxiety screen and the PCL-C, clinical insomnia measured by the Insomnia Severity Index (ISI), and sleep medication use from the Pittsburg Sleep Quality Index (PSQI). In addition, fast-food consumption, dietary supplement use, caffeine intake, physical activity and sedentary time, have been included.

Physical health, illness, and injury. Body mass index calculated from self-reported height and weight, physical health symptoms (e.g., pain, somatic symptoms), reproductive health, and quality of life/functional health assessed by the Short Form 36-item Health Survey for Veterans (SF36-V) or Veterans RAND 12 Item Health Survey have been assessed over time. In addition, traumatic brain injury, motor vehicle injury, hospital days and lost workdays due to illness or injury have been assessed over time.

Medical conditions and health care utilization. Self-reported medical diagnoses (e.g., asthma, diabetes, heart disease, cancer, sleep apnea, chronic bronchitis, emphysema, PTSD, infertility), complementary and alternative medicine use, medication use, disability, and vaccinations (e.g., anthrax and smallpox) have been assessed over time. More recently, access to healthcare (e.g., health insurance coverage), and health and mental health care utilization have been assessed.

Table 1.
Survey measures

Sociodemographic factors	Financial problems Marital status Occupation (e.g., military and civilian)* Educational attainment Employment and household income Homelessness Household composition and relationship quality Sexual orientation Gender identity
Military service factors	Combat experiences Environmental exposures* Deployments (e.g., locations and dates)* Military satisfaction Military separation* Morale and unit cohesion
Stressful life events	Stressful life events Sexual harassment and assault Adverse childhood experiences Discrimination, bullying, harassment, and hazing Intimate Partner Violence (IPV) Stress around transition out of service

	Substance use (veteran/separated only)
Psychosocial factors	Posttraumatic stress disorder* Depression* Panic/anxiety* Disordered eating Social support Anger Posttraumatic growth, self-mastery Suicide risk Firearm ownership/storage Community support
Health-related behaviors	Tobacco and alcohol use Sleep (e.g., duration, medications, disorders) Fast food, dietary supplements, caffeine intake Physical activity and sedentary behavior
Physical health, illness, and injury	Body Mass Index (BMI) Physical health symptoms (e.g., pain, somatic symptoms) Reproductive health* Pregnancy Quality of life /functional health Hospital days and lost work days* Traumatic brain injury* Motor vehicle injury Respiratory health*
Medical conditions and health care utilization	Medical diagnoses* Medications (e.g., pain)* Disability Complementary and alternative medicine Vaccination (i.e., anthrax and smallpox; COVID)* Access (e.g., health insurance) and health and mental health care utilization*

*Objective measures, in addition to self-reported measures, have been available for this variable throughout the Study period.

Table 2.
MILLENNIUM COHORT SURVEY INSTRUMENTS

Instrument:	**Assesses:**
Short Form 36-item Health Survey for Veterans (SF-36V) or Veterans RAND 12 Item Health Survey	Physical, mental, and functional health
Patient Health Questionnaire (PHQ)	Depression, anxiety, panic syndrome, binge-eating, bulimia nervosa, and alcohol abuse
Posttraumatic Stress Disorder (PTSD) Checklist-Civilian	

Version (PCL-C (2001-2019/PCL-5 (2019+)	Post-traumatic stress disorder
CAGE questionnaire	Alcohol problems
Insomnia Severity Index (ISI)	Sleep
Pittsburgh Sleep Quality*	Quality and patterns of sleep
National Survey of Families & Household*	Marital satisfaction
Modified Adverse Childhood Experiences (ACE)*	Childhood trauma
Short Dimension of Anger Reaction	Anger disposition
National Health and Nutrition Examination Survey (NHANES)*	Physical activity level
Posttraumatic Growth Inventory (PTGI) *	Posttraumatic growth (positive outlook)
Deployment Risk and Resilience Inventory*	Military and unit support
Social Readjustment Rating Scale*	Stressful life events
Multidimensional Scale of Perceived Social Support	Special support
Perlin Mastery Scale	Self mastery

*full inventory not used

Assessment of Psychiatric Conditions

Since 2001, the Millennium Cohort Program has used the 17-item PCL-C (slightly modified version) to assess PTSD symptoms and probable PTSD, which is based on the DSM-IV criteria. In 2013, The definition of posttraumatic stress disorder (PTSD) changed markedly between the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) and DSM-5, creating challenges for studies spanning this transition.

To evaluate the ability to compare and assess PTSD, based on DSM-IV and DSM-5 criteria, using PTSD Checklists (PCLs), during the 2019-2020 data collection cycle the Millennium Cohort Study implemented an IRB-approved experiment in a small group of follow-up web responders.

The findings of this experiment indicated that PTSD can be successfully assessed and compared over time with either PCL instrument in veteran and military populations.[104]

Assessment of Physical Conditions

Those military personnel who deploy and sustain an injury and are in both the Millennium Cohort Study and Joint Theater Trauma Registry (JTTR) will be looked at over the long term in order to better understand the effects of combats injuries on psychological and functional health outcomes. The JTTR provides data in detail

about wounds received and the medical care provided from combat support hospitals, aboard ships and aircraft, and throughout the course of their treatment.

Morbidity Tracking

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

Bias and External Validity

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

Supplemental Medical and Administrative Data

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

These data will complement subjective measures with objective measures of exposures and health outcomes. Appropriate agreements/approvals will be in place prior to any data sharing for any linkages. Additionally, the following sources are available:

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

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

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

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

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

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

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

Recruit Assessment Program (RAP) - This electronic database represents a collection of baseline demographic, medical, psychological, occupational, and risk factor data from U.S. Marine Corps recruits at Marine Corps Recruit Depot in San Diego, CA at the time of their entry into military service.

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

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

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

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

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

Family Advocacy Program (FAP) - The Family Advocacy program provides various treatment and support services for perpetrators and victims of spouse and child abuse and neglect, 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.

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

National 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.

VA National Enrollment Database - This database consists of veterans eligible for VA care.

VA National Patient Care Database (NPCD) - NPCD combines several VA databases, including Patient Treatment File (PTF) and Outpatient Clinic File (OPC).

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

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

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

Virtual Pooled Registry Cancer Linkage System (VPR-CLS) provides a single location to facilitate access to and use of high-quality cancer surveillance data for minimal risk linkage studies.

Individual Longitudinal Exposure Record (ILER) is an individual, electronic record for each service member and future Veteran designed in collaboration between VA and the Department of Defense (DoD) to link service member and veteran data to known exposures.

Millennium Cohort Feedback Survey

The Millennium Cohort Study (MSC) feedback survey was developed specifically for this study by MCS staff and is designed to assess a variety of factors including those that have motivated and/or discouraged MCS participants to stay connected with the study. This survey will help us gather crucial information about participant recruitment and study retention, such as reasons for non-response, correlates of non-response, motivations to participate, acceptability of study communication methods, and recommendations for improvement. This data will be utilized in the design of the future surveys and survey operations to maximize retention and increase participation from previous non-responders. The survey will be available to participants via physical copy sent through the postal service and on the Internet at www.millenniumcohort.org.

Participant tracking

In the Millennium Cohort Study, henceforth 'the study', maintaining contact with our research participants is crucial for obtaining accurate and complete data over the study's period of performance. Loss to follow-up can introduce bias and compromise the validity and reliability of study findings. Despite diligent efforts, some participants have become lost to follow-up due to invalid or outdated contact information that makes it challenging to collect essential survey information and maintain the integrity of the study. For this reason, the study will utilize external resources such as LexisNexis and TransUnion, comprehensive databases of public records, and other government resources as a solution for obtaining current email and postal addresses for study participants.

To ensure that the study is obtaining contact information for the correct individual, the study will provide LexisNexis or TransUnion, henceforth the 'vendor', with the name, SSN, DOB, and last known address of all study participants for whom email, and postal mailing address are needed by the study. The name, SSN, DOB, and last known address will be provided to the vendor via DoD SAFE.

The vendor will provide the study with the current and historical email and postal addresses for all study participants. The email and post addresses must be linked to the individual participant via name, SSN, DOB, and last known address. Then every 6 months the vendor will conduct a new inquiry where they will only report to the study any new email or postal addresses.

The website states in the FAQ's "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. We may also utilize commercial sources such as LexisNexis, TransUnion, and other government resources to obtain up-to-date contact information."

Given the size of the cohort and the highly mobile nature of this population, it is crucial that participants can swiftly and easily update their contact details (including name, address, and email) with the study staff to ensure uninterrupted receipt of study communications.

On the contact information update page, participants are prompted to provide their Subject ID along with the specific details they wish to update. Additionally, participants are asked to provide their birth year as verification of their identity.

Once the participant completes the form and submits it, the website application forwards the request to a mail (SMTP) server for processing. The email is promptly placed in a queue, and an attempt to send it to the study team at usn.nhrc-MilcohortInfo@health.mil is made almost immediately.

Upon successful transmission, the email is removed from the queue, and the server logs the message as sent. If, for any reason, the email fails to send, it remains in the queue for 5 minutes before a retry is initiated. The system will continue attempting to send the email for up to 1 hour before generating a failed send message. To safeguard participant Personally Identifiable Information (PII), the logs are deleted daily at 0100 PST.

If a participant does not provide their birth year on the form, upon receipt, study staff will contact the participant to verify their identity. Only upon successful verification will the participant's contact information be updated in the database.

Additionally, participants may be asked to provide an email address upon completing their survey. All participants who complete the online survey will be given the option to select a gift code from various vendors. Following vendor selection, participants will be given the choice to receive a copy of the code, which will be displayed on the subsequent page. If they opt to receive the code copy, they will be prompted to enter their email address.

Once the participant enters their email address and submits the form, the website application forwards the request to a mail (SMTP) server for processing, following the same process as detailed above to ensure successful transmission and logging while prioritizing data security and privacy.

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
: PDTS	: Yes
: AHLTA	: Yes
: CHCS	: Yes
: PDHRA	: Yes
: PHDA	: Yes
: TMDS	: Yes

PII-Only Systems:

MHS Information System	Requesting Data
DMDC	: Yes
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: ESSENCE	: Yes
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: CDR	: 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: MOR	: Yes
Other MHS System May include PII and/or PHI List other system here: POTS	: 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: SADR	: Yes
Other MHS System May include PII and/or PHI List other system here: TEDN	: Yes
Other MHS System May include PII and/or PHI List other system here: TENDI	: Yes
Other MHS System May include PII and/or PHI List other system here: Death	: 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 are necessary for computer matching of electronic sponsor demographic and exposure data with deployment, occupational, vaccination, and healthcare utilization data related to individual health status. The Millennium Cohort Study matches existing records or specimens to those contained in other Department of Defense (DoD) electronic data sources (SSNs would be destroyed prior to data analysis). The use of SSN as a unique identifier is needed for this database where there is potential for duplicate registration and no other means of unique identification exists. Therefore, 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 signed SSN Justification Memo for the current survey cycle can be found in Appendix K External Approvals.

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.)

The Millennium Cohort Study has the following agreements in place:

- *CRADA*
  - University of Southern California: In support of the NIH funding for the project entitled, "Contextual Effects on Cardiometabolic Health: Evidence from a Natural Experiment" (NIH grant 1 R01 HL141870-01A1)
- *Data Sharing Agreement*
  - Defense Health Agency Data Sharing Agreement (DHA DSA)
  - VA/ORD/CSP: DUA is a bilateral agreement which allows NHRC to transfer data to VA and the VA to transfer data to NHRC
- *Educational Partnership Agreement (EPA)*
  - San Diego State University
- *HIPAA Waivers/DUA*
  - Data Request - Uniformed Services University (USU)- Labor Outcome
  - Data Request - Uniformed Services University (USU)- Healthy Behaviors
- *Inter/Intra-Agency Agreement (IAA)*
  - NIOSH—(NMR 9443) Used to obtain addresses for participants via IRS
  - VA—(NMR 4150) Supports VA Collaboration (Department of Veterans Affairs OPH (10P3) and ORD (10P9))
  - VA—(NMR 9558) Supports VA Collaboration
- *Knowledge Transfer Agreement (KTA)*
  - U.S. Army Public Health Center (APHC)
  - Preservation of the Force and Family (POTFF), United States Special Operations Command (USSOCOM)
  - Humana Government Business, Inc. (Humana Military)
  - DoD Sexual Assault Prevention and Response Office (SAPRO)
  - Defense Suicide Prevention Office (DSPO)
  - U.S. Army Public Health Center (APHC)
- *Memorandum of Agreement (MOA)*
  - VA and DoD—supports MVP collaboration (see below)
  - VA Million Veteran Program (MVP) (NMR 9958). We contact participants giving them the option to opt out of being contacted by the MVP study team.
  - National Center for Health Statistics—National Death Index (NMR 4143)—Receive death records
  - United States Army Center for Environmental Health Research (USACEHR) (NMR 9418)—Supports the Millennium Cohort BioMarkers Study
- *Memorandum of Understanding (MOU)*
  - Army Analytics Group (AAG)—(NMR 9971)—Use of AAG's secured cloud-based system (Person-Event Data Environment (PDE))—Millennium Cohort data uploaded into the cloud for analysis.
  - Office of People Analytics (OPA)—objective is to share survey data from OPA and Millennium Cohort Program

NHRC manages or has access to numerous established military data sets. Information from these data sources can be used to supplement the survey instruments and enhance the ability to track study outcomes. Data from the Millennium Cohort surveys will be linked to Department of Defense personnel and medical records obtained from the following sources: DMDC (Data Manpower Data Center) and Defense Health Administration (DHA). For mortality data, we submit requests to Armed Forces Medical Examiner System (AFMES), Armed Forces Health Surveillance Branch (AFHSB), JPC (Joint Pathology Center), NDI (National Death Index), Defense Suicide Prevention Office (DSPO), DMDC and VA (US Department of Veterans Affairs). We will link to VA medical and personnel data as well as the DoD Joint Theater Trauma Registry (JTTR) and the Navy/Marine Corps Trauma Registry (CTR). These data will complement subjective measures with objective measures of exposures and health outcomes.

These databases are accessed electronically through secure computers located at the Naval Health Research Center. Unique identifiers are used to link each participant with their electronic data; however, in some cases name and SSN will be provided. All data upon receipt will be confidentially maintained on-site in our secure

computer database. No data regarding a child and his/her health will be linked from any source for the purposes of this study. Appropriate agreements/approvals will be in place prior to any data sharing for any linkages. Collected data will be maintained until all research questions under the study objectives are answered.

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.

N/A

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.

Statistical Analysis

Statistical analyses of Millennium Cohort survey data and linked datasets, including military and medical records, encompass a wide variety of approaches, depending on the scope and complexity of the research question, the hypothesis to be tested, and available data. Descriptive statistics will be generated using t-tests, analysis of variance (ANOVA), chi-square tests, and other approaches depending on the form of the data and the scope of comparison. These statistics will also be used identify any outlying responses in collected data as part of the data cleaning process. Estimations of effect and association (e.g., risk or hazard ratios, odds ratios) will be generated using regression methods, including linear, Cox proportional hazards regression, logistic and log-linear regression, generalized estimating equations, and structural equation modeling. With the expansion of available data resulting from additional enrollments, survey waves, and linkages with external datasets, we will employ machine learning and ensemble methods for generating hypotheses.

The inclusion of potential confounding variables into statistical models for each analysis will be informed by causal inference considerations, including the use of directed acyclic graphs (DAGs) and change-in-estimate criteria. Covariates commonly included in statistical models are: age or birth year, gender, occupation, marital status, race/ethnicity, educational attainment, deployment status, branch of service, income, length of military service, and prior diagnosed health conditions. The use of stratified analyses and tests for effect measure modification (i.e., statistical interaction) will be determined based on *a priori* considerations and observed heterogeneity in results. Common sub-group analyses include those stratified by sex, service branch, component, deployment status, veteran status, and military occupation.

Statistical programs that will be used in include SAS, Mplus, SPSS, and R.

Morbidity Tracking

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

Bias and External Validity

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

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

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

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

Sampling Non-respondents

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

Missing Data/Attrition

Subject matter experts from the Institute for Measurement, Methodology, Analysis and Policy (IMMAP) at Texas Tech University assisted in meeting the OMB requirement to provide an approach to handle missing data and adjustments for selective attrition. A subcontract between NHRC/Henry Jackson Foundation and Texas Tech was established for this project. Informed by this work, analyses include multiple imputation to address missing data and attrition concerns.

Interpretation of Results

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

All research work will be reviewed and approved by the NHRC's Institutional Review Board (IRB). Investigators will report study results to various policy groups including:

- Research Working Group-In conjunction with other deployment health research, the Research Working Group will receive annual progress updates and review study progress in light of other federally sponsored veteran research. The Research Working Group update will be included in the annual report to Congress.
- U.S. Army Medical Research Acquisition Activity Annual Peer Review-This annual review is generally conducted by the American Institute of Biological Sciences (AIBS). Several AIBS scientists are invited to review deployment health research programs.

Both the Millennium Cohort Study and the Millennium Cohort Family Study, collectively the Millennium Cohort Program (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. 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 Millennium Cohort or Family Study 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.

11.2 Sample Size:

260257

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

1506400

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

Panel 1 (2001): 77,047 enrolled
Panel 2 (2004): 31,110 enrolled
Panel 3 (2007): 43,439 enrolled
Panel 4 (2011): 50,052 enrolled
Panel 5 (2020): 58,609 enrolled

11.5 Please provide a justification for your sample size

We estimated the necessary study sample sizes by knowing the estimated incidence for our healthy young population and using the following equation (94):

Formula 1: $N=\{ZaÖP(1-P)\ (1/q1+1/q2) + ZbÖP1\ (1-P1)\ (1/q1) +P2\ (1-P2)\ (1/q2)\}2$

$$\frac{}{\frac{}{(P1-P2)2}}$$

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

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

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

Outcome (ICD-9 Codes)	Incidence Rate	Relative Risk	80% Power	90% Power
Any cause hospitalization	0.222	1.2	2,934	3,927
		1.5	508	679
		2.0	139	185

Hypertension (401-404)	0.0035	1.2	245,449	328,650
		1.5	44,602	59,720
		2.0	13,367	17,897
Diabetes (250)	0.0016	1.2	538,049	720,436
		1.5	97,802	130,953
		2.0	29,327	39,267
Stroke (436)	0.0001	1.2	8,623,049	11,546,086
		1.5	1,567,802	2,099,253
		2.0	470,327	629,757
Myocardial infarction (410)	0.0005	1.2	1,723,849	2,308,198
		1.5	313,402	419,637
		2.0	94,007	125,873
Renal failure (584)	0.0001	1.2	8,623,049	11,546,086
		1.5	1,567,802	2,099,253
		2.0	470,327	629,757
Asthma (743)	0.0004	1.2	2,155,049	2,885,566
		1.5	391,802	524,613
		2.0	117,527	157,365

In addition to hospitalization data from DoD facilities, we searched the medical literature to obtain reasonable incidence rates of these medical conditions to confirm or refute our hospitalization-based estimates. We found, as expected, for most conditions that data from population-based studies yielded higher incidence rates for conditions that do not usually require hospitalization for diagnosis and treatment. This means that the sample size calculations that we have presented are likely to represent conservative estimates, and that smaller effect sizes (i.e., relative risks) will be detectable with 80% power than are shown in Tables 1 and 2. Hypertension incidence in middle-aged men in the Atherosclerosis Risk in Communities Study was estimated at 0.172 over a 6-year follow-up period, for an annual incidence of 0.032.(95) A similar estimate of hypertension incidence comes from an additional study of middle-aged normotensive subjects (mean age 44 years) followed over a 7-year period (cumulative incidence 0.255, annual incidence 0.042). (96,97) These estimates are considerably smaller than the cumulative incidence estimate of 0.0035 over 3 years (or approximately 0.0012 annually) used in the sample size calculations. The same is true for asthma, with an annual incidence reported in the literature of 0.001, compared with the 3-year cumulative incidence of 0.0004 (or 0.00013 annually) based on DoD hospitalization data, and diabetes mellitus (0.0016 per 3 years based on hospitalization data or 0.0005 annually, compared to an annual incidence of 0.0018 in the U.S. in the 25-44 year age category based on data from the 1990-92 National Health and Nutrition Examination Survey (**http://diabetes-in-america.s-3.com/contents.htm** - Chapter 4).

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

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

Outcome (ICD-9 Codes)	Incidence Rate	Relative Risk	80% Power	90% Power
Any cause	0.444	1.2	991	1,326
		1.5	155	206
		2.0	33	43
Hypertension (401-404)	0.0070	1.2	122,249	163,688
		1.5	22,202	29,727
		2.0	6,647	8,899

Diabetes (250)	0.0032	1.2	268,549	359,581
		1.5	48,802	65,343
		2.0	14,627	19,584
Stroke (436)	0.0002	1.2	4,311,049	5,772,406
		1.5	783,802	1,049,493
		2.0	235,127	314,829
Myocardial infarction (410)	0.0011	1.2	783,049	1,048,486
		1.5	142,347	190,599
		2.0	42,691	57,161
Renal failure (584)	0.0002	1.2	4,311,049	5,772,406
		1.5	783,802	1,049,493
		2.0	235,127	314,829
Asthma (743)	0.0009	1.2	957,271	1,281,766
		1.5	174,024	233,013
		2.0	52,194	69,885

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

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

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

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

From our previous studies, we can estimate that among the 2.7 million U.S. servicepersons serving on January 1, 2001, less than 20,000 (< 0.7%) will have served in the Gulf War, 185,703 (6.9%) will have served in Southwest

Asia (since August 1991), 86,263 (3.2%) will have served in the Bosnia conflict (since December 1995), and 18% will have served in more than one conflict. Approximately 15% of the force will be women. These data will be used in planning the stratified, probability-based sampling.

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

The study group sizes are:
Southwest Asia, Bosnia, Kosovo Veterans-30,000
Millennium Cohort-70,000

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

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

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

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

12.0 Participant Information

12.1 Subject Population:

At the time of enrollment into the study, all participants will be a member of the US military serving on active duty, Reserve Guard, or National Guard, have 1 to 5 years for service, and be over the age of 18.

Due to the longitudinal nature of the study and time frame in which data will be collected (until the year 2068), the age ranges and special categories for this study can include all ages above 18 years old and many of the special categories.

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.

- [ ] 0-17
- [x] 18-24
- [x] 25-34
- [x] 35-44
- [ ] 45-54
- [ ] 55-64
- [ ] 65-74
- [ ] 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	Members of the regular active duty, National Guard, or Reserve U.S. military.
2	1-5 years of military service.

12.6 Exclusion Criteria:

Order Number	Criteria
1	For Panel 1 (2001) we will avoid selecting servicepersons who have been deployed to the Gulf War, or who have been deployed to Southwest Asia, Bosnia, or Kosovo prior to September 1997.

13.0 Recruitment and Consent

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

The sample for each enrollment panel will be drawn randomly from the electronic rosters of active-duty and reserve personnel at Defense Manpower Data Center (DMDC), California. The cohort will be selected as a probability sample, stratified for deployment vs. nondeployment, active duty vs. reserve, and male vs. female.

All selected subjects will receive an IRB approved invitation email and/or postal letter asking them to participate in the study and complete a web-based questionnaire. Once a subject completes their online questionnaire, the study team will send one final contact letting them know that their submission was received and to thank them for their participation.

If a subject does not respond to the initial invitation, the study team will send reminder emails and postal items, to include postcards and paper questionnaires, to the subject to encourage participation for the duration of the survey cycle.

No further communication will be attempted with service members who do not respond after the last reminder contact, who do not consent, or who withdraw their consent before the end of the recruitment period. Service members will consent by signing an on-line or paper informed consent statement and completing a questionnaire.

Thank You notes (an e-mail or post card depending on the cost and available budget) will be sent to service members who complete their survey before the end of the enrollment period. The same procedures will be followed for administering the follow-up questionnaires except that the follow-up questionnaire invitation letter and reminders will be sent only subjects who completed the baseline questionnaire.

Informed consent documents are updated just prior to periods of recruitment and enrollment. Therefore, the Millennium Cohort Study consent form will be updated every three to six years.

Marketing for Participant Recruitment and Retention

The Millennium Cohort Study team has collaborated with the NHRC PAO and other organizations develop marketing materials to aid in the recruitment of new participants for the baseline survey and to re-engage follow-up participants. All proposed marketing materials have been/will be submitted for review and approval prior to distribution.

Recruiting Service Member Spouses for the Millennium Cohort Family Study

To facilitate the recruitment of service members' spouses into the Millennium Cohort Family Study, all responders who, upon completion of their 2020 Millennium Cohort Study baseline survey, are flagged as married by DMDC and who have a marital status of either married or separated on the baseline survey will be directed to a secure incentive fulfillment page operated by Anderson Direct & Digital (AD&D). In addition to requesting their current mailing address for incentive fulfillment, these participants will be asked to provide their spouse's email address with the following message: 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.

Please see section 13.2 for more detailed information regarding the process of compensation for participation.

Service member spouses will be invited to participate in the Millennium Cohort Family Study at a later date. The Millennium Cohort Family Study will maintain the consent form, Privacy Act, HIPAA Authorization, survey documents and participant contacts for their study under protocol NHRC.2015.0019.

Recruiting Service Members for the Family Cohort Study Single Parent Module

Upon completion of their Millennium Cohort Study survey, all 2020 baseline survey responders who fit the criteria below based on their self-reported data, will be invited to participate in the Millennium Cohort Family Study single parent module. This module was designed to align with the parenting and child sections of the Family Study surveys in order to broaden the definition of military families.

Marital status:

Single, never married
Divorced

Widowed

Minor children (17 or younger):
Yes

On the final page of the Millennium Cohort Study survey, all 2020 baseline survey responders that meet the single parent criteria mentioned above will see the following message:

Single Parents Matter – 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 will receive a $10 gift card for answering an additional set of questions, which should take no longer than 10-15 minutes to complete. You will be receiving an email shortly with additional details and instructions.*

During the data import, all participants that are deemed 'single parents' will be flagged to receive an automated email from the Millennium Cohort Family Study inviting them to complete the Single Parent Module of the Millennium Cohort Family Study Survey. The invitation email has been submitted for review and approval.

The Millennium Cohort Family Study will maintain the consent form, Privacy Act, HIPAA Authorization, survey documents and participant contacts for the single parent module under protocol NHRC.2015.0019. No service member will receive an invitation email until the Family Study has received IRB approval for the consent form, Privacy Act, HIPAA Authorization, and single parent survey.

Dyad Invitation Experiment

The need to understand the impact of war on military families has never been greater than during the past decade, with more than three million military spouses and children affected by deployments to Operations Iraqi Freedom and Enduring Freedom. Understanding the impact of the recent conflicts on families is a national priority, however, most studies have examined spouses and children individually, rather than concurrently as families. The Department of Defense (DoD) has authorized the largest study of military families in US military history (the Millennium Cohort Family Study), which includes dyads of military service members and their spouses. A dyad is a group of two people; in this case a military service member and their spouse.

The Millennium Cohort Study of service members and the Millennium Cohort Family Study of military spouses (Family Study) plans to conduct an experiment to determine the impact of the timing of service member–spouse dyadic invitations sent to request participation in the Family Study versus the Millennium Cohort Study, as well as the nature of specific incentives during the course of the Family Study Panel 2 recruitment cycle. A group of 2,000 service member–spouse dyads from the Family and Millennium Cohort Study sampling frames were 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 the Family Panel 2 recruitment. Married service member–spouse 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	RECRUTIMENT TYPE	
Single	**Dyadic**	
Post	Group1	Group3
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. Additional details about the experiment are included in the Millennium Cohort Family protocol (NHRC.2015.0019) sections 10.1, 13.1, and 13.2.

Millennium Cohort Study Feedback Survey
The population for this project will be all currently enrolled participants in Panels1-5 of the Millennium Cohort Study.

All eligible participants will receive an invitation email and/or postal letter asking them to participate in the feedback survey by completing a paper or web-based survey. Once a participant completes their survey, the study team will send one final contact letting them know that their submission was received and to thank them for their participation.

If a subject does not respond to the initial invitation, the study team will send two (2) reminder emails to the participant to encourage participation for the duration of the survey cycle.

Consent Addendum and HIPAA Authorization
Beginning in the 2019 survey cycle (2019-2021), the Millennium Cohort Study attempted to engage existing study participants to review and sign an IRB approved consent addendum. The addendum informed the participants that: (1) the length of the study has been extended past its original 21 years to 67 years; (2) that other databases that the study links with has been expanded to include 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; and (3) that the study has obtained a Certificate of Confidentiality (CoC) from the National Institutes of Health (NIH).

Additionally, during the 2019 survey cycle, the Defense Health Agency required the study to engage existing study participants to review and sign an IRB approved DHA HIPAA Authorization to allow the study to obtain requested participant Military Health System data.

Per IRB guidance, the study can and will continue to engage existing study participants to review and sign the consent addendum and DHA HIPAA Authorization until such time that the participant signs the forms, they contact the study team and refuse to sign the forms, or a waiver of consent and/or HIPAA waiver is granted by the NHRC IRB and/or Privacy Officer.

Changes to the Informed Consent Addendum
After concluding the 2019-2021 survey cycle, the Study realized many participants didn't fully grasp the Addendum's significance. Unaware of the consequences, many unknowingly missed the opportunity for continued participation by neglecting to sign the Informed Consent Addendum. Subsequent attempts to rectify this through postal mail and email revealed that many may have seen the Addendum as simply informative, overlooking the essential need for their signature.

To address misconceptions surrounding the Informed Consent Addendum, the Study sought and obtained approval from the IRB Chair to modify the Addendum. The Study has been approved to remove the signature requirement and instead clearly state that completion and return of the survey itself signifies agreement to the updated terms. This updated Addendum will be provided during the 2024-2025 to all participants who do not yet have one on file.

13.2 Compensation for Participation:

We plan to follow standard techniques (92,93) of gaining high participation percentages: pre-survey introductory postcard mailing, cover letter with survey, postcard reminders, and three repeat survey mailings (Appendix G). We will mail the subjects a preliminary postcard to alert them to the forthcoming survey. This will also allow us to gather address information inexpensively for subjects who have changed addresses after our data extraction. The questionnaire will next be sent by first-class U.S. mail, with a cover letter describing the study, and a consent form. The investigators will employ a commercial address tracking company to locate subjects

with inaccurate addresses. One month after the initial mailing, a postcard reminder will be sent. Two months after the first survey mailing, a second survey with a cover letter will be mailed, and this will again be followed with another reminder postcard 1 month later. Four months after the second questionnaire mailing, a final questionnaire with cover a letter will be mailed, and this mailing will again be followed with a third postcard reminder. After three survey mailings, a tracking service and additional data updates will be used to find correct addresses for undelivered mail.

An IRB-approved investigation into whether Millennium Cohort Study response rates were affected by incentives offered prior to survey completion was conducted during the 2014-2016 survey cycle. For the 2014-2016 pre-incentive investigation, all participants with a current postal address were randomly assigned one of five pre-incentives: a two-dollar bill, a five-dollar gift card, a magnet, entry into a drawing for an iPad, or no pre-incentive. Pre-incentives were mailed in September 2014 along with an invitation to participate in the 2014-2016 survey. Additionally, since some participants did not get a pre-incentive by design or because of outdated contact information, the team sent challenge coins to all participants who completed the survey as another means of increasing retention and to keep contact with participants.

The number of participants in each group was determined a priori based on incentive availability, cost, and current literature. A total of 1,000 participants received entry into the iPad drawing. This number was chosen to ensure that the odds of winning one of the two available iPads were no greater than 1 in 500 and equates to approximately $2 per person. The group that did not receive an incentive included 5,000 participants. This number was chosen because the literature and past experience suggested that this would be the least effective method to increase survey response. Resource availability dictated that 10,040 participants receive a gift card. The remaining participants were allocated evenly between the cash and magnet groups, each with a final total of 78,203 participants. Literature indicated that cash would elicit the highest response rates, thus the study team ensured that this was one of the largest groups. The magnet was a nominal gift of equal value ($2) and was also predicted to have a high success rate in inducing response. After the pre-incentives were mailed, we received 10,770 (6.2%) returned incentives due to outdated mailing addresses. These participants were removed from the analyses since we were unable to contact them via postal mail and therefore could not assess the pre-incentive effect on their response.

Results from the 2014-2016 investigation determined that a $2 bill and a $5 gift card had higher response rates among participants who received them, compared to those who received no pre-incentive (Table 1). Participants given a $2 bill or $5 gift card had an approximately 27-28% higher odds of responding compared with those who were not given a pre-incentive. There was no observed difference in the odds of responding to the survey among participants who were entered into the iPad drawing or sent a magnet compared to those who did not receive a pre-incentive.

Table 1. Survey response rate and odds of response by pre-incentive type

	Survey Response*	
	% response	Odds Ratio (95% CI)
Total	32.4†	
Pre-Incentive Type		
No pre-incentive	30.4	1.00 (ref)
$2 bill	35.0	1.27 (1.18, 1.35)
Gift card	35.5	1.28 (1.18, 1.39)
Drawing/lottery	29.4	0.97 (0.83, 1.15)
Magnet	29.5	0.94 (0.88, 1.01)

*Logistic regression model adjusted for age, gender, race/ethnicity, marital status, education, service branch, military service status, service component, accession group, and foreign address. After adjustment, incentive type was statistically significantly associated with response (p-value < 0.001).
†Total includes all enrolled, living Millennium Cohort participants with a currently known postal mailing address.

In addition to overall response rate, another area of specific interest was the effectiveness of pre-incentives in getting previous non-responders to re-engage in the study. These results indicated that the pre-incentives effective in the general study population (gift card and cash) were also the most effective among previous non-responders (Table 2). A total of 8.6% of last cycle's (2011-2013) non-responders who received a cash pre-incentive responded to the 2014 survey, and 8.3% responded after receiving the gift card, compared with 4.9% who did not obtain a pre-incentive. Participants given a $2 bill or $5 gift card had an approximately 82% or 77% greater odds of responding, respectively, compared with those who did not receive a pre-incentive.

Table 2. Survey response rate and odds of response by pre-incentive type among 2011 survey non-responders

	Survey Response*	
	% response	Odds Ratio (95% CI)
Total	6.8†	
Pre-Incentive		
Letter	4.9	1.00 (ref)
Cash	8.6	1.82 (1.43, 2.33)
Gift card	8.3	1.77 (1.34, 2.33)
Lottery	3.8	0.77 (0.40, 1.48)
Magnet	5.1	1.03 (0.80, 1.32)

*Logistic regression model adjusted for age, gender, race/ethnicity, marital status, education, service branch, military service status, service component, accession group, and foreign address. After adjustment, incentive type was statistically significantly associated with response (p-value < 0.001).
†Total includes enrolled, living Millennium Cohort participants with a currently known postal mailing address, and did not complete a 2011 Millennium Cohort survey.

This investigation not only indicated that pre-incentives were effective in boosting survey response rates, but also that certain types of pre-incentives were more successful than others, namely cash and gift cards. This information will help to maximize study retention and reduce costs. Based on the findings from this IRB-approved investigation, the Millennium Cohort Study will invest in monetary incentives for the upcoming survey cycle to enhance participant engagement and increase the survey response rate. All original ODCs for the purchase of these incentives have been submitted as a part of this package.

During the latest OMB and RCS approval process the use of incentives by the Millennium Cohort Study was reviewed and approved by the Office of the General Counsel for Navy Medicine on February 25, 2022. All external approvals have submitted as part of this package in Appendix K.

Through an existing sub-contract with Anderson Direct & Digital (AD&D), the Millennium Cohort study will offer each participant who completes the web survey their choice of a Millennium Cohort ball cap, a challenge coin, or a $5 gift code to Starbucks or Amazon. On the final page of the web survey, the participant will have the option to choose their gift by clicking a radio button. For those participants that choose a hat or coin, this radio button will redirect the participant to the AD&D secure gift fulfillment page. Here, the participant will confirm their gift selection and provide AD&D with their current mailing address for fulfillment.

On the last page of the Millennium Cohort 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 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.

For those participants that choose a gift code, upon their selection confirmation the Millennium Cohort web page will page will display the gift code from the chosen vendor.

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

Not applicable.

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?

[x] Waiver of documentation of informed consent
[ ] Waiver or alteration of informed consent

Please explain why your study is eligible for the requested waiver

The Millennium Cohort Study is eligible for the requested waiver of documentation of informed consent because while initially planned for a 21-year duration, the Millennium Cohort study received an extension in 2013, stretching its timeframe to 67 years and setting its new period of performance to 2068. To reflect this change and accommodate additional data linkages and a Certificate of Confidentiality, and in order to harmonize informed consent across the Study panels, the Study developed an Informed Consent Addendum with guidance from the Naval Health Research Center's Institutional Review Board Chair. This addendum informed participants of the updated terms and required their wet or digital signature (paper or online) to confirm their awareness. Distribution of the addendum began in the 2019-2021 survey cycle, with attempts to collect signatures during two additional periods outside ongoing data collection.

After concluding the 2019-2021 survey cycle, the Study realized many participants didn't fully grasp the Addendum's significance. Unaware of the consequences, many unknowingly missed the opportunity for continued participation by neglecting to sign the Informed Consent Addendum. Subsequent attempts to rectify this through postal mail and email revealed that many may have seen the Addendum as simply informative, overlooking the essential need for their signature.

To address misconceptions surrounding the Informed Consent Addendum, the Study sought and obtained approval from the IRB Chair to modify the Addendum. The Study has been approved to remove the signature requirement and instead clearly state that completion and return of the survey itself signifies agreement to the updated terms. This updated Addendum will be provided during the 2024-2025 to all participants who do not yet have one on file.

Please explain the consent process:

For all newly invited participants, an informed consent statement will be included in both the on-line and paper questionnaires. The informed consent statement will include a phone number and e-mail address of the Millennium Cohort Study team and the NHRC IRB chair. Service members can contact these individuals if they have questions.

The on-line survey will include an “I Agree” button that subjects will click to signify that they have read the information and agree to participate. Once the button is selected, the subject will be redirected to the research survey questionnaire. The paper questionnaire’s informed consent will be the first page of the questionnaire after the cover page. Subjects will be required to sign and print their names for the informed consent to be valid. Subject medical data will not be obtained unless service members provide informed consent.

Changes and/or updates to the original Informed Consent will be provided to participants in an Informed Consent Addendum. The online survey and paper survey's Addendum will immediately follow the Privacy Act and Agency Disclosure Notice and will be located before the first survey question. The Addendum will clearly state that completion and return of the survey itself signifies agreement to the updated terms.

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 may change their mind and revoke their permission for this project to collect or use their health information at any time. Per the consent form, to revoke their permission, they must contact the study team at the email or phone number provided in the consent form and on the study website. When they revoke their permission, no new questionnaire or health information about them will be gathered after that date and they may no longer be allowed to participate in the study. Per the consent form, information that has already been gathered may still be used and there is no guarantee that it will be removed from the electronic database for this study. They also have the right to review an electronic copy of their survey and medical information for as long as the survey and health information are maintained by contacting the study team.

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 protocol uses demographic, occupational, and deployment data, as well as survey data and existing medical data. Thus, the study poses no physical risk to the participants. The data of interest are, however, of a sensitive nature, and strict procedures will be followed to minimize loss of confidentiality. Although personal identifiers will be kept and utilized to ensure proper linkage of data, they will be protected such that no individual could be identified in any report.

Records and computer files will be maintained securely in accordance with DoD regulations. The potential loss of confidentiality for participants who complete the online survey is minimized because completed surveys are transmitted to NHRC over Secure Sockets Layer (SSL) data transmission lines.

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 are in place to ensure that confidential information will not be used or abused in ways that might directly or indirectly harm the individuals involved:

Administrative

- All study staff will receive training in confidentiality protection procedures.
- Supervisors will monitor staff to ensure that they follow proper confidentiality procedures.

- An annual review of confidentiality procedures will be conducted.
- If study staff resign or otherwise leave the program, they will remain under obligation to protect the confidentiality of all data collected as part of the study.

Procedural

- The respective service survey approval managers will review the participant contacts and paper questionnaire. Their approval will be required before initiating any mailings.
- The participants will be informed of the process that will be used to link their answers with pre-existing data. It is required that NHRC's IRB permit the investigators to forgo use of the formal informed consent documentation.
- 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 (Appendix L). 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 (Appendix K).

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

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

Administrative safeguards

- A Certificate of Confidentiality (CoC) issued by the National Institutes of Health (NIH) has been obtained for this study. CoCs protect participants' privacy such as 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.

Physical safeguards

- NHRC is located on a secure access-controlled site. Personnel access to NHRC is controlled by a DoD-issued access card. Visitors must be escorted at all times.

Computer Security

- To gain entry into the study database, staff will be required to enter their personal ID numbers and password.
- Study staff will download data through secure data transmission links meeting standard DoD requirements. The data will be stored on existing NHRC information systems network. This system meets current DoD data security requirements.
- 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. All data will be carefully guarded and used only to meet the stated study objectives.
- The NHRC network firewall is in place to deter unauthorized access to these files.
- Personal identifying information will be removed from the analytic database once the survey, medical facility use, and demographic information are linked and stored separately. Only the data mangers, who are familiar with the database, will link personal identifiers with the data for the initial match or any subsequent matches, and the identifiers will again be stripped following the match.

- The study database will reside within the NHRC network environment. There are no subcontractors who would have access to or possession of this database at any time.
- Information transmitted over the Internet will be done so using SSL-encrypted transmission lines. Further, users will have to enter their unique study ID number and last four digits of their social security number to send completed questionnaires.
- Appendix M details the website security procedures.

The PHI/PII collected in the survey (if any) will be specified in the informed consent document and used with authorization from the subject as stipulated in the informed consent document. The informed consent agreement includes the following required information: a description of the information to be used; the name of the person (s) requesting the use; the name of the person(s) who may use the requested PHI/PII, (i.e., the intended recipients, a description of each purpose of the requested use, the length of time that the data will be maintained tied to an expiration date or an expiration event, a statement regarding the individual's right to revoke authorization for use of PHI/PII and whom to contact in writing to revoke the authorization, a statement regarding the individual's right to inspect hard copies of any PHI/PII collected, and who to contact in writing to inspect the contributed data). The study participants will also be asked to sign a DSA approved HIPAA Authorization. Participant medical data will not be obtained from Military Health System (MHS) sources unless participants provide a signed Authorization.

Our use of PHI/PII involves no more than minimal risk to the individuals since we will implement procedures to control access to the information collected. Each individual invited to join the study will be assigned a subject identification number (SID). Two databases will be created for study use. The first database (identified) will contain participant data such as name, contact information (phone, address, and email), data of birth, and SID. This database will be the source of names and addresses when individuals are contacted and will be used for tracking purposes. The second analytic database (redacted) will store participant questionnaire responses and relevant administrative data in conjunction with the SID and without identifiers. This procedure will separate individual identifiers from participant survey data, while making it possible to pair names and contact information with SIDs for update and tracking purposes. The principal investigator controls access to both the analytic and identified databases, which are located onsite at NHRC on a secure DoD controlled network. Records and computer files will be maintained securely in accordance with DoD regulations (NMRDCINST 5870.4). Access to PHI/PII will be restricted to onsite NHRC investigators who have signed the Investigator Compliance Attestation. Identifiable data sets will be shared only with those co- investigators listed on the protocol who have signed the Investigator Compliance Attestation. Identifiable data will not be re-used or re-disclosed to any other entity. Data will be maintained securely at NHRC both within the physical environment and IT environment, as per NAVHLTHRSCHCENINST 6500.1A. Hard copies of completed surveys will be stored in locked file cabinets in buildings 337 and 347. Further, as mentioned above, all electronic data are stored as password-protected files that are stripped of personal identifiers, such as names, and will retain only study-specific subject identification numbers. Data are managed and analyzed using only these de-identified data files, which will be destroyed after a minimum of six years following completion of the study, or as dictated by any future required retention periods, whichever is longer. Findings will only be released as an aggregate; no individuals will be identified. Hard copies of completed surveys will be securely destroyed per the disposition instructions of the active SORN. Please see Appendix O for the active SORN.

Millennium Cohort study participant names and postal addresses will be provided to Anderson Direct & Digital (Anderson) by a secure encrypted website so they can solicit participants by postal mail. Anderson will be required by contract to keep the information confidential, not use the information beyond the purposes of the investigation, and destroy the names and addresses upon the project's completion.

Solicitation of participants by Anderson is performed on an individual basis by postal mail letter and post card that ask them to complete a web-based survey; e-mail reminders are sent by NHRC study staff from servers located at NHRC. Participants who chose to volunteer will access the server at LightEdge Solutions (LightEdge), in San Diego Data Center using a unique username (SID) that will be provided in all correspondence. On the survey login page, the participant's SID and DoD ID Number or the last four of their SSN are keyed in by the participant. The participant's SID and digits 6-10 of their DoD ID Number or the last four of their SSN are held in memory by the web server over an encrypted Secure Sockets Layer (SSL) connection (Hypertex Transfer Protocol Secure [HTTPS]) using the Transport Layer Security (TLS) 1.2 protocol and Advanced Encryption Standard (AES) Galois/Counter Mode (GCM) 128-bit block cipher. Digits 6-10 of the keyed-in DoD ID Number or the last four of their SSN are then hashed by the server using the earlier described method and compared against the stored hash value in the SID-hashed identifier log. At this point, the SSN or DoD ID Number information which was held in memory is discarded (it is not stored) and the user is either granted or denied access to the survey and assigned a session token.

Questionnaire responses stored at LightEdge are transferred to NHRC by encryption and participant's IP addresses are not included in the transfer. All transfers between other participating organizations (NHRC, DMDC, VA) are accomplished using the DoD SAFE site. All transmittals of PII and questionnaire and medical data are performed separately.

In summary, records and computer files will be maintained securely in accordance with DoD regulations and contracts. PII and data will be transmitted separately and stored in separate file servers at NHRC. The potential loss of confidentiality for participants who complete the online survey is minimized because no PII is collected on the survey, digits 6-10 of their DoD ID Number or the last four of their SSN are hashed then matched and not stored, and surveys are encrypted while they are transmitted. Sharing of data between DMDC, NHRC, LightEdge, Anderson, and VA is accomplished using encrypted sites. Data storage is on government computers with their inherent required security protocols.

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

While participation in this study may not directly benefit study subjects, their participation may help the researchers and the military understand the impacts of military deployment, military occupations and general military service on long-term service member health. Even if they have not or will not ever deploy, they are encouraged to participate so the investigators can understand similarities and differences between service members wo do and do not deploy.

14.5 Privacy for Subjects:

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

This study involves surveying participants on-line and via paper questionnaire and collecting existing medical data and does not involve any direct interaction with individuals or their biological specimens. All paper questionnaires will be kept in locked files. When data are entered into computer files for analysis, the participant' s answers will be identified only by a special study identification number (SID) known to participant and research team members. This number is located on the barcode of the study envelope and survey for that participant. Their social security number and any other personal identification information will be removed from their questionnaire and data file upon return to the researchers. Even if someone outside the research team broke into the files, it would be impossible for them to identify the participant's data. To minimize the risk of anyone breaking into the data files, those 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 group data, so that no individual study participant can be identified.

The PHI/PII collected in the survey (if any) will be specified in the informed consent document and used with authorization from the subject as stipulated in the informed consent document. The informed consent agreement includes the following required information: a description of the information to be used; the name of the person (s) requesting the use; the name of the person(s) who may use the requested PHI/PII, (i.e., the intended recipients, a description of each purpose of the requested use, the length of time that the data will be maintained tied to an expiration date or an expiration event, a statement regarding the individual's right to revoke authorization for use of PHI/PII and whom to contact in writing to revoke the authorization, a statement regarding the individual's right to inspect hard copies of any PHI/PII collected, and who to contact in writing to

inspect the contributed data). The study participants will also be asked to sign a DSA approved HIPAA Authorization. Participant medical data will not be obtained from Military Health System (MHS) sources unless participants provide a signed Authorization.

Our use of PHI/PII involves no more than minimal risk to the individuals since we will implement procedures to control access to the information collected. Each individual invited to join the study will be assigned a subject identification number (SID). Two databases will be created for study use. The first database (identified) will contain participant data such as name, contact information (phone, address, and email), data of birth, and SID. This database will be the source of names and addresses when individuals are contacted and will be used for tracking purposes. The second analytic database (redacted) will store participant questionnaire responses and relevant administrative data in conjunction with the SID and without identifiers. This procedure will separate individual identifiers from participant survey data, while making it possible to pair names and contact information with SIDs for update and tracking purposes. The principal investigator controls access to both the analytic and identified databases, which are located onsite at NHRC on a secure DoD controlled network. Records and computer files will be maintained securely in accordance with DoD regulations (NMRDCINST 5870.4). Access to PHI/PII will be restricted to onsite NHRC investigators who have signed the Investigator Compliance Attestation. Identifiable data sets will be shared only with those co- investigators listed on the protocol who have signed the Investigator Compliance Attestation. Identifiable data will not be re-used or re-disclosed to any other entity. Data will be maintained securely at NHRC both within the physical environment and IT environment, as per NAVHLTHRSCHCENINST 6500.1A. Hard copies of completed surveys will be stored in locked file cabinets in buildings 337 and 347. Further, as mentioned above, all electronic data are stored as password-protected files that are stripped of personal identifiers, such as names, and will retain only study-specific subject identification numbers. Data are managed and analyzed using only these de-identified data files, which will be destroyed after a minimum of six years following completion of the study, or as dictated by any future required retention periods, whichever is longer. Findings will only be released as an aggregate; no individuals will be identified. Hard copies of completed surveys will be securely destroyed per the disposition instructions of the active SORN. Please see Appendix O for the active SORN.

Millennium Cohort study participant names and postal addresses will be provided to Anderson Direct & Digital (Anderson) by a secure encrypted website so they can solicit participants by postal mail. Anderson will be required by contract to keep the information confidential, not use the information beyond the purposes of the investigation, and destroy the names and addresses upon the project's completion.

Solicitation of participants by Anderson is performed on an individual basis by postal mail letter and post card that ask them to complete a web-based survey; e-mail reminders are sent by NHRC study staff from servers located at NHRC. Participants who chose to volunteer will access the server at LightEdge Solutions (LightEdge), in San Diego Data Center using a unique username (SID) that will be provided in all correspondence. On the survey login page, the participant's SID and DoD ID Number or the last four of their SSN are keyed in by the participant. The participant's SID and digits 6-10 of their DoD ID Number or the last four of their SSN are held in memory by the web server over an encrypted Secure Sockets Layer (SSL) connection (Hypertex Transfer Protocol Secure [HTTPS]) using the Transport Layer Security (TLS) 1.2 protocol and Advanced Encryption Standard (AES) Galois/Counter Mode (GCM) 128-bit block cipher. Digits 6-10 of the keyed-in DoD ID Number or the last four of their SSN are then hashed by the server using the earlier described method and compared against the stored hash value in the SID-hashed identifier log. At this point, the SSN or DoD ID Number information which was held in memory is discarded (it is not stored) and the user is either granted or denied access to the survey and assigned a session token.

Questionnaire responses stored at LightEdge are transferred to NHRC by encryption and participant's IP addresses are not included in the transfer. All transfers between other participating organizations (NHRC, DMDC, VA) are accomplished using the DoD SAFE site. All transmittals of PII and questionnaire and medical data are performed separately.

In summary, records and computer files will be maintained securely in accordance with DoD regulations and contracts. PII and data will be transmitted separately and stored in separate file servers at NHRC. The potential loss of confidentiality for participants who complete the online survey is minimized because no PII is collected on the survey, digits 6-10 of their DoD ID Number or the last four of their SSN are hashed then matched and not stored, and surveys are encrypted while they are transmitted. Sharing of data between DMDC, NHRC, LightEdge, Anderson, and VA is accomplished using encrypted sites. Data storage is on government computers with their inherent required security protocols.

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

Not applicable.

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.

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 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

The PI will report to the IRB any reportable events in a timely manner as outlined below:

- Data Slip/Breach will be reported within 24 hours from the time the incident was identified
- Protocol deviation/violations 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
☑ N/A

18.5 Sponsor (organization/institution/company):

☑ N/A

If applicable, provide sponsor contact information:

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

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20.2 Abbreviations and Acronyms:

Completion email for web survey completers

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

On behalf of the Millennium Cohort Study team, thank you for completing your Millennium Cohort survey! Your participation in this important health study will benefit future generations of military service members.

Your Millennium Cohort Study survey was submitted on <date> at <time>.

If you selected a hat or coin as your thank you gift, you should receive it within 6-8 weeks. If you have any questions or comments, or do not receive your gift, please do not reply to this message. Instead please contact the study team at usn.nhrc-MilcohortInfo@health.mil. If you would prefer to reach us by phone, please dial toll-free (888) 942-5222.

Thank you for your valuable contribution to this critical study!

Very Sincerely,
The Millennium Cohort Study Team

****

If you are a Veteran or service member in crisis or concerned about one, please connect with qualified responders for confidential help at the Veteran Crisis Line by DIALING 988 then PRESS 1 or texting 838255. You can get more resources at VeteransCrisisLine.net.

For any questions, please contact the Millennium Cohort Study Team at usn.nhrc-MilcohortInfo@health.mil or call toll free 1-888-942-5222 or DSN 553-7465 and reference your Subject ID: <xxxxxxx>

The Millennium Cohort Study is an authorized Department of Defense research project. Report Control Symbol #DD-NAVY-2678, Office of Management and Budget Approval # 0703-0064, and Primary Institutional Review Board Protocol #NHRC.2000.0007.

If you would like this email address to be removed from our email list, please visit <unsubscribe code>

Thank you card for responders that choose to receive a hat

Thank you for taking part in the 2024-2025 Millennium Cohort Study survey!

Your involvement, along with that of other participants, is crucial in helping us understand the long-term health impacts of military service on both current and former service members. We sincerely appreciate your contribution.

The data collected from you and other participants will be used to help to inform and improve interventions, clinical practice guidelines, and policies of key stakeholders, including Department of Defense and Department of Veterans Affairs leadership. This study will help us investigate why some individuals experience no specific health issues following their military service and deployments, while others may develop health symptoms and concerns.

This is the largest study of military health ever conducted in the United States. We plan to follow-up with participants until 2068 to assess any changes in individual health that may be linked to military service.

Thank you once again for your invaluable contribution to the Millennium Cohort Study.

Very respectfully,
The Millennium Cohort Study Team

APPENDIX G. MILLENNIUM COHORT PARTICIPANT CONTACT MATERIALS

NEW ADDITIONS

Completion email for web survey completers

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

On behalf of the Millennium Cohort Study team, thank you for completing your Millennium Cohort survey! Your participation in this important health study will benefit future generations of military service members.

Your Millennium Cohort Study survey was submitted on <date> at <time>.

If you selected a hat or coin as your thank you gift, you should receive it within 6-8 weeks. If you have any questions or comments, or do not receive your gift, please do not reply to this message. Instead please contact the study team at usn.nhrc-MilcohortInfo@health.mil. If you would prefer to reach us by phone, please dial toll-free (888) 942-5222.

Thank you for your valuable contribution to this critical study!

Very Sincerely,
The Millennium Cohort Study Team

****
If you are a Veteran or service member in crisis or concerned about one, please connect with qualified responders for confidential help at the Veteran Crisis Line by DIALING 988 then PRESS 1 or texting 838255. You can get more resources at VeteransCrisisLine.net.

For any questions, please contact the Millennium Cohort Study Team at usn.nhrc-MilcohortInfo@health.mil or call toll free 1-888-942-5222 or DSN 553-7465 and reference your Subject ID: <xxxxxxx>

The Millennium Cohort Study is an authorized Department of Defense research project. Report Control Symbol #DD-NAVY-2678, Office of Management and Budget Approval # 0703-0064, and Primary Institutional Review Board Protocol #NHRC.2000.0007.

If you would like this email address to be removed from our email list, please visit <unsubscribe code>

Thank you card for responders that choose to receive a hat

Thank you for taking part in the 2024-2025 Millennium Cohort Study survey!

Your involvement, along with that of other participants, is crucial in helping us understand the long-term health impacts of military service on both current and former service members. We sincerely appreciate your contribution.

The data collected from you and other participants will be used to help to inform and improve interventions, clinical practice guidelines, and policies of key stakeholders, including Department of Defense and Department of Veterans Affairs leadership. This study will help us investigate why some individuals experience no specific health issues following their military service and deployments, while others may develop health symptoms and concerns.

This is the largest study of military health ever conducted in the United States. We plan to follow-up with participants until 2068 to assess any changes in individual health that may be linked to military service.

Thank you once again for your invaluable contribution to the Millennium Cohort Study.

Very respectfully,
The Millennium Cohort Study Team

END NEW ADDITIONS

4th of July Postcard - Back
Art for the front was part of a previously approved IRB submission.

Department of Defense
Deployment Health Research Department
c/o Naval Health Research Center
PO Box 85777
San Diego, CA 92186-5777

MILLENNIUM COHORT STUDY

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PERMIT #3909

ADDRESS SERVICE REQUESTED

As we celebrate our nation's independence with friends and family, let us also remember and honor the courageous men and women that protect our freedom. Their sacrifices and dedication safeguard the liberties we cherish.

Thank you for your continued support of this important project! Together, we contribute to understanding the challenges and needs of our service members, ensuring their well-being and resilience.

Very respectfully,
The Millennium Cohort Study Team

Primary Institutional Review Board Protocol # NHRC.2000.0007.

4th of July Email
Subject Line: Celebrating Independence Day & Supporting Service Members

Dear <name>,

As we celebrate our nation's independence with friends and family, let us also remember and honor the courageous men and women that protect our freedom. Their sacrifices and dedication safeguard the liberties we cherish.

You should receive a 4th of July postcard in the mail from the Millennium Cohort Study team. You can also view it online by visiting our website at
<link>

Thank you for your continued support of this important project! Together, we contribute to understanding the challenges and needs of our service members, ensuring their well-being and resilience.

Very respectfully,
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April 2024 - Pre-notice Newsletter/Research Brief – New Enrollee

WELCOME TO THE MILLENNIUM COHORT STUDY!

Please keep us updated

- Have you recently moved or changed your email address?
- Has your name changed?

Please visit our website **www.millenniumcohort.org** to update your contact information.

Your **Subject ID** can be found below the barcode on the address side of this newsletter.

It's almost time to update your health information. The 2024 survey will be available on our website soon!

Dear Participant,

Welcome to the Millennium Cohort Study!

I would like to take this opportunity to sincerely thank you for joining this important research study. As the head researcher, I am humbled every day by the sacrifices that you and your fellow service members make for our country.

Although you recently became a part of our community within the last three years, in 2021, we marked the 20-year anniversary of the Millennium Cohort Study.

Back in 2001, we started with a little over 77,000 participants, many of whom were deployed after the events of 9/11. Today, as the largest and longest-running cohort in military history we have more than a quarter of a million participants from all service branches including Reserve and National Guard. This study's continued success would not be possible without service members like you.

Thank you for your service, and for your participation to this study.

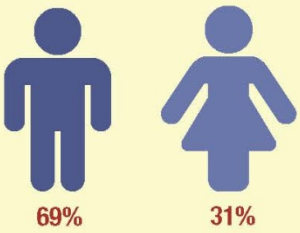
Very respectfully,

Rudy Rull, PhD, MPH
Principal Investigator, Millennium Cohort Study

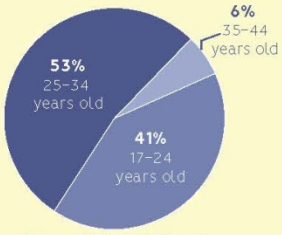
PARTICIPANT PROFILE

The Millennium Cohort Study continues to be the U.S. Department of Defense's largest and longest-running study and recently celebrated its 20th Anniversary. Over a quarter of a million service members enrolled between 2001 and 2021 and you are an important part of making it one of the largest cohort studies in the world! You represent your service branch, gender, and age group, so your participation is incredibly valuable to the continued success of this study.

Below is a breakdown of the data that describes key characteristics of the **58,609** newly enrolled (Panel 5) members of the Cohort. Where do you fit in?



Remaining involved with the study as you age is critical to answering many challenging questions about the long-term effects of military service on health and well-being.



Age of the Cohort

Separation Status

99% of participants are still actively serving

Weight

37% of males and 52% of females have a body mass index (BMI) of 18.5–24.9 kg/m², which is in the healthy weight range

Education

32% of participants have at least an associate degree

Alcohol

6% of participants drink above recommended limits*

*7 drinks/week for women and 14 drinks/week for men

Smoking

94% of participants have either never smoked or have quit smoking

Marital Status

44% of participants are currently married

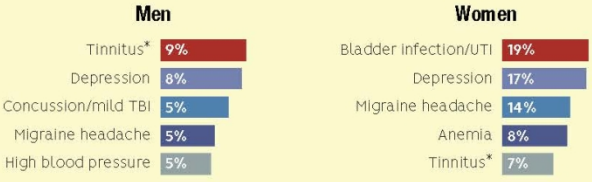
Sleep

Participants get an average of 6.4 hours of sleep per night

Exercise

91% of participants exercise at least 2 times per week

5 most commonly reported health issues



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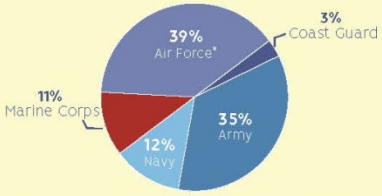
Cohort by service branch at time of enrollment



*At this time, the Air Force count includes Space Force service members.

IMPACT ON POLICY

U.S. Army photo by Adam Garlington

The main objective of the Millennium Cohort Study is to provide evidence-based knowledge to inform and improve interventions, clinical practice guidelines, and policies of key stakeholders, including Department of Defense (DoD) and Veteran's Administration (VA) leadership.

Since the launch of the cohort in 2001, the Millennium Cohort Study has investigated the impact of military service, including deployments and other occupational exposures, on long-term mental, physical, and behavioral health of service members and veterans.

Along with our publications, we also fulfill requests for research that will be used to aid in policy decisions. For example, our team recently provided results and findings describing the impacts of sexual harassment and sexual assault on service members to the Office of Personnel and Readiness, Health Services Policy and Oversight. We have also conducted analyses examining adverse mental health outcomes among Army veterinarians and veterinary technicians, as requested by the Commanding Officer of the Walter Reed Army Institute of Research.

The unique strength of the Millennium Cohort Study is our ability to measure long-term health outcomes over a wide range of exposures. We hope study results will help define healthcare policies, guide prevention and treatment programs, and strengthen opportunities for future generations of military personnel. Examples of findings from the Millennium Cohort Study that have been used to inform policy include:

Women's Health

The 2020 National Defense Authorization Act (NDAA) directed the Millennium Cohort Study to provide annual reports to Congress on gynecological and perinatal health through 2022.

Substance Use

The Institute of Medicine (IOM) issued a report in 2013 entitled "Substance Use Disorders in the U.S. Armed Forces" that included direct mention of the Millennium Cohort Study and the unique capability to examine substance use in service members and military families.

Respiratory Health

In 2020, the National Academies Press published a consensus report on respiratory health outcomes among service members who were deployed to the Persian Gulf region and Afghanistan. Specific focus of the analysis was on health outcomes of exposure to airborne hazards associated with service in these regions. In particular, the study evaluated and summarized "emerging evidence on respiratory health outcomes in service members from research such as the Millennium Cohort Study."[1] The report summarized findings across multiple studies and recommendations for future research and policies as related to respiratory health.

Health Promotion/Disease Prevention

The Millennium Cohort Study is considered a population health resource for informing performance and readiness optimization of active duty personnel. Data from the study on obesity and deployability have been used to inform current body composition standards. Specific policy changes have been made in DoD recruitment and retention policies. In addition, information has been used to inform Veteran's Health Administration (VHA) weight management programming.

FEATURED RESEARCH

Why is Sleep Research Important?

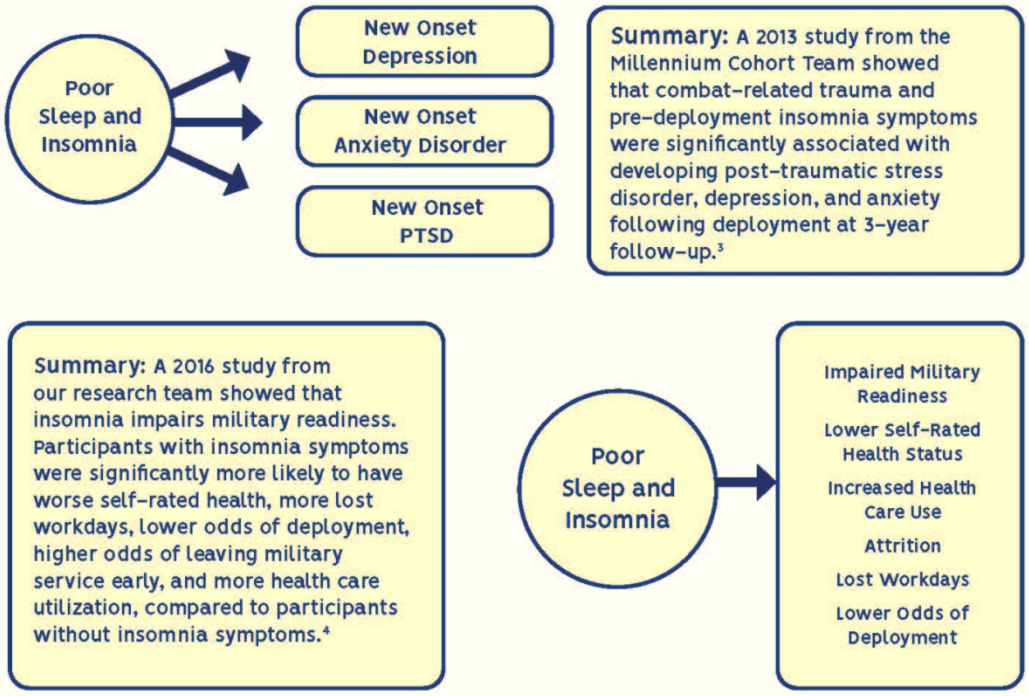
Sleep is essential for good health. Not getting enough uninterrupted sleep negatively affects a person's attention, learning and memory, and physical health.

- Sleep deficiency (too short or too long of sleep) and untreated sleep disorders are associated with a growing number of health problems, including heart disease, high blood pressure, diabetes, obesity, and depression, all of which can be harmful to military readiness.
- In addition to health problems, poor sleep is associated with lost worker productivity, and poor sleep and fatigue can cause accidents, making sleep a serious public health issue.[2]
- Sleeping 7–9 hours per night is essential for optimal performance of the service member.

Key Points: What did the Millennium Cohort Study Find?

The Millennium Cohort Study is collaborating with leading sleep researchers to conduct research to understand how sleep affects health over time and influences readiness and warfighter performance. Some example studies are featured below in Figure 1.

Figure 1. Millennium Cohort Study Sleep Research Results



FEATURED RESEARCH

Why is Research on Tobacco Use Important?

Tobacco use, through its many forms (cigarettes, vaping, cigars, smokeless tobacco), has many negative health effects and is related to diseases such as cancer, heart disease, and chronic obstructive pulmonary disease (COPD). Tobacco use is the leading cause of preventable death in the world.[5]

- Cigarettes and smokeless tobacco products are more often used among service members than the U.S. population.
- Regular tobacco use leads to diminished force readiness, medical morbidity (chronic conditions) and mortality (early death), and increased spending for medical costs.
- According to the Military Health System, "using tobacco in any form poses a threat to readiness and the overall health of the force."[6]
- It is thought that smoking is used as a coping strategy for the stress experienced in military deployments.

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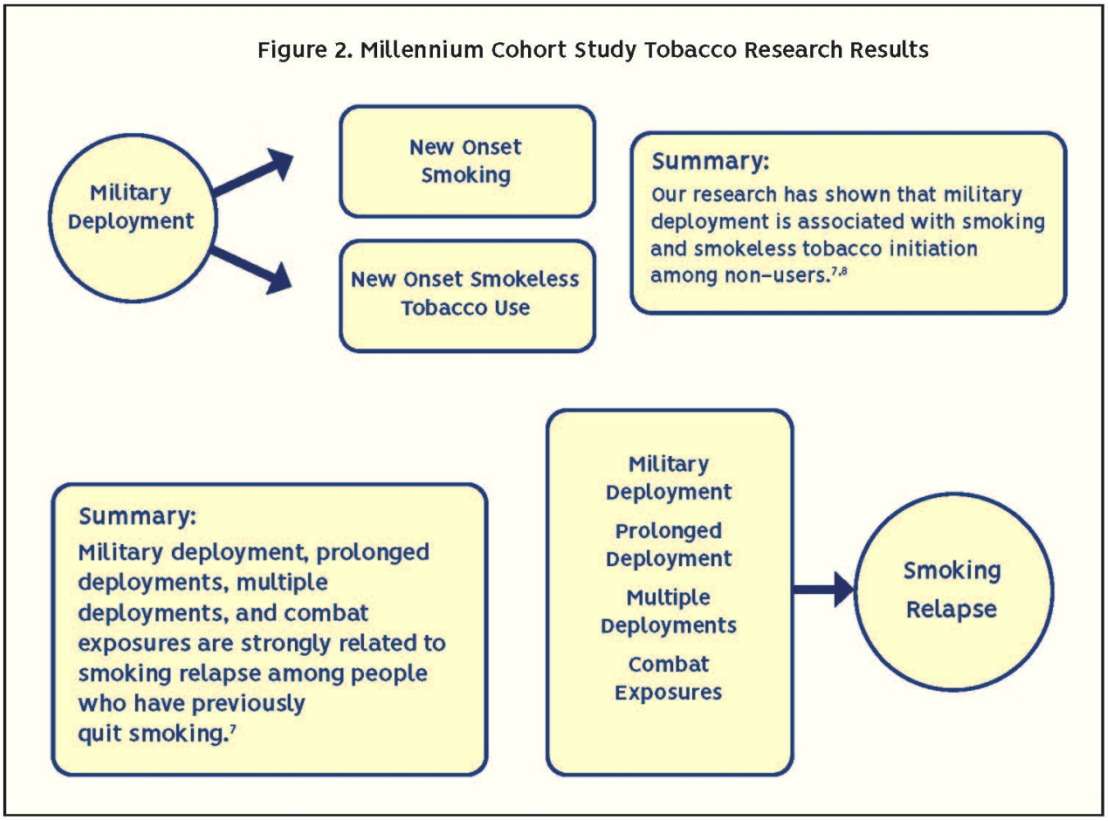
The Millennium Cohort Study is collaborating with leading tobacco researchers to conduct research to understand how military service and deployment affect tobacco use trends, mental and physical health in relation to tobacco use, and tobacco cessation. Some example studies are featured below in **Figure 2**. We are currently collecting data related to vape use and will be reporting on this in the future.

Figure 2. Millennium Cohort Study Tobacco Research Results



RECENTLY PUBLISHED PROJECTS

Racial, Ethnic, and Sex Disparities in Mental Health Among U.S. Service Members and Veterans

Mental health experiences vary among people of different backgrounds. This study explored whether similar differences exist within the U.S. military, focusing on how factors like race, ethnicity, and gender might influence the mental health of service members and veterans. This paper is available online ahead of print at the *American Journal of Epidemiology.*

Individual and Military Factors That Modify the Association Between Recent Sexual Trauma and Health Outcomes Among U.S. Service Members and Veterans

Experiences like sexual harassment and assault can take a toll on both your mind and body, affecting people in military and civilian life alike. This study looked at whether personal experiences and military service influence how sexual trauma impacts health, including anxiety, depression, physical pain, and sleep problems. This paper was published in the September 2023 issue of *Journal of Interpersonal Violence.*

Lifetime Traumatic Brain Injury and Risk of Post-Concussive Symptoms

Many service members have experienced traumatic brain injuries (TBIs). This study looked at whether having more TBIs makes symptoms like headaches, memory problems, and trouble sleeping (called post-concussive symptoms) more likely. This paper was published in the June 26, 2023 issue of *Journal of Neurotrauma.*

Single and Repeated High-Level Blast, Low-Level Blast, and New-Onset Self-Reported Health Conditions in the U.S. Millennium Cohort Study: An Exploratory Investigation

Service members exposed to blasts may experience various health issues. This study investigated whether service members who experienced powerful blasts (from incoming fire) or smaller ones (from their own artillery) were more likely to report health problems such as anxiety, depression, hearing loss, ringing in the ears, tiredness, and severe headaches. This paper was published in the March 21, 2023 issue of *Frontiers in Neurology.*

Identifying At-Risk Marines: A Person-Centered Approach to Adverse Childhood Experiences, Mental Health, and Social Support

While past studies have linked tough childhood experiences (like abuse or neglect) with health problems later in life, they often examined each type of experience separately. This study took a different approach by looking at how unique combinations of these experiences might affect people differently, giving us a clearer understanding of these connections. This project was published in the March 15, 2023 issue of *Journal of Affective Disorders.*

Contribution of Post-Trauma Insomnia to Depression and Posttraumatic Stress Disorder in Women Service Members

This project examined whether women service members and veterans who experienced recent combat and/or sexual trauma were more likely to struggle with sleep problems (insomnia) compared with women who did not report these recent experiences, and whether insomnia was linked with anxiety, depression, or other mental health issues. This paper was published in the March 9, 2023 issue of *Sleep.*

RECENTLY PUBLISHED PROJECTS CONTINUED

Risk and Protective Factors for Cancer Mortality Among United States Service Members and Veterans (2001–2018)

This study examined factors, including health behaviors and military experiences, that could affect the risk of dying from cancer and focused on those who served in the wars in Iraq and Afghanistan. This paper was published in the May 1, 2023 issue of *Cancer Epidemiology, Biomarkers & Prevention.*

The Bi-Directional Relationship Between Post-Traumatic Stress Disorder and Obstructive Sleep Apnea and/or Insomnia in a Large U.S. Military Cohort

This study explored whether sleep problems like sleep apnea and insomnia could both cause and be caused by PTSD in service members and veterans, and whether experiences such as combat deployment could affect these relationships. This project was published in the December 2022 issue of *Sleep Health.*

REFERENCES

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6. Military Health System Communications Office. Spit smokeless tobacco out – for good. 2020. https://www.health.mil/News/Articles/2020/02/20/Spit-smokeless-tobacco-out-for-good.

7. Hermes ED, Wells TS, Smith B, Boyko EJ, Gackstetter GG, Miller SC, Smith TC; Millennium Cohort Study Team. Smokeless tobacco use related to military deployment, cigarettes and mental health symptoms in a large, prospective cohort study among US service members. Addiction. 2012 May;107(5):983-94. PMID: 22126651.

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Millennium Cohort Study
Deployment Health Research Department
PO Box 85777
San Diego, CA 92186-5777

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123 STREET NAME
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BARCODE

SUBJECT ID

April 2024 - Pre-notice Newsletter/Research Brief – Follow-up

THE MILLENNIUM COHORT STUDY LAUCHES SOON!

Please keep us updated

- Have you recently moved or changed your email address?
- Has your name changed?

Please visit our website **www.millenniumcohort.org** to update your contact information.

Your **Subject ID** can be found below the barcode on the address side of this newsletter.

It's almost time to update your health information. The 2024 survey will be available on our website soon!

Dear Participant,

I want to express my heartfelt thanks for your commitment to the Millennium Cohort Study. As the head researcher, I'm humbled every day by the sacrifices that you and your fellow service members make for our country.

We started this journey in 2001 with a small group of over 77,000 participants, many of whom courageously went on missions after 9/11. Today, we take pride in the impressive growth of our study, with over a quarter of a million participants from all military branches, including Reservists and National Guardsmen. Your invaluable contributions have been key to this remarkable achievement.

Thank you for your unwavering service and ongoing dedication to this study. Your participation plays a crucial role in shaping the future of healthcare for our nation's heroes.

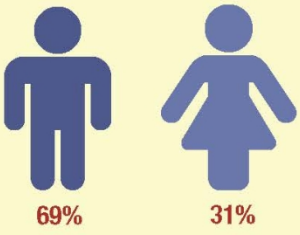
Very respectfully,

Rudy Rull, PhD, MPH
Principal Investigator, Millennium Cohort Study

PARTICIPANT PROFILE

The Millennium Cohort Study continues to be the U.S. Department of Defense's largest and longest-running study and celebrated its 20th Anniversary in 2021. Between 2001 and 2021, the Millennium Cohort Study has enrolled over a quarter of a million service members making it one of the largest cohort studies in the world! You represent your service branch, gender, and age group, so your participation is incredibly valuable to the continued success of this study.

Below is a breakdown of the data that describes key characteristics of the **201,619** participants that joined in the Cohort between 2001 and 2011. Where do you fit in?



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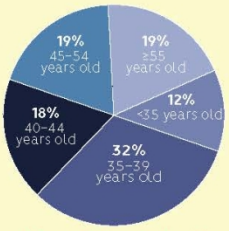


Age of the Cohort

Separation Status

75% of participants have separated from the military and are no longer on active duty

Weight

16% of males and 32% of females have a body mass index (BMI) of 18.5–24.9 kg/m², which is in the healthy weight range

Education

49% of participants have at least an associate degree

Alcohol

12% of participants drink above recommended limits*

*7 drinks/week for women and 14 drinks/week for men

Smoking

93% of participants have either never smoked or have quit smoking

Marital Status

73% of participants are currently married

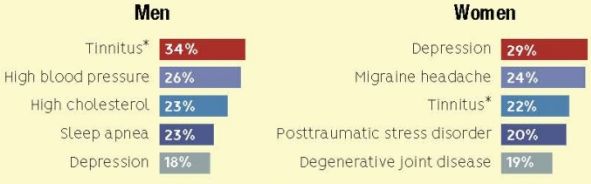
Sleep

Participants get an average of 6.4 hours of sleep per night

Exercise

87% of participants exercise at least 2 times per week

5 most commonly reported health issues



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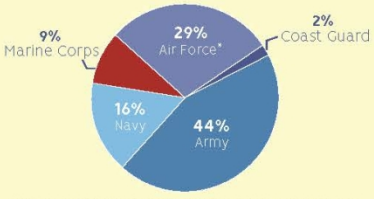
Cohort by service branch at time of enrollment



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Why is Sleep Research Important?

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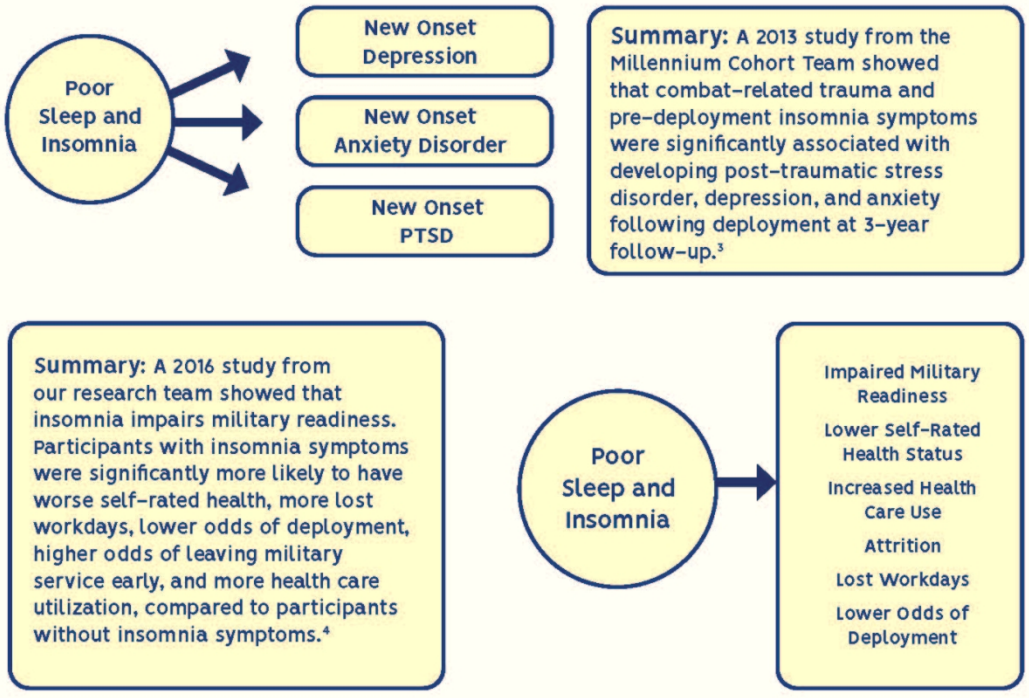

FEATURED RESEARCH

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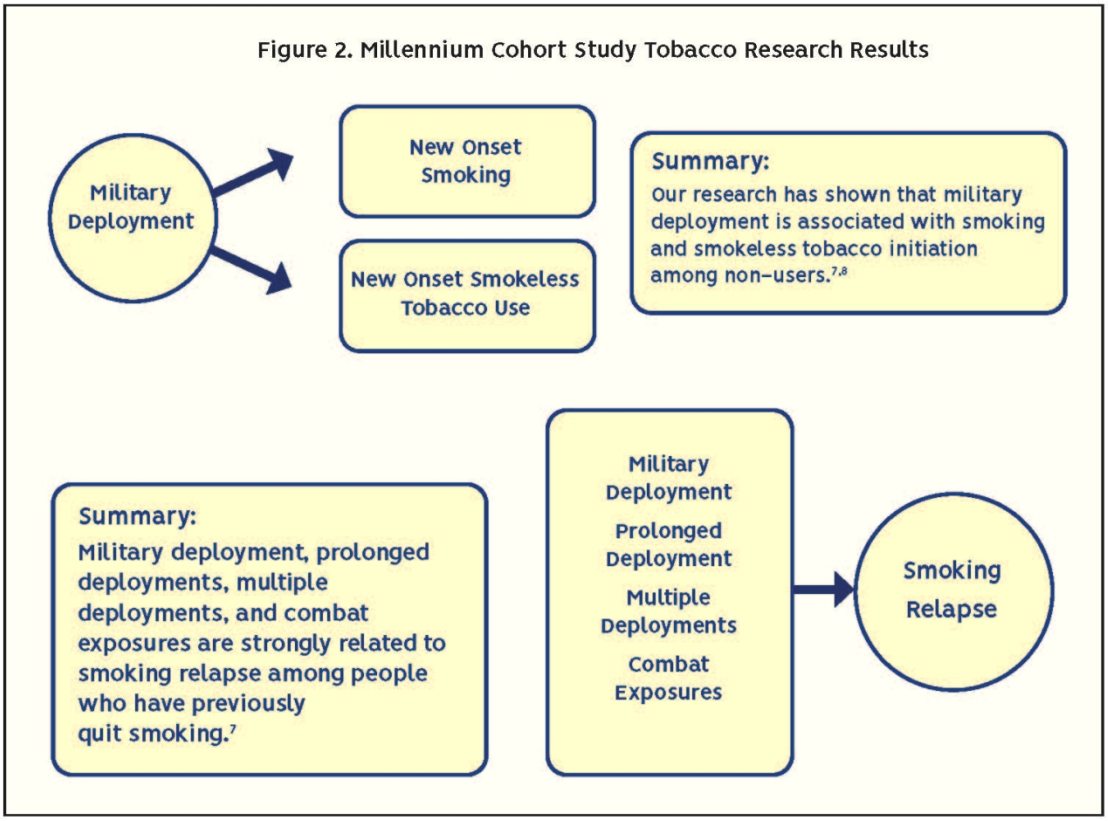

RECENTLY PUBLISHED PROJECTS

Racial, Ethnic, and Sex Disparities in Mental Health Among U.S. Service Members and Veterans

Mental health experiences vary among people of different backgrounds. This study explored whether similar differences exist within the U.S. military, focusing on how factors like race, ethnicity, and gender might influence the mental health of service members and veterans. This paper is available online ahead of print at the *American Journal of Epidemiology.*

Individual and Military Factors That Modify the Association Between Recent Sexual Trauma and Health Outcomes Among U.S. Service Members and Veterans

Experiences like sexual harassment and assault can take a toll on both your mind and body, affecting people in military and civilian life alike. This study looked at whether personal experiences and military service influence how sexual trauma impacts health, including anxiety, depression, physical pain, and sleep problems. This paper was published in the September 2023 issue of *Journal of Interpersonal Violence.*

Lifetime Traumatic Brain Injury and Risk of Post-Concussive Symptoms

Many service members have experienced traumatic brain injuries (TBIs). This study looked at whether having more TBIs makes symptoms like headaches, memory problems, and trouble sleeping (called post-concussive symptoms) more likely. This paper was published in the June 26, 2023 issue of *Journal of Neurotrauma.*

Single and Repeated High-Level Blast, Low-Level Blast, and New-Onset Self-Reported Health Conditions in the U.S. Millennium Cohort Study: An Exploratory Investigation

Service members exposed to blasts may experience various health issues. This study investigated whether service members who experienced powerful blasts (from incoming fire) or smaller ones (from their own artillery) were more likely to report health problems such as anxiety, depression, hearing loss, ringing in the ears, tiredness, and severe headaches. This paper was published in the March 21, 2023 issue of *Frontiers in Neurology.*

Identifying At-Risk Marines: A Person-Centered Approach to Adverse Childhood Experiences, Mental Health, and Social Support

While past studies have linked tough childhood experiences (like abuse or neglect) with health problems later in life, they often examined each type of experience separately. This study took a different approach by looking at how unique combinations of these experiences might affect people differently, giving us a clearer understanding of these connections. This project was published in the March 15, 2023 issue of *Journal of Affective Disorders.*

Contribution of Post-Trauma Insomnia to Depression and Posttraumatic Stress Disorder in Women Service Members

This project examined whether women service members and veterans who experienced recent combat and/or sexual trauma were more likely to struggle with sleep problems (insomnia) compared with women who did not report these recent experiences, and whether insomnia was linked with anxiety, depression, or other mental health issues. This paper was published in the March 9, 2023 issue of *Sleep.*

RECENTLY PUBLISHED PROJECTS CONTINUED

Risk and Protective Factors for Cancer Mortality Among United States Service Members and Veterans (2001–2018)

This study examined factors, including health behaviors and military experiences, that could affect the risk of dying from cancer and focused on those who served in the wars in Iraq and Afghanistan. This paper was published in the May 1, 2023 issue of *Cancer Epidemiology, Biomarkers & Prevention.*

The Bi-Directional Relationship Between Post-Traumatic Stress Disorder and Obstructive Sleep Apnea and/or Insomnia in a Large U.S. Military Cohort

This study explored whether sleep problems like sleep apnea and insomnia could both cause and be caused by PTSD in service members and veterans, and whether experiences such as combat deployment could affect these relationships. This project was published in the December 2022 issue of *Sleep Health.*

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Millennium Cohort Study
Deployment Health Research Department
PO Box 85777
San Diego, CA 92186-5777

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PERMIT # 3909

ADDRESS SERVICE REQUESTED

JOHN SMITH
123 STREET NAME
CITY, STATE ZIP

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BARCODE

SUBJECT ID

April 2024 - Pre-notice Newsletter/Research Brief Email
Subject Line: The Millennium Cohort Study and your Invaluable Contribution

Dear <name>,

As the Principal Investigator of the Millennium Cohort Study, I extend my deepest gratitude for your commitment to this landmark study as well as for the sacrifices you have made for our nation.

Since the launch of the study in 2001, our study has proudly grown from 77,000 participants to over a quarter of a million, spanning all service branches and including Reservists and National Guardsmen. This remarkable achievement would not have been possible without your invaluable contributions.

You should have recently received a newsletter from the Millennium Cohort Study team, highlighting the upcoming survey launch, the impact of our research on policy decisions, and other key updates. If you haven't received the newsletter, it is accessible online at
<link>

In the event you haven't received the newsletter, please take a moment to update your mailing address with the study team. To do so, simply visit our website at <link> and click on "Update Contact Info."

Thank you for your unwavering service and your commitment to this study. Your participation contributes significantly to shaping the future of healthcare for our nation's heroes.

Very respectfully,
Rudy Rull, PhD, MPH
Principal Investigator, Millennium Cohort Study

****

If you are a Veteran or service member in crisis or concerned about one, please connect with qualified responders for confidential help at the Veteran Crisis Line by DIALING 988 then PRESS 1 or texting 838255. You can get more resources at VeteransCrisisLine.net.

For any questions, please contact the Millennium Cohort Study Team at usn.nhrc-MilcohortInfo@health.mil or call toll free 1-888-942-5222 or DSN 553-7465 and reference your Subject ID: <xxxxxxx>.

The Millennium Cohort Study is an authorized Department of Defense research project. Note Report Control Symbol #DD-NAVY-2678, Office of Management and Budget Approval # 0703-0064, and Primary Institutional Review Board Protocol #NHRC.2000.0007.

If you would like this email address to be removed from our email list, please visit <unsubscribe code>

May 2024 - Memorial Day Postcard

May 2024 - Memorial Day Postcard Back

Department of Defense
Deployment Health Research Department
c/o Naval Health Research Center
PO Box 85777
San Diego, CA 92186-5777

MILLENNIUM COHORT STUDY

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PERMIT #3909

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ADDRESS SERVICE REQUESTED

Subject ID: <XXXXXX> Mail ID: <XXXXXX-XXXXXX>

Dear <name>,

On this Memorial Day, we unite to honor the courageous men and women who sacrificed their lives for our nation's freedom. We reflect on the true cost of our liberties and acknowledge the profound debt we owe to those who paid it.

On this day, our thoughts also extend to you, our veterans and active-duty service members, and we express appreciation for your ongoing sacrifices. Your dedication and bravery are truly admirable, and the impacts of your service continue to resonate within us.

Very respectfully,
The Millennium Cohort Study Team

<Pkg/Bag>
#BWNMHNL
<Keyline>
<Name>
<St2>
<St1>
<City>, <ST> <ZIP>

Primary Institutional Review Board Protocol # NHRC.2000.0007.

May 2024 - Memorial Day Email
Subject Line: Honoring our Heroes on Memorial Day

Dear <name>,

On this Memorial Day, we unite to honor the courageous men and women who sacrificed their lives for our nation's freedom. We reflect on the true cost of our liberties and acknowledge the profound debt we owe to those who paid it.

You should soon receive a Memorial Day postcard in the mail from the Millennium Cohort Study team. You can also view it online by visiting our website at
<link>

Wishing you a meaningful Memorial Day as we honor our fallen heroes.

Very respectfully,
The Millennium Cohort Study Team

****

If you are a Veteran or service member in crisis or concerned about one, please connect with qualified responders for confidential help at the Veteran Crisis Line by DIALING 988 then PRESS 1 or texting 838255. You can get more resources at VeteransCrisisLine.net.

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June 2024 launch letters. Each participant would get one of the following 3 versions:

1) Launch Letter with $5 Gift Card
   All 2019 paper responders, single parents, predicted non-responders that responded last cycle

2) Launch Letter with $5 Gift Card
   2019 non-responders that responded via paper to a previous cycle, predicted non-responders that did not respond last cycle, random sample of previous non-responders

3) Launch Letter without Gift Card
   All others not included in previous groups

MILLENNIUM COHORT STUDY
Committed to Understanding Service Member and Veteran Health

<John Sample>
<1234 Street Address
<Extra Street Address>
<City Name, ST 12345-3789>

Dear <name>,

We recently contacted you announcing our plans to launch our next follow-up survey as part of the ongoing Millennium Cohort Study. This is the largest and longest-running health study in history assessing wellbeing, chronic illness, and other physical and psychological concerns affecting current and former U.S. service members.

The site is now open, and we welcome your participation. Your input is crucial to the success of this study. We understand that your time is valuable, and we want to express our sincere gratitude for your willingness to contribute to this important research.

Completing the survey is easy and convenient!

We've made it as simple as possible for you to complete the survey online. Simply visit our secure website at ***www.millenniumcohort.org*** or scan the QR code below.

Your Subject ID is: *<XXXXXX>*

As a token of our appreciation, we're enclosing a $5 gift card with this letter. Upon **completing the survey online**, you can choose between an additional $5 gift card or a Millennium Cohort Study hat or challenge coin.

Your responses are essential!

Even if you are no longer on active duty, or are not experiencing any health concerns, your responses are still very important. We strive to gather data from a wide range of participants to gain a deeper understanding of the health and wellbeing of our service members, past, present, and future.

We hope to hear from you soon.

Very respectfully,
The Millennium Cohort Study Team

Scan this code with your mobile device to be taken directly to the survey login page

For any questions, please contact the Millennium Cohort Study Team at ***usn.nhrc-MilcohortInfo@health.mil*** or call toll free 1-888-942-5222 or DSN 553-7465, and reference your Subject Id: ***<SID>***

The Millennium Cohort Study is an authorized Department of Defense research project. Note Report Control Symbol # DD-HA(AR)2106, Office of Management and Budget Approval # 0720-0029, and Primary Institutional Review Board Protocol # NHRC.2000.0007.

DEPLOYMENT HEALTH RESEARCH DEPARTMENT
P.O. BOX 85777 • SAN DIEGO, CA 92186-5777 • DSN: 553-7465 • PHONE: 888-942-5222 •

MILLENNIUM COHORT STUDY

Committed to Understanding Service Member and Veteran Health

<John Sample>
<1234 Street Address
<Extra Street Address>
<City Name, ST 12345-3789>

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Your Subject ID is: *<XXXXXX>*

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Your responses are essential!

Whether you're on active duty, retired, or haven't experienced health issues, your voice matters. By participating, you'll not only help us quickly analyze survey results, but you'll directly contribute to improving the health and wellbeing of all service members, leaving a lasting legacy for generations to come.

We hope to hear from you soon.

Very respectfully,
The Millennium Cohort Study Team

Scan this code with your mobile device to be taken directly to the

For any questions, please contact the Millennium Cohort Study Team at ***usn.nhrc-MilcohortInfo@health.mil*** or call toll free 1-888-942-5222 or DSN 553-7465, and reference your Subject Id: ***<SID>***

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DEPLOYMENT HEALTH RESEARCH DEPARTMENT
P.O. BOX 85777 • SAN DIEGO, CA 92186-5777 • DSN: 553-7465 • PHONE: 888-942-5222 •

MILLENNIUM COHORT STUDY
Committed to Understanding Service Member and Veteran Health

<John Sample>
<1234 Street Address
<Extra Street Address>
<City Name, ST 12345-3789>

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Your Subject ID is: *<XXXXXX>*

After you submit your questionnaire online, you will have the opportunity to select a $5 gift card or a Millennium Cohort hat or coin as a small way of expressing our appreciation for your previous and continued efforts to make a difference in the lives of current and future military members.

Your responses are essential!

Even if you are no longer on active duty, or are not experiencing any health concerns, your responses are still very important. We strive to gather data from a wide range of participants to gain a deeper understanding of the health and wellbeing of our service members, past, present, and future.

We hope to hear from you soon.

Very respectfully,
The Millennium Cohort Study Team

Scan this code with your mobile device to be taken directly to the survey login page

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DEPLOYMENT HEALTH RESEARCH DEPARTMENT
P.O. BOX 85777 • SAN DIEGO, CA 92186-5777 • DSN: 553-7465 • PHONE: 888-942-5222 •

June 2024 - Launch Email - All 2019 responders
Subject Line: Complete Your Survey Online and Choose Your Thank-You Gift

Dear <name>,

We recently invited you to participate in a follow-up survey as part of the ongoing Millennium Cohort Study.

The site is now open, and we welcome your participation. We have made it as easy as possible to complete your survey online.

Simply visit our website by using the following link.
<link>
Your Subject ID is: <XXXXXX>

If you did not receive your invitation letter, please be sure to reach out to the study team to update your mailing address.

After completing your survey online, you will have the opportunity to select a $5 gift card or a Millennium Cohort Study hat or coin as a small token our appreciation for your ongoing participation in this project. Completing your survey online is fast, convenient, secure, and environmentally friendly!

Even if you are no longer on active duty, or are not experiencing any health concerns, your responses are still very important. We strive to gather data from a wide range of participants to gain a deeper understanding of the health and wellbeing of our service members, past, present, and future.
We hope to hear from you soon.

Very respectfully,
The Millennium Cohort Study Team

****

If you are a Veteran or service member in crisis or concerned about one, please connect with qualified responders for confidential help at the Veteran Crisis Line by DIALING 988 then PRESS 1 or texting 838255. You can get more resources at VeteransCrisisLine.net.

For any questions, please contact the Millennium Cohort Study Team at usn.nhrc-MilcohortInfo@health.mil or call toll free 1-888-942-5222 or DSN 553-7465 and reference your Subject ID: <xxxxxxx>.

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If you would like this email address to be removed from our email list, please visit <unsubscribe code>

June 2024 - Launch Email - All 2019 non-responders
Subject Line: Complete Your Survey Online and Choose Your Thank-You Gift

Dear <name>,

We recently invited you to participate in a follow-up survey as part of the ongoing Millennium Cohort Study. If you did not receive your invitation letter, please be sure to reach out to the study team to update your mailing address.

The site is now open, and even though we have not heard from you for a while, we still welcome your participation. We have made it as easy as possible to complete your survey online.

Simply visit our website by using the following link.
<link>
Your Subject ID is: <XXXXXX>

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We hope to hear from you soon.

We hope to hear from you soon.

Very respectfully,
The Millennium Cohort Study Team

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If you would like this email address to be removed from our email list, please visit <unsubscribe code>

June 2024 - Reminder Email (Service Specific)
Subject Line: Your Input Needed: Complete the New Millennium Cohort Study Survey Today!

Dear <name>,

We know how busy you are, and that's why we would be grateful if you can find a few minutes to complete the new survey from the Millennium Cohort Study.

By completing your survey, you'll help us understand the unique health needs of <service specific branch members> like you, past and present. The crucial data you provide will guide us in building stronger support systems for all of our U.S. military members.

Would you please take a few minutes and respond now? To get started, simply visit our website at <link>
Your Subject ID is: <XXXXXX>

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

Very respectfully,
The Millennium Cohort Study Team

****

If you are a Veteran or service member in crisis or concerned about one, please connect with qualified responders for confidential help at the Veteran Crisis Line by DIALING 988 then PRESS 1 or texting 838255. You can get more resources at VeteransCrisisLine.net.

For any questions, please contact the Millennium Cohort Study Team at usn.nhrc-MilcohortInfo@health.mil or call toll free 1-888-942-5222 or DSN 553-7465 and reference your Subject ID: <xxxxxxx>.

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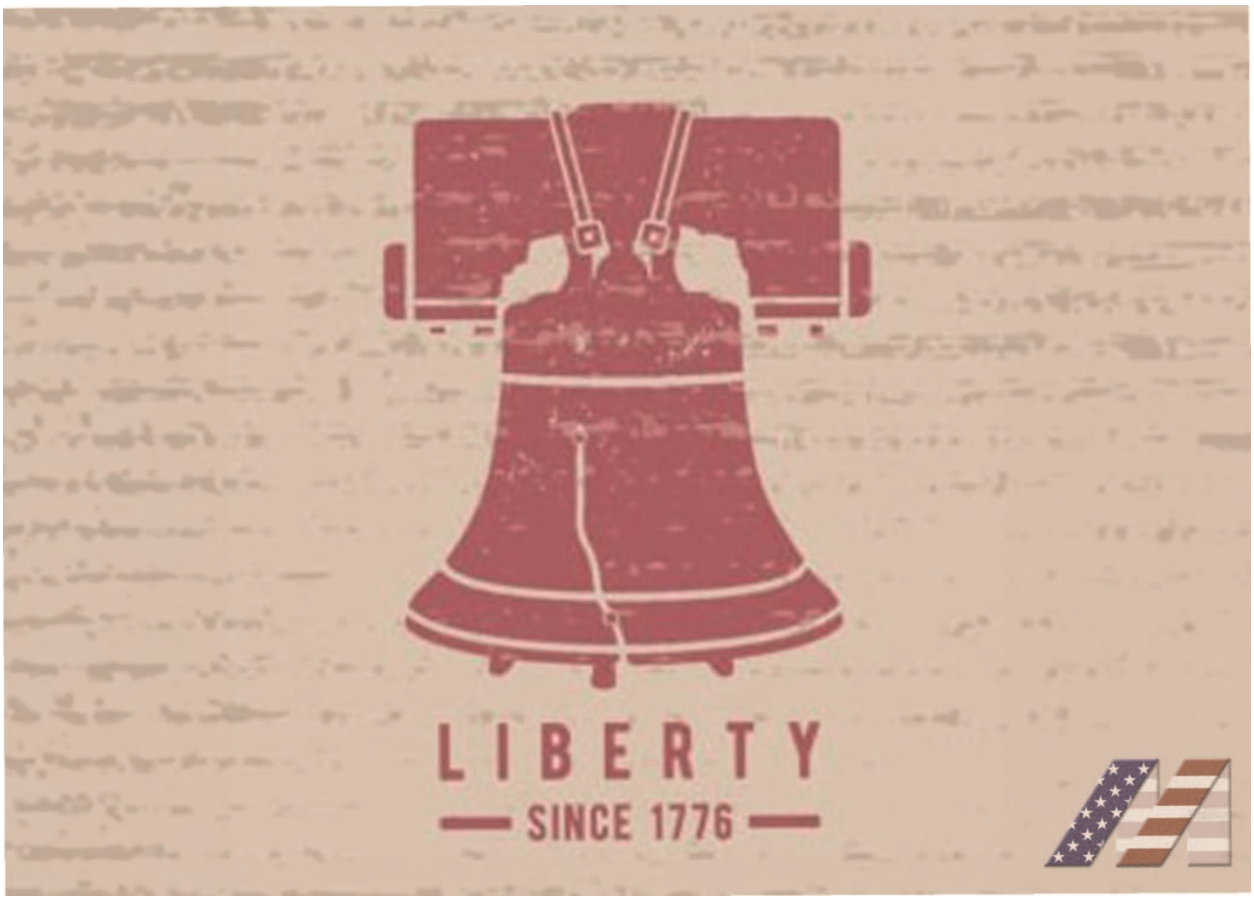
July 2024 - 4th of July Postcard



July 2024 - 4th of July Postcard Back

Department of Defense
Deployment Health Research Department
c/o Naval Health Research Center
PO Box 85777
San Diego, CA 92186-5777

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ADDRESS SERVICE REQUESTED

Subject ID: <XXXXXX> Mail ID: <XXXXXX-XXXXXX>

Dear <name>,

As we celebrate our nation's independence with friends and family, let us also remember and honor the courageous men and women that protect our freedom.

The Millennium Cohort Study survey is available online. If you've completed the survey, thank you! If not, visit **www.millenniumcohort.org** and use the Subject ID above.

Your input will contribute improvement of health services for all service members, past, present, and future.

Thank you for your continued support of this important project!

Very respectfully,
The Millennium Cohort Study Team

Scan this code with your mobile device to go directly to survey the log in page.

<Pkg/Bag>
<SEQ>
#BWNMHNL
<Keyline>
<Name>
<St2>
<St1>
<City>, <ST> <ZIP>

Primary Institutional Review Board Protocol # NHRC.2000.0007.

60147

July
4th of July Email
Subject Line: Celebrate Independence Day with Impact: Participate in the Millennium Cohort Study

Dear <name>,

As we gather with friends and family to celebrate the independence of our great nation, let us also remember and honor the courageous men and women that protect our freedom.

The 2024-2025 survey effort for the Millennium Cohort Study is currently active. With the information you provide, we will be able to contribute to the improvement of health services for all service members, past, present, and future.

If you have already completed and submitted your survey, please accept our sincere thanks.

If you have not already done so, simply visit our website by using the following link.
<link>
Your Subject ID is: <XXXXXX>

You should also receive a 4th of July postcard in the mail from the Millennium Cohort Study team. You can also view it online by visiting our website at
<link>

Thank you for your continued support of this important project!

Very respectfully,
The Millennium Cohort Study Team

****

If you are a Veteran or service member in crisis or concerned about one, please connect with qualified responders for confidential help at the Veteran Crisis Line by DIALING 988 then PRESS 1 or texting 838255. You can get more resources at VeteransCrisisLine.net.

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If you would like this email address to be removed from our email list, please visit <unsubscribe code>

July - Newsletter Email - Responders
Subject Line: Stay Informed: Read Our Latest Newsletter and Survey Reminder

Dear <Name>,

We are pleased to share with you our most recent study updates in our latest semi-annual newsletter, which includes summaries of our new scientific publications.

To read the newsletter, simply visit our study website at https://millenniumcohort.org/newsletters. This link will take you to the page where you can download the newest edition of our newsletter.

We encourage you to take a few moments to explore the current and past newsletters and learn about study updates and results. Our aim is to help you understand how your participation is contributing to an increased understanding of service member and Veteran health.

Your participation in this study means a lot to us, and we appreciate the contributions you've made. This newsletter is our way of keeping you informed about study results and engaged in the progress we're making.

Thank you once again for your continued support and participation. We're excited for you to explore the latest edition of our Study Newsletter.

Very respectfully,
The Millennium Cohort Study Team

****

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If you would like this email address to be removed from our email list, please visit <unsubscribe code>

July - Newsletter Email - Non-Responders
Subject Line: Stay Informed: Read Our Latest Newsletter and Survey Reminder

Dear <Name>,

We are pleased to share with you our most recent study updates in our latest semi-annual newsletter, which includes summaries of our new scientific publications.

To read the newsletter, simply visit our study website at https://millenniumcohort.org/newsletters. This link will take you to the page where you can download the newest edition of our newsletter.

The 2024-2025 survey effort for the Millennium Cohort Study is currently active. We know that you are busy and that your time is valuable, and that's why we would be grateful if you can find a few minutes to complete your survey now. With the information you provide, we will be able to contribute to the improvement of health services for all service members, past, present, and future.

Your participation in this study means a lot to us, and we appreciate the contributions you've made. This newsletter is our way of keeping you informed about study results and engaged in the progress we're making.

Thank you once again for your continued support and participation. We're excited for you to explore the latest edition of our Study Newsletter.

Very respectfully,
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****

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If you would like this email address to be removed from our email list, please visit <unsubscribe code>

August - Reminder Email
Subject Line: Millennium Cohort Study Supports Preventive Healthcare Month

Dear <Name>,

August is Preventive Healthcare Month. Preventive care, like annual wellness exams, checkups and cancer screenings, can help find and treat diseases early before they cause serious health problems that can affect daily living and job performance.

The Millennium Cohort Study is dedicated to understanding how certain conditions develop and how they might be prevented. Help us continue this important work by completing your Millennium Cohort Study survey today.

To get started, simply visit our website at:
<link>
Your Subject ID is: <XXXXXX>

With your input, we hope to better understand how preventive healthcare impacts service members' long-term health. Your insight and knowledge, based on your unique military experiences, are the most important part to achieving this goal.

Thank you for working with us to help protect, promote, and strengthen the health of our service members and Veterans.

Very respectfully,
The Millennium Cohort Study Team

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If you are a Veteran or service member in crisis or concerned about one, please connect with qualified responders for confidential help at the Veteran Crisis Line by DIALING 988 then PRESS 1 or texting 838255. You can get more resources at VeteransCrisisLine.net.

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August letters on the next 2 pages. Each participant that has not yet completed their survey would get one of the following 2 versions:

1) Letter with Sample Survey
   Being sent to all other non-responders.

2) Q1 Cover Letter
   Being sent to historic paper responders that have not yet completed their survey. The survey has been submitted as a separate component of this modification.

<John Sample>
<1234 Street Address
<Extra Street Address>
<City Name, ST 12345-3789>

Dear <Name>,

Did you know there's a new online survey for our Millennium Cohort Study? We've been sending out information about it in recent months, and we want to make sure you don't miss out. Remember, even if you're retired or no longer in the military, your participation is crucial to this study!

Many participants have expressed curiosity about the types of questions included in the survey. So, we thought we'd give you a sneak peek with the included sample! The questionnaire covers a wide range of topics, including physical health, emotional well-being, and personal life experiences.

Complete your survey online and choose a gift

Simply visit our website at ***www.millenniumcohort.org*** or scan the **QR code** below**.** To log in you'll need your Subject ID number which is **<XXXXXX>**.

As a token of our appreciation, **online survey participants** can choose a $5 gift card to one of several popular vendors or a Millennium Cohort Study cap or coin. Completing your survey online is fast, convenient, and allows us to save time and resources, which enables us to offer these gifts.

Your participation makes a difference

The unique strength of this study lies in its ability to follow the long-term health of current and former service members. This allows us to understand how military experiences impact the health of our nation's heroes. Through these results, we aim to shape better healthcare policies, enhance prevention programs, and improve treatment options for generations of those who serve. This important work would not be possible without the ongoing contributions of participants like you. Every step you take with us strengthens this vital mission.

Thank you so much for your continued participation in this important project!

Very respectfully,
The Millennium Cohort Study Team

Scan this code with your mobile device to be taken directly to the survey login page

For any questions, please contact the Millennium Cohort Study Team at ***usn.nhrc-MilcohortInfo@health.mil*** or call toll free 1-888-942-5222 or DSN 553-7465, and reference your Subject Id: ***<SID>***

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DEPLOYMENT HEALTH RESEARCH DEPARTMENT
P.O. BOX 85777 • SAN DIEGO, CA 92186-5777 • DSN: 553-7465 • PHONE: 888-942-5222 •

Sample Survey

MILLENNIUM COHORT STUDY
SAMPLE QUESTIONS

Many participants have expressed curiosity about the types of questions included in the survey. So, we thought we'd give you a sneak peek with this sample! The questionnaire covers a wide range of topics, including physical health, emotional well-being, and personal life experiences.

To complete your survey visit ***www.millenniumcohort.org***, click "Start Survey", and enter your Subject ID (located on the enclosed letter).

SLEEP QUALITY

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

Please rate your sleep pattern for the **past 2 weeks**.

	None	Mild	Moderate	Severe	Very severe
Difficulty falling asleep	O	O	O	O	O
Difficulty staying asleep	O	O	O	O	O
Problem waking up too early	O	O	O	O	O
Snoring	O	O	O	O	O

PHYSICAL HEALTH

Over the **past 3 years**, approximately how many days were you unable to work or perform your usual activities because of illness or injury? Exclude lost time for pregnancy and childbirth.

O None O 1 day O 2-5 days O 6-10 days O 11-15 days O 16-20 days O 21-60 days O >60 days

In the **last 3 years**, has your doctor or other health professional told you that you have any of the following conditions?			If **YES**, in what year were you **first** diagnosed?
Hypertension (high blood pressure)	O No	O Yes →	☐☐☐☐
High cholesterol requiring medication	O No	O Yes →	☐☐☐☐
Coronary heart disease	O No	O Yes →	☐☐☐☐
Heart attack	O No	O Yes →	☐☐☐☐
Stroke	O No	O Yes →	☐☐☐☐
Emphysema/COPD (chronic obstructive pulmonary disease)	O No	O Yes →	☐☐☐☐
Chronic bronchitis	O No	O Yes →	☐☐☐☐
Asthma	O No	O Yes →	☐☐☐☐

WELL-BEING

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

O Excellent O Very good O Good O Fair O Poor

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

	No, not limited at all	Yes, limited a little	Yes, limited a lot
Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	O	O	O
Climbing **several** flights of stairs	O	O	O

SUPPORT AND COPING

Please indicate how you feel about each statement.	Very strongly disagree	Strongly disagree	Mildly disagree	Neutral	Mildly agree	Strongly agree	Very strongly agree
There is a special person who is around when I am in need.	O	O	O	O	O	O	O
I get the emotional help and support I need from my family.	O	O	O	O	O	O	O
I have a special person who is a real source of comfort to me.	O	O	O	O	O	O	O
I have friends with whom I can share my joys and sorrows.	O	O	O	O	O	O	O
My family is willing to help me make decisions.	O	O	O	O	O	O	O
I can talk about my problems with my friends.	O	O	O	O	O	O	O

In the **past 3 years**, about how often have you participated in or volunteered for any of the following community groups or organizations?

	Never	Once or twice	Once a month	Once a week	More than once a week
Veteran Service Organization (e.g., Veterans of Foreign Wars, American Legions, Disabled American Veterans, Wounded Warrior Project, Iraq and Afghanistan Veterans of America)	O	O	O	O	O
Other veteran-oriented groups (e.g., virtual or social media groups and/or in-person social or activity groups)	O	O	O	O	O
Community service or volunteer organizations/events (e.g., local shelter, Kiwanis club)	O	O	O	O	O
Other social groups (e.g., churches or other religious groups, sports teams, etc.)	O	O	O	O	O

ALCOHOL AND TOBACCO USE

In the **past year**, have you used any of the following tobacco/nicotine products?

Cigarettes	O No	O Yes
Cigars	O No	O Yes
Electronic cigarettes or vape products	O No	O Yes

Do you **CURRENTLY** use *electronic cigarettes* or *vape* products?

O No, not at all O Yes, some days O Yes, every day

In the **past year**, how **often** did you typically drink any type of alcoholic beverage?

O Never O Rarely O Monthly O Weekly O Daily

In the **past year**, on how many **days** did you have 5 or more drinks of any alcoholic beverage? If NONE, please enter 0. ☐☐☐ days

FAMILY AND RELATIONSHIPS

Including yourself, how many people currently reside in your household? Please do not include anyone that does not live and sleep in your household the majority of the time, such as visiting relatives.

☐☐ Adults (18 and older) ☐☐ Children (17 and younger. Please include any biological, adopted, or foster children.)

What is your **current** marital status? Choose the single best answer.

O Single, never married O Currently married O Separated O Divorced O Widowed

HEALTH CARE

What kind of health coverage or insurance do you currently have? Mark all that apply.

O No health coverage or insurance
O TRICARE or military health insurance
O VA health care (Department of Veterans Affairs/ Veterans Health Administration)
O Medicaid
O Medicare
O Other private insurance

OCCUPATIONAL / ENVIRONMENTAL EXPOSURES & INJURY

In the past 3 years, have you had an injury, such as from a fall, blow to the head, blast exposure, motor vehicle crash, sports, or any other cause that resulted in any of the following?

	No	Yes	Don't know
Being dazed right after the injury?			
Being confused or not thinking clearly right after the injury?	O	O	O
Not remembering the actual injury right after it happened?			
Not remembering things that happened right after the injury?	O	O	O
Losing consciousness or being knocked out?			

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

During the service ☐☐ injuries

After leaving the service ☐☐ injuries

VETERANS SECTION

How would you describe your return to civilian life after military service?

O Very easy O Somewhat easy O Somewhat difficult O Very difficult

---

How long did it take you to find paid employment after leaving the military?

O Less than 1 month
O 1 to 4 months
O 5 to 8 months
O 9 months to 1 year
O More than 1 year
O I have been pursuing my education or training since leaving the military
O I have not found paid employment
O I have not looked for paid employment

FINANCIAL WELL-BEING

These next questions are about the financial status of you and your household.

Are you able to pay for all necessary expenses each month, such as mortgage/rent, debt payments, and groceries?	O No	O Yes
Does your household have at least 3 months of your typical income set aside in case of an unexpected financial event?	O No	O Yes
Does your household have the insurance coverage you and/or your family would need if an unexpected financial event were to occur (for example, disability insurance, property insurance, and/or life insurance)?	O No	O Yes

<John Sample>
<1234 Street Address
<Extra Street Address>
<City Name, ST 12345-3789>

Dear <Name>,

Did you know there's a new online survey for our Millennium Cohort Study? We've been sending out information about it in recent months, and we want to make sure you don't miss out. Remember, even if you're retired or no longer in the military, your participation is crucial to this important project!

Complete your survey online and choose a gift

To complete your survey online, simply visit our website at ***www.millenniumcohort.org*** or scan the **QR code** below**.** To log in you'll need your Subject ID number which is **<XXXXXX>**.

Each survey cycle, almost 100,000 participants complete their survey **online** and this year we hope to increase that number. As a token of our appreciation, **online survey participants** can choose a $5 gift card to one of several popular vendors or a Millennium Cohort Study cap or coin. Completing your survey online is fast, convenient, and allows us to save time and resources, which enables us to offer these gifts.

Prefer to complete the paper survey?

If you prefer, you can also complete the enclosed survey and return it to us in the postage-paid envelope.

Your participation makes a difference

The unique strength of this study lies in its ability to follow the long-term health of current and former service members. This allows us to understand how military experiences impact the health of our nation's heroes. Through these results, we aim to shape better healthcare policies, enhance prevention programs, and improve treatment options for generations of those who serve. This important work would not be possible without the ongoing contributions of participants like you. Every step you take with us strengthens this vital mission.

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Very respectfully,
The Millennium Cohort Study Team

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DEPLOYMENT HEALTH RESEARCH DEPARTMENT
P.O. BOX 85777 • SAN DIEGO, CA 92186-5777 • DSN: 553-7465 • PHONE: 888-942-5222 •

September 2024 - Reminder Email
Subject Line: Your Participation Can Help Improve Mental Health Care for Service Members

Dear <Name>,

Mental health is vital to everyone's overall health but is often overlooked or stigmatized. Millennium Cohort Study research shows that mental health conditions like PTSD, depression, and anxiety can often coexist with other problems like insomnia, substance abuse, or unhealthy weight, all of which can lower quality of life.

By completing your current Millennium Cohort Study survey, you will help us better understand the impact of military service on the long-term mental health and quality of life of service members. To get started, simply visit our website at:
<link>
Your Subject ID is: <XXXXXX>

A 2016 study using Millennium Cohort Study data found that service members with combat deployments developed PTSD and other mental health disorders (anxiety, depression, etc.) more often than those with non-combat deployments or no deployments.

The research team is working to better understand and identify risk factors for these mental health conditions. Through this investigation, the team can strengthen prevention measures and inform policies to promote mental health care and education.

Our research team can only conduct this important work due to the continued involvement of our dedicated participants.

Thank you for your time and consideration.

Sincerely,
The Millennium Cohort Study Team

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If you are a Veteran or service member in crisis or concerned about one, please connect with qualified responders for confidential help at the Veteran Crisis Line by DIALING 988 then PRESS 1 or texting 838255. You can get more resources at VeteransCrisisLine.net.

For any questions, please contact the Millennium Cohort Study Team at usn.nhrc-MilcohortInfo@health.mil or call toll free 1-888-942-5222 or DSN 553-7465 and reference your Subject ID: <xxxxxxx>.

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September 2024 - Reminder Email
Subject Line: Your Continued Participation in the Millennium Cohort Study Matters

Dear <Name>,

As a member of the Millennium Cohort Study, we are reaching out to you today to ask for your continued participation in this important research project. Information from participants like you is crucial in determining the potential impact of military service on the health and well-being of our service members and veterans.

How to Participate
It is easy to participate in the Millennium Cohort Study. Simply visit our website by using the following link.
<link>
Your Subject ID is: <XXXXXX>

Why Your Participation Matters
Your continued participation in the Millennium Cohort Study is essential for several reasons:

Representation: You have been carefully selected to represent your fellow Soldiers, Sailors, Airmen, Guardians, and Marines. Your responses will help us to understand the experiences of a wide range of service members, including those from different branches of service, different ranks, and different backgrounds.

Limited Sample Size: There are a limited number of service members and Veterans taking this survey. This makes every individual response even more important. Your continued participation will help us to ensure that the study results are representative of the entire population of service members and veterans.

Long-Term Impact: The greatest benefits of this study will not be known for many years. However, your continued participation now will help us to follow changes in your health and well-being over time. This information will be invaluable in understanding the long-term effects of military service.

Your Contribution Makes a Difference**:** Your participation in the Millennium Cohort Study is a vital contribution to our understanding of the health and well-being of our nation's service members and veterans. Your responses will help us to identify potential health risks, develop effective interventions, and improve the lives of countless individuals.

Thank you for your continued support of this important project!

Very respectfully,
The Millennium Cohort Study Team

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October - Research Brief Email
Subject Line: New Research Findings and Survey Reminder

Dear <Name>,

Does military service have an impact on long-term health? When you joined the Millennium Cohort Study, you took a step towards helping answer this important question. Your continued participation is vital to reaching this goal!
We are pleased to share with you our most recent research summary which can be found on the study website at https://millenniumcohort.org/participant/briefs.

If you have not yet had an opportunity to complete your Millennium Cohort Study survey, you can do so by going online to our secure website:
<link>
Your Subject ID is: <XXXXXX>

When you complete the survey online, you will receive your choice of a $5 gift card to one of several popular vendors.

Your participation in our study means a lot to us, and we appreciate the contributions you've made. This research summary is our way of keeping you informed about study results and engaged in the progress of the study.

Thank you once again for your continued support and participation.

Very respectfully,
The Millennium Cohort Study Team

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October
Reminder Email

Dear <Name>,

Military service can present a range of physical and mental stressors, from daily duties to deployment and combat. The Millennium Cohort Study aims to document these stressors and their impact on the health of current and former service members. Even if you don't feel stressed by your military experience, your input is still invaluable.

We're currently gathering information about participants' experiences and health status. If you have not yet had an opportunity to complete your Millennium Cohort Study survey, you can do so by going online to our secure website:
<link>
Your Subject ID is: <XXXXXX>

By reviewing the common stressors that participants report having, we hope to make further strides in research toward developing the most effective ways to approach stress management among military personnel. This research is not possible without your participation. You can help us recognize the underlying causes of stress in the military by participating in our survey.

Thank you for working with us to help protect, promote, and strengthen the health of our service members and Veterans.

Very respectfully,
The Millennium Cohort Study Team

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November 2024- Veterans Day Postcard
Art is TBD and will be submitted at a later date.

Dear <Name>,

On Veterans Day, we honor the sacrifices and bravery of those who have served. From the frontlines to the home front, your selfless service is a testament to your courage and devotion to our nation.

While we owe a debt of gratitude that can never be repaid, the Millennium Cohort Study Team strives to show our appreciation through action. By gathering valuable information through our survey efforts, we are working towards improving the well-being of current and future veterans across the country.

The Millennium Cohort Study stands united in support of our veterans.

Very respectfully,
The Millennium Cohort Study Team

Primary Institutional Review Board Protocol # NHRC.2000.0007.

November 2024 - Veterans Day Email

Dear <Name>,

On Veterans Day, we honor the sacrifices and bravery of those who have served. From the frontlines to the home front, your selfless service is a testament to your courage and devotion to our nation.

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

The Millennium Cohort Study stands united in support of our veterans.

Very respectfully,
The Millennium Cohort Study Team

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November 2024 - Reminder Email
Subject line: Protect Our Military's Health: Complete Your Survey Today

Dear <Name>,

Tobacco use is the leading preventable cause of death that claims the lives of over 400,000 Americans per year. Compared with the general population, smoking rates are notably higher among service members. As military service comes with its own set of challenging stressors, smoking can be a common and unhealthy way of coping.

Our research suggests that service members who smoke tend to have lower fitness levels and are at greater risk for physical injury.

Whether you're a smoker or not, your involvement is crucial in helping us learn more about how tobacco affects the health of our military personnel.

Please take a few minutes to complete the current survey at
<link>
Your Subject ID is: <XXXXXX>

Understanding and addressing modifiable behaviors like tobacco use is essential for enhancing the health, wellbeing, and readiness of our military members.

Very respectfully,
The Millennium Cohort Study Team

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Partial Completer Email 1
Subject Line: Your Input Matters: Finish Your Millennium Cohort Survey

Dear <Name>,

We noticed you started the Millennium Cohort Study questionnaire, but you didn't hit the "Submit Survey" button. Your input is critical to the success of this project, as it helps us understand the long-term health impacts of military service.

Please take a few minutes to complete the survey at
<link>
Your Subject ID is: <XXXXXX>

As a thank you, you'll get to choose between a Millennium Cohort coin, hat, or a $5 gift card after you submit your responses.

Your participation makes a huge difference, so we greatly appreciate it!

Very respectfully,
The Millennium Cohort Study Team

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Partial Completer Email 2
Subject Line: Your Input Matters: Finish Your Millennium Cohort Survey

Dear <Name>,

It looks like you started the Millennium Cohort Study but haven't quite completed it. Can you take the time to do so now?

We understand that your time is very valuable, but your participation in this landmark study is very important.

Please take a few minutes to complete the survey at
<link>
Your Subject ID is: <XXXXXX>

Your continued involvement in this important project makes it possible to inform and guide prevention measures that positively impact former, current, and future U.S. service members.

Thank you in advance for now completing this important survey.

Very respectfully,
The Millennium Cohort Study Team

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