APPENDICES

Appendix 1. Informed Consent Form

CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

Study Title:

At-home **B**reast **O**ncology care **D**elivered with **E**-health solutions – The ABODE Study

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Please note that the security of e-mail messages is not guaranteed. Messages may be forged, forwarded, kept indefinitely, or seen by others using the internet. Do not use e-mail to discuss information you think is sensitive. Do not use e-mail in an emergency since e-mail may be delayed.

Source of Funding:
This study is funded by the Academic Health Science Centre Alternative Funding Plan (AHSC AFP), Canadian Institutes of Health Research (CIHR) and Princess Margaret Cancer Foundation Donors.

Introduction:
You are being asked to take part in a research study. Please read the information about the study presented in this form. The form includes details on study's risks and benefits that you should know before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study doctor or study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your

decision, feel free to talk about this study with anyone you wish including your friends, family, and family doctor. Participation in this study is voluntary.

Background/Purpose:
The COVID-19 pandemic has significantly impacted healthcare service delivery, highlighting the need for high quality virtual patient care. We have customized a mobile application for patients with breast cancer to use. This app delivers patient education materials, has an instant chat with the research team, and administers surveys.

The purpose of this study is to understand how use of the app affects patient experiences of care.

You are being asked to take part in this study because you have been diagnosed with breast cancer. Up to 200 participants will participate in this study at UHN.

Study Design:
This is a randomized study. "Randomized" means that participants will be randomly assigned either to take part in an experimental or in a control group. There will be a 1:1 randomization ratio, meaning that for every one person put into the experimental group, there will be another one person put into the control group.

- ✓ The control group will receive standard care.
- ✓ The experimental group will receive standard care and will have access to the app.

To be in the study, you will need to have access to a mobile phone with ability to use the Breast Cancer Treatment Application (the app) and have access to Internet.

The Breast Cancer Treatment Application (BCTA) is a mobile application developed by a Canadian Company, NexJ Health Inc. ("NexJ").

Study Visits and Procedures:

✓ All participants

You will review and you will have to agree to the Fitbit Terms of Use in order to be in the study. Then, you will receive a Fitbit Inspire 2, which you can keep after completion of the study. You will be asked to agree that your Fitbit data will be collected within the app.

✓ *If you are randomized to the experimental group*

You will be asked to download and use the Breast Cancer Treatment Application for 13 months after enrollment and to keep the app on your device (e.g. cellphone) until the end of the study. Before you download and access the app, you will review and you will have to agree to NexJ's End User License Agreement in order to be in the study.

While you are using the Breast Cancer Treatment Application, you will be connected with an E-coach; however, continued communication with the E-coach is optional. If you

choose to continue to communicate, the frequency can be determined jointly, according to your preference.
The E-coach can provide emotional support, offer information, and help you to navigate how to find information. They are UHN volunteers and have completed all necessary training required by the organization. In addition, your E-coach is trained through the Healing Beyond the Body group at UHN. This program makes sure that the mental, emotional, social, interpersonal and practical aspects of living with cancer are addressed. The E-coaches for this study have also received special training so that they can offer support via the Breast Cancer Treatment Application.

✓ *If you are randomized to the control group*

You will be registered on a limited version of the Breast Cancer Treatment Application which will be used only to collect your Fitbit data for analysis. You won't have access to the app or its features and you will not download the BCTA on your device. Using your email address, the study team will create an account for you on the BCTA for Fitbit data collection only.

During the study:
We will ask you about

- your knowledge, skills, and confidence in managing your own health.
- your experiences, well-being, use of health services (for example, how many times you contact your care team),
- your experience using the app and Fitbit

You will be asked to fill out the questionnaires at the beginning of participation, at 6 and 12-months after surgery. We will e-mail you a link to complete these questionnaires. The questionnaires will have questions about:

- Your knowledge, skills, and confidence in managing your own health
- The impact your breast cancer diagnosis has you
- Any feelings of anxiety or depression
- The general state of your health
- Gender identity, sexual orientation, race, spoken languages, disability status

Use of Health services. The study team will collect data on participants' use of health services from the Wait Time Information System (WTIS), National Ambulatory Care Reporting System (NACRS), and Discharge Abstract Database (DAD). These databases contain information on hospital visits for patients nation-wide. We will use your MRN and year of birth to get the data from these databases.

User experience. If you are using the app, we will ask you about your experience in using the app.

Fitbit data. We will collect data from your Fitbit activity tracker, including:

- Heart-rate
- Sleep
- Activity and exercise

- Food, weight, and water logs

The study team will collect *information from your medical chart*. Only information that is needed for the study will be collected. The information collected will include dates of your appointments, information on your diagnosis, treatment, surgery, pathology, and overall health.

We will also conduct interviews. During the interviews, we will ask participants about their experience and feedback about the app. Please indicate at the end of this consent form whether you would like us to contact you about the interview part in the future.

No additional visits are required to participate in this study.

Risks:
There are no foreseeable risks to the participant that may arise from participation in this study. However, you may feel uncomfortable answering some questions. You can skip any questions in the questionnaires and still take part in the study.

Benefits:
There is no personal benefit to participating in this study. In the future, information from this study may help to develop other e-Health apps for use in clinic.

Reminders and Responsibilities:

- Do NOT participate in any other studies with an e-Health app for the duration of the study.
- Let us know via the instant chat or email if you would like to stop participating or using the app.
- Wear the Fitbit as much as possible throughout the study period. It's okay if you need to take it off sometimes.

Alternatives to Being in the Study:
You can choose not to participate in this study. This will not affect your treatment.

Confidentiality:
Your data will be shared as described in this consent form, and the terms of use of NexJ and Fitbit. All personal information such as your name, phone number, and medical record number will be removed from the data and replaced with a number. A list linking the number with your name will be kept by the study team in a secure place separate from your file.

Personal Health Information

If you agree to join this study, the study doctor and the study team will look at your personal health information and collect only the information they need for the study. Personal health information is any information that could identify you and includes your:

- name,
- year of birth,
- e-mail and/or telephone number and mailing address
- Fitbit User ID #
- new or existing medical records, that includes types, dates and results of medical tests or procedures, as well as complications from surgery if any
- information on which app features you use (frequency, time, function)

For participants who are using the Breast Cancer Treatment Application, the study team will also look at the information stored in the app and collect only the information they need for the study. Chat data will be stored in the app, however, these data will not be monitored, accessed, or analyzed.

Representatives of the University Health Network (UHN) including the UHN Research Ethics Board may come to the hospital to look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study is following proper laws and guidelines:

The study doctor will keep any personal health information about you in a secure and confidential location for 15 years.

Your participation in this study will also be recorded in your medical record and the UHN computer system.

Research Information in Shared Clinical Records
The UHN shares the patient information stored on its computers with other hospitals and health care providers in Ontario so they can access the information if it is needed for your clinical care. The study team can tell you what information about you will be stored electronically and may be shared outside of the UHN. If you have any concerns about this, or have any questions, please contact the UHN Privacy Office at 416-340-4800, x6937 (or by email at privacy@uhn.ca).

Results from this study are planned to be published in a peer-reviewed scientific journal in manuscript format. No identifying information will be included at any point during data analysis, presentation or publication.

As required by the terms of use of the PAM-13 scale, we will submit the de-identified data set (i.e. data identified by a number only) to Insignia Health at research@insigniahealth.com. Participants cannot be identified by this information. Insignia Health will not alter, share, or publish the data. However, they will compare the data to their wider data set and use this information to continually refine PAM and PAM-based guidance for coaches, clinicians, and patients. Any analysis performed by Insignia Health on the de-identified data can be shared back with the researcher.

In addition, as required by the terms of use of the and the EORTC questionnaires, we will submit the responses to those questionnaires to the EORTC Quality of Life Group. This will include responses to questions about quality of life and about the quality of the information that was received during treatment.

Voluntary Participation:
Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now, and then change your mind later. You may leave the study at any time without affecting your care.

We will give you new information that is learned during the study that might affect your decision to stay in the study.

Withdrawal from the Study:
If you decide to leave the study, the information collected before you left the study will still be used in order to help scientific integrity of the study. No new information will be collected without your permission. *If you are using the app* and wish to stop using or delete the app, you may do so and please let the study team know.

Costs and Reimbursement:
There is no cost to this study. The Breast Cancer Treatment Application used in this study is a free app for you. The Fitbit device will be provided to you free of charge.

Rights as a Participant:
By signing this form, you do not give up any of your legal rights against the investigators, sponsor or involved institutions for compensation, nor does this form relieve the investigators, sponsor or involved institutions of their legal and professional responsibilities.

Conflict of Interest:
Researchers have an interest in completing this study. Their interests should not influence your decision to participate in this study.

Questions about the Study:
If you have any questions, concerns or would like to speak to the study team for any reason, please contact:

Emma Reel, Research Coordinator: emma.reel@uhnresearch.ca
Dr. Tulin Cil, Principal Investigator: tulin.cil@uhn.ca

If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the University Health Network Research Ethics Board (UHN REB) or the Research Ethics office number at 416-581-7849. The REB is a group of people who oversee the ethical conduct of research studies. The UHN REB is not part of the study team. Everything that you discuss will be kept confidential.

You will be given a signed copy of this consent form.

Consent:
This study has been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to the use of my information as described in this form. I agree to take part in this study.

Future Studies
In addition, I agree to be contacted by the study team about the future interviews.
☐YES ☐NO

Print Study Participant's Name	Signature	Date

My signature means that I have explained the study to the participant named above. I have answered all questions.

Print Name of Person Obtaining Consent	Signature	Date

Appendix 2. Other Health App Questionnaire (OHA)

Other Health App (OHA) Questionnaire

In order to understand the impact of the ABODE breast cancer treatment app, we are going to ask you a few questions about any other e-health apps you are using.

1. Have you used any other healthcare-related apps since starting the study? For example, fitness trackers (other than the Fitbit you were provided), apps that educate about disease/cancer, virtual e-coaching, or other health-focused apps.

   Response options: Yes/No/Unsure

2. If yes:

   a) Which one(s)? - Free text

   b)How often? Daily, weekly, monthly, occasionally

Prompt after they complete the questions:

Thank you! As a reminder, we ask that you do not participate in any other research studies at UHN that use health-care apps. You can contact the ABODE Research Assistant at abodestudy@uhn.ca if you have any questions.

Version Date: 08-MAR-2023

Appendix 3. 1-10 Days Post-Operative Surveys

Post-Operative Questionnaire

SCREENING QUESTIONS

1. **Please confirm you've had your breast cancer surgery.** *(Day 1 only)*

□ Yes
□ No {if no, close the survey and send alert to RA to verify surgery date}

2. **Please confirm you had a {main surgery type}.** *(Day 1 only)*

□ Yes
□ No {send alert to RA to verify pathway}
□ If no, what surgery did you have? _____

3. **Please confirm it is {number of days} past your surgery. We're asking because this survey should only be filled out on certain days.** *(Day 1-10)*

□ Yes
□ No {if no, close the survey}

FOLLOW UP CARE

1. Did you feel you had all your questions answered prior to your discharge home from surgery? *(Day 1 AND 10 **only**)*

□ Yes
□ No
□ Prefer not to answer

{If no} What questions did you have that were not answered? _____

2. Since your discharge, have you had an unscheduled medical visit related to your surgery? Check all that apply. *(Day 10 **only**)*

□ No
□ Yes, at my family doctor {If yes} What was the date and reason? _____

□ Yes, at a walk-in clinic {If yes} What was the date and reason? _____

□ Yes, at an urgent care centre {If yes} What was the date and reason? _____

□ Yes, at the emergency department {If yes} What was the date and reason? _____

□ Prefer not to answer {If yes} What was the date and reason? _____

3. Since your discharge from surgery, have you tried to contact your surgery team outside of your scheduled appointments? *(**Daily** from Day 1-10)*

□ No
□ Yes

□ Prefer not to answer

{If yes} Did you get a reply?

□ No
□ Yes
□ Prefer not to answer

{If yes} What was the reason for contacting your surgery team? _____
{If no} If you need assistance with contacting your surgery team, send us a message on the chat.

PAIN *(Day 1 to Day 10)*

4. On a scale of 1 to 10, what is your pain score today?

0- no pain
1
2- mild and tolerable
3
4-distressing
5
6-intense
7
8-utterly horrible
9
10- the worst pain you have ever had
□ Prefer not to answer

4.

5. How much does pain interfere with your usual or daily activities?

□ Not at all
□ A little bit
□ Somewhat
□ Very much
□ Completely
□ Prefer not to answer

6. Have you noticed any of the following sensations: pins and needles, an electric shock sensation, burning sensation, numbness, the lightest touches causing pain (e.g., clothes on your skin), or painful itching?

□ Yes
□ No
□ Prefer not to answer

{If yes} How much does this kind of pain interfere with your usual or daily activities? (pins and needles, an electric shock sensation, burning sensation, numbness, the lightest touches causing pain, or painful itching)

□ Not at all
□ A little bit
□ Somewhat
□ Very much
□ Completely
□ Prefer not to answer

{Push after participant answers} *People experience pain in different ways after breast surgery. Some strange sensations are normal. They are often caused because your nerves are healing from surgery. If you are concerned about the amount of pain you're experiencing, you can call the surgical clinic or nurse navigator.*

7. In the last 24 hours, have you taken _____ to control your pain? (One medication per page on app)

Pain Medication	Number of Pills
Advil or Ibuprofen	□0 □1 □2 □3 □4 □5+ □ Prefer not to answer
Asprin or Acetylsalicylic Acid	□0 □1 □2 □3 □4 □5+ □ Prefer not to answer
Aleve or Naproxen	□0 □1 □2 □3 □4 □5+ □ Prefer not to answer
Tylenol or Acetaminophen (not including Tylenol 3)	□0 □1 □2 □3 □4 □5+ □ Prefer not to answer
Tylenol 3	□0 □1 □2 □3 □4 □5+ □ Prefer not to answer
Hydromorphone	□0 □1 □2 □3 □4 □5+ □ Prefer not to answer
Oxycodone	□0 □1 □2 □3 □4 □5+ □ Prefer not to answer
Gabapentin	□0 □1 □2 □3 □4 □5+ □ Prefer not to answer
Celebrex or Celecoxib	□0 □1 □2 □3 □4 □5+ □ Prefer not to answer
Cannabis	Free text entry

Other (including herbal/non-prescription drugs)	Free text entry

8. Do you feel that your pain is being well controlled with the medication you used?
□ Not at all
□ A little bit
□ Somewhat
□ Very much
□ Completely
□ Prefer not to answer

FEVER & SHORTNESS OF BREATH *(Day 1 to Day 10)*

9. Have you had a fever (temperature greater than 100.4 F or 38 C) in the past 24 hours?
□ Yes =
□ No
□ Prefer not to answer

{If yes} High fevers are not that common and it may be worth checking in with your care team. Send us a message through the chat if you need help getting their contact information.

10. Have you had shivering or shaking chills in the past 24 hours?
□ Yes
□ No
□ Prefer not to answer

{If yes} Shivering and chills is not that common and it may be worth checking in with your care team. Send us a message through the chat if you need help getting their contact information.

11. Have you had any shortness of breath in the past 24 hours?
□ Yes
□ No
□ Prefer not to answer

{If yes} Shortness of breath is not that common and it may be worth checking in with your care team. Send us a message through the chat if you need help getting their contact information.

FATIGUE *(Day 1 to Day 10)*

12. How much does the fatigue resulting from your surgery interfere with your usual or daily activities?

□ Not at all
□ A little bit
□ Somewhat
□ Very much
□ Completely
□ Prefer not to answer

INCISION *(Day 1-2)* *It is normal to have some bruising, tenderness, and a small amount of dried blood around the incision site or on the steri strips on your incision. You may also notice a pink/red colour to your skin. This could be on your chest, arm, neck, back and/or hip. This is the cleaner used during surgery. Feel free to take a wet washcloth and gently wash away the discolouration.*

13. Do you have concerns about your incision site?

□ No
□ Yes
□ Prefer not to answer

{If yes} What are your concerns? _____

INCISION *(Day 2-10)* *It is normal to have some bruising, tenderness, and a small amount of dried blood around the incision site or on the steri strips on your incision.*

14. Do you have concerns about your incision site?

□ No
□ Yes
□ Prefer not to answer

{If yes} What are your concerns? _____

15. Have you noticed redness around your surgical site(s) that is expanding? (Redness that is not caused by the antiseptic used in surgery.)

□ No
□ Yes
□ Prefer not to answer

16. Have you noticed bruising around your surgical site on your breast and/or underarm?

□ No
□ Yes
□ Prefer not to answer

{If yes} Is the bruising:

□ Severe
□ Very severe
□ Prefer not to answer

ANXIETY *(Day 1 to Day 10)*

21.How often do you feel anxiety about your recovery from surgery?
□ Never
□ Rarely
□ Occasionally
□ Frequently
□ Almost constantly
□ Prefer not to answer

OTHER *(Day 1 to Day 10)*

22. Are there any other concerns you have today?

_____ (allow no text entry)

□ increasing
□ decreasing
□ stable
□ Prefer not to answer

{If yes} Bruising that is increasing in size is not that common and it may be worth checking in with your care team. Send us a message through the chat if you need help getting their contact information.

Some soft swelling is normal after surgery for a few weeks. It is normal to have swelling at the breast or chest and up to an egg-sized swelling in the armpit.

17. Do you have swelling at your surgical site or armpit that is causing discomfort or bothering you?
□ No
□ Yes
□ Prefer not to answer

CONSTIPATION (Day 4, 6, 8 for AUTOLOGUS Participants only)

18. Since your operation have you been able to look after personal toileting and hygiene unaided?

□ None of the time
□ Some of the time
□ Usually
□ Most of the time
□ All of the time
□ Prefer not to answer

19. Have you had a bowel movement (pooped) in the past 2 days?

□ Yes
□ No
□ Prefer not to answer

{If no} 20. What is the severity of your constipation at its worst?

□ None
□ Mild
□ Moderate

Appendix 4. Breast Cancer Treatment Application Review Survey

P2. Program Satisfaction

1. How would you rate your overall program experience?
   a. Excellent
   b. Very good
   c. Good
   d. Fair
   e. Poor

2. Please comment on the rating that you selected. Any feedback is greatly appreciated and will be used to identify opportunities for improvement.

3. On a scale of 1-10, how likely are you to recommend this program to others?
   a. Not very likely (minimum score: 1)
   b. Very likely (maximum score: 10)

P3. Platform Experience

1. What device(s) did you access our platform, NextJ Connected Wellness on? Check all that apply.
   a. Computer or laptop
   b. Smartphone
   c. Tablet
   d. Other (Please specify):

2. How would you rate the ease of using our platform?
   a. Scale range (1-10); Step size (1)
   b. Very hard to use (minimum value)
   c. Very easy to use (maximum value)

3. On average, how much time did you spend on the program each week?
   a. Less than 15 mins
   b. 15-30 mins
   c. 31 mins - 1 hour
   d. 1-2 hours
   e. Other (Please specify):

4. Are there any challenges you are encountering with using our platform? If so, let us know here:

P4. Content

Throughout your program, you had access to educational content such as workbooks and resources in the Health Library.

1. Please indicate your agreement with the following statements about the workbooks:
   a. The workbooks helped me learn something new.
      i. Strongly Disagree (1)
      ii. Disagree (2)
      iii. Neutral (3)
      iv. Agree (4)
      v. Strongly Agree (5)
   b. The information in the workbooks was easy to follow and understand.
   c. The length of the workbooks was just right (not too short and not too long).
   d. The number of workbooks was just right (not too many or too little).

2. Please indicate your agreement with the following statements about the library:
   a. The library helped me learn something new.
      i. Strongly Disagree (1)
      ii. Disagree (2)
      iii. Neutral (3)
      iv. Agree (4)
      v. Strongly Agree (5)
   b. The information in the library was easy to follow and understand.
   c. The length of the library resources were just right (not too short and not too long).
   d. The number of library resources were just right (not too many or too little).
3.

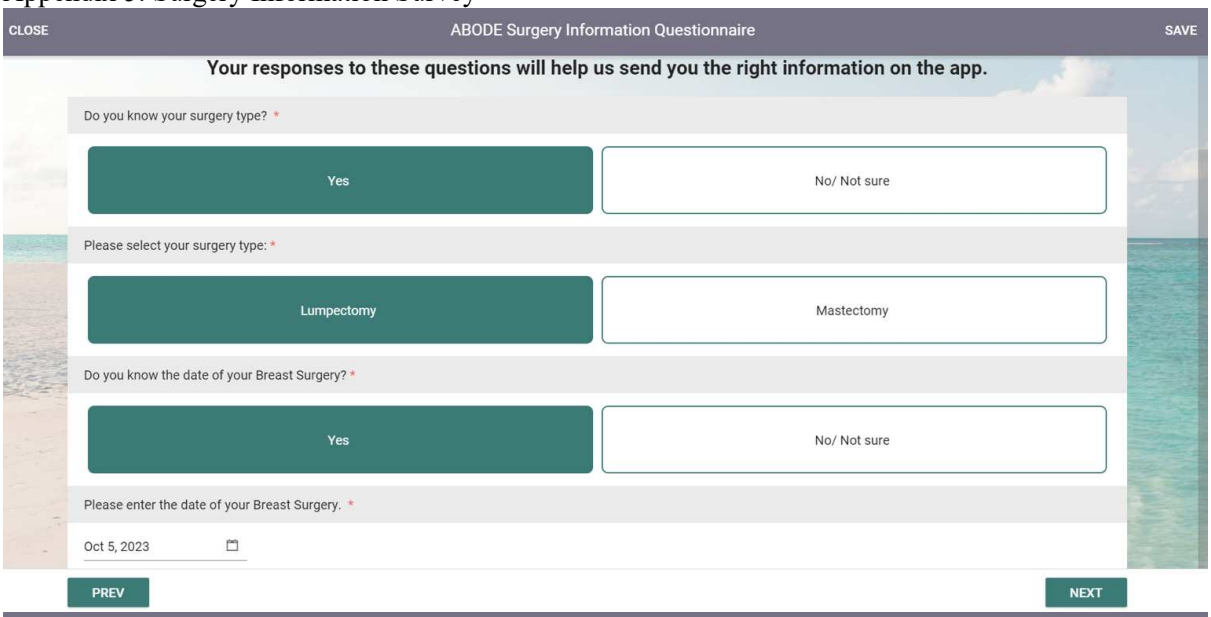
P5. Other Feedback

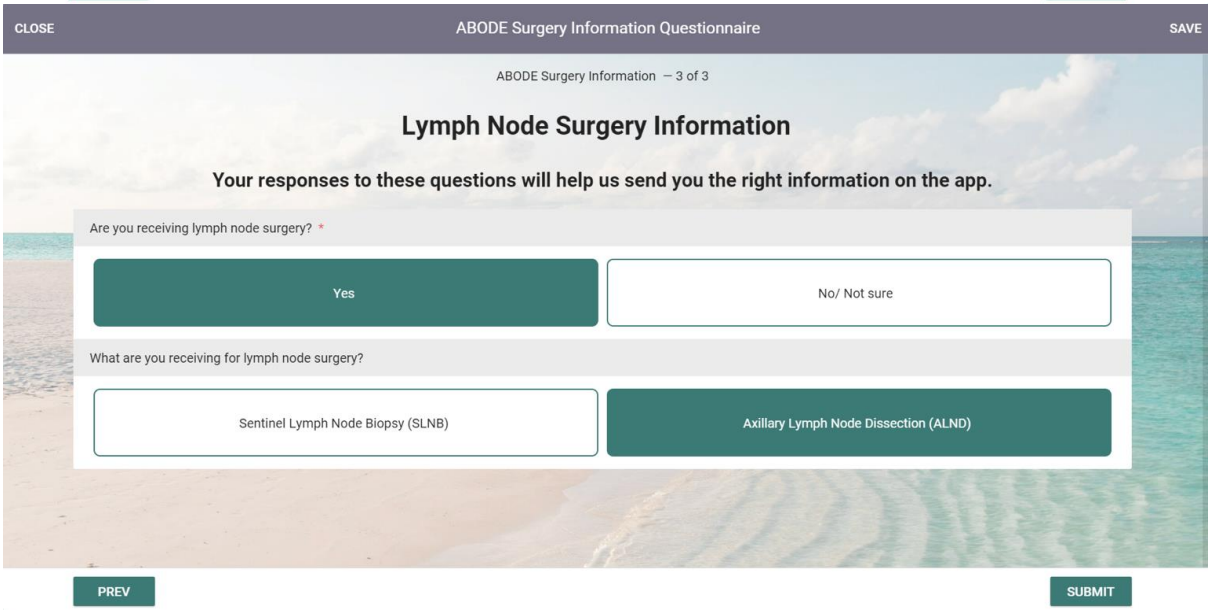
If you'd like to share other feedback about the program, let us know here:

P6. Thank You!

Thank you for your feedback. We appreciate your time and look forward to reviewing your responses.

Appendix 5. Surgery Information Survey





Appendix 6. Study Screening Form

STUDY SCREENING FORM

Study Title: The ABODE Study

Principal Investigator: Dr. Tulin Cil

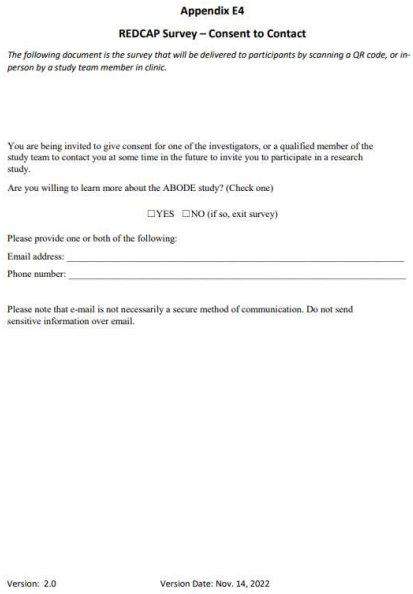
Please fill out this form before a potential participant is approached for informed consent.

Date of Assessment (dd/mmm/yyyy)	
MRN	
First Name	
Last Name	
Patient has access to an electronic device with internet connection (e.g., smartphone, tablet, desktop)?	☐ YES ☐ NO
Patient has been diagnosed with **early stage invasive breast cancer** & will have **surgery as the first step** in treatment?	☐ YES ☐ NO
Patient has a valid email address?	☐ YES ☐ NO
Patient can communicate in English?	☐ YES ☐ NO
Email Address	
Additional Comments	

Version: 2.0 Version Date: Nov. 14, 2022

Appendix 7. Recruitment Poster

Appendix 8. Consent to Contact Form



Appendix E4

REDCAP Survey – Consent to Contact

The following document is the survey that will be delivered to participants by scanning a QR code, or in-person by a study team member in clinic.

You are being invited to give consent for one of the investigators, or a qualified member of the study team to contact you at some time in the future to invite you to participate in a research study.

Are you willing to learn more about the ABODE study? (Check one)

☐YES ☐NO (if so, exit survey)

Please provide one or both of the following:

Email address: _____

Phone number: _____

Please note that e-mail is not necessarily a secure method of communication. Do not send sensitive information over email.

Version: 2.0 Version Date: Nov. 14, 2022