Informed Consent Form for Participation in a Research Study

The SEAMLESS Study: A randomized waitlist-controlled trial evaluation of a SmartphonE App-based MindfuLnEss intervention for cancer SurvivorS

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PROTOCOL ID: HREBA.CC-18-0029
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STUDY COORDINATOR: Dr. Utkarsh Subnis; Contact: (403) 476-2465;
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WHY *Am* I BEING ASKED TO TAKE PART IN THIS RESEARCH STUDY?

You are being invited to participate in this research study because we are looking for cancer patients who have completed their cancer treatments. The purpose of this study is to test the effectiveness of a smartphone mobile-app based mindfulness program for cancer survivors. The program teaches individuals the principles of mindfulness and how to effectively apply them to deal with stress, illness, and the demands of daily life. Participants learn techniques such as meditation, relaxation, body awareness exercises, and gentle yoga through audio-recordings and interactive lessons available on the *Am* Mindfulness app.

Our research team has studied mindfulness-based interventions extensively for the past two decades in cancer patients. We first developed a face-to-face group-based program called Mindfulness-Based Cancer Recovery (MBCR). This MBCR program has shown a variety health benefits for cancer patients. These benefits include better management of stress, mood, the symptoms/side-effects of cancer treatments and better physical health and immunity. However, face-to-face MBCR may not be practical for many patients due to limitations such as travelling, scheduling conflicts and lower immunity.

Therefore, we are evaluating an app-based MBCR program, so you can take the program in the comfort and convenience of your home or preferred location. The basis for the current study is

to test if mindfulness techniques delivered to cancer survivors through the smartphone mobile app *Am* are effective in managing symptoms. Specifically, we want to know if app-based mindfulness can reduce, symptoms of stress, anxiety, depression, fatigue, and improve physical functioning in cancer survivors.

This informed consent form provides information about the study to assist you with making an informed decision. It should give you a basic idea of what the research study is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, please ask contact the study coordinator, Dr. Utkarsh Subnis (P: 403-476-2465, e: utkarsh.subnis@ahs.ca). Take the time to read this form carefully and to understand any accompanying information.

You are encouraged to ask questions, and can contact the study coordinator, Dr. Utkarsh Subnis (P: 403-476-2465, e: utkarsh.subnis@ahs.ca) at any time. When all your questions have been answered to your satisfaction, you can decide if you want to be in the study or not. If you decide to participate in this study, you will need to electronically sign and date this consent form. You will receive a copy of the signed form.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

We plan to enroll about 78 people in this study at the Tom Baker Cancer Centre.

WHAT WILL HAPPEN DURING THIS STUDY?

Individuals who are enrolled in the study, will participate for a total of one year. During this year, you will receive the app-based program for one month, and you will be required to access the app daily for 20-30 minutes. The other tasks involved in this study involve completing online surveys regarding your emotional and physical well-being. Answering the survey questions will take about 30-40 minutes at each time-point. You, will be asked to take surveys before the study starts (baseline), 2 weeks after starting the program, and at 3, 6 and 12 month marks after your enrollment, please see Table 1. The study as a whole should take about two years (24-26 months) to complete and the results should be known in about three years' time.

If you decide to participate then you will be "randomized" into one of the groups described below. Randomization means that you are put into a group by chance (like flipping a coin or pulling a name out of a hat). There is no way to predict which group you will be assigned to. You will have a 50% chance of being placed in either group. Neither you, the research staff, nor the researcher can choose what group you will be in.

- **What are the two groups in this study?**

We will be comparing two groups of patients. The first is the immediate intervention group, which will do the *Am* smartphone app-based mindfulness program immediately after enrollment. The second is the waitlist control group, who will be in a 3-month waiting period and will do the same app-based mindfulness program after 3 months. Both groups will have patients who have completed their cancer treatments at least 2 week prior to enrollment. There will be no group interaction between members of either group.

WHAT ARE MY RESPONSIBILITIES SHOULD I DECIDE TO PARTICIPATE IN THIS STUDY?

If you choose to participate in the research you will be expected to:

- Agree to be randomly assigned to the immediate intervention group or the waitlist control group (like the flip of a coin). You don't get to choose which group you get, we assign you.
- Complete the assessments and activities involved in this study are described in Table 1:

Table 1: Study activities by group for SEAMLESS Study

Study activity	Time(Weeks/Month)	Description of study activity	Study Group	
			Immediate Group	Waitlist group
Assessment 1-Baseline	Month 0	Answer online questionnaires	☑	☑
Intervention	Month 1	Take *Am*-app mindfulness program	☑	
Assessment 2	At 2 weeks	Answer online questionnaires at mid-point of the *Am*-app program	☑	
Waiting	Months 1, 2 & 3	Be in waiting period		☑
Assessment 3	Month 1.5 (6 weeks)	Answer online questionnaires after completing mindfulness program or after waiting period of 4-5 weeks	☑	☑
Assessment 4 (Follow-up)	Month 3	Answer online questionnaires after completing mindfulness program or after waiting period of 3 months	☑	☑
Intervention	Month 3 (or 3.5)	Take *Am*-app mindfulness program (waitlist group)		☑
Assessment 4a (Waitlist group)	Month 4	Answer online questionnaires at mid-point of the *Am*-app program		☑
Assessment 4b (Waitlist group)	Month 4.5	Answer online questionnaires after completing the *Am*-app program		☑
Assessment 5 (Follow-up)	Month 6	Answer online questionnaires (6 months after baseline assessment)	☑	☑
Assessment 6 (Follow-up)	Month 12	Answer online questionnaires (12 months after baseline assessment)	☑	☑

- Answer a package of survey questions online at each assessment point, which will take about 30-40 minutes. The online surveys ask questions that measure your symptoms and health status such as stress, anxiety, depression, fatigue, physical function.

Your Responsibilities (…Continued from above)

- You do not need to answer any question(s) that you do not wish to answer or may not feel comfortable with. You will be part of this study regardless of your responses to the questionnaires.
- When your program begins, you will be guided to download the *Am* Mindfulness app on your phone; the app is available on the Google Play store or Apple App store.
  - Play store: https://play.google.com/store/apps/details?id=com.mobiointeractive.wildflowers2
  - App store: https://itunes.apple.com/ca/app/am-mindfulness/id1300628961?mt=8
- If you do not have a data plan with your smartphone device, please contact our study coordinator, Dr. Utkarsh Subnis at 403-476-2465 or utkarsh.subnis@ahs.ca; he will provide you support with regards to obtaining a data plan.
- You will be required to access the *Am* mindfulness app daily for 20-30 minutes, and complete the tasks described in each unit of instruction, for example listening to guided meditation or dharma talk and writing a daily reflection journal.
- The app-based program will run for 4 consecutive weeks, and you can complete your tasks and activities at any time of the day that is convenient to you.
- The *Am* app will collect information with regards to how many times you have accessed the app, and whether you have completed the program.
- The *Am* app can also analyze data with regards to your indicators of stress, such as heart-rate, respiration, emotional state if you choose to input that information, by reporting it in the app through the mood-board feature, or from the color video of your face. Providing this data to *Am* (e.g. your stress, heart-rate etc.) is completely voluntary and not part of the primary outcome of interest in this study. It will provide us data for exploratory analysis.

WHAT WILL HAPPEN IF I CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

Participation in this research is completely voluntary. You are free to withdraw at any time. You can choose to end your participation in this research study (called early withdrawal) at any time without having to provide a reason and without penalty. Withdrawal from the study will not jeopardize your health care or entitlement to services offered through the Department of Psychosocial Resources of the Tom Baker Cancer Centre. If you decide to withdraw from the study, only the data you provided before withdrawing will be saved; this data helps us maintain an accurate record of patients in our study.

In the event that you do stop participating in the app-based program or inform the researchers that you are no longer interested in the study, we will ask you to complete a short phone interview about your reasons for dropping out of the group or study. This phone interview is voluntary and not mandatory, but will provide important information for future reference.

WHAT ARE THE RISKS/DISCOMFORTS OF PARTICIPATING IN THIS STUDY?

We have not identified any significant risks related to this study. The mindfulness activities are generally safe and you can avoid certain practices if you have any physical limitations. If you feel the need for psychological support or counsel, counseling services through the Department

of Psychosocial Resources, Tom Baker Cancer Center (403-355-3207) are available and are free of cost to cancer patients, including their family members and caregivers.

WHAT ARE THE POTENTIAL BENEFITS OF PARTICIPATING IN THIS STUDY?

If you agree to participate in this study, there may or may not be a direct benefit to you. If you have problems with stress or other symptoms, your condition may be improved during the study but there is no guarantee that this research will help you. However, the mindfulness meditation exercises are generally enjoyable and beneficial for most participants. The information we get from this study may help us to provide better treatments in the future for patients with symptoms of stress or other health problems.

WILL THERE BE COSTS INVOLVED WITH PARTICIPATING IN THIS STUDY?

Participation in the *Am* app-based group program is a free service for study participants, and you will not incur any expenses from your involvement.

WILL I BE COMPENSATED FOR PARTICIPATING IN THIS STUDY?

You will not be paid for your participation in this study. You will have access to the paid-version of the *Am* mindfulness app for 12 months.

HOW WILL MY PERSONAL INFORMATION BE KEPT PRIVATE?

If you decide to participate, the researcher and study staff will only collect information they need for this study. They will do everything that they can to make sure that this data is kept private/confidential. All information provided by you will be treated with full confidentiality. Initially participants will be assigned an ID number and this will be used on all forms and data collection tools to protect your identity. Data collected from you online will be stored in servers with the highest levels of encryption and password-protection which will be available only to the researchers and authorized study staff. Any hard copy data (paper etc.) will only be kept in the researcher's office under lock and key at the Holy Cross Centre. All data will be stored according to ethics board regulations following the completion of the study. We will keep your personal data and study records stored for 7 years after the end of the study.

No data relating to this study that includes your name will be released outside of the study site nor will it be published by the researcher. Sometimes, by law, the researcher may have to release information including names to regulatory bodies and therefore absolute confidentiality cannot be guaranteed. However, every effort will be made to make sure that your information is kept confidential.

The researcher or study staff will need to look at your Tom Baker Cancer Centre medical files/records or at those kept by other health care providers that you may have seen in the past (e.g., your family doctor). Any information that they get from these records will only be what is needed for the purpose of this study. It will be kept confidential to the extent permitted by the applicable laws and will not be disclosed or made publicly available, except as described in this consent document. The researchers will verify medical records using data collected and stored

within Alberta Health Services electronic medical records, always in accordance with the Alberta Health Information Act.

Data from your online surveys will be collected using the online survey program, REDCAP. This data will be stored in secured servers with appropriate firewalls which are managed by the Clinical Research Unit at the University of Calgary. Access to the REDCAP survey data is strictly restricted to the study staff.

Data collected by your *Am* mindfulness app will also be treated with strict privacy restrictions. The data on your app will be linked with a randomly generated study ID#. The key to the study ID# will not be available to *Am*'s developer, *Mobio Interactive*, Inc. Hence, no personnel at Mobio will be able to identify you as a participants from this study, as the data will be tagged with ID#s. If you choose to use the selfie camera to see you biological stress levels, there will be no recording of your video that will be generated or stored in *Am* or anywhere else. More details about this process can be found on our study website: www.seamless-study.ca (website under development). After every 3 days, Mobio Interactive will provide us information about your attendance on the app through an encrypted spreadsheet file delivered through a secure shared cloud storage (Dropbox) folder. We will then securely store this data on our servers for analysis. Only the study staff will have the ability to decode this file and find out your attendance on the app.

However, given the on-line nature of the study, there are always security risks, hence we cannot give an absolute guarantee of privacy. Please know that the study team, along with App developers are using the latest security protocols and data networks conforming to the most rigorous standards of data protection and privacy. Also all research and app data will be stored in servers located in Canada, and will never leave Canadian borders.

All research data gathered for the study may be used within presentations, publications, and other research purposes. Whenever your data is used for research purposes, no personal information will be included and your identity will always be kept confidential.

WHAT ARE MY RIGHTS AS A PARTICIPANT IN THIS STUDY?

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study. You have the right to be informed of the results of this study once the entire study is complete. If you would like to be informed of these results, please sign up for our online study newsletter available at our website: <seamless-study.ca/signup; *site under development*>. In this newsletter we provide participants with ongoing and updated information regarding this study every three months, such as number of people enrolled in the study, as well as results regarding the effectiveness of app-based mindfulness interventions.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected. By signing this form, you do not give up any of your legal rights against the hospital, researchers, sponsor, institutions or their agents

involved for compensation, nor does this form relieve these parties from their legal and professional responsibilities.

IS THERE ANY CONFLICT OF INTEREST RELATED TO THIS STUDY?

The developers of the *Am* app are co-investigators on this project, namely Mark Thoburn and Bechara Saab; who are the co-founders of Mobio Interactive Inc., which was incorporated as an Ontario corporation in 2013, and both are majority shareholders of the company at ~40% each.

No conflicts of interest have been declared by the principal investigator or any other co-investigator.

IF I SUFFER A RESEARCH-RELATED INJURY, WILL I BE COMPENSATED?

In our experience, participants have not experienced any serious injury from participating in mindfulness programs. In the event that you suffer injury as a result of participating in this research, no compensation will be provided to you by The Tom Baker Cancer Center, the University of Calgary, Alberta Health Services or the Researchers. You still have all your legal rights. Nothing said in this consent form alters your right to seek damages.

WHERE CAN I FIND ONLINE INFORMATION ABOUT THIS STUDY?

A description of this study will be available on <www.seamless-study.ca> *(website in development)*. This website will not include information that can identify you. You can search for this website at any time. Also, this study has been registered at the clinicaltrials.gov database, and a description of this study is available at https://clinicaltrials.gov/ct2/show/NCT03557762

WHO DO I CONTACT FOR QUESTIONS RELATED TO THIS STUDY?

If you have questions about taking part in this study you should talk to the study coordinator or the principal researcher. These persons are listed below:

Study Research Assistant: Katherine-Ann Piedalue: 403-476-2455 katherine-ann.piedlue@ahs.ca
Study Coordinator: Dr. Utkarsh Subnis; Phone: 403-476-2465; email: utkarsh.subnis@ahs.ca
Study Principal Investigator: Dr. Linda E Carlson; Phone: 403-355-3207; Fax: 403-283-6032
Email: l.carlson@ucalgary.ca

If you have questions about your rights as a participant or about ethical issues related to this study and you would like to talk to someone who is not involved in the conduct of the study, please contact the **Office of the Health Research Ethics Board of Alberta.**
Telephone: 780-423-5727 | Toll Free: 1-877-423-5727

UNDERSTANDING AND SIGNATURES PAGE

If you choose to be part of this study, we will need your consent. In order to provide consent to participate in this study, please click "YES" to all the questions provided below, then click the "I agree" box above the consent statement, and enter your first and last name in the box below.

Yes **No**

Do you understand that you have been asked to take part in a research study?	☐	☐
Do you understand why this study is being done?	☐	☐
Do you understand the potential benefits and risks/discomforts of taking part in this study?	☐	☐
Do you understand what you will be asked to do should you decide to take part in this study?	☐	☐
Do you understand that you are free to leave the study at any time, without out having to give reason or without penalty?	☐	☐
Do you understand that we will be collecting information about you for use in this study only?	☐	☐
Do you understand that by signing this consent form you are allowing the study team to verify information about you from your personal medical records?	☐	☐
Do you understand that by signing this consent form that you do not give up any of your legal rights?	☐	☐
Do you feel that you had enough time and opportunity to consider the information provided to you by way of asking questions, having conversations with others and considering your options?	☐	☐

By clicking on "I agree" below, you are indicating that you have understood to your satisfaction the information regarding your participation in this research project and agree to participate. In no way does this waive your legal rights nor release the investigators or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing your health care. Also, please enter your name (First name, Last name) and select the date in the fields below.

☐ I AGREE ☐ I DISAGREE

By checking this box and typing my name below, I am electronically signing this consent form

Enter your name (First name, Last name) DATE <Survey Tool> <DD/MM/YYYY> and <Time>

SUBMIT

** The research ethics board, which oversees the ethical conduct of research involving humans, has reviewed and accepted this study (Ethics ID: HREBA.CC-18-0029). **