A. VOLUNTARY CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Epidemiologic Investigation of Health Effects Associated with Dietary Supplements

Thank you for considering participating in this study. This consent form is meant to inform participants of the reasons for the study and what is involved. Please review this consent form and sign at the bottom of this page.

You are being asked to volunteer to participate in a research study called “Epidemiologic Investigation of Health Effects Associated with Dietary Supplements” conducted by the Department of Defense (DoD) including researchers at the Naval Health Research Center (NHRC) in San Diego, California, the United States Army Research Institute of Environmental Medicine (USARIEM) in Natick, Massachusetts, and the United States Army Public Health Center (APHC) at Aberdeen Proving Ground, Maryland. Your participation is completely voluntary.

Why is this study being done?

The purpose of this study is to better understand the types of dietary supplements being used by active duty Service members who are serving in the Air Force, Army, Navy, and Marine Corps, and to determine adverse events that might be associated with the supplements. Dietary supplements are substances like vitamins, minerals, proteins, amino acids, herbs, and the like.

You were selected to be a part of this study by a random sample drawn from active duty rosters. Your participation is completely voluntary; however, it is important that enough Service members volunteer to participate, even if you do not take supplements, in order to provide the DoD with important information about the similarities and differences between Service members who do and do not take supplements, the types of supplements being used, the reasons for their use, and adverse events that might be associated with them. About 60,000 active duty Service members will take part in this study.

What will participation involve?

You are being asked to complete a baseline survey online and another follow-up survey online 6 months later. Each survey will take about 20-30 minutes to complete. The survey contains questions on your use of any supplements; behaviors such as exercise and eating habits; sleep patterns; mood; and military experiences including deployments. You must complete the survey on your off-duty time. Demographic information (age, gender, race/ethnicity, rate/rank) will also be obtained from DoD data sources and merged with your survey responses. Your data will be confidentially maintained and will not be accessible by your command or others not involved in this research study. For your consideration in completing of the survey, you have received $1.

Do you have to participate?

No, you do not have to participate. Your participation is 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, you will not lose any benefit to which you are otherwise entitled.

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

The main risks to you are those associated with the inappropriate disclosure of personal information that we collect from or about you. While inappropriate disclosure has the potential to impact reputation,
insurability, 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.

Will you be provided medical care based on your responses?

No. This is a survey study and data collected will not be used to make decisions about treatment that any individual should receive. If you feel you might need medical care or counseling, for any reason, you should contact the appropriate health care provider. By signing this consent form, you will not be giving up any legal rights.

Are there benefits to taking part in this study?

While your participation in this study will not directly benefit you, your participation is a critical step in understanding supplement use and to determine possible adverse events associated with using supplements. Even if you do not take supplements you are encouraged to participate so the investigators can understand similarities and differences between Service members who take supplements and those who do not. You have received $1 to complete this first questionnaire and will receive another $1 when the time comes to complete the second questionnaire (about 6 months after the first questionnaire).

What health information will be collected and will it be kept confidential?

Federal regulations give you certain rights related to your health information. These include the right to know who will have access to the information. If you choose to be in this study, only the study staff will obtain the following information about you, including information that will identify you. The survey contains questions on your use of any supplements; behaviors such as exercise and eating habits; sleep patterns; mood; and military experiences including deployments. Demographic information (age, gender, race/ethnicity, rate/rank) will also be obtained from DoD data sources and merged with your survey responses. 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, in password-protected files, secured 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 is protected. All data will be maintained until all research questions have been addressed.

Once you complete the first questionnaire, we will obtain, from the Armed Forces Health Surveillance Branch, medical information about you for the 6-month period from the time you completed the questionnaire. This information will include codes that describe illnesses or injuries you may have experienced, when you saw a health care provider, results of laboratory tests, and prescribed medications. We will then join your medical information with your questionnaire responses. This will allow us to look at dietary supplements in relation to Service member health. We may contact you at a later date if we need some additional information. Six months after filling out the first questionnaire, we will ask you to complete another questionnaire asking you the same questions we asked the first time. Medical information about you will be obtained again, from the Armed Forces Health Surveillance Branch, for the 6-months period prior to and after completing the second questionnaire.
You may change your mind and revoke (take back) your permission to collect or use your health information at any time. To revoke your permission, you must write to the person in charge of the study, Daniel Trone, Ph.D., at daniel.w.trone.civ@mail.mil. When you revoke your permission, no new questionnaire or health information about you will be gathered after that date and you may no longer be allowed to participate in the study. 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. You also have the right to review an electronic copy your survey and medical information for as long as of the survey and health information are maintained by contacting the person in charge of the study. For survey information contact Daniel Trone, Ph.D., at daniel.w.trone.civ@mail.mil. For medical information contact Joseph Knapik, Sc.D., at joseph.j.knapik.ctr@mail.mil.

Joseph Knapik, Sc.D., is responsible for storing your medical information and other health information collected about you during the study. The questionnaire and medical information is transferred between organizations encrypted or scrambled while in transit (via a DoD “SAFE” website. “SAFE” stands for Safe Access File Exchange). Information will only be understandable when it reaches the investigator’s databases. We will need to retain your personal information (name and social security number) until the study is completed but will delete it after that. 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 is protected. The data will be maintained until all research questions have been addressed and for at least 6 years afterward. Access to all data will be limited to staff involved in this study. The health information you disclose on the survey will not be used by or disclosed (released) to another institution.

The results of this study may be published in DoD technical reports, scientific journals, or presented at scientific meetings. No publication or presentation about the research study described above will reveal your identity without another authorization from you. Lastly, individuals from official government agencies, such as the Department of Defense, the U.S. Navy, and the U.S Army, may inspect your research records to ensure that the rights and safety of all research participants are protected. As a result, they may see your name, but they are bound by rules of confidentiality not to reveal your identity to others.

By electronically signing this consent form, you are giving permission to use the health information listed above for the purposes described in this form. If you refuse to give permission, you will not be able to be in this study.

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

Taking part in this study is your choice. Your participation must be completely voluntary. If you decide to take part, you may still leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any benefit to which you are otherwise entitled.

If you do choose to leave the study, contact Daniel Trone, Ph.D. (daniel.w.trone.civ@mail.mil) or Joseph Knapik, Sc.D. (joseph.j.knapik.ctr@mail.mil) as soon as you can so they can ensure an orderly withdrawal. Your participation may also be ended by the investigators without your consent; while this is not anticipated, available funding or other logistical considerations could conceivably result in the early termination of the study.

Major new findings that develop during the course of the research that may relate to your willingness to continue participation will be provided to you.
What if you have questions about the study?

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions. You should contact the following individuals to answer your questions:

For questions about the research, contact Daniel Trone, Ph.D., at daniel.w.trone.civ@mail.mil or (619) 767-4567; or Joseph Knapik, Sc.D., at joseph.j.knapik.ctr@mail.mil or (443)752-3350.

For questions about the ethical aspects of this study or subjects’ rights, contact William Becker, Ph.D., at 619-553-8424 or USN.NHRC.IRB@mail.mil. He is the Chairman of the Naval Health Research Center Institutional Review Board, a group of people who review the research to protect your rights and who have reviewed and approved this study.

CONSENT TO TAKE PART IN THIS RESEARCH STUDY

You have read the information in this consent form. You understand that this is research. By checking the box below, you freely give your consent to be in this research study as it has been described above. You authorize the use and disclosure of your medical information to the persons listed in the medical information and privacy section of this consent for the purposes described above. You may print or save a copy of this form for your personal records and a statement informing you about the provisions of the Privacy Act (check this box        if you would like to print or save a copy).

(WEB VERSION WILL HAVE CHECK BOX AND DATE/TIME STAMP)

______________________________ _______________________________ ________________
Signature of research volunteer Printed name of research volunteer Date
**PRIVACY ACT STATEMENT**

**AUTHORITY:** Authority to request this information is granted under Title 5, U.S. Code 136, Department of Defense Regulations, Executive Order 9396, DoD RCS#DD-HA(AR)xxxx (expires mm/dd/yy), and NHRC.2016.0025 (initial approval 01/30/2017. Personal identifiers will be used to link survey data with medical and other military records stored in DoD databases. 32 CFR Part 219, Protection of Human Subjects; 45 CFR Part 46, Protection of Human Subjects; DoDI 3216.02, “Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research,” October 20, 2011; 45 CFR Parts 160 and 164, Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules; and E.O. 9397 (SSN), as amended.

**PURPOSE:** Information is collected to enhance basic medical knowledge, or develop tests, procedures, and equipment to improve diagnosis, treatment, or prevention of illness, injury, or performance impairment under research protocol NHRC.2016.0025, entitled “Epidemiologic Investigation of Health Effects Associated with Dietary Supplements.” The project objective is to understand supplement use during military service and determine adverse events (AEs) that might be associated with supplement use.

**ROUTINE USES:** In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act of 1974, the DoD “Blanket Routine uses” under 5 U.S.C. 552a(b)(3) apply to this collection. Medical research information will be used for analysis and reports by the Department of the Navy and Defense, and other U.S. Government agencies, provided this use is compatible with the purpose for which the information was collected. Use of the information may be granted to non-Government agencies or individuals by the Navy Surgeon General following the provisions of the Freedom of Information Act or as may be indicated in the accompanying Informed Consent Form.

**DISCLOSURE:** Provision of information is voluntary. There are no penalties for not providing requested information, but failure to provide the requested information may result in failure to be accepted as a research volunteer in an experiment or removal from the program.

**PUBLIC BURDEN STATEMENT:**

Public reporting burden for this collection of information is estimated at 20-30 minutes per survey, 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 any other aspect of this collection of information, including suggestions for reducing the burden, to the Dietary Supplement Health Effects Study team, PO Box 85315, San Diego, CA 92186. 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.