

INSTRUCTIONS TO PATIENTS INTERESTED IN PARTICIPATING IN “BOVINE LEUKEMIA VIRUS” STUDY

- 1.) You can find out more about the study and what your participation would involve by calling the Plastic Surgery Department 415-444-2633 or by going onto our website www.kaisersanrafael.org/departement/plastic surgery and clicking on the “BLV Study” link**
- 2.) If you wish to participate, please notify the Plastic Surgery Department at the above number.**
- 3.) You should review the “Consent to Participate in a Research study” form for this study. You can obtain a copy by downloading it from our website or by arranging to pick it up or have it mailed from the Plastic Surgery Department.**
- 4.) Dr. DeLaney or another member of our staff will contact you to review the study and answer your questions.**
- 5.) When you have your regular pre-op visit for your surgery, come to the Plastic Surgery Department (after your physical exam in your surgeon’s office). In a short visit we will**
 - obtain your signed permission for the study,**
 - enroll you as a participant**
 - inform you of your rights as a study participant**
 - give you a “nurse instruction” slip to bring with you on the day of your surgery identifying you as a study participant**
 - give you a lab slip and chilled blood collection vial to take to the laboratory for an immediate blood draw**

That’s all you need to do! Thank you for your interest.

KAISER FOUNDATION HOSPITALS
THE PERMANENTE MEDICAL GROUP, INC
SAN RAFAEL

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: BOVINE LEUKEMIA VIRUS IN HUMAN LEUKOCYTES/ MAMMARY EPITHELIUM

STUDY PURPOSE

You are being invited to participate in a research study being conducted by researchers at Kaiser Permanente, San Rafael, and the School of Public Health at University of California at Berkeley. You are being invited to participate because you are scheduled to have an operation that will involve the removal of breast tissue. Participants will include women who are planning to have an operation to remove breast cancer tissue as well as women who are planning to have a breast operation, but are not known to have breast cancer.

The purpose of this study is to see if a relationship exists between breast cancer and a virus called BLV. BLV, Bovine Leukemia Virus, infects cattle and is present in milk and beef. BLV causes lymphoma (a cancer of lymphocytes) in a very small number of infected cattle. It is also present in the mammary cells of dairy cows. There is some evidence of BLV infection in humans who eat the meat and dairy products of infected cows. Some humans have antibodies to BLV, and BLV proteins and genetic material have been found in mammary epithelium (human breast cells) and leukocytes (white blood cells). Studies have shown that environmental (rather than genetic) factors may be responsible for a majority of cases of breast cancer. The data suggest that diet, particularly a diet that includes animal products, may play a role.

In this study, the researchers will be collecting breast tissue specimens and blood samples from women undergoing breast operations for either benign or malignant disease (cancer) conditions of the breast. The tissue and blood samples will be tested to check for the presence of the BLV virus or antibodies to it. About 70 women are expected to participate in this study.

STUDY PROCEDURES

If you decide to participate in this study, the researchers will ask for your permission to have a piece of the tissue that will be removed from your breast in your upcoming surgery sent to the School of Public Health at UC Berkeley for analysis for the presence of BLV. You will also be asked to have a sample of blood (4 ml, about one teaspoon) drawn and sent to the UC Berkeley School of Public Health to test for the presence of antibodies to BLV. This blood draw can be done at the same time as your routine preoperative blood draw(s). If you are having blood drawn for the study at the same time as a preoperative blood draw, a separate tube will be used to draw the study sample. You will also be giving your consent to allow the researchers to review your medical records to check your medical information, such as the presence or absence of breast cancer. You will not be contacted again by the researchers for the purposes of the study, unless blood test results are unclear or need to be repeated.

Detection of BLV or antibodies to BLV will not change your treatment, as there is currently no known treatment for BLV or clinical need for treatment. Neither you nor your doctor will be given the results of the tests, as it is not currently known if BLV is harmful in any way. The study is expected to take

approximately five years. Should you test positive for BLV and our understanding of the virus changes, and treatment of the BLV infection is needed, we will try to let you know.

RISKS

There are no surgical risks specifically associated with this study because the breast tissue being studied will be tissue already removed in the course of your planned surgery.

In order to obtain a sample of your blood, you may experience some minor discomfort with the insertion of the needle to draw your blood. Possible side effects from blood drawing include feeling faint, inflammation of the vein, pain, bruising, or bleeding at the site of puncture. There is also the slight possibility of infection.

BENEFITS

There are no direct benefits to study participants from being in this study. The researchers hope that the information learned from this study will increase scientific knowledge about the causes of breast cancer.

INJURY

Any injury or condition experienced by a member of the Kaiser Foundation Health Plan (KFHP) as a result of being in this study will be covered in accordance with the member's Health Plan Coverage, as described in the Evidence of Coverage.

ALTERNATIVES

You may choose not to participate in this study. Your planned breast surgery or other treatment will be the same whether or not you participate in this study.

COSTS / PAYMENTS

You do not have to pay to be in this study. If you are mistakenly charged a copayment for having a blood draw solely for this study, you may contact the Principal Investigator (address and phone number in "Questions" section below) and request reimbursement. You will not be paid for participating in this study.

CONFIDENTIALITY

The researchers will keep information about you obtained for this study confidential and will not disclose it without your written permission. However, your personal information may be disclosed if required by law. In addition, the Kaiser Permanente Northern California Institutional Review Board (a formal committee that reviews research studies to protect the rights of participants) and other regulatory agencies may look at and/or copy your research records, for quality assurance and data analysis. All information obtained about you for this study will be identified only by an identification number. The tissue and blood samples sent to the University of California for analysis will be labeled with an identification number and not your name. Your specimens will be stored for the five-year duration of the study, and then they will be destroyed. Your identity will not be revealed in any publication or release of results.

VOLUNTARY PARTICIPATION / TERMINATION

Your participation in this study is completely voluntary. You are free to refuse to participate in this study. Your decision will not affect your medical care. If you decide to participate, you can change your mind at any time without any effect on your medical care or eligibility for future care or membership in KFHP. You may be withdrawn (dropped) from the study by the researchers with or without your consent if the study terminates or if the data proves unreliable.

QUESTIONS

Any study-related questions, problems, injuries, or requests for reimbursement for copayments (see "Costs/Payments" section above) should be directed to the Principal Investigator at Kaiser Permanente:

Anne R. DeLaney, MD
Chief, Department of Plastic Surgery
Kaiser Permanente Medical Center
99 Montecillo Road
San Rafael, CA 94903
(415) 444-2633

Questions about your rights as a study participant, comments, or complaints about the study may also be directed to the Institutional Review Board for the Protection of Human Subjects, Kaiser Foundation Research Institute, 1800 Harrison Street, Oakland, CA 94612, toll free telephone (866) 241-0690.

I have read the above and am satisfied with my understanding of the study, its possible risks, benefits, and alternatives. My questions about the study have been answered. By signing this document, I agree to participate as explained above in the research study "*Bovine Leukemia Virus in Human Leukocytes/Mammary Epithelium*". I will be given a copy of this five-page consent form, which includes the Authorization to Use and Disclose Protected Health Information, and a copy of the "Research Participants' Bill of Rights."

Signature of Study Participant

Date

Printed Name of Study Participant

Signature of Person Obtaining Consent

Date

**AUTHORIZATION
TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION**

STUDY TITLE: BOVINE LEUKEMIA VIRUS IN HUMAN LEUKOCYTES/ MAMMARY EPITHELIUM

Why is this authorization required?

The Privacy Rule is a federal law designed to safeguard your Protected Health Information (PHI). Your PHI is individually identifiable information about you, including your physical or mental health, the receipt of health care, or payment for that care. The Privacy Rule requires that researchers obtain your written authorization to participate in this study.

By signing this authorization, you will permit Kaiser Permanente researchers to use and disclose your PHI for the purpose of the research study named above. Your PHI will only be used and disclosed as described in this authorization, except as otherwise required by law.

Must I agree to this authorization to participate in the research?

Yes, in order to participate in this research study, you must agree to the uses and disclosures of your PHI as described in this authorization.

Who will use or disclose my PHI?

Kaiser Permanente researchers and the research team will use your PHI for the purposes of this study. Kaiser Permanente researchers will not disclose your PHI unless required by law.

What is the purpose of the use or disclosure of my PHI?

Kaiser Permanente researchers will use your PHI, including your research and/or medical record, to conduct the study and determine research results. In addition, others at Kaiser Permanente, for example, the Institutional Review Board that approved the study, may also review your research or medical record, or both, to monitor the study.

Information from your research record and medical record used and disclosed for the study may include, for example, laboratory and other tests.

When will this authorization expire?

This authorization will expire at the end of this research study.

Can I withdraw this authorization?

Yes, at any time during this study you may decide that you no longer want to have your PHI used or disclosed as part of this study. If so, you must write a letter stating that you withdraw your authorization and send it to:

Anne R. DeLaney, MD
Chief, Department of Plastic Surgery
Kaiser Permanente Medical Center
99 Montecillo Road
San Rafael, CA 94903

If you withdraw your authorization, you may be required to end your participation in the study.

Kaiser Permanente researchers may continue to use your PHI that was obtained before you withdrew your authorization. Kaiser Permanente researchers will not disclose your PHI after they receive your written request except as required by law. For example, even if you withdraw your authorization, Kaiser Permanente researchers may be required by law to record and report anything that relates to your safety or the safety of others.

Will I get a copy of this authorization?

The researcher who is obtaining this authorization from you must give you a copy of this form after you sign it.

Authorization signatures

This authorization has been explained to me, and all of my questions have been answered. By signing below, I am giving my permission to allow the use and disclosure of my PHI for the research study as described above.

Signature of Participant

Date