



Consent Form



- **What is the study about?**

You are being asked to be a volunteer in a research study called "The Millennium Cohort Study." This study will follow the long-term health of military personnel during and after their military service. The purpose is to assess the health risks of military deployment, military occupations, and general military service. 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 as of October 2000 in the regular active duty, Reserve, and National Guard forces. **It is very important that you participate because no one else can provide the data your country and fellow service men and women need from you.**

- **What will participation involve?**

You are being asked to do the following:

1. Complete the attached questionnaire today. The questionnaire asks about your physical and mental health. The questions are similar to what a doctor or mental health professional might ask you on your first visit with specific questions related to possible traumatic life events or experiences of military service. You are also being asked to complete 6 similar surveys that will be sent to you once every 3 years, for a total of 21 years. Filling out the questionnaire will take about 30 minutes each time you complete it.
2. Grant permission for researchers to review electronic military records of your deployments, assignments, promotions, and health care use. These data are very important in determining if your military service, occupation, and operational exposures are likely to have caused any of your illnesses, injuries, or diseases.

You will be contacted semi-annually to verify your contact information. In addition, there is a 3% chance that you will be contacted by telephone to confirm your original answers on the questionnaire. Participants will be selected at random for this verification. You are one of approximately 140,000 volunteers who are being asked to participate in this very important study.

- **What risks are involved in the study?**

The data collection procedures are not expected to involve any risk or discomfort to you. The only risks to you are those associated with the inappropriate disclosure of the data you provide. However, this research group has collected similar information from hundreds of studies during the past several years without any cases of inappropriate disclosure.

- **How will your data be protected against those risks?**

All questionnaires will be kept in locked files. 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 Department of Defense (DoD) computers protected by all the measures required by DoD computer security regulations. All members of the research team with access to the 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 (e.g., all males or all privates), so that no individual study participant can be identified. Similar procedures have been used to protect data in previous studies conducted within the Naval Health Research Center.

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

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• **How is your data protected if you complete the questionnaire using the Internet web site option?**

All information collected through the Internet questionnaire option is done by using Secure Sockets Layer (SSL) data transmission lines. SSL encrypts, or scrambles, all the questionnaire data sent over the Internet. The data will only be understandable when it reaches the investigator database. The same methods of protection listed above will then be followed to further protect your information.

• **What are the benefits of participating in the study?**

While we cannot guarantee that your participation in this study will directly benefit you, it is possible that should we learn that your military service has put you at risk for disease, we may be able to notify you and this risk might be reduced. **More importantly, your participation will help define health care policy for future generations of military personnel and guide prevention and treatment programs for years to come.**

• **Will you be provided medical care based on your responses?**

No. This is a population-based study and the data collected will not be used to make decisions about treatment that any individual should receive. If you feel that you might need medical care or counseling you should make contact with the appropriate health care personnel.

• **Do you have to participate?**

No, you do not! 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 if you later drop out of the study, you will not lose any rights or benefits to which you are otherwise entitled.

• **Who can provide additional information if you need it?**

Questions about the research (science) aspects of this study should be directed to the principal investigator of the Millennium Cohort Study at telephone (619) 553-7027. You may also refer to the web site at www.MillenniumCohort.org for more information. Questions about the ethical aspects of this study, your rights as a volunteer, or any problem related to the protection of research volunteers should be directed to Christopher G. Blood, JD, MA, Chairperson, Institutional Review Board, Naval Health Research Center, at telephone (619) 553-8386 or by email at blood@nhrc.navy.mil

• **Where can you find your records if you wish to review them?**

The principal investigator will be responsible for storing the consent form and other research records related to this study. The records will be stored at the DoD Center for Deployment Health Research, Naval Health Research Center, P.O. Box 85122, San Diego, CA 92186-85122.

VOLUNTARY CONSENT

I consent to participate in the study described above. My consent is completely voluntary and is based solely on the information provided in this consent form.

Volunteer's signature

Date (mm/dd/yy)

Volunteer's printed name (first, middle initial, last)

Please keep this "Participant Copy" for your personal records. Please remember to sign and date the Consent Form attached to your questionnaire booklet.

