Informed Consent Agreement

Study Title: Evaluating the Impact of Digital Behavioral Interventions to Address Insomnia and Depression in Breast Cancer Survivors Using an Adaptive Design
Protocol #: IRB-SBS 7466

Please read this consent agreement carefully before you decide to participate in the study.

Purpose of the research study: Cancer can impact all aspects of life. While the primary focus of treatment is on eliminating or containing the cancer, the psychological toll can sometimes go unnoticed for breast cancer survivors. Researchers and clinicians do not have a lot of information about how we can provide psychological support through mobile technology.

The purpose of this study is to gather information about how people respond to and use digital health interventions delivered through technology like computers and smartphones. Our research team previously tested a behavioral smartphone app program called SPARK among breast cancer survivors and found it was able to improve their mood symptoms. Our team also tested a behavioral internet program called SHUTi among older adults and found it was able to improve their sleep. Both of these programs have the potential to significantly improve accessibility of care for the large number of breast cancer survivors who need mental and behavioral treatments. The ultimate goal of this project is to determine if SPARK and SHUTi can be used to improve the mood and sleep in breast cancer survivors. Your participation in this study will benefit future breast cancer survivors by finding accessible and cost effective ways of providing supportive care. SHUTi and SPARK are not FDA approved and that is why we are doing this research to see if they help breast cancer survivors with insomnia and mood symptoms.

What you will do in the study: You are being asked to be in this research study because you received news of a breast cancer diagnosis within the last 5 years. You do not have to take part in this study. You should only agree to take part in this study after reading this consent form and discussing it with the study team. You may also discuss this with your family, friends, health care providers or others before you make a decision. Taking part of this study is not expected to interfere, nor should it replace, any usual care you are receiving.

This entire study from this moment to the final thing you do will last approximately 14 months.

Study Schedule

Step	Weeks	Study Phase	What will I do?	Time required?
1	0	Screening	Complete Online Interest Form Review/Sign Consent Form Phone Interview	60 minutes
2	1	Pre-Assessment	Complete Questionnaires	30 minutes
3	2-11	Intervention (Phase 1)	Use Assigned Program/Intervention	360 minutes (6 hours)
4	11	Assessment after 9 weeks	Complete Questionnaires	30 minutes

(5)	(11-20)	Intervention (Phase 2, if needed)	Use Assigned Program/Intervention	360 minutes (6 hours)
6	20	Post- Assessment 9 weeks after Step 4	Complete Questionnaires	30 minutes
7	37	Post- Assessment 6 months after Step 4	Complete Questionnaires	30 minutes
8	63	Post- Assessment 12 months after Step 4	Complete Questionnaires	30 minutes

You will be asked to complete an Online Interest Form. You will answer questions about your mood, sleep, mood symptoms, cancer history, and willingness to do the study requirements. You will also provide contact information. Submitting the Interest Form does not guarantee that you will be able to participate in the study. It will allow us to save this data and contact you soon to determine if you may be eligible for the study.

If you appear to be eligible for the study, the Study Coordinator will contact you to arrange a phone interview. Additional details about the study will be provided during the call. This will typically occur within 48 hours of receipt of the online interest form but may take up to 7 days.

SCREENING (PHONE INTERVIEW)

- The Study Coordinator will call you at your appointment time.
- We will ask you to identify yourself. We will review the study's requirements, which include receiving a breast cancer diagnosis in the past 5 years and current mood and insomnia symptoms. You can discuss any questions or concerns you may have about participating in the study.
- Next, we may ask you some additional questions about your mood symptoms, cancer history, general health, and health history. You will also be asked questions about whether you feel suicidal. In cases of suicide risk, a clinical psychologist on the team may follow-up with you to ask some more questions.
- If you are eligible for the study, you will be sent a Welcome email with directions for accessing your assigned digital program.
- If you are not eligible for the study, you will be told at that time.
- If you agree to participate, you will do the following:
    - We will email you a unique website address to access the online consent form.
    - We will walk through this consent form with you to make sure you are fully informed about the study.
    - If you would like additional time to review this consent form before agreeing to participate, we can set up a time to call back to continue the screening phone interview.
    - If you agree to participate in this study, you will check the box at the bottom of the electronic version of this form and digitally sign your name to consent to the study. Click submit.
    - The program will allow you to download a copy of the consent form. We will store the document in our database as well.

PRE-ASSESSMENT

- **Questionnaire:** You will complete an online Questionnaire asking about your general health, sleep, mental health, health habits, and daily life activities.

- If you have any concerns about the questions, please contact the Project Investigator (email: pic2u@uvahealth.org, or call toll-free: 1-833-762-0853).
- You may receive reminder emails from our study team to complete the Questionnaire.
- After you complete it, you will advance to the Intervention study phase. For the next 9 weeks, you will use your assigned program. You can start immediately.

PHASE 1 INTERVENTION

You will be randomly assigned to 1 of 3 study groups. You are just as likely to be assigned to one group as any other group. Neither you nor the researchers can choose, or change, your group.

GROUP 1 - Patient Education Group:

You will use an internet program containing general health information. This includes topics related but not limited to exercise, bone health, sun exposure, diet, dietary supplements, microbes, respiratory viruses, heart health, and posture. You may access the program as often as you want. Each topic takes approximately 30-45 minutes to complete. The information in this program is scientifically supported and based on the most up to date information.

GROUP 2 – SPARK Group:

You will use a smartphone app program designed to improve your mood through brief and interactive exercises. It is made up of a suite of activities. Each one focuses on one skill related to mood or distress management. Each activity can be completed in a matter of minutes. Each activity contains step-by-step instructions to help change behaviors and thoughts that can contribute to mood symptoms. You may receive automated prompts from the activities encouraging you to engage with them. Each week, you will use 1 of the SPARK activities until you have tried all of them. You are encouraged to continue using the activities that you find helpful and to discard the ones that are not. We expect it may take you up to one week to benefit from each activity. SPARK has been tested in a recent study involving women with breast cancer.

GROUP 3 – SHUTi Group:

You will use a website program designed to provide tailored instructions about how to improve your sleep. The program is made up of six Cores which are like chapters in a book. Cores are completed one at a time in order. Each Core is expected to take 45 to 60 minutes to complete. Each Core contains information and exercises designed to help change behaviors and thoughts that can contribute to sleep problems. You will receive automated emails encouraging you to complete tasks. You will be asked to complete weekly to dos and enter daily Sleep Diaries to track your sleep. We expect it may take you up to one week to complete a Core. After you complete a Core, you will have one week to review and practice what you learned in the Core. Seven days later the next Core will unlock so you can open it to start it. To review and follow the Core recommendations may take you another 30 to 45 minutes. SHUTi has been tested extensively in the general population as well as a recent study involving women with breast cancer.

ASSESSMENT AFTER 9 WEEKS AND PHASE 2 INTERVENTION (if needed)

After using your assigned program for 9 weeks, you will complete the post 9 week assessment online. You will answer questions about your sleep, mood, health, activities, and well-being. You may receive reminder emails to complete this assessment.

If you were assigned to either SPARK or SHUTi for the first 9 weeks, you may be randomly assigned (like the flip of a coin) to receive an added program— SPARK or SHUTi— whichever program you did not receive initially, for another 9 weeks. The determination of whether you will be randomly assigned depends on your responses to this assessment. If you were assigned to the Patient Education you will not receive an added program.

FOLLOW UP POST ASSESSMENTS

You will complete Post-Assessment Questionnaires online 9 weeks later, 6 months later, and 12 months later. These assessments will be similar to the pre-assessment and assessment after 9 weeks. You will answer questions about your sleep, mood, health, activities, and well-being. You may receive reminder emails to complete these Post-Assessments.

Time required: The study will require about 15-16 hours of your time. This is only a rough estimate that includes all assessments and intervention activities, as well as a possible phase 2 intervention that is not applicable to everyone in the study. All components of this study will be completed remotely, by Internet or phone.

Risks: Risks and side effects related to completing the questionnaires and using the apps include:

Breaches of privacy and/or confidentiality

- The risk of a violation of privacy and confidentiality is rare. This means someone outside of the study team may see your private health information. The study team will take precautions to treat your information as highly sensitive.

Emotional discomfort due to:

- **Internet concerns**
  Some adults may not have concerns doing online activities (going to a website, giving information, etc.). Others may feel less comfortable doing this. Some may have concerns about the confidentiality of their digital data.
- **Answering questions of a personal nature**
  Questions of a sensitive and personal nature will be asked during the study during the phone screen. These include questions about medical history, depression, and sleep. This may cause some slight emotional discomfort for some. If you do not wish to answer a question, you may skip it and to the next question.
- **Increased tiredness due to restricted time in bed (only applicable to those who receive SHUTi)**
  - You may contact us if you have significant concerns. We will provide recommendations based on your situation.
  - You will be told to avoid operating a car or other heavy machinery when you feel tired.
  - We will instruct you to contact your primary care provider or seek professional help at a sleep clinic as needed.

Benefits: We cannot promise that you will be helped by being in this study. You may benefit from being in this study, particularly with improvements in your sleep and mood. Information researchers get from this study may help others in the future.

Confidentiality: The information that you give in the study will be handled confidentially. Your information will be assigned a code number. The list connecting your name to this code will be kept in a

locked file. When the study is completed and the data have been analyzed, this list will be destroyed. Your name will not be used in any report.

Who will see your private information?

- *The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results*
- *People or groups that oversee the study to make sure it is done correctly*
- *The sponsor(s) of this study, and the people or groups it hires to help perform or review this research*
- *People who evaluate study results, which can include sponsors and other companies that make the drug or device being studied, researchers at other sites conducting the same study, and government agencies that provide oversight such as the Food and Drug Administration (FDA) if the study is regulated by the FDA.*

If you tell us that someone is hurting you, or that you might hurt yourself or someone else, the law may require us to let people in authority know so they can protect you and others.

Voluntary participation: Your participation in the study is completely voluntary.

Right to withdraw from the study: You have the right to withdraw from the study at any time without penalty.

How to withdraw from the study: If you want to withdraw from the study, please send an email or letter to the researchers listed on this form. There is no penalty for withdrawing. You can still receive payment for the study. Payment can be prorated based on what study components you have completed. If you would like to withdraw after your materials have been submitted, please contact

Philip Chow, Ph.D.
Department of Psychiatry and Neurobehavioral Sciences
P.O. Box 400400, Charlottesville, VA 22904-0400
Email: pic2u@uvahealth.org

Payment: You will be paid up to $140 in gift cards for finishing this study. The gift cards will be sent about a week after you complete each assessment listed below. If you do not finish the study, you will be paid based on your completion of the following:

- $40 after completing the Assessment after 9 weeks (Step 4, Study Schedule table on pgs. 1-2)
- $30 after completing the Assessment 9 weeks later (Step 6)
- $30 after completing the Assessment at 6 month follow up (Step 7)
- $40 after completing the Assessment at 12 month follow up (Step 8)

All payments will be sent via email. If you decide not to finish this study, you will be paid based on the assessments that you complete as noted above. However, if the study leader decides you should not continue, but you met full criteria and completed the necessary steps in the timeline presented, you will be paid the full amount for the study.

Using data beyond this study: The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

Information obtained from you during this study may be used in future research. Your information may be shared with other researchers inside or outside of the University of Virginia. They will not be sent with information that could identify you such as name, address or phone number.

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.

Please contact the researchers on the study team listed below to:

- **Obtain more information or ask a question about the study.**
- **Report an illness, injury, or other problem.**
- **Leave the study before it is finished.**

Principal Investigator: Philip Chow, Ph.D.
Department of Psychiatry and Neurobehavioral Sciences
P.O. Box 400400, Charlottesville, VA 22904-0400
Telephone: 434-924-8082
Email: pic2u@uvahealth.org

You may also report a concern about a study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

Tonya R. Moon, Ph.D.
Chair, Institutional Review Board for the Social and Behavioral Sciences
One Morton Dr Suite 400
University of Virginia, P.O. Box 800392
Charlottesville, VA 22908-0392
Telephone: (434) 924-5999
Email: irbsbshelp@virginia.edu
Website: https://research.virginia.edu/irb-sbs
Website for Research Participants: https://research.virginia.edu/research-participants

UVA IRB-SBS # 6002

You may print a copy of this consent for your records.
You will also receive a copy of your signed consent via email.

Electronic Signature Agreement:

☐ I agree to provide an electronic signature to document my consent

Study Agreement:

☐ I agree to participate in the research study described above.