Multi-site Research Consent Form

Title of Research Study: ***Time toxicity of cancer: the time demands of cancer-related activities and their impact on well-being and quality of life***

This is a multi-site research study, meaning that the study is taking place at several locations. This consent includes two parts to explain the study. Part 1 describes the key information you need to know before deciding to participate in this study. Part 2 includes additional information about how the study will be carried out at this location.

Investigator Team Contact Information: ***Rachel I. Vogel, Ph.D.***
This study is being led by Rachel I. Vogel, Ph.D. at the University of Minnesota. You can contact Dr. Vogel by email at isak0023@umn.edu, phone at 612-624-6928 or by mail: 420 Delaware Street SE, MMC 395, Minneapolis, MN, 55455. To learn who is leading the study at this location and their contact information, see Part 2 of this consent form.

For questions about research appointments, the research study, research results, or other concerns, call the study team listed in Part 2 of this consent form.

Supported By: This research is supported by a research grant from the National Institutes of Health, National Cancer Institute.

University of Minnesota Financial Interest Disclosure: The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study. The University of Minnesota holds equity and royalty interests in Daynamica, the mobile app to be used in this study, 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. See Part 2 of this consent for any additional financial interests for this location.

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?

Doctors and investigators are committed to your care and safety. There are important differences between research and treatment plans:

- The goal of research is to learn new things in order to help groups of 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.
- The goal of clinical care is to help you get better or to improve your quality of life. Doctors can make changes to your clinical care plan as needed.

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

We are asking you to take part in this research study because you have been diagnosed with advanced stage ovarian or metastatic breast cancer and are currently receiving therapy for cancer at a participating clinic site.

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?

Cancer and its treatment can have multiple demands on patients' time, including time spent on care itself (appointments, taking medication), travel and wait times, and other activities such as scheduling, paperwork, dealing with bills and insurance, and organizing one's schedule in order to accommodate time for these activities. The purpose of this study is to measure the time patients spend on cancer-related healthcare using a mobile device and how these time demands affect quality of life.

How long will the research last?

We expect that you will be in this research study for approximately 28 days.

What will I need to do to participate?

You will be asked to install an app on your personal smartphone and complete daily short end-of-day surveys. Before using the app, you will be asked to complete a baseline survey. After the 28 days, you will be asked to complete an end-of-study survey.

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?

There is a possibility that you may feel uncomfortable answering questions on the survey, but you can skip any questions that you do not want to answer.

Will being in this study help me in any way?

There are no benefits to you from your taking part in this research.

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 key information listed above.

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 complete the study consent and HIPAA forms securely online or through the mail. You would then do the following items over the next 28 days.

1. Complete a baseline survey (~15 minutes).
    - Includes questions related to your physical and emotional symptoms and health following treatment
    - Will be provided in person, mailed, or sent online for completion
2. Download and install app from Google Play or Apple App Store on your smart phone.
    - Use the mobile app for 28 days
    - Keep smartphone location and motion services active
    - Confirm and correct detected activities and trips
    - Complete daily well-being surveys within the app
3. Complete a final survey (~15 minutes) on day 28.
    - Will be provided in person, mailed, or sent online for completion
4. Remove the app from your phone.

Specific details about where the procedures will take place locally are listed in Part 2 of this consent form.

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 surveys or mobile app. You are free to skip any sections of the follow up survey or questions asked. There is 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 (such as the Quality Assurance Program of the Human Research Protection Program (HRPP)). 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.

For additional information about what information might be shared with authorities, see "What may be shared with authorities?" in Part 2.

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

We will use and may share data for future research. They may be shared with researchers/institutions outside of University of Minnesota. We will not ask for your consent before using or sharing them. We will remove identifiers from your data, which means that nobody who works with them for future research will know who you are.

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 possible total of $175 for your time and effort.

For how you will be compensated at this location, ***"How will I be compensated at this location?" in Part 2 of this consent.***

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 for this location that we have provided and discussed.

How will my information be used in publications and presentations?

We may publish the results of this research in scientific, medical, academic or other journals or reports, or present the results at conferences. Information that makes it easy to identify you (such as your name and contact information, SSN and medical records number) will not be part of any publication or presentation. If you have an extremely unique or rare condition that is not shared by many others, it is possible that some people may be able to determine your identity even without these identifiers.

PART 2: LOCAL STUDY INFORMATION FOR UNIVERSITY OF MINNESOTA

Who can I contact if I have questions?

Local Investigator Name: Rachel I. Vogel, PhD Investigator Departmental Affiliation: Department of Obstetrics, Gynecology and Women's Health Phone Number: 612-624-6928 Email Address: isak0023@umn.edu	Local Study Staff: Katherine Brown Phone Number: 612-624-9904 Email Address: brow3238@umn.edu

How many people will be studied?

We expect about 40 people here will be in this research study out of 80 people in the entire study nationally.

Where will study activities take place locally?

Completing the surveys could happen online, through paper mailing, or in person at the time of a clinic visit. Downloading and using the mobile application will occur at home.

What may be shared with authorities?

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

How will I be compensated locally?

If you agree to take part in this research study, we will pay you up to $175 total: $25 for completing the baseline survey and downloading the mobile app, $125 for completing the mobile app 28-day data collection, and $25 for completing the post-study survey.

Payments will be made using a pre-paid debit card called Greenphire ClinCard. It works like a bank debit card. We will give you a debit card and each time you receive a payment for participation in this study, the money will be added to the card after each completed task.

You may use this card at any store that accepts MasterCard or you can use a bank machine to remove cash. However, there may be fees drawn against the balance of the card for cash withdrawals (ATM use) and inactivity (no use for 6 months). We will give you the ClinCard Frequently Asked Questions information sheet that answers common questions about the debit card. You will also receive letters with additional information on how you can use this card and who to call if you have any questions. Be sure to read these letters, including the cardholder agreement, for details about fees.

The debit card system is administered by an outside company. The company, Greenphire, will be given your name, address, and birthdate. They will use this information as part of the payment process. Greenphire will not receive any information about your health status or the study in which you are participating.

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