Informed Consent Form for Participation in a Research Study

ERAS – OncoRe:
A Protocol for Mobile App Postoperative Home Monitoring after Enhanced Recovery Oncologic Surgery

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Sponsor/Funder(s): Alberta Health Services/Alberta Cancer Foundation

You are being invited to participate in a research study because you will be having cancer-related breast, breast reconstruction, or gynecological surgery and your surgery will be organized according to ERAS (Enhanced Recovery After Surgery) practices. 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.

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. All questions should be answered to your satisfaction before you decide whether to participate.

Taking part in this study is voluntary. You may choose not to take part. If you do 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 to which you are entitled.

Your surgeon and the study doctor's research assistant 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 via the secure RedCap electronic data collection system. You will receive a copy of the signed form.

WHAT IS THE BACKGROUND INFORMATION FOR THIS STUDY?

Developments in cancer surgery have introduced new practices under what is known as ERAS (Enhanced Recovery After Surgery). These practices have been shown to improve patients' recovery experiences and to reduce hospital stays. Also, developments in hand held (mobile) technology, such as smartphones, are being used in health care more and more. In this project we have designed a smartphone application which can monitor your recovery at home. Patients can respond to questions that appear on their mobile device on the days following their surgery. That information will be sent to a secure and confidential server where the surgeon and health care team can monitor how the patient is recovering at home. This is not meant to be a replacement for your relationship with your surgeon.

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 evaluate the quality of recovery at home by using smartphone technology for patients who have had gynecological or breast cancer surgery under ERAS practices.

WHAT ARE OTHER OPTIONS IF I DECIDE NOT TO PARTICIPATE IN THIS STUDY?

You do not have to take part in this study in order to receive continued medical care. If you choose not to participate in this study, you will simply receive the regular standard of care without the possibility of using the smartphone app that this study is testing.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Up to 72 people will take part in this study.

WHAT WILL HAPPEN DURING THIS STUDY AND WHAT ARE MY RESPONSIBILITIES?

You will discuss the details of this study with a research assistant. If you agree to be in the study you will review and sign the consent form via the RedCap secure data collection system and then be randomly assigned to one of two study groups (see ASSIGNMENT TO A GROUP below). Once consent is signed you will be screened to ensure you meet the eligibility requirements of the study.

If you are eligible and agree to continue, you will, at a minimum:

- Complete 2 sets of questionnaires online. These questionnaires ask you about your recovery, costs related to followup appointments, and how you feel about your healthcare. You will fill these out online via a secure website at 2 weeks and 6 weeks after your surgery. We estimate it will take you about 30 minutes each time.
- Keep a record of costs associated with your followup visits.
- Keep a record of anytime you call, email, or visit your surgeon, family doctor, walk-in clinic, or emergency room about your surgical recovery.
- Attend any scheduled post-operative appointments with your surgeon during the study period.
- Be discharged from the study 6 weeks after your surgery but you will continue with your usual relationship with your surgeon as required.

If you are assigned to the group that will be using the smartphone app, in addition to the responsibilities above, you will:

- Follow provided instructions to download and install the smartphone app on your smartphone and password protect your phone during the study period.
- Undergo training in the use of this app as well as instruction on how to take and upload

wound photographs.

- Submit the information requested by the smartphone app daily from the day of discharge up until 2 weeks after your surgery. You will continue to submit this information once per week from 2 weeks after your surgery until 6 weeks after your surgery. We anticipate that it will take you 5 minutes or less each time you enter the data into the smartphone app.

ASSIGNMENT TO A GROUP

The study is a randomized control trial. This means that participants in the study will be randomly assigned to one of two groups. Randomization means that you are put into a group by chance (like flipping a coin). There is no way to predict which group you will be assigned to. You will have a 50/50 chance of being placed in either group. Neither you, the study staff, nor the study doctor can choose what group you will be in. You will be told which group you are in.

In this study one group will use the smartphone application during their recovery. The other group will receive the usual care that does not include the smartphone app.

WHAT ARE THE POTENTIAL RISKS FROM PARTICIPATING IN THIS STUDY?

There are no major risks anticipated to participants participating in this study. ERAS® protocols have been shown to be safe and effective and only patients suitable for this surgical route are offered ERAS® pathways.

The "risks" of using a mobile phone or tablet device are:

1. An impact on the timing of diagnosis of complication, though mobile phone monitoring may also offer a higher likelihood of early detection of possible complications.
2. Security issues due the risk that someone could steal and possibly break into the contents of the phone; however, the mobile phones used in this study are double encrypted and password protected, and information is transmitted in accordance with Canadian's Personal Information Protection and Electronic Documents Act.
3. The risk of injury from dropping the mobile phone on a surgical wound, using the mobile phone while driving or operating machinery, distraction during other tasks, mobile phone overuse syndrome, and repetitive strain injury; however, these risks are no higher than patients regularly using a smartphone are currently exposed to and the time required for the patient to complete their daily log is only 5 minutes.
4. Anxiety arising through possible loss or damaged device. This is a possible "risk" that is no greater than normally associated with owning a cell phone.

Every effort has been made to use the most secure electronic transmission and storage standards available to the study team. However, as with all electronic information transfer, there is a risk, although highly unlikely, that the information could be accessed by a hacker.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

If you agree to participate in this study there may or may not be a direct benefit to you. The information we collect from this study may help us to provide better home support for patients

undergoing cancer surgery.

HOW LONG WILL I BE PARTICIPATING IN THIS STUDY?
Your participation in this study will end 6 weeks after your surgery.

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 will provide written notice to the study coordinator, Carmen Webb carmen.webb@ahs.ca. Any data collected to this point will be kept as part of the study unless you provide written instructions within 4 days of withdrawing from the study that you wish to have it deleted. Your healthcare will not be influenced by your participation or non-participation in this study.

HOW WILL MY PERSONAL INFORMATION BE KEPT CONFIDENTIAL?
We will respect your privacy. Any collected or obtained personal information (information about you and your health that identifies you as an individual) will be kept confidential and protected to the fullest extent of the law. All personal information collected will be kept in a secure location. The study staff, authorized representatives from the Heath Research Ethics Board of Alberta or employees of Health Canada may look at your personal information for purposes associated with the study. They will only be allowed to see your records under the supervision of the study doctor and will be obligated to protect your privacy and not disclose your personal information. None of your personal information will be given to anyone without your permission unless required by law.

Only members of the research team will have access to the information. All participants will be identified only by a personal identification number, not by name. The information we report will be anonymous and consist of responses from groups of people, not individuals. All questionnaires will be stored in a secured storage area. Electronic files will be stored on a password-protected computer on the secure hospital server and will be accessible only to members of the research team.

WILL MY HEALTHCARE PROVIDER(S) BE INFORMED OF MY PARTICIPATION IN THIS STUDY?
Your family doctor/healthcare 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/healthcare provider know, if you like.

WILL THERE BE ANY COSTS INVOLVED WITH PARTICIPATING IN THIS STUDY?
If you are assigned to the group using the smartphone app and depending on your smartphone data plan, it is possible that you may incur costs related to upload data via the smartphone app. Any data charges incurred will not be reimbursed.

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 this study once the entire study is complete. If you would like to be informed of these results, please contact the study doctor.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected. By signing this form you do not give up any of your legal rights against the hospital, investigators, sponsor, involved institutions for compensation or their agents, nor does this form relieve these parties from their legal and professional responsibilities.

IS THERE CONFLICT OF INTEREST RELATED TO THIS STUDY?
There are no conflicts of interest declared between the study doctor and sponsor of this study.

WHERE CAN I FIND ONLINE INFORMATION ABOUT THIS STUDY?
A description of this clinical trial will be available on http://www.clinicaltrials.gov.
This website will not include information that can identify you. You can search for this website at any time.

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 coordinator or study doctor. These person(s) are:

Carmen Webb	403-521-3251
Name	Telephone
Claire Temple-Oberle	403-521-3012
Name	Telephone

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

You will be given a copy of this signed and dated consent form prior to participating in this study.

SIGNATURES

Part 1 - to be completed by the potential 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 what you will be asked to do should you decide to take part in this study?	☐	☐
Do you understand the alternatives to participating in this study?	☐	☐
Do you understand that you are free to leave the study at any time, without 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 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 doctor 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