Informed Consent to Participate in Research

Study Title: PROgress TRACKER Breast Cancer Registry

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Sponsor: Breast Cancer Canada

The ethics of this study have been reviewed and approved by the University of Calgary through the Health Research Ethics Board of Alberta – Cancer Committee and VERITAS National Ethics Review Board.

This **Consent Form** includes:

- ✓ The purpose of the research
- ✓ Possible risks and benefits
- ✓ Your rights if you join the study

1. Study Overview

We invite you to join this research registry or "study". We are conducting this registry to learn about what patients' lives look like after a breast cancer diagnosis and any form of breast cancer therapy. The study will also help us give better care to future patients.

You are being asked to join because you:

- Have been diagnosed with breast cancer at any stage 0, I, II, III or IV
- Reside in Canada

If you join, you will take surveys (also known as questionnaires) about your health and well-being. You can take the surveys wherever you have access to the internet and can receive and send e-mail.

Key Points:

- Participating in any research study is your choice.
- You may or may not benefit from being in the study. Knowledge we gain from this research may help others.
- There are few risks to being in this study. Some questions on the study surveys may upset you.
- If you join the study, we will send you surveys every 3 months for up to 10 years. You can quit at any time.
- If you decide to quit the study, it won't affect your care with your medical teams.
- You can contact us (Breast Cancer Canada or Principal Investigator) at any time if there is anything you don't understand, if you want more information, or if you want to quit the study.
- Take the time to talk about the study with your doctor, study staff, Breast Cancer Canada volunteer and your family and friends. It's your choice to be in the study. If you decide to join, please sign the end of this consent form. You'll get a copy to keep. No one can force you to join this study.

2. Nature and Registry Purpose

Breast cancer is the most common malignancy in women, and one in eight Canadian women are diagnosed with breast cancer according to Canadian Cancer Statistics. Although breast cancer in men is rarer, around 270 men received this diagnosis per year.

Treatments for breast cancer have progressed substantially over the past years. Early screening, improvements in cancer diagnosis and treatments and better information campaigns have led to an increased number of long-term breast cancer survivors. Side effects are common after breast cancer treatments such as surgery, radiation, chemotherapy and hormone therapies. The breast cancer experience can affect your life in many ways.

We are doing this research registry to learn about what patients' lives look like after breast cancer diagnosis and any treatment required as a result to understand the impact to your life. The registry data and analysis will also help us give better care to future patients.

As a breast cancer patient, you are invited to participate in PROgress Registry, a database of patients over 18 years old with breast cancer.

What is a research database or Registry?

It is a place where researchers share information from studies, like survey answers. They put the information into a system, where it is stored with information from other studies. Other researchers can look at the information to learn more about health and treatment. For the PROgress tracker Breast Cancer Registry, Breast Cancer Canada has enlisted a research group called POET from the University of Calgary who have expertise in developing and managing large databases or registries.

3. Nature of your participation

If you decide to take part in the study, the following information will be first collected from you to the best of your knowledge:

- Demographics: Date of birth, biological sex, gender identity, universal healthcare identifier, highest level of education, postal code: (to determine your province of residence), ethnicity, current employment status
- Financial and personal situation: financial concern, need financial assistance, caregiver status for someone.
- Medical information of breast cancer diagnosis: date of diagnosis, stage of disease, type of mutation, previous recurrence to your cancer.
- Any procedures or treatment received for your breast cancer: breast biopsy, surgery, radiation therapy, systemic therapy [oral or IV medications (hormone therapy, targeted therapy, chemotherapy, immunotherapy)]
- Participation to a clinical trial

Then every 3 months, you will you will take surveys. You can choose how to take the surveys. It can be:

1. Online. We will send you a link to the survey. The link will not have any information that could identify you.
2. On the phone. We will call you and ask you the questions.

Each survey takes about 3 to 5 minutes to complete and multiple surveys will be sent each time for a total of 15 to 30 minutes to complete all surveys in each 3-month questionnaire period. The surveys will ask you about how you are doing during and after your breast cancer diagnosis and treatment. You can skip any questions you want. You can also pause the survey and come back to complete the survey questions within a 2-week period.

We will contact you by email every 3 months for up to 10 years to complete surveys. We may have a volunteer contact you if you have not completed a survey period.
The surveys will ask about your general well-being, and topics that may be sensitive, like:

- Any signs of depression you may have
- Any symptoms or side effects that you may have as a result of being diagnosed and treated for breast cancer.
- How much you worry or feel nervous
- Sexual health
- Your finances and going back to work or school
- Information about your job and relationships

Your answers to the survey questions will be used in research analysis. You will not take any medicines for this registry or have any tests done.
If we send you a survey, but do not receive it back, we may contact you by phone, email or mail to make sure you got the survey and remind you to complete it. You can tell us how you would like to be contacted. If your contact information changes (for example emails to you bounce back to us), we may search online for updated contact information.

You can participate in this study for as long as you would like. There is no limit to how many people can join the study.

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4. Risks and Benefits

Possible Benefits

Taking part in this study may or may not help you. The information from this study may help future patients get better care during and after their experience with breast cancer.

Possible Risks

There are few risks with taking the surveys.

Some of the questions or topics may upset you. Your doctor will not contact you about your responses, so if you have any concerns about your feelings or thoughts, tell your doctor right away.

If you do not feel comfortable responding to a question, you may choose not to answer it.

There is also a small risk that someone could find out which answers are yours. We will do everything we can to keep your answers confidential

5. Your Rights to Ask Questions and Leave

Being in this study is your choice. You can choose not to be in the study or leave this study at any time. If you choose not to join or leave this study, it will not affect your regular medical care in any way.

If you leave the study after giving us survey answers, we will keep the data you have provided and not request further surveys from you.

You have the right to ask questions about the study at any time. If you have questions about the study, please contact:

Dr. Omar Khan or Dr. Doris Howell

Call:

Email: doris.howell@uhn.ca; omar.khan@albertahealthservices.ca

If you want to talk to someone outside this study about general problems, concerns, or questions, please contact:

Breast Cancer Canada

Call: 1-800-567-8767

Email: protracker@breastcancerprogress.ca

If you want to leave the study, please contact:

Breast Cancer Canada

Call: 1-800-567-8767

Email: protracker@breastcancerprogress.ca

If you have questions about your rights as a research participant, please contact:

National central ethics committee contact at ?????

You will receive a copy of this consent form for your records. You do not lose any of your legal rights by signing this consent form.

6. Early end of Study

The sponsor may end your participation, without your consent, if there are reasons for abandoning the project by mail or email.

You may also be told to leave the study for reasons such as:

- You don't meet the study requirements

- It would be harmful to you to stay in the study
- The study is stopped for any reason

7. Confidentiality and Use of Information

We will do our best to make sure that your survey answers are not seen by anyone else. However, there is a small risk that someone could find out which survey answers belong to you.

Any data collected about you as a participant during this Registry will not identify you by name. You will be identified only by an alpha-numeric code. The key to the code linking your name to your registry file will be kept by the sponsor. The participant's first and last name and contact information will be stored for one year following the end of the Registry.

If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

We will not tell anyone that you are in this study. However, some of your information may be shared if required by law. If this happens, we will do our best to make sure that it will not identify you.

Patient medical records will never be consulted by Breast Cancer Canada staff member. The information collected for the purposes of the Registry is based on patient's declaration only. None of the information collected will be provided to member of medical staff or to the medical center where you receive treatment.

To make sure the study is running ethically, some government agencies or other groups that manage the conduct of the study on behalf of Breast Cancer Canada may need access to some of the information in your study records. Your survey responses in the research database may also be shared with organizations that have databases that will allow for a greater depth of knowledge with combined data.

Some of these organizations are:

- Breast Cancer Canada
- VERITAS Ethics Review Board; Institutional Review Board (IRB) or ethics committees; HREBA (Health Research Ethics Board of Alberta)
- POET program at the University of Calgary
- Health Canada
- Cancer programs in Canada that develop cancer management policies
- Other cancer research programs
- Other database systems in health care such as Canadian Institute for Health Information

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 the information they see or receive about you, except where disclosure may be required by law. The POET program team will ensure that any

personal health information collected for this study is kept in a secure and confidential location at the University of Calgary, Alberta, Canada as also required by law.

Even though the likelihood that someone may identify you from the 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.

Studies involving humans sometimes collect information on race and ethnicity as well as other characteristics of individuals because these characteristics may influence how people respond to different therapeutic interventions. Providing information on your race or ethnic origin is voluntary.

It is expected that the information collected during the study will be used in analyses and will be published and/or presented to the scientific community at meetings and in journals, but your identity will remain confidential. When research results are published, we will make every attempt to share the findings with you to be able to see how the study is progressing.

Your survey results may also be used in studies you specifically consent to, or for process improvement and evaluation within PROgress Tracker database.

8. Participating in future sub-studies.

You may be contacted for your interest to participate in additional surveys as a sub or add-on study that would be incorporated within this PROgress Tracker database registry. You can choose to participate or not to participate in these additional survey questionnaires, which does not exclude you from ongoing participation in the PROgress Tracker database

9. Cost and Reimbursement

It will not cost you anything to join this registry. You will not be paid for taking part in this registry.

Inform Consent Form

TITLE: Protocol for Collection of PROgress TRACKER Breast Cancer Registry Data

- I've read and understand this consent form. The type of study and the reason for the study has been explained to me.
- I've had the chance to ask questions, and I understand the answers I've been given. I understand that I may ask questions at any time during the study.
- I freely agree to take part in the study.
- I've had the chance to talk about taking part in the research with a family member or friend, if I want.
- I understand that…
  - I may not directly benefit from taking part in the study.
  - My name and personal information will not be identified even if information gained during the study is published.
  - My survey results will be stored in the PROgress tracker Database and can be seen by researchers for future studies.
  - I can leave this study at any time, and doing so won't affect my current care or future treatment.
  - I will be given a copy of this consent form.
  - I do not give up any legal rights by signing this form.
  - My survey results will not be shared with my doctor. If I have any problems with my breast cancer or treatment for breast cancer, I will discuss this my doctor on my own.
  - I may be asked to participate in other add-on studies with additional questionnaires, that I can choose to or not to participate which does not exclude me from ongoing participation in the PROgress Tracker database

Electronic consent will be obtained from participants directly into the Database, with final signed copy sent via email to the participant as an output from the data capture program.

Please enter your name/surname: Please write today's date (DD/MM/AAAA):

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Please sign your name.

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