ACAM2000® MYOPERICARDITIS REGISTRY

VOLUNTARY WRITTEN CONSENT TO PARTICIPATE IN A RESEARCH STUDY

What is the study about?

You are being asked to volunteer for a research study titled "ACAM2000® Myopericarditis Registry". Myopericarditis is an inflammation of the heart wall or the membrane that surrounds the heart. Your participation is completely voluntary. If there is anything in this Consent Document that you do not understand, be sure to ask the investigators to explain that portion of the study. If you have any questions, do not hesitate to ask them.

Why is this study being done?

The purpose of this study is to gather information on the natural history of myopericarditis following receipt of the ACAM2000® vaccine. This includes looking at risk factors and predictors of disease outcome. This study is being conducted by researchers at the Naval Health Research Center in San Diego, California, in combination with sanofi pasteur, the vaccine manufacturer and sponsor of this study. A total of 200 people will take part in this study.

Vaccination is the only defense against smallpox, which is caused by the variola virus. The World Health Organization announced in 1980 that naturally occurring smallpox had been eradicated worldwide following the last reported case in 1977. Although eradicated, the disease is feared as a potential agent of bioterrorism because of its lethality, its transmissibility, the lack of known treatment, and its suspected acquisition by nations that support terrorism. In the wake of the September 11, 2001 terrorist attacks, the United States (US) Government began to immunize health workers, first responders and military personnel against smallpox in preparation for a possible terrorist attack.

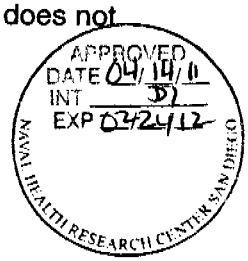
The ACAM2000® smallpox vaccine, which the Food and Drug Administration (FDA) recently licensed, is a live vaccinia virus vaccine. The vaccinia virus used in the newly licensed vaccine was derived from the previously licensed Dryvax® smallpox vaccine, and is produced using modern manufacturing practices. Although safety studies are conducted before a vaccine is licensed, the FDA requires long-term monitoring of individuals who receive newly licensed products. This Registry meets one of the FDA post-licensing requirements. If the monitoring requirements are not met, the FDA could cancel the license of ACAM2000®, and this smallpox vaccine would no longer be available to protect our men and women that are potentially at risk.

We are asking you to take part in this study because you are a current or former member of the active duty, Reserve, or National Guard, in any branch of service, who received the ACAM2000® smallpox vaccine, and then developed symptoms or other findings of myopericarditis, or were categorized by the ACAM2000® Adjudication Committee as having myopericarditis.

What will participation involve?

As required by the FDA, an Adjudication Committee has/will review a minimal amount of your medical data without identifiers to categorize you as a myopericarditis case. The information may include sex, age, cardiac related laboratory test results, and cardiac related physician reports. The file does not have information that could be used to identify you personally.

You are being asked to do the following:



Complete the enrollment survey online, on paper, or by phone. You are also being asked to complete a similar shorter survey follow-up survey in 6 months (or sooner if your myopericarditis diagnosis was more than 6 months ago), then once every 6 months thereafter, for a maximum of 5 years (a maximum of 11 surveys). Follow-up stops two years after your myopericarditis symptoms end. If your symptoms do not end, follow-up stops 5 years after you joined the study. Each survey will take between 20 and 40 minutes to complete. The survey asks about your symptom history, general health, familial cardiac risk factors, and vaccine history. We will connect your survey data with other data maintained by the DoD, or federal and state agencies, on your military service, deployments, and medical care. If you received care for any cardiac related issues that was not paid for by the DoD, we will ask you to sign a medical records release form so that we can gain access to these data.

Note that if you agree to participate in this study and you are a female who becomes pregnant soon after receiving the smallpox vaccine, we will refer you to the National Smallpox Vaccine in Pregnancy Registry (Pregnancy Registry), managed by researchers at the Naval Health Research Center. The referral will include your name, contact information, smallpox vaccination date, and estimated date of pregnancy onset. An individual from the Pregnancy Registry may contact you to further determine your eligibility. The purpose of the Pregnancy Registry is to determine what impact the vaccine may have on reproductive health outcomes.

Individuals from official government agencies, such as the DoD and the U.S. Navy, may inspect your research records to ensure that the rights and safety of all research participants are protected. To ensure compliance with FDA subject protection guidelines, study monitors from the FDA and/or sanofi pasteur may conduct an onsite review and audit of study materials, which may include consent documents and original medical records. NHRC study staff will accompany external monitors at all times. Personal Health Information will not be transferred, recorded, or otherwise removed from NHRC. To the extent permitted by the applicable laws and regulations, your confidentiality will not be violated. By providing your oral or written consent to the information in this Informed Consent Form, you are authorizing such access.

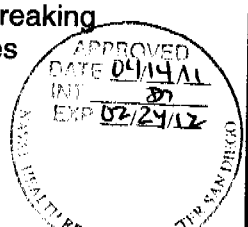
There are no anticipated costs to you if you choose to participate in this study. Participation will not affect the health care you receive. If you are experiencing any symptoms or have any concerns about your health, you should contact your health care provider.

What are the risks involved in the study?

If you choose to participate, you may feel uncomfortable answering some of the survey questions. You may skip any questions you feel uncomfortable answering. The data collection procedures are not expected to involve any risk to you. The only risks to you are those associated with the inappropriate disclosure of data you provide. However, this research group has collected similar information from numerous studies over many years without any cases of inappropriate disclosure. By signing this consent form, you will not be giving up any legal rights.

How will your data be protected against those risks?

Dr. Ava Marie S. Conlin is responsible for storing your health information and other information collected about you during the study. All surveys will be kept in locked files in locked buildings. 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 survey. Your social security number and any other personal identification information will be removed from your survey and data file upon return to the researchers. 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.

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.

Are there benefits to taking part in this study?

Although there are no expected direct benefits to you personally, your participation will help researchers learn more about the natural history of myopericarditis following receipt of the ACAM2000® vaccine, which could guide prevention and treatment programs for future recipients of the ACAM2000® vaccine.

Do you have to participate?

Participation in this Registry is voluntary; you do not have to participate. If you decide to participate, you can stop at any time you wish. If you choose not to participate or to discontinue your participation, you will not lose any benefit to which you are otherwise entitled, including routine medical care. 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, 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. Significant new findings developed during the course of the research study will be provided to you in a timely manner. To end participation, contact Registry staff at NHRC-VaccineRegistry@med.navy.mil, or (619) 553-9255.

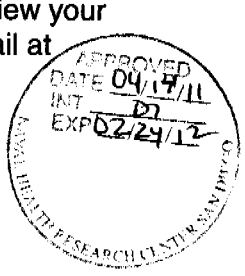
Your participation may also be ended by the investigators. While this is not anticipated, available funding or other logistical considerations could conceivably result in the study not running its full course.

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 ACAM2000® Myopericarditis Registry Study, Dr. Ava Marie S.Conlin at 619-767-4489 or ava.conlin@med.navy.mil. For questions about the ethical aspects of this study or subjects' rights, contact Christopher G. Blood, Chairperson, Institutional Review Board, Naval Health Research Center, at 619-553-8386 or NHRC-IRB@med.navy.mil. The NHRC Institutional Review Board, which is responsible for protecting the rights and welfare of study subjects, has reviewed and approved this study.

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

The principal investigator will be responsible for storing the consent forms 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, 140 Sylvester Road, San Diego, CA 92106-3521. You can review your surveys until the study ends by contacting the Principal Investigator at 619-767-4489 or by email at NHRC-VaccineRegistry@med.navy.mil.



CONSENT TO TAKE PART IN THIS RESEARCH STUDY

You have read the information in this consent form. You 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. By signing below, 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 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

Preferred Survey Completion method: (please circle one) Email Phone Mail

Email Address: _____ Phone: _____

Address: _____ City:_____ State: ___ Zip_____

PRIVACY ACT STATEMENT

This statement serves to inform you of the purpose for collecting personal information required by ACAM2000 Myopericarditis Registry and how it will be used.

Authority. 32 CFR Part 219, Protection of Human Subjects; 45 CFR Part 46, Protection of Human Subjects; DoDD 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research," March 25, 2002; 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.

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.

Attached: Consent form for this experiment, signed by the research participant.

NHRC USE ONLY

Consent received by NHRC Personnel

_____ _____ _____

Signature Name Date