

MILLENNIUM COHORT FAMILY STUDY CONSENT FORM



Millennium Cohort
Family Study

What is the study about?

You are being asked to be a volunteer in a longitudinal study called "**The Millennium Cohort Family Study**" conducted by the US Department of Defense (DoD). The purpose of this research is to assess the interrelated health effects of military service on service members, spouses and their children. You were selected to be a part of this study because you have been identified as a spouse of a service member (Sponsor) who is a participant in the main Millennium Cohort Study. Your participation is completely voluntary; however, it is important that a large representative sample participate in order to evaluate the availability of resources and the level of support that is needed in the lives of military service members and their families.

What will participation involve?

You are being asked to do the following: Complete the survey. You are also being asked to complete 7 follow-up surveys over 21 years, with one survey to complete every 3 years. The survey will take about 45 minutes to complete each time. The surveys contain questions on a broad range of health, medical, and behavioral issues concerning yourself, your spouse, and your children (if you have any). Some of the questions are of a sensitive nature, but that is to allow us to more fully understand the dynamics of health care utilization and health care needs. We will connect your survey data to other medical and personnel data maintained by the Department of Defense and the Department of Veterans Affairs. Any survey information you provide about your child(ren) will NOT be linked to any other data, or medical records.

Nominal incentives will be offered for your participation. Upon completion of the survey, you will have a choice of a \$10 gift card. Gift cards will be mailed to you within 6 weeks of survey completion.

What risks are involved in the study?

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 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.

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 to discontinue your participation, you will not lose any benefit 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 investigators at FamilyCohortInfo@med.navy.mil or (800) 571-9248. You may also go to www.familycohort.org for more information. Questions about the ethical aspects of this study or your rights as a volunteer should be directed to Christopher G. Blood, JD, MA, Chairperson, Institutional Review Board, Naval Health Research Center, at NHRC-IRB@med.navy.mil or (619) 553-8386.

How will your data be protected against any risks?

All information collected through the Internet survey is done by 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. Your social security number and any other personal identification information will be removed from your survey and data file. Even if someone outside the research team broke into the data 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. Individuals from official government agencies may inspect research records to ensure the rights and safety of all research participants are protected. All data will be maintained until all research questions have been addressed.

The principal investigator will be responsible for storing the research records related to this study. The records will be stored at the Deployment Health Research Department, Naval Health Research Center, 140 Sylvester Road, San Diego, CA 92106-3521. You may change your mind and revoke your permission to further collect health information about you at any time. If you revoke your permission, no new health information about you will be gathered after that date. However, information that has already been gathered may still be used for analyses. Collected data will be maintained until all research questions are answered. To review your electronically submitted survey or end further participation in this data collection effort, contact the principal investigators at FamilyCohortInfo@med.navy.mil or (800) 571-9248.

What are the benefits of participating in the study?

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

Will you be provided medical care based on your responses?

No. This is a population-based study and 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.

Study Contacts/Termination

You will be contacted semi-annually to verify your contact information, and once every three years to complete the survey. You are one of approximately 10,000 volunteers being asked to participate in this important study.

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 the study.

Participation is completely voluntary but DoD investigators will greatly appreciate your involvement in this research effort to help us better understand the risk factors associated with various health outcomes and to better understand the medical needs of military families.

Printed Name	Signature	Today's Date