INFORMATION SHEET
CROSS sectional study of cardiovascular Function and risk profiles
In BRCA muTation carriers (CROSSFIT Study)

INVESTIGATORS:

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BACKGROUND

You have previously been tested and found to have a gene alteration called 'BRCA mutation', which increases the chance of certain kinds of cancer. Scientists are now wondering if the BRCA mutation might also increase the chance of other health problems, such as the heart or blood vessels, called 'cardiovascular' disease.

PURPOSE

We would like to perform several tests to study your cardiovascular system in detail. In this way, we will learn about risk factors in people with the BRCA mutation, and how to develop the best ways to help.

DESCRIPTION OF THE STUDY

If you decide you would like to take part in this project, you will be scheduled for these tests at the University of Alberta. We will do our best to schedule all tests on one day:

- **A physical examination** with blood pressure, pulse, temperature, breathing rate, weight, listening to lungs and heart, and looking for signs of heart problems. This will include questions about your health, reproductive and smoking history**.**
- **Questionnaire** asking you to rate any symptoms you may be experiencing. This will take 5 minutes to complete.
- **A blood sample** will measure total blood cell count, heart and kidney function. A fasting blood sample will measure the amount of fats in your blood. An **electric heart tracing** (**ECG**) will check the electrical activity of your heart.
- **DEXA** (low-energy whole body X-ray) will measure your bone density and body composition (amount of lean and fat tissue in your body). While you lie flat on an X-ray table, a scanner moves slowly over your body. This test takes about 30 minutes.
- **MRI scan** of your heart will be performed at the Mazankowski Alberta Heart Institute to check your heart function. This tests takes about 45 minutes.
- **Maximum exercise ability and oxygen use (VO2 test**). This test will be performed on a stationary bike. The test will begin with easy pedaling that will become a little more difficult every 1 – 2 minutes. A special mouthpiece and nose clip will be used to measure your oxygen uptake as you breathe. A number of electrodes (electrical contacts) will be placed on your chest and side of your neck, connected to a computer that will measure your heart rate and function. Throughout the test, your heart rate and blood pressure will be measured. The exercise test usually lasts 8 to 10 minutes and specially trained health care workers will supervise the test**.** **Please bring a change of clothes and shoes for exercising.**

Sample Banking for Future Research

You may also be asked if samples of your blood and urine can be stored for future research in the Alberta Research Tumor Bank. You will be given another consent form asking for your written permission.

POSSIBLE BENEFITS

You may not personally derive benefit by participating in this study. The information we learn from this study may be helpful to patients in the future.

POSSIBLE RISKS

- **Blood Tests:** You may feel some discomfort from the needle when blood drawn. There is also a small risk of fainting, swelling, bruising, bleeding or (rarely) local infections at the site of the needle punctures.
- **Exercise Tests:** The exercises that you will perform are generally regarded as very safe. All testing and exercise sessions will be performed under appropriate supervision. Data from individuals with or without heart disease suggests that the likelihood of having a heart attack or dying during a bicycle test is 1 in 10,000 tests. The mouthpiece that is used during the exercise test may make your mouth feel dry. You may also experience temporary muscle soreness after the exercise tests.
- **DEXA:** you will be exposed to a very small amount of radiation with these tests, less than you might receive in one day outdoors in the sun. The risk from this amount of radiation has been categorized by the Alberta Health Services Regional Radiation Safety Committee as "very low".
- **Cardiac MRI**: Exposure to the magnetic fields in an MRI machine has no known harmful effects. As part of usual MRI procedure, you will be asked a series of questions to make sure it is safe before you have an MRI scan.

COSTS

You may be coming to the University of Alberta more often than if you were not participating in this study. As a result, there may be some extra costs for you such as gasoline, child care or meals. You are eligible to receive $25 to assist with these costs.

COMPENSATION FOR INJURY

If you become ill or injured as a result of participating in this study, necessary medical treatment will be available at no additional cost to you. By signing this consent form you are not releasing the investigator(s), institution(s) and/or sponsor(s) from their legal and professional responsibilities.

CONFIDENTIALITY

At the exercise center, it is possible that you may meet other people participating in this study. During the study we will be collecting health data about you. We will do everything we can to make sure that this data is kept private. No data relating to this study that includes your name will be released outside of the study doctor's office or published by the researchers. Sometimes, by law, we may have to release your information with your name so we cannot guarantee absolute privacy. However, we will make every legal effort to make sure that your health information is kept private.

The study doctor or study staff may need to look at your personal health records held at the study doctor's office, and/or kept by other health care providers that you may have seen in the past (i.e. your family doctor). Any personal health information that we get from these records will be only what is needed for the study. During research studies it is important that the data we get is accurate. For this reason your health data, including your name, may be looked at by people from the University of Alberta, the University of Alberta auditors and members of the Research Ethics Board.

By signing this consent form you are giving permission for the study doctor/staff to collect, use and disclose information about you from your personal health records as described above. After the study is done, we will still need to securely store your health data that was collected as part of the study. At the University of Alberta, we keep data stored for 5 years after the end of the study. If you leave the study, we will not collect new health information about you, but we will need to keep the data that we have already collected.

VOLUNTARY PARTICIPATION

Being in this study is your choice. You are free to withdraw from the research study at any time, and your continuing medical care will not be affected in any way. If the study is not undertaken or if it is discontinued at any time, the quality of your medical care will not be affected. If any knowledge gained from this or any other study becomes available which could influence your decision to continue in the study, you will be promptly informed.

CONTACTS

If you have any questions or concerns, please contact the investigators: Edith Pituskin PhD at 780-432-8221, Barbara Krause MD at 780-432-8518 or Ian Paterson MD at 780-407-1857**.**
If you have any questions regarding your rights as a research participant, you may contact the Health Research Ethics Board at 780-492-2615. This office is independent of the study investigators.

CONSENT FORM: CROSS sectional study of cardiovascular Function and risk profiles In BRCA muTation carriers (CROSSFIT Study)

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Please answer the following questions:	**Yes**	**No**
Do you understand that you are being asked to be in a research study?	___	___
Have you read and received a copy of an attached information sheet?	___	___
Do you understand the benefits and risks in taking part in this research study?	___	___
Have you had an opportunity to ask questions and discuss this study?	___	___
Do you understand that you are free to withdraw from the study at any time without having to give a reason and without affecting your future medical care?	___	___
Has the issue of confidentiality been explained to you, and do you understand who will have access to your medical records?	___	___
Do you want the investigators to inform you family doctor that you are participating in this study? If so, give his/her name _____	___	___

Who explained this study to you? _____

I agree to take part in this study: Yes ___ No ___

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Witness Date

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

_____ _____
Signature of Investigator or Designee Date