Study Title:

# Assessing the Usability and Workflow Impact of a Mobile-based Breast Cancer Survivorship Care Plan in the Oncology Practice

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MAYO CLINIC

Name and Clinic Number

**Approval Date:** **October 18, 2021**
**Not to be used after:** **July 8, 2022**

# RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

**Study Title:** Assessing the Usability and Workflow Impact of a Mobile-based Breast Cancer Survivorship Care Plan in the Oncology Practice

**IRB#:** 19-002448

**Principal Investigator:** Daniela Stan, MD, Summer Allen, MD and Colleagues

## Key Study Information

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| This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered. | |
| **It's Your Choice** | This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part. |
| **Research Purpose** | The purpose of this research is to investigate the usability of an interactive care plan to help with potential symptoms caused by the cancer treatments and to remind you to perform important tasks such as being active, checking your chest wall and breasts and obtaining mammograms, if needed.<br><br>You have been asked to take part in this research because you are a woman who was recently diagnosed and treated for breast cancer. |
| **What's Involved** | Study participation involves installing an app on your smart device, through which we will monitor your symptoms through monthly surveys and send education materials for self-management, if needed. We will also send daily notifications to keep active and monthly mindfulness education materials. You will be in this study for 12 months. |

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| **Key Information** | You will receive multiple surveys and notifications that may cause aggravation due to the time required to interact with these notifications. The questions addressing your quality of life may cause some psychological distress. You can choose to not answer the surveys and /or reminders.<br><br>You will not need to pay for being part of this study. There are no tests or procedures as part of this study.Benefits from being in this study may include alleviating the symptoms of fatigue, insomnia, hot flashes, and sexual dysfunction; increasing your physical activity level and improving your quality of life; and, feeling that the breast cancer care team is closely monitoring your symptoms and available to help in between your regular clinic appointments.<br><br>You do not have to participate in the study to continue receiving the same medical care from your breast cancer team. |
| **Learn More** | If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us. |

## Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

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## Contact Information

| If you have questions about … | You can contact … |
|---|---|
| ▪ Study tests and procedures<br>▪ Materials you receive<br>▪ Research-related appointments<br>▪ Research-related concern or complaint<br>▪ Research-related injuries or emergencies<br>▪ Withdrawing from the research study | **Principal Investigator(s):**<br>Daniela Stan, MD<br>**Phone:** (507) 284-2772<br>OR<br>Summer Allen, MD<br>**Phone:** (507) 226-4936<br><br>**Study Team Coordinator Contacts:**<br>Julie Maxson, CCRP<br>**Phone:** (507) 266-0284<br>Or<br>Stephanie Lindeen, RN<br>**Phone:** (507) 293-0233<br><br>**Institution Name and Address:**<br>Mayo Clinic<br>200 First Street SW<br>Rochester, MN 55905 |
| ▪ Rights of a research participant | **Mayo Clinic Institutional Review Board (IRB)**<br>**Phone:** (507) 266-4000<br>**Toll-Free:** (866) 273-4681 |
| ▪ Rights of a research participant<br>▪ Any research-related concern or complaint<br>▪ Use of your Protected Health Information<br>▪ Stopping your authorization to use your Protected Health Information<br>▪ Withdrawing from the research study | **Research Subject Advocate (RSA)**<br>**(The RSA is independent of the Study Team)**<br>**Phone:** (507) 266-9372<br>**Toll-Free:** (866) 273-4681<br>**E-mail:** researchsubjectadvocate@mayo.edu |
| ▪ Billing or insurance related to this research study | **Patient Account Services**<br>**Toll-Free:** (844) 217-9591 |

**Other Information:**
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

## Why are you being asked to take part in this research study?

You are being asked to be part of this research study because you were recently diagnosed and treated for breast cancer at Mayo Clinic, Rochester.

## Why is this research study being done?

We are conducting this study to assess the feasibility of delivering just-in-time educational materials through the Mayo Mobile App, to help monitor your recovery and alleviate the side effects of breast cancer treatments, and to improve your general quality of life. Our goal is to develop a new and convenient way to deliver breast cancer survivor care aimed to improve your symptom control and monitor your progress in between appointments.

## Information you should know

**Who is Funding the Study?**
The study is being sponsored by both the Department of Oncology and the Department of Family Medicine at Mayo Clinic, Rochester, MN.

**Information Regarding Conflict of Interest:**
No conflict of interest has been identified in this study.

Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

## How long will you be in this research study?

You will be in this study for 12 months.

## What will happen to you while you are in this research study?

At the beginning of the study, you will be asked to verify that you have the Mayo Mobile App and a Patient Online Services (portal) account on your mobile device (smartphone or tablet). During the study, you will be receiving monthly surveys of four common symptoms: fatigue, hot flashes, insomnia, and sexual dysfunction, asking you to rate these symptoms from 0-10. Based on your answers to these surveys, you may be offered educational materials that will be delivered through the App, to help with the bothersome symptoms. You have a choice to request more materials, if needed.

In addition, you will receive a monthly questionnaire to help identify any symptoms that may be associated with recurrence of your cancer; monthly reminders to perform breast and/or chest wall examinations; monthly links to mindfulness activities; daily reminders to be physically active; and, an annual reminder to obtain a mammogram, if applicable. At the beginning of the study and at months 1, 3, 6 and 12, you will receive a 29-questions quality of life survey to assess how this care plan impacts your general wellness changes over time throughout the study. You will also complete a Patient Self-Efficacy questionnaire to be completed at enrollment, Day 180 and at the end of the study. At 6 months and at the end of the study you will receive a Participant Satisfaction Survey, to help us understand your experience with the intervention.

## What are the possible risks or discomforts from being in this research study?

You may be bothered by the frequency of the reminders. If this happens, you can contact the study team to decrease the frequency. You may be disturbed by some of the quality of life questions that include assessment of your anxiety and depression levels. At any point during the study if you are feeling distress we ask that you contact a member of your breast cancer care team.

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

## Are there reasons you might leave this research study early?

You may leave this study at any time. Your medical care will not be compromised and you will receive the same medical care whether you chose to stay or leave the study. Reasons to leave the study early may include feeling that the educational information provided does not add value to your medical condition, if the reminders and surveys become a nuisance, or for any other reasons.

## What if you are injured from your participation in this research study?

**Where to get help:**
If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

**Who will pay for the treatment of research related injuries:**
Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. Treatment costs for research-related injuries not covered by your insurance will be paid by Mayo Clinic.

## What are the possible benefits from being in this research study?

Benefits from being in this study may include alleviating the symptoms of fatigue, insomnia, hot flashes, and sexual dysfunction; increasing your physical activity level and improving your quality of life; and, feeling that the breast cancer care team is closely monitoring your symptoms and available to help in between your regular clinic appointments.

## What alternative do you have if you choose not to participate in this research study?

You will continue receiving the same medical care from your breast cancer team, should you choose not to participate in this study. Other resources for dealing with symptoms and increasing the physical activity are available, such as printed materials, consultations with the Women's Health Clinic, Sleep Clinic, Psychology, and Physical Therapy, are available.

## What tests or procedures will you need to pay for if you take part in this research study?

You will not need to pay for being part of this study. There are no tests or procedures as part of this study.

**If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.**

## Will you be paid for taking part in this research study?

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

## Will your information or samples be used for future research?

Your information or samples collected for this study will not be used or shared for future research studies even if the identifiable information such as your name, Mayo Clinic number or date of birth is removed.

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## How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. Your information obtained from this study will be stored under a study number assigned to you, without any identifying information. The study number will be linked to your identifying information in a separate document, kept separately from the study information and available only to study personnel. All the data will be kept electronically in password protected documents.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

### Your health information may be collected from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

### Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

### Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- Other Mayo Clinic staff involved in your clinical care.
- The sponsor(s) of this study and the people or groups hired by the sponsor(s) to help perform this research.
- The Mayo Clinic Institutional Review Board that oversees the research.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- A group that oversees the data (study information) and safety of this research.

### How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you, but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media), information that identifies you will not be used.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

### Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

## Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

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You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
201 Building 4-60
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Subject Advocate at: researchsubjectadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts until the end of this study, unless you cancel it. The study does not end until all data has been collected, checked (or audited), analyzed, and reported. Because research is an ongoing process, we cannot give you an exact date when the study will end. Sometimes this can be years after your study visits and/or activities have ended.

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## Enrollment and Permission Signatures

**Your signature documents your permission to take part in this research.**

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature

**Person Obtaining Consent**

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature