Participant ID:
Sample ID:

INFORMED CONSENT FORM FOR PARTICIPATION IN A RESEARCH STUDY

STUDY TITLE: Investigation of a Novel Blood Test to Identify Breast Cancer (IDBC)

LAY TITLE: Blood-based identification of breast cancer

PRIMARY INVESTIGATOR: Dr. Kristina Rinker

ADDRESS OF INVESTIGATOR: Arnie Charbonneau Cancer Institute
University of Calgary
Health Research Innovation Centre
2AA-07, 3280 Hospital Dr. NW
Calgary, AB T2N 4Z6

STUDY SPONSOR: Syantra Inc.

Non-Emergency contact numbers are noted at the end of this document under the section heading “WHO DO I CONTACT FOR QUESTIONS?”.

For assistance with terminology within this consent form, please refer to the Canadian Cancer Society Glossary of Terms at http://info.cancer.ca/e/glossary/glossary.html.

You are being invited to participate in a research study because you have:

- recently received a mammography result with a score of 1-5 under the Breast Imaging-Reporting Data System (BI-RADS); or
- recently completed a physical breast exam with a normal outcome

This consent form provides detailed information about the study to assist you with making an informed decision. Please read this document carefully and ask any questions you may have. All questions should be answered to your satisfaction before you decide whether to participate.

The study staff will tell you about timelines for making your decision. You may find it helpful to discuss the study with family and friends so that you can make the best possible decision within the given timelines.

Taking part in this study is voluntary. You may choose not to take part or, if you choose to participate, you may leave the study at any time without giving a reason. Deciding not to take part or deciding to leave the study will not result in any penalty or any loss of medical or health-related benefits or care to which you are entitled.

The study coordinator will discuss this study with you and will answer any questions you may have. If you do consent to participate in this study, you will need to sign and date this consent form. You will receive a copy of the signed form.

WHAT IS THE BACKGROUND INFORMATION FOR THIS STUDY?

Syantra Inc., in cooperation with the University of Calgary, has developed a test that is believed to enable detection of breast cancer from a blood sample. Research has been conducted over the last five years using both breast cancer cells and human blood samples to create the test, and results have shown good performance. To date, over 300 patient samples have been investigated, leading to the need for additional data to validate the test. Material in the blood appears to contain information associated with the presence of breast cancer, and may offer a way to identify individuals who can benefit from detailed breast imaging or a breast tissue biopsy.

Health Canada, the regulatory body that oversees the use of natural health products, drugs and devices in Canada, has not approved the sale or use of this product to detect breast cancer, although they have allowed its use in this study.

The Health Research Ethics Board of Alberta – Cancer Committee (HREBA-CC), which oversees the ethical acceptability of research involving humans, has reviewed and granted ethics approval for this study.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to investigate a new blood test that may be useful for breast cancer detection. In the future, this test may benefit women by providing important information about their likelihood of having breast cancer. This test may further provide information on the type of breast cancer that is present for individuals who receive a positive result. It may also allow for earlier and more targeted treatment.

In order to achieve these outcomes women who have recently completed mammography and/or a physical breast exam will be invited to provide a small amount of blood. This blood will be analyzed using the test, and results compared to mammography scores and any subsequent tissue samples that may be taken as part of regular investigations or interventions. All blood samples will be analyzed in a blind environment, meaning that the study team will not know anything about the sample or the donor. In this way, the performance of the test will be directly evaluated against the current standards for diagnosing and classifying breast cancer.

WHAT IF I DECIDE NOT TO PARTICIPATE IN THIS STUDY?

Your participation in the study will not have any influence on your medical care. The test being investigated does not affect treatment, and is completely voluntary.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Up to 1,200 people will take part in this study.

WHAT WILL HAPPEN DURING THIS STUDY?

STUDY INTERVENTION

If you agree to study participation, you will be asked to confirm you have no previous history of cancer. You will then be provided with a laboratory requisition to have a blood sample taken from a vein by Calgary Laboratory Services (CLS) or DynaLIFE Dx.

If you are in Calgary, you will visit CLS in the North Tower at the Foothills Medical Centre, or other specified CLS location. If you are in Edmonton, you will visit a pre-specified DynaLife Dx Patient Care Centre.

This study requires a blood sample to be taken. Briefly, you will be asked to place your arm in a flat position, and a tourniquet will be tied onto your arm. A needle with tubing attached will be inserted into your vein. A vacuum collection tube will be pushed onto the end of the tubing, and blood will flow into the tube. The tourniquet will be removed. Blood will flow into the tube until the sample draw is complete. Once the first tube is filled, a second and third tube may be collected. The total amount of blood collected will be 3 – 6 mL (about 2/3 to a little more than a teaspoon) per tube. When the needle is removed from your vein, you will be asked to provide pressure to the puncture site. The blood sample(s) will be sent to a study approved laboratory in Calgary where they will be analyzed.

As a study participant, you agree to allow access to your breast imaging information (mammograms, ultrasounds, etc.), as well as any laboratory results from tumour biopsies or surgically removed specimens.

Some blood samples will be selected for additional testing. The purpose of this testing is to develop a detailed description of the blood sample characteristics, because this information may improve the function and use of the test in the future. There are two primary goals for additional testing. The first goal is to investigate which part of the blood sample contains the signature being detected by the test (for example, cells or plasma). The second goal is to establish large scale gene expression profiles to determine if people in different locations and/or with different ethnicities have different characteristics that affect test performance. Information collected as part of these investigations will be used to improve the ability of the test to detect breast cancer in the population. Please indicate whether or not you agree to allow your sample(s) to be used for additional testing by marking the appropriate box below.

I agree to allow my blood sample(s) to be used for additional testing according to approved study protocols:

☐ Yes ☐ No Participant's Initials _____

QUESTIONNAIRES

Upon agreement to participate in the study, you will be provided with a questionnaire. The purpose of the questionnaire is to collect information about you and your health history. Questions included on the questionnaire are largely related to factors that may affect breast cancer risk, such as whether or not you smoke, if you have relatives who have had cancer, and your history of childbirth. Other questions are related to medications you may take, and whether or not you have used any hormone based therapies. Answers provided on the questionnaire will aid the study team in interpreting blood test results when combined with results from other testing that may be conducted to determine the presence or absence of breast cancer. The questionnaire will take about 5 minutes to complete.

The information you provide is for research purposes only, and will remain strictly confidential, as described in this document. Some of the questions are personal; you may choose not to answer them.

IDENTIFICATION OF SAMPLES

To protect your identity, your samples and clinical information will be labeled with a de-identified study code by the Alberta Cancer Research Biobank, who will be coordinating the study. All of your personal information will be stored according to Alberta Health Service and Alberta Health Information Act policies, and your identity will not be made available to the study team conducting analysis of the blood samples.

Despite protections being in place, there is a risk of unintentional release of information that could lead to loss of privacy. Due to technological advances in genetics, there is also a risk of unintentional release of genetic information from the samples. However, no hereditary genetic testing (to look at whether cancer runs in your family) will be performed on your samples.

WITHDRAWAL OF SAMPLES

If you no longer want your samples to be used in this research, you should tell the study coordinator. The study coordinator will ensure the samples are returned to the hospital from which they were obtained, if needed, or destroyed.

If tests have already been done on your sample(s), it will not be possible to withdraw those results. However, no further testing will be done.

WHAT ARE THE POTENTIAL RISKS OF PARTICIPATING IN THIS STUDY?

The risks of the blood sample draw are well established. You may experience some light headedness, bruising and bleeding. You will be asked to stay at the lab if you are light headed or have any bleeding that is not stopped by applying pressure.

Although no funds have been set aside to compensate you in the event of injury or illness related to study procedures, you do not give up any of your legal rights for compensation by signing this form.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

You will not personally benefit from participating in this study. By serving as a study volunteer, you will contribute new information, which may benefit individuals in the future.

The information obtained from this study may help provide better breast cancer detection tests in the future, and may impact treatment for breast cancer patients.

WHAT ARE MY RESPONSIBILITIES AS A STUDY PARTICIPANT?

If you choose to participate in this study, you will be expected to:

- Undergo a blood draw (as described above) prior to undergoing a biopsy;
- Complete and return the questionnaire
- Allow access to your breast imaging information, and any laboratory results from tumor biopsies or surgically removed specimens

HOW LONG WILL I BE PARTICIPATING IN THIS STUDY?

You will only be asked to provide blood one time. This blood will be collected before you have any tissue-based intervention, including a biopsy. Analysis results of any biopsy, or from any tissue that may be removed as part of breast cancer treatment, will be collected from your health record by authorized study staff. This information collection will take place after you provide your blood sample, and does not require any action on your part.

WILL THERE BE ANY LONG-TERM FOLLOW-UP INVOLVED WITH THIS STUDY?

There is no long-term follow up requirement for donation of additional blood. You may choose to give permission to the study coordinator or member of the study team to attempt to obtain study-related information about your health status in the future to further evaluate the performance of the test. This may include contacting your care physician, or contacting you by phone or letter (i.e., future contact).

I agree to future contact by the study team:

☐ Yes ☐ No Participant's Initials: _____

Name/phone number of care physician: _____

In addition, the study team may also attempt to obtain study-relevant information about your health information from public sources such as patient registries (e.g., cancer registries).

CAN I CHOOSE TO LEAVE THIS STUDY EARLY?

You can choose to end your participation in this research (called early withdrawal) at any time without having to provide a reason. If you choose to withdraw early from the study you are encouraged to contact the study coordinator or study staff.

HOW WILL MY PERSONAL INFORMATION BE KEPT CONFIDENTIAL?

If you decide to participate in this study, study staff will only collect the information needed for the study.

Records identifying you, including information collected from your medical files/records, such as your Electronic Medical Records (EMR), Netcare, charts, etc., will be kept confidential to the extent permitted by the applicable laws, and will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organizations may look at your identifiable medical/clinical study records at the site where these records are held for quality assurance purposes, and/or to verify that the information collected for the study is correct, and follows proper laws and guidelines:

- The Alberta Cancer Research Biobank, the research group coordinating this study;
- Members of the Regulatory/Audit team at the University of Calgary, for quality assurance purposes;
- The Health Research Ethics Board of Alberta – Cancer Committee, which oversees the ethical conduct of this study;
- Health Canada, which oversees the use of natural health products/drugs/devices in Canada and the conduct of clinical trials;

Authorized representatives of the above organizations (and the organizations listed below) may receive information related to the study from your medical/clinical study records. This information will be kept confidential in a secure location, and may be used in current or future relevant health research. Your name or other information that may identify you will not be provided (i.e., the information will be de-identified). The records received by these organizations will be coded with a number. The key that indicates what number you have been assigned will be kept secure by the researchers directly involved with this study, and will not be released.

The following organizations may receive study data:

- Syantra Inc., the sponsor of the study;
- The US FDA, which oversees the use of health products/drugs/devices in the United States and the conduct of clinical trials;
- The MHRA/NICE Program in the United Kingdom that evaluates and develops guidance for products to be used within the National Health Service

Any disclosure of your identifiable health information will be done in accordance with federal and provincial laws, including the Alberta Health Information Act (HIA). The organizations listed above are required to have organizational policies and procedures to protect information they see or receive about you, except where disclosure may be required by law. The study coordinator will ensure that any personal health information collected for this study is kept in a secure and confidential location established by the Alberta Cancer Research Biobank, as also required by law.

If the results of this study are published, your identity will remain confidential. It is expected that the information collected during the study will be used in analyses, and will be published/presented to the scientific community at meetings and in journals. This information may also be used as part of a submission to regulatory authorities around the world to support the approval of the test. Not all of the regulatory authorities that may receive study results are listed above.

Even though the likelihood that someone may identify you from study data is very small, it can never be completely eliminated. Every effort will be made to keep your identifiable information confidential, and to follow the ethical and legal rules about collecting, using and disclosing this information.

Any study-related information sent outside of Canadian borders may increase the risk of disclosure of information. This is because laws in those countries dealing with protection of information may not be as strict as in Canada. However, any study data that is transferred outside of Canada will be coded (this means it will not contain your personal identifying information such as your name, address, medical health number or contact information). All information will be transferred in compliance with all relevant Canadian privacy laws. By signing this consent form, you are consenting to the disclosure of your coded information to organizations located outside of Canada.

Studies involving humans sometimes collect information on race and ethnicity as well as other characteristics of individuals. This is because these characteristics may influence how cancer affects different groups of people. Providing information on your race or ethnic origin is voluntary, but will aid in determining the outcomes of the research.

WILL MY HEALTHCARE PROVIDER(S) BE INFORMED OF MY PARTICIPATION IN THIS STUDY?

If you agreed to future contact, your family doctor/health care provider may be informed that you are taking part in the study. This will help the study team to attempt to obtain study-related information about your health status in the future. If you do not want your family doctor/health care provider to be informed, please mark the box below.

- ☐ I do not wish for my family doctor/health care provider to be informed that I am participating in the study. Participants initials: _____

If you did not agree to future contact, your family doctor/health care provider will not be informed by the study team that you are taking part in the study. You can choose to let your family doctor/health care provider know, if you like.

WILL THERE BE ANY COSTS INVOLVED WITH PARTICIPATING IN THIS STUDY?

The blood test will be given to you free of charge for taking part in this study. Taking part in the study may result in added costs to you. For example:

- There may be costs associated with hospital or clinic visits such as parking and transportation fees

Study staff will work to schedule your blood sample donation at the same time as your regular appointment, or at a location with no parking fees, to reduce the likelihood of incurring any additional costs.

WILL I BE COMPENSATED FOR PARTICIPATING IN THIS STUDY?

You will not be paid for taking part in this study.

WHAT ARE MY RIGHTS AS A PARTICIPANT IN THIS STUDY?

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study.

You have the right to be informed of the results of research once the entire study is complete. If you would like to be informed of these results, please contact the study coordinator.

By signing this form, you do not give up any of your legal rights against the hospital, investigators, sponsor, involved institutions or their agents for compensation, nor does this form relieve these parties from their legal and professional responsibilities.

IS THERE CONFLICT OF INTEREST RELATED TO THIS STUDY?

The Principal Investigator, Kristina Rinker is a co-founder of, and shareholder in, Syantra Inc., the sponsor of the study. Her spouse is also a Syantra shareholder and employee. The three (3) study co-investigators have no ownership or financial relationship with Syantra Inc., and will serve to ensure that the study is conducted in an appropriate scientific manner.

The University of Calgary and the Alberta Cancer Research Biobank are receiving financial payment from Syantra Inc. to cover the cost of conducting this study. Researchers and staff from these organizations have no ownership or financial relationship with Syantra Inc., and will not receive any direct benefit for conducting the study.

WHO DO I CONTACT FOR QUESTIONS?

If you have questions about taking part in this study, or if you suffer a research-related injury, you should talk to the study investigator, co-investigator or study coordinator. These person(s) are:

Name	Telephone
Kristina Rinker, PhD	403-210-9733
Bobbie-Jo Docktor, MD	403-944-4530
Danielle Simonot (Study Coordinator)	403-521-3131

If you have questions about your rights as a participant or about ethical issues related to this study and you would like to talk to someone who is not involved in the conduct of the study, please contact the Office of the Health Research Ethics Board of Alberta – Cancer Committee at:

Telephone: 780-423-5727 Toll Free: 1-877-423-5727

SIGNATURES

Part 1 - To be completed by the participant.

	Yes	No
Do you understand that you have been asked to take part in a research study?	☐	☐
Do you understand why this study is being done?	☐	☐
Do you understand the potential benefits of taking part in this study?	☐	☐
Do you understand the risks of taking part in this study?	☐	☐
Do you understand what you will be asked to do should you decide to take part in this study?	☐	☐
Do you understand that you are free to leave the study at any time, without out having to give reason and without affecting your future health care?	☐	☐
Do you understand who will see your records, including health information that identifies you?	☐	☐
Do you understand that by signing this consent form you are giving us permission to access your health information and specimens, if applicable?	☐	☐
Do you understand that by signing this consent form your de-identified data can be used in publications/presentations and applications for regulatory approval related to the test?	☐	☐
Do you understand that by signing this consent form that you do not give up any of your legal rights?	☐	☐
Have you had enough opportunity to ask questions and discuss this study?	☐	☐

By signing this form, I agree to participate in this study.

Signature of Participant	PRINTED NAME	Date

Part 2 - to be completed by the study coordinator or designee who conducted the informed consent discussion. Only complete this section if the potential participant has **agreed** to participate.

I believe that the person signing this form understands what is involved in the study and has freely decided to participate.

Signature of Person Conducting the Consent Discussion	PRINTED NAME	Date

Part 3 - to be completed only if the participant is unable to read or requires assistance of an oral translator/interpreter.

- The informed consent form was accurately explained to, and apparently understood by the participant.
- Informed consent was freely given by the participant.

Signature of Impartial Witness/Interpreter	PRINTED NAME	Date

You will be given a copy of this signed and dated consent form. Please keep the copy with your medical records.