Consent Form

Title of Research Study: App-Assisted Day Reconstruction to Reduce Treatment Burden and Logistic Toxicity in Cancer Patients

Investigator Team Contact Information: Rachel I. Vogel, Ph.D.

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

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Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

What is research?

- The goal of research is to learn new things in order to help people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.

Why am I being invited to take part in this research study?

We are asking you to take part in this research study because you are currently being treated for cancer by physicians associated with MHealth Fairview.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

Little research has been done on logistic toxicity - the toxic effects of the logistic burden of carrying out cancer treatment tasks on patient well-being. Steps can be taken that could reduce logistic toxicity in cancer care

delivery. However, implementing these interventions requires tools that can reliably track patients' behavior and well-being in navigating the day-to-day logistic burden of undertaking cancer treatment tasks.

The purpose of this study is to understand the time and logistic burdens of cancer care and to develop a mobile application that would help track these burdens.

How long will the research last?

We expect that you will be in this research study for up to 3 months with a total interaction time of about 90 minutes, including completing screening and consent (estimated 15 minutes), an interview (45 minutes) which will be recorded and a follow-up survey 2-3 months after completing the interview (15 minutes).

What will I need to do to participate?

You will be asked to participate in an in-person, phone or video interview with a member of our study team asking about sources of logistic toxicity for you and for your input on features that the mobile app should include. A few months later you will be sent an online survey to complete.

More detailed information about the study procedures can be found under "What happens if I say yes, I want to be in this research?"

Is there any way that being in this study could be bad for me?

You may not feel comfortable disclosing the information asked in the interview. You are free to skip any questions asked in the interview and follow-up survey. You may withdraw from this study at any time.

Will being in this study help me in any way?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others (especially cancer patients in general) include identification of logistic toxicity and tools to help measure and change it.

What happens if I do not want to be in this research?

There are no known alternatives, other than deciding not to participate in this research study.

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?

We expect about 20 people will be in this research study.

What happens if I say "*Yes, I want to be in this research*"?

If you agree to be in this study, we would ask you to do the following things:

1. Provide consent and complete a screening survey.
2. Participate in a recorded 45-minute interview led by a study team member.
3. Complete an online follow-up survey to review the user interface sketches and app function narratives.

What happens if I say "Yes", but I change my mind later?

You can leave the research study at any time and no one will be upset by your decision.

If you decide to leave the research study, contact the investigator so that the investigator can ensure you do not receive any additional study communication. The study team will use any data provided before you decided to leave the study unless otherwise specified.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. This means that your choice not to be in this study will not negatively affect your right to any present or future medical care.

What are the risks of being in this study? Is there any way being in this study could be bad for me? (Detailed Risks)

You may not feel comfortable disclosing the information asked in the interview. You are free to skip any sections of the follow up survey or questions asked. There is also some risk of a data breach involving the information we have about you. We comply with the University's security standards to secure your information and minimize risks, but there is always a possibility of a data breach.

Will it cost me anything to participate in this research study?

- There will be no cost to you for any of the study activities or procedures.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance. Daynamica, the company creating the mobile application, will also have access to your data. The University of Minnesota holds equity and royalty interests in Daynamica, pursuant to an exclusive license agreement with Daynamica. This relationship has been reviewed and managed by the University of Minnesota in accordance with its conflict of interest policies. If you would like further information about this interest, please contact Jon Guden, Associate Director, Conflict of Interest Program, at jguden@umn.edu.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

What will be done with my data when this study is over?

Your data will not be used for any future research after this study is complete.

Will anyone besides the study team be at my consent meeting?

You may be asked by the study team for your permission for an auditor to observe your consent meeting. Observing the consent meeting is one way that the University of Minnesota makes sure that your rights as a research participant are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the study team. The auditor will not document any personal (e.g. name, date of birth) or

confidential information about you. The auditor will not observe your consent meeting without your permission ahead of time.

Whom do I contact if I have questions, concerns or feedback about my experience?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

Will I be compensated for my participation?

If you agree to take part in this research study, we will pay you a $50 gift card for completing the interview and a $20 gift card for completing the follow-up survey.

Use of Identifiable Health Information

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Those persons who get your health information may not be required by Federal privacy laws (such as the 1099 Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission. Please read the HIPAA Authorization form that we have provided and discussed.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Consent Form

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

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