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Supporting **C**ollaborative Care to **O**ptimize **P**sychosocial **E**ngagement in the Cancer Setting (**SCOPE**) Study

RESEARCH STUDY CONSENT DOCUMENT

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We are asking you to be in a research study. The purpose of this Consent Document is to give you the information you will need to help you decide whether to be in the study. Please read the document carefully.

KEY INFORMATION ABOUT THIS STUDY

PURPOSE: The main goal of this study is to determine if new technology tools for patients and their clinical team can help improve patient care; decrease symptoms such as low mood, loss of interest in usual activities, difficulties with sleep, low energy, and poor concentration; and improve overall quality of life. **Your consent is being sought to participate in this research study.**

PATIENT CARE: All patients, whether or not they participate in this study, will receive psychosocial services as part of their cancer care.

PARTICIPATION: Your participation is completely voluntary and can be withdrawn at any time without penalty. Participation will last for up to 12 months, depending on where you are in your cancer treatment when you enroll in the study

STUDY DESIGN: Patients who decide to participate will be randomized (like flipping a coin) into one of two groups: 1) Technology-Enhanced Collaborative Care and 2) Usual Collaborative Care. At the end of the entire study (about 3-years), these two groups will be compared in terms of patient symptoms, daily functioning, quality of life, use of health care services, and other measures to determine if the new technologies had an effect on these outcomes.

STUDY PROCEDURES: Participants will be asked to complete a series of surveys at baseline (enrollment), and after 3-months, 6-months and 9-months. These surveys will take about 15-30 minutes to complete.

Some participants may be asked to have one or more of their sessions with their social worker audio–recorded. The purpose of recording the session is to assess the social worker's adherence to the Collaborative Care Model, not to gather information from or about you. You are free to decline this part of the study.

Participants assigned to the Technology group will be provided a link to a new web-based app that they can use on their phone, tablet, or computer. The app would allow participants to monitor their mood, symptoms, and activities, and to receive and share information with their clinical social worker. Content and usage data will be collected from the new app and participants may also be asked to participate in a one-hour interview or focus group.

PRIVACY AND CONFIDENTIALITY: All of your data will be assigned a unique study ID and be kept confidential on secure encrypted servers at the University of Washington.

RISKS, STRESS, OR DISCOMFORT: You may feel discomfort or stress from some of the questions asked on the surveys, or from having a social work session audio recorded. You are free to skip any of the questions and you are free to decline to have part or all of a session recorded. As with all research studies, there is also a risk that private information could be revealed. Although extremely unlikely, a breach in confidentiality and a resulting loss of privacy could be embarrassing and stressful.

BENEFITS: Participation may not benefit you directly. Filling out the follow up surveys may help you more closely monitor your symptoms and the knowledge gained from this study will contribute to advancements in helping patients with similar conditions in the future. If you are assigned to the Technology group, you may benefit from closer monitoring of your mood, symptoms and activities, and more timely sharing of information with your clinical social worker.

INCENTIVES: All participants will be sent e-gift cards for each survey completion as a thank you. Those selected and agreeing to be interviewed or in a focus group will be sent an additional e-gift card for their participation.

YOUR RIGHTS AS A PARTICIPANT: Some of the survey questions are sensitive. You are free to skip any question you don't want to answer. You may also decline to participate in specific study tasks, such as the possible audio recorded treatment session and interview or focus group. You may also withdraw from the study at any time without penalty or change in your care.

You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a participant, and anything else about the research or this form that is not clear by emailing us at scopestudy@uw.edu or calling us at 206-616-3032. You may review our Research Participants FAQ which answers common questions, the link accessible in this section and available at sites.uw.edu/scopestudy. You may also request a phone or Zoom appointment to go over this document and ask questions. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent."

If you decide to participate, at the end of this consent section, you would click YES - CONTINUE and you will be taken to a HIPAA Authorization form for review and approval. From there you will be directed to the baseline survey. This survey will take about 15-30 minutes to complete. You do not have to complete the survey at this time, but we request that you complete it within the next week. You can also start and save

your work and come back to it later. If you do not complete the survey at this time you will receive an email from scopestudy@uw.edu with the web link to continue the survey at a later time.

PURPOSE OF THE STUDY

A diagnosis of cancer often causes symptoms such as low mood, loss of interest in usual activities, difficulties with sleep, low energy, and poor concentration. Many people who receive a diagnosis of cancer report they have several of these symptoms. The main goal of this study is to determine if new technology tools for patients and their clinical team can help improve patient care, decrease some of these symptoms, and improve overall quality of life. The study is called the **S**upporting **C**ollaborative Care to **O**ptimize **P**sychosocial **E**ngagement in the Cancer Setting (**SCOPE)** Study.

PARTICIPANT SELECTION

This study is taking place at several cancer care centers in the Puget Sound area. All of these sites offer psychosocial care as part of their cancer care. Under this approach, clinical social workers meet with patients in person, through secure video conferencing, or over the phone to help patients decrease their distressing symptoms and improve their quality of life.

For the study, we plan to enroll about 400 patients from these study sites. Patients being treated for cancer who are experiencing distressing symptoms may be eligible to participate.

VOLUNTARY PARTICIPATION

Patient participation in this research is entirely voluntary. It is your choice whether to participate or not. Either way, you would receive psychosocial care, as well as the same cancer treatment as you normally would at your cancer center.

If you decide to enroll in the study, you may change your mind later and withdraw from the study at any time without penalty. If you decide to no longer be in the study, no new information will be collected from you. However, data previously collected may continue to be part of the study unless you specifically request to have all of your data removed.

STUDY PROCEDURES

Length of Study

Patient participation will be up to 12 months. Actual length depends on when in the course of your cancer treatment you enroll into the study.

Periodic Surveys

As a participant, you would be asked to complete a series of four surveys. The first set would be administered shortly after you enroll in the study. The second would be administered at about 3 months after enrolling, the third after about 6 months, and the fourth after about 9 months.

These surveys may be completed on a cell phone, a tablet, a computer, over the telephone or through video conferencing with research staff, or on a paper survey sent through postal mail, depending on your preference. We expect it will take you about 15-30 minutes to complete each survey.

The surveys ask about how you are feeling, how you are functioning, what you've been doing, how satisfied you are with different parts of your life, what health care services you are receiving, and related questions. You would not have to answer every question and are free to skip any questions you choose.

Access to Collaborative Care

All participants in the study will be provided Collaborative Care, which is a team-based approach to psychosocial care that is integrated and coordinated with a person's overall cancer care. Collaborative Care is currently part of standard care at Fred Hutch, but not at MultiCare.

Possible Access to New Technology

After completing the baseline survey, you would be randomly assigned (like flipping a coin) to one of two study groups:

(1) Technology-Enhanced Collaborative Care group (Technology group)

(2) Usual Collaborative Care group

If you are assigned to the Technology group, we would send you a link to a web-based app that you can use on your phone, tablet, or computer. We would provide instructions on how to use this app and how to receive additional assistance, as needed. The app would allow you to monitor your mood, symptoms, and activities, and to receive and share information with your clinical social worker. You would have access to this new app while you are enrolled in the study. The app would not access your contacts or browsing history; only the data entered directly through the app and data on how you use the app would be available to researchers.

If you are randomly assigned to the Usual Collaborative Care group, you would not receive a link to the new technology. Your care would otherwise be the same as those assigned to the Technology group.

Possible Interview or Focus Group (Technology-Enhanced Collaborative Care group only)

If you are assigned to the Technology group, you may also be asked to participate in an hour-long interview or focus group about your experience with the new technology. Participating in these interviews or focus groups is not required. If you are asked, you can decline and still be in the study. If you decide to participate in the interview or focus group, you can still change your mind during the event, or even afterwards if you decide you don't want your interview or focus group input to be used in the study.

Possible Recording of Social Work Session(s)

Part of our research will also look at how clinical social workers are delivering care. To do this, we plan to audio record some of their sessions. Recording sessions will allow researchers to better understand whether Collaborative Care is delivered as intended. These recordings will be made for research purposes only.

If your sessions are identified for recording, your clinical social worker would ask if you would be willing to have your session recorded for these research purposes. You do not have to agree to have the session recorded. You also have the right to stop the recording at any point, request deletion of any part of the recording, or ask for it not to be used after it is recorded. You can still continue in the study and will receive the same care, regardless of whether or not you agree to have your sessions recorded.

Data extracted from Electronic Medical Records and Clinical Social Worker's Patient Registry

Regardless of which group you are assigned to, we would collect the same kinds of data about you, your diagnosis, and your treatment from your Electronic Medical Record and from your clinical social worker's

patient registry. We would use this information to compare patient characteristics and outcomes between those in the Technology group and those in the Usual Collaborative Care group.

Summary

Aside from possible access to the new technology, study participants in both groups are treated the same. You would have access to the same care, be asked to complete the same surveys, and be provided the same value of gift cards. We would collect the same kinds of information about you and your care. Patients not participating in this study would receive the same cancer treatment and psychosocial care as you normally would at your cancer center.

Summary of Study Procedures & Incentives				
When	**Who**	**What**	**Time Required**	**Gift Card**
Baseline	All Participants	Survey	20-30 minutes	$50
3-Months	All Participants	Survey	15-30 minutes	$25
6-Months	All Participants	Survey	15-30 minutes	$50
9-Months	All Participants	Survey	15-30 minutes	$25
Between 3 and 12 months	Some participants assigned to the Technology group	Possible Interview or focus group	1 hour	$45

RISKS, STRESS, OR DISCOMFORT

You may feel discomfort or stress from some of the questions asked on some of the surveys, or from having a social work session audio recorded. You are free to skip any of the questions and you are free to refuse to have part or all of a treatment session recorded.

If during the course of this study you inform study staff that you are having thoughts of harming yourself in some way, study clinicians will assist you in getting additional help. This may include talking with you and/or your health care providers to further evaluate these risks.

If you participate in a focus group, there is a risk that your identity or experiences shared within that group may be communicated to someone outside the group. This risk exists even though we will not collect private or sensitive information from the focus groups and will instruct all participants not to share identifies or input from the focus group with anyone outside the group.

As with all research studies, there is a risk that private information may be revealed. Although the research team will make every effort to protect your private information and guard against any loss of privacy, accidental breaches in confidentiality do sometimes occur. Although extremely unlikely, a breach in confidentiality and a resulting loss of privacy could be embarrassing and stressful.

BENEFITS

You may not directly benefit from participating in this study. However, filling out the follow up surveys may help you more closely monitor your symptoms. You may also benefit from knowing that knowledge gained from this study will contribute to improving the care, health, functioning, and quality of life of those with cancer. If you are assigned to the Technology group, you may benefit from closer monitoring of

your mood, symptoms and activities, and more timely sharing of information with your clinical social worker.

SOURCE OF FUNDING

This study is funded by the National Cancer Institute (NCI).

COST, INCENTIVES, AND COMPENSATION

There is no cost to you for participating in this study. We will send you via email a $50 electronic gift (e-gift) card for completing the baseline survey, a $25 e-gift card for completing the 3-month survey, a $50 e-gift card for completing the 6-month survey, and a $25 e-gift card for completing the 9-month survey, for a possible total value of $150. You will be given a choice of at least two types of e-gift cards. These will be distributed within 2 weeks of survey completion. If you are selected for and participate in an interview or focus group, you would be sent an additional electronic gift card valued at $45.

Please note UW policy requires that we track and report gift card distributions to UW Financial Management. If in the course of a single tax year you end up participating in multiple studies with the UW and receive more than $600 in incentives/compensation, the University will need to report these distributions as miscellaneous income to the IRS.

RESEARCH-RELATED INJURY

If you believe your participation has caused harm, please contact the study's Principal Investigator, Jesse Fann at 206-606-1030, the study's Research Team at 206-616-3032, or email us at scopestudy@uw.edu. Alternatively, you may contact the Human Subjects Division at (206) 543-0098 or hsdinfo@uw.edu .

USE OF DATA IN FUTURE RESEARCH

The information we obtain from you for this study might be used in future studies. We will remove anything that might identify you from the data. Once we do, that information may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

CONFIDENTIALITY OF RESEARCH INFORMATION

The data we collect in this study will be held confidential on a secure server at the University of Washington. Your contact information (name, email address, phone number) will be used only for administering study activities. All the data collected from you will be de-identified and assigned a Unique Study ID. The link between your identifying information and your Study ID will be kept in a separate password-protected computer file with access given only to a few researchers involved in the study. This Master Key, the link between your identifier and the research data, will be destroyed after the records retention period required by state and/or federal law.

Study data may be shared in presentations and published research. Any mention of names or associations that could reveal participant's identities will be removed.

We have a Certificate of Confidentiality from the National Institutes of Health (NIH). This helps us protect your privacy. The Certificate means that we do not have to give out information that could identify you, even if we are asked to by a court of law. We would use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the institutions conducting the research, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- legal authorities, if we learn of child abuse, elder abuse, or intent to harm others;
- clinical authorities, if we learn of the intent to harm yourself.

The Certificate expires when NIH funding for this study ends. Currently this is June 30, 2025. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected.

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.

QUESTIONS?

If you have questions about this research or decide you no longer want to participate, or if you believe your participation has caused harm, please contact the research team at scopestudy@uw.edu or 206-616-3032. You are also free to contact any of the researchers listed on the first page of this document with specific questions. If you have questions about your rights as a research participant, please contact the UW's Human Subjects Division at (206) 543-0098 or hsdinfo@uw.edu. If you need additional psychosocial services, please contact your clinical social worker. If you are in need of emergency services, please call 911 or the National Suicide Prevention Lifeline at 1-800-273-8255.