

Millennium Cohort Study

VOLUNTARY CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Why is this study being done?

You are being asked to be a volunteer in a longitudinal research study called "The Millennium Cohort Study" sponsored by the US Department of Defense (DoD). Your participation is completely voluntary. This study will follow the long-term health of military personnel during and after their military service. The purpose is to assess the impacts of military deployment, military occupations and general military service on health. You have been scientifically selected to represent your service branch, gender, service type, military occupation and age group from among the over two million military personnel serving in the regular Active Duty, Reserve, and National Guard forces. Your participation will help determine the long-term health effects of military service, inform healthcare policy for future generations of service members, and guide prevention and treatment programs for years to come.

What will happen if you decide to take part in this study?

You are asked to complete the attached survey today. You are also asked to complete follow-up surveys until 2068, with one survey to complete approximately every three years. Filling out the survey will take about 45 minutes each time you complete it. The surveys contain questions on a broad range of health topics, including medical conditions, health behaviors and exposures that may affect your health. 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.

What are the risks if you take part in this study?

The data collection procedures are not expected to involve any risk or discomfort to you. The main risks to you are those associated with the inappropriate disclosure of data that we collect from or about you. While inappropriate disclosure has the potential to impact your reputation, insurability, or employability, it is important for you to understand that this research group has collected similar information from numerous studies over many years without any cases of inappropriate disclosure. There is also the risk of possible discomfort from answering some sensitive questions, but you may skip any question(s) that make you uncomfortable. If you feel that you might need medical care or counseling you should make contact with the appropriate health care personnel.

Are there benefits to taking part in this study?

While your participation in this study will not directly benefit you, your participation will help inform health care policy for future generations of military personnel and guide prevention and treatment programs for years to come.

How will your data be protected against any risks?

To prepare the verification data needed to access the online survey server, the participant enters the last 4 of the SSN which is run through an algorithm to provide a message that has no key to unlock it; it is a one-way process. It is used for verification purposes only on the web survey login page and is not stored; it is discarded. When the message for a participant is sourced and matched, the survey is open to the participant and the survey data is stored in a database managed by the Naval Health Research Center, Deployment Health Research Department Information Technology staff.

The principal investigator is responsible for storing your health information and other information collected about you during the study. All paper questionnaires will be kept in locked files and all information collected through the internet survey is protected using Secure Sockets Layer (SSL) data transmission lines. SSL encrypts, or scrambles, all survey data sent over the Internet. Information will only be understandable when it reaches the investigator database. When your data are entered into computer files for analysis, your answers will be identified only by a special study identification number known to you and research team members. This number is located on the barcode of your study envelope and survey. Your social security number and any other personal identification information will be removed from your 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 your 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. Similar procedures have been used to protect data in previous studies conducted within this research center. According to the DoD Policy "Interim Regulations to Improve Privacy Protections for DoD Medical Records" dated October 31, 2000, the information you provide is for research purposes only and may not be disclosed except for specifically authorized purposes or with the consent of the individual about whom the information pertains. Identifiers may be removed and the de-identified information (or bio-specimens) may be used for future research without additional informed consent from the subject. Uses and disclosures of this information shall comply with provisions of the Privacy Act and implementing regulations.

We will do everything we can to keep others from learning about your participation in the research. To further help us protect your privacy, the investigators have obtained a Confidentiality Certificate from the Department of Health and Human Services. The investigators can use this certificate to refuse to disclose information (for example if there were a court subpoena) that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure would be necessary, however, upon request of DHHS for the purpose of audit or evaluation.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. For example, if an insurer or employer learns about your participation and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

What are your rights if you take part in this study?

Your participation must be completely voluntary. If you decide to participate, you can stop at any time you wish or skip any question you choose. If you choose not to participate or to discontinue your participation, you will not lose any benefit to which you are otherwise entitled. You may change your mind and revoke your permission to further collect or use your health information at any time. If you revoke your permission, no new health information about you will be gathered after that date. However, unless specified otherwise, information that has already been gathered may still be used for analyses. Collected data will be maintained until all research questions are answered. To end participation, contact the principal investigator at DoD.milcohortinfo@mail.mil, or (888) 942-5222.

Your participation may also be ended by the investigators. While this is not anticipated, available funding or other logistical considerations could conceivably result in the early termination of this study.

Will there be other study opportunities?

In the future you may be invited to enroll in other sub-studies of separate but related research efforts that may involve a variety of tests including neurocognitive testing and blood samples. These invitations may afford additional opportunities to support the well-being of military personnel and their families. They may also offer monetary or nominal incentives. You are free to voluntarily accept or reject these invitations. There will be no penalty for not participating and your decision will not affect your participation in this research project.

What if you have questions about the study?

Questions about the research (science) aspects of this study should be directed to the principal investigator of the Millennium Cohort Study at DoD.MillenniumCohortPI@mail.mil or (888) 942-5222. You may also refer to the web site at www.MillenniumCohort.org for more information. For questions about the ethical aspects of this study or subjects' rights, contact the Institutional Review Board Chairman at 619-553-8424 or USN.NHRC.IRB@mail.mil. The Naval Health Research Center Institutional Review Board is a group of people who review the research to protect your rights.

CONSENT TO TAKE PART IN THIS RESEARCH STUDY

By signing below, you agree that you have read the information in this consent form. You have been given an opportunity to ask questions about this study and its procedures and risks, as well as any of the other information contained in this consent form. All of your questions have been answered to your satisfaction. You understand that this is research. You freely give your consent to be in this research study as it has been explained to you. You authorize the use and disclosure of your health information to the persons listed in the health information and privacy section of this consent for the purposes described above. You consent to the use of information collected about you during this study to be used for future research efforts. You have been given a copy of this form for your personal records and a statement informing you about the provisions of the Privacy Act.

Signature of Research Participant

Printed Name of Research Participant

Date

Privacy Act Statement

You have rights under the Privacy Act.

The following statement describes how that ACT applies to this study:

The Privacy Act System of Records Notice (SORN) for this study is N6500-1. The SORN was published on the Defense Privacy and Civil Liberties Division (DPCLD) website on November 14, 2014 and can be found by visiting: <https://dpclد.defense.gov/Privacy/SORNsIndex/DOD-Component-Article-View/Article/570396/n06500-1/>

Authority: Authority to request this information is granted under: 10 USC 136, Under Secretary of Defense for Personnel and Readiness, 10 USC 1782, Surveys of Military Families, 10 USC 2358, Research and Development Projects, Under Secretary of Defense Memorandum #: 99-028, 30 SEP 99 "Establishment of DoD Centers for Deployment Health" and Executive Order 9396, Numbering System for Federal Accounts Relating to Individual Persons.

Purpose: To create a probability-based database of service members and veterans who have, or have not, deployed overseas so that various longitudinal health and research studies may be conducted over a 67-year period. The database will be used: (a.) To systematically collect population-based demographic and health data to evaluate the health of Armed Forces personnel throughout their careers and after leaving the service. (b.) To evaluate the impact of operational deployments on various measures of health over time including medically unexplained symptoms and chronic diseases to include cancer, heart disease and diabetes. (c.) To serve as a foundation upon which other routinely captured medical and deployment data may be added to answer future questions regarding the health risks of operational deployment, occupations, and general service in the Armed Forces. (d.) To examine characteristics of service in the Armed Forces associated with common clinician-diagnosed diseases and with scores on several standardized self-reported health inventories for physical and psychological functional status. (e.) To provide a data repository and available representative Armed Forces cohort that future investigators and policy makers might use to study important aspects of service in the Armed Forces including disease outcomes among an Armed Forces cohort.

In addition to revealing changes in service member and veteran health status over time, the Millennium Cohort Study will serve as a data repository, providing a solid foundation upon which additional epidemiological studies may be constructed.

Routine Uses: The information provided in this questionnaire will be maintained in data files at the Deployment Health Research Department at the Naval Health Research Center and used only for medical research purposes. Use of these data may be granted to other federal and non-federal medical research agencies as approved by the Naval Health Research Center's Institutional Review Board. In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 522a(b)(3).

To the Department of Veterans Affairs (DVA) for (1) considering individual claims for benefits for which that DVA is responsible; and (2) for use in scientific, medical and other analysis regarding health outcomes research associated with military service. To the Department of Health and Human Services, Centers for Disease Control and Prevention for use in scientific, medical and other analysis regarding health outcome research associated with military service.

NOTE: All disclosures to the DVA and HHS must have prior approval of the Naval Health Research Center Institutional Review Board and a Memorandum of Understanding must be entered into to ensure the right and obligations of the signatories are clear. Access to data 1) is provided on need-to-know basis only; 2) must adhere to the rule of minimization in that only information necessary to accomplish the purpose for which the disclosure is being made is releasable; and 3) must follow strict guidelines established in the data sharing agreement. To the Social Security Administration (SSA) for considering individual claims for benefits for which that SSA is responsible. The DoD 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of systems of records notices apply to this system.

NOTE: This system of records contains individually identifiable health information. The DoD Health Information Privacy Regulation (DoD 6025.18-R) issued pursuant to the Health Insurance Portability and Accountability Act of 1996, applies to most such health information. DoD 6025.18-R may place additional procedural requirements on the uses and disclosures of such information beyond those found in the Privacy Act of 1974 or mentioned in this system of records notice.

Voluntary Disclosure: Completion of the questionnaire is voluntary. Failure to respond to any of the questions will NOT result in any disadvantages or penalties except possible lack of representation of your views in the final results and outcomes.

Agency Disclosure Notice

The public reporting burden for this collection of information, OMB Control Number 0703-0064, is estimated to average 45 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or burden reduction suggestions to the Department of Defense, Washington Headquarters Services, at whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number.