

Consent to be part of a Research Study

Title of Study: Does Milk with IGF-1 lead to increased incidence of Breast Cancer in Women?

**The University of Texas Health Science Center at San Antonio
(UTHSCSA)**

Study to be conducted at:

**Cancer Therapy and Research Center (CTRC)
7979 Wurzbach Rd.
San Antonio, TX 78229**

Information about this form

You may be eligible to take part in a research study. This form gives you important information about the study. You will be asked to sign in more than one place in this document.

Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Please tell the researchers or study staff if you are taking part in another research study.

Taking part in this study is completely voluntary. You do not have to participate if you do not want to. You do not have to participate in this study in order to get standard medical treatment. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are entitled.

General Information – “Who is conducting this research?”

Principal Investigator

The Principal Investigator (PI) is the researcher directing this study; the PI is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is Maria P. Carrillo from the Clinical Laboratory Sciences Department at UT Health Science Center at San Antonio.

The Co-Principal Investigator shares the principal investigator’s responsibilities for this study. The Co-Principal Investigators for this study are Raquel Clark, Cheryl Golson, Jeannie Seiler, and Diana Trinh from the Clinical Laboratory Sciences Department at UT Health Science Center at San Antonio.

If you require further information regarding the financial arrangements described in this paragraph, you should discuss the matter with the Principal Investigator.

Purpose of this study – “Why is this study being done?”

You are being asked to take part in a research study designed to see if dairy consumption has an effect on breast cancer occurrence. The ingestion of dairy products from cows routinely treated with growth hormone could be a risk factor for developing breast cancer in women. The FDA has approved the use of growth hormone in dairy cows in order to increase milk

Consent to be part of a Research Study

Title of Study: Does Milk with IGF-1 lead to increased incidence of Breast Cancer in Women?

production. This study is designed to follow the normal dietary dairy consumption of premenopausal women.

The researchers hope to learn the relationship between increased IGF-1 in cow's milk and breast cancer rate in premenopausal women. We hope the results of this study will give us a better understanding of the cause of breast cancer development. Your participation in this study will provide important information that may assist in the fight against breast cancer.

Information about Study Participants – “Who is participating in this research?”

You are being asked to be a participant in this study because you are a pre-menopausal woman between the ages of 40 to 50 and are without any medical or family history of cancer. In addition, you are being selected because your dairy intake meets 1 of our 3 identified study groups: regular dairy drinkers, organic dairy drinkers, or non-dairy drinkers.

How many people are expected to take part in this study?

This study will enroll approximately 300 study participants in the Bexar County area.

Information about Study Procedures – “What will be done if you decide to be in the research?”

If you decide to take part in this research study, you will be asked to sign this consent form. Upon completion of consent, you will be asked to take part in a screening process that will help to determine your continued participation in this research study.

After you have been approved to participate in this 1-year study, you will be asked to attend approximately 13 visits with the researchers or study staff. Following the 1st scheduled visit, the remaining visits will be held monthly for the duration of the study. All of these visits will take place at the Cancer Therapy and Research Center (CTRC).

Screening – exams, tests, and/or procedures will be done after you sign this consent to participate. This screening is done to find out if you can continue in the study (screening procedures). We may be able to use the results of exams, tests, and/or procedures you completed before enrolling in this study. You will be told which results we will obtain and which procedures will not have to be repeated. Any procedure described below as “standard care” would be done even if you do not take part in this research study.

- General Health Survey – We will ask you to fill out a questionnaire about your health, dietary habits, and family medical history.
- Physical examination – We will measure your height, weight, listen to your heart, your pulse, blood pressure, etc. as a part of routine standard care.
- Mammogram – We will perform an examination of your breasts to ensure that you do not have breast cancer before the study begins. Further description of this procedure is described below.
- Blood draw – Blood will be taken from a vein in your arm to look for breast cancer tumor markers. Like the mammogram, this will help us ensure that you do not have breast cancer before the study begins. No more than 20 mL (or about 4 teaspoons) of blood will be drawn.

Consent to be part of a Research Study

Title of Study: Does Milk with IGF-1 lead to increased incidence of Breast Cancer in Women?

The results of the screening exams, tests, and/or procedures will be reviewed to determine whether you will be allowed to continue in the study. If you are not allowed to continue in the study, the researcher will discuss the reasons with you.

Assignment to Study Groups –

When it is determined that you are that you will be allowed to continue in the study, you will be assigned to 1 of our 3 specified groups depending on your type of milk consumption: regular milk drinkers, organic milk drinkers, or non-dairy drinkers. Once you have been placed into one of these groups, you may not switch the type of milk you normally prefer to drink.

- Milk Drinkers – This group will consist of 100 participants that strictly adhere to drinking at least 1 serving of milk per day. Vouchers will be provided monthly for up to 5 gallons of “**Great Value**” milk; you are discouraged from drinking all other brands of milk for the duration of this study.
- Organic Milk Drinkers - This group will consist of 100 participants that strictly adhere to drinking at least 1 serving of organic milk per day. Vouchers will be provided monthly for up to 5 gallons of “**Horizon**” organic milk; you are discouraged from drinking all other brands of milk for the duration of this study.
- Non-Milk Drinkers – This group will consist of 100 participants that strictly adhere to drinking 0 servings of any type of milk.

Study Procedures - as a participant, you will undergo the following procedures:

Overview:

If you decide to participate in this study, we will provide you with a health survey to fill out and take a personal and family medical history from you. In addition, a routine physical examination and blood draw will be performed. All of the above procedures are part of the screening process, which will be conducted today after you have signed and agreed to the terms stated in this consent form.

At each of the scheduled 13 visits, you will have your blood drawn in the morning from a vein in your arm to measure IGF-1 levels. You do not need to fast for these blood draws. However, we do ask that you **do not** exercise before coming in. No more than 10 mL of blood will be drawn (or 2 teaspoons). Between the monthly visits, we will ask that you keep a daily food diary and perform a monthly self breast exam. You will be provided with a diary to log in your daily food intake and instructions on how to perform a monthly self breast exam. Milk drinkers will be provided with 5 milk vouchers (1 voucher = 1 gallon) per month. The daily food diary may be turned in online at your convenience or turned in during the monthly visits. You will also be asked to report the results of your monthly self breast exams during these monthly visits so that if you believe you have an abnormal self breast exam, a follow-up mammogram can be done to prove or disprove your suspicions. If this does occur, the option to continue in the study may be discussed with you.

During the 1st and last visits of this study, you will be given a mammogram and an extra blood draw in addition to your monthly blood draws. It is recommended that you not wear deodorant,

Consent to be part of a Research Study

Title of Study: Does Milk with IGF-1 lead to increased incidence of Breast Cancer in Women?

talcum powder or lotion under your arms or on your breasts on the day of the mammogram exams, since these can appear as calcium spots. The mammograms will be examined for any signs of breast cancer. The additional blood draw will help us to detect tumor markers that may indicate breast cancer.

Below are the procedures described in detail on what you will most likely experience in this study:

- **Mammogram**
 - The routine mammograms will be performed during the first and last visits.
 - Film screen mammography involves minimal radiation exposure.
 - A skilled technologist positions and compresses the breast between two plates.
 - The compression of the breast is necessary to flatten and reduce the thickness of the breast in order to take the pictures.
 - A highly specialized camera will take two x-ray pictures of each breast from two directions.

- **Blood Draw**
 - Blood drawings will be performed during every visit and scheduled in the morning.
 - Fasting before the blood drawing is not required.
 - Please **do not** exercise before the blood drawing.
 - A skilled technologist will clean the inside of your elbow with alcohol. Then, a needle will be inserted into a vein in your arm to draw out blood into a tube.
 - The first and last visit will experience no more than 20 mL (or 4 teaspoons) of blood drawn. The monthly blood drawings will have no more than 10 mL (or 2 teaspoons) of blood drawn.
 - Please inform the technologist if you have any bleeding disorders before you get your blood drawn.

Could your participation end early? There are several reasons why the researchers may need to end your participation in the study (early withdrawal). Some reasons are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

The researchers will discuss your options for medical care when your participation in this study ends.

Risks – “What are the risks of participation in the research?”

Risks from the specific research procedures

There are risks to taking part in this research study. One risk is that you may have side effects due to the procedures done while on the study.

Consent to be part of a Research Study

Title of Study: Does Milk with IGF-1 lead to increased incidence of Breast Cancer in Women?

Side effects can range from mild to serious. Serious side effects are those that may require hospitalization, are life threatening or fatal (could cause death).

The frequency that people experience a certain side effect can range from many (likely), few (less likely) or only one or two (rarely).

Side effects from this study will usually go away soon after the procedure is completed. In some cases, side effects can be long lasting or may never go away.

Everyone taking part in the study will be watched carefully for any side effects. However, the study doctors don't know all the side effects that may happen. Be sure to tell your study doctor immediately, about any side effect that you have while taking part in the study.

The following section will describe the risks related to each procedure that is part of this research study. You should talk to your study doctor about any side effects or other problems that you have while taking part in the study.

Risks and side effects related to the **Mammogram** include those which are:

Likely and not serious

- Tight and somewhat painful sensation is experienced when the breast is compressed during the mammogram procedure.

Very Rare but Serious

- The compression during the mammogram procedure may lead to distant and lethal spread of malignant cells by rupturing small blood vessels in or around small, undetected breast cancers.
- The premenopausal breast is sensitive to radiation and may increase breast cancer risk by 1%.

Risks and side effects related to the **Blood Draw** include those which are:

Likely and not serious

- Discomfort at the site of puncture with the needle
- Possible bruising
- Swelling and tenderness at the puncture site

Less likely

- Fainting or feeling light headed

Rare

- Blood clot in the vein preventing flow of blood through it
- Excessive bleeding
- Infection

For more information about risks and side effects, ask one of the researchers or study staff.

We will tell you about any significant new findings which develop during the course of this research which may relate to your willingness to continue taking part.

Consent to be part of a Research Study

Title of Study: Does Milk with IGF-1 lead to increased incidence of Breast Cancer in Women?

Are there Risks related to withdrawing from the study?

If you decide to withdraw from this study early, please discuss your decision with the principal investigator. The researcher may ask you to complete study withdrawal procedures at a final study visit. This visit includes a mammogram and a blood draw for IGF-1 measurement and breast cancer tumor markers. There is no risk to you if you do not complete the final withdrawal procedures and you can choose not to participate in them.

Concerns for sexually active women: You should not become pregnant while taking part in this study because we do not know how the mammogram procedures could affect a fetus, if a woman becomes pregnant during the study. It is important that you talk to your study doctor about avoiding pregnancy during this study. If you think you might have become pregnant while you are in this study, you must tell one of the study doctors right away so that management of the pregnancy and the possibility of stopping the study can be discussed.

If you are a woman who is pregnant or could be pregnant, you cannot take part in this study because we do not know how the mammogram procedures might affect a developing fetus.

Are there risks if you also participate in other research studies?

Being in more than one research study at the same time, or even at different times, may increase the risk to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

What if a research-related injury occurs?

The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even though the researchers are careful to avoid them. If you believe that you have been harmed, notify the researchers as soon as possible. You may also need to tell your regular doctors.

In the event of a research-related injury or if you experience an adverse reaction, please immediately contact your study doctor. See the section "Contact Information" for phone numbers and additional information.

If you are injured as a result of the research procedures, your injury will be treated. You will be responsible for any charges. We have no plans to give you money if you are injured.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

Benefits – "How could you or others benefit from your taking part in this study?"

The possible benefit of your participating in this study is that this study provides testing that could be an early identifier for breast cancer for those who do not normally receive annual exams or testing. In general, this study may help to better understand the cause of breast cancer. There is no guarantee or promise that you will receive any benefit from this study.

Consent to be part of a Research Study

Title of Study: Does Milk with IGF-1 lead to increased incidence of Breast Cancer in Women?

We hope the information learned from this study will benefit other people with similar conditions in the future.

Alternatives – “What other options are there to participation in this study?”

Not participating in this research is an option. The researcher will discuss all of your options with you.

Compensation – Will there be any compensation for participation?

You will be paid \$210 by check for the entire study. You will be paid \$50 for the 1st and last visit and \$10 after the completion of all visits in between, totaling to \$210. If you decide to drop out in the middle of the study, you will be paid for the part of the study that you have completed.

The compensation you receive may be taxable. When the total compensation paid to someone participating in one or more studies is \$600 or more in one calendar year, the institution must report the amount to the IRS. The IRS considers it earned income and treats it like any other income.

Please note that if you are on record as owing money to the State of Texas, such as for back child support or a delinquent student loan, the compensation will be applied to that debt and you will not receive a check.

Costs – Will taking part in this study cost anything?

No. You will not have to pay any money to take part in this study.

Confidentiality – How will your records be kept confidential?

Information we learn about you in this study will be handled in a confidential manner, within the limits of the law. If we publish the results of the study in a scientific journal or book, we will not identify you. The Institutional Review Board and other groups that have the responsibility of monitoring research may want to see study records which identify you as a subject in this study. Additional details are described in the “Authorization to Use and Disclose Protected Health Information as part of a Research Study.”

Contact Information – Who can you contact if you have questions, comments or complaints?

If you have questions now, feel free to ask us. If you have additional questions, comments or complaints later or you wish to report a problem which may be related to this study please contact: Maria P. Carrillo.

To use the pager, you need to have a touch tone (push button) telephone. Dial the pager number as you would any phone number. When you hear 3 short high pitched beeps, dial in the number where you want the doctor to call you back. Push the # button, hang up and wait for the doctor to return your call.

Consent to be part of a Research Study

Title of Study: Does Milk with IGF-1 lead to increased incidence of Breast Cancer in Women?

Primary contact:

Maria P. Carrillo can be reached at 210-567-8800 (office), 210-376-7649 (home), or 210-989-4432 (pager).

If primary is not available, contact

Cheryl Golson can be reached at 210-567-8800 (office), 210-947-5935 (home), or 210-923-5752 (pager).

The University of Texas Health Science Center committee that reviews research on human subjects (Institutional Review Board) will answer any questions about your rights as a research subject, and take any comments or complaints you may wish to offer. You can contact the IRB by calling 210-567-2351, or by mail to IRB, UTHSCSA, Mail Code 7830, 7703 Floyd Curl Drive, San Antonio, TX 78229-3900.

Consent to be part of a Research Study

Title of Study: Does Milk with IGF-1 lead to increased incidence of Breast Cancer in Women?

Research Consent Signature Section

If you agree to participate in this research sign this section. You will be given a signed copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE

- You have read the above information.
- Your questions have been answered to your satisfaction.

Adult Signature Section

You have voluntarily decided to take part in this research study.

_____ Printed Name of Subject	_____ Signature of Subject	_____ Date	_____ Time
_____ Printed Name of Witness	_____ Signature of Witness	_____ Date	_____ Time
_____ Printed Name and Title of Person Obtaining Consent	_____ Signature of Person Obtaining Consent	_____ Date	_____ Time

Authorization to Use and Disclose Identifiable Health Information as part of a Research Study

Title of Study: Does Milk with Increased IGF-1 lead to increased incidence of Breast Cancer in Women?

This section describes the use of your health information. If you agree to allow the researcher to use your private information, you will be asked to sign at the end of this section.

Confidentiality – Will your health information be protected?

Research policies require that private information about you be protected. This is especially true for your health information.

However, the law sometimes allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study.

What is Protected Health Information (PHI)?

Protected Health Information is information about a person's health that includes information that would make it possible to figure out whose it is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to the investigators and the research study staff (individuals carrying out the study) to see and use your health information for this research study. In carrying out this research, the health information we will see and use about you will include:

- Your medical history
- Results from any and all blood work
- Information that we get from your medical record
- Information you give us during your participation in the study such as during interviews or from questionnaires
- Demographic information (i.e. your age, marital status, etc.)

We will get this information by asking you, asking your doctor and by looking at your chart at the Cancer and Therapy Research Center (CTRC).

How will your PHI be shared?

Because this is a research study, we will be unable keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- the sponsor of the study
- the committee that checks the study data on an ongoing basis, to determine if the study should be stopped for any reason.
- the members of the local research team
- The Institutional Review Board and the Compliance Office of the University of Texas Health Science Center at San Antonio, and other groups that oversee how research studies are carried out.

Parts of your PHI may be photocopied and sent to a central location or it may be transmitted electronically, such as by e-mail or fax.

The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here.

Authorization to Use and Disclose Identifiable Health Information as part of a Research Study

Title of Study: Does Milk with Increased IGF-1 lead to increased incidence of Breast Cancer in Women?

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information. If you choose not to let these groups collect, use and share your health information as explained above, you will not be able to participate in the research study.

How will your PHI be protected?

In an effort to protect your privacy, the study staff will use code numbers instead of your name, to identify your health information. Initials and numbers will be used on any photocopies of your study records. If the results of this study are reported in medical journals or at meetings, you will not be identified.

Do you have to allow the use of your health information?

You do not have to allow the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties but you will not be allowed to participate in the study. After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you need to say this in writing and send your letter to:

Maria P. Carrillo
C/O The University of Texas Health Science Center
7703 Floyd Curl Drive
San Antonio, Texas 78229-3900

If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?

The federal rules say that you can see the health information that we collect about you and use in this study. Contact the study staff if you have a need to review your PHI collected for this study.

You will only have access to your PHI for up to 1-year following the completion of your participation in this study.

Because of the type of research, you can only access your PHI when the study is done. At that time, you have the right to see and copy the medical information we collect about you during the study, for as long as that information is kept by the study staff and other groups involved.]

How long will your PHI be used?

By signing this form, you agree to let us use and disclose your health information for purposes of the study at any time in the future. There is no expiration date because we do not know how long it will take us to finish doing all of the analyses and we will need to use your health information for as long as it takes.

Authorization to Use and Disclose Identifiable Health Information as part of a Research Study

Title of Study: Does Milk with Increased IGF-1 lead to increased incidence of Breast Cancer in Women?

Authorization Signature Section

If you agree to the use of your protected health information in this research, sign this section. You will be given a signed copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE:

- You have read the above information.
- Your questions have been answered to your satisfaction about the collection, use and sharing of your protected health information.

Adult Signature Section

You authorize the collection, use and sharing of your protected health information as described in this form.

_____ Printed Name of Subject	_____ Signature of Subject	_____ Date	_____ Time
_____ Printed Name of Witness	_____ Signature of Witness	_____ Date	_____ Time
_____ Printed Name and Title of Person Obtaining Authorization	_____ Signature of Person Obtaining Authorization	_____ Date	_____ Time