INFORMED CONSENT TO BE A RESEARCH SUBJECT AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**PranaScience Institute LLC / "Pilot study of group video Yogic breathing app in breast cancer survivors"**
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KEY INFORMATION

Breast cancer remains a leading cause of cancer deaths; however, recent improvements in treatment have improved survivorship. As a result of this improvement, more individuals are living with the long-term side effects of cancer treatment. Therefore, methods that incorporate lifestyle and mind-body approaches are becoming increasingly used in the patient treatment pathway. In this pilot study, PranaScience Institute will develop and test a group video mobile application (study app) for Yogic Breathing (YB). YB is shown to reduce symptomatic conditions associated with several conditions including breast cancer. For this initial feasibility study, PranaScience will collaborate with the Medical University of South Carolina (MUSC) to implement the study app-based program in breast cancer survivors. This research will study the study app to understand if the YB could be delivered via the study app, if participants are able to practice it satisfactorily, and if there is any symptom relief by the YB practice. In the control group, participants will be directed to the Attention Control (AC) feature of the study app, which guides users to focus on a mindfulness activity not involving yogic breathing. Participants will be randomly assigned to the YB or AC study plan (with 20 participants per group). Breast cancer survivors who have completed radiation therapy within last 2 months will be recruited for this study and provided access to the study app for a 12-week program. The study app will record total practice times (how long, and how often). Virtual visits by a study yoga instructor during group video sessions will measure participant compliance with proper technique. Feasibility will be examined by evaluating intervention delivery factors (for example, ease of use, satisfaction, barriers) and resource needs (for example, staff time, session length, software or mobile connection challenges). Acceptability of using the mobile study app to support symptom management for participants will be evaluated using a satisfaction and system usability scale. Behavioral survey measures will help guide effect sizes and power calculations for the next larger-scale study (for example, perceived stress, anxiety, depression scale,

symptom inventory). Biomarkers in the saliva (tumor suppressors [genes that help regulate cell division and replication], cytokines [proteins affecting cells in the immune system]), and fingernails (cortisol [a steroid hormone that plays a role in the body's metabolism, immune system, and stress response], proteomic [protein] changes) will be measured at baseline (beginning) and end of study at 12 weeks. All findings from this pilot study will be synthesized to refine the mobile study app in preparation for large-scale evaluation in Phase II involving all-study site participants with cancer.

An investigator on this study has an ownership interest in PranaScience. As a result, the investigator may benefit financially from a successful study. Additional steps have been taken to manage the potential conflict of interest that this financial arrangement may create. Please speak with your study doctor if you have questions about this.

A. PURPOSE OF THE RESEARCH

The purpose of this study is to develop and test a group video mobile study application that will train participants with breast cancer to practice a breathing exercise in hopes of improving symptom management.

- Information from this study will be used to design future large-scale studies to determine the effectiveness of the mobile study app in cancer survivorship and stress management.

Please read this consent form carefully and take your time making your decision. As your investigator or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. You are being asked to participate in this study because you have breast cancer and have completed radiation treatment in the last two months. The study is sponsored by the National Institutes of Health. Approximately 40 people will take part in this study in total.

B. PROCEDURES

Following consent and enrollment onto study, you will have a pre-study visit (week 1). During this pre-study visit at the study site, which will consist of small groups (2-5 people), we will collect information on the following privately from you and other participants: your perceived levels of stress, depression, anxiety, sleep quality, and cancer symptom distress as well as information about your demographics and medical history using standardized questionnaires. After this private data collection step, you will join a group training session with a yoga instructor to familiarize you with the study app features and the study YB exercise.

Prior to and following the YB exercise, we will collect your saliva samples (about half a teaspoon by passive drooling into a tube). We will also collect your nail clippings from 8 of your fingernails (self-clipping using a clean nail clipper). You will attend another session on week 12, again consisting of 2-5 people, at which time point the data will be

collected as in the first visit. Additionally, we will ask you to fill a questionnaire on how easy it was to use the mobile study application.

You will also be asked to attend a focus group meeting at the study site within one month of the 12 week visit where you will be asked how you feel about the program and the study app, and the meeting will be audiotaped for identifying themes. The information you provide will be helped to inform future study application design changes.

In between study visits, you will be asked to use the mobile study app, completing 3, 10 minute exercises, 5 days a week. You will be randomized (like the flip of a coin) to one of the yogic breathing (YB) or attention control (AC) groups. Those in the AC group will do a mindfulness practice guided by the mobile study application. In addition, you will be contacted by a study staff member weekly to remind you to comply with the exercises. The mobile study applications will also send "nudges" and reminders throughout the day. You will engage with the research study app (YB or AC) along with other participants in groups of 2-7 at your own convenience. You may practice the YB or AC activity with either a group of participants, through the video conferencing feature of the study app, or on your own. Information about how many times you practice YB or AC using the app, how long you practice, and how many times you practiced using the solo or group practice functions of the study app will be collected directly from the study app.

After the second study visit, you will be invited to participate in a sixty-minute focus group interview about your experience using the study app. This interview will be audio recorded.

C. DURATION

Participation in the study will take about three visits over a period of 16 weeks, as well as daily practices with the study app.

D. RISKS AND DISCOMFORTS

Yogic breathing (YB) or Attention Control (AC) exercises do not pose any potential physical and psychological risks to participants. The training provided at the beginning of the study will provide you with some familiarity with the exercises before you do them independently. Study staff are able to provide you with additional support should you need it throughout the study.

Given that some of the procedures take place in a group setting, there is a risk of loss of confidentiality and anonymity. We advise that information in group sessions should stay private and confidential and should not be shared outside of the research study visit. Your first name will be shared with other members in the group sessions, and other study app users involved with this study. You may choose to not use the camera feature or use an Avatar instead of your face during the group practices, if you do not

wish to appear on camera during this study. There are no known adverse events for the study procedures. There may be risks that are unknown.

Some people feel uncomfortable when answering questions about the quality of their life. Though it is always better to have fully completed questionnaires, you do not need to answer any questions that make you feel uncomfortable.

You will have audio recording of your voice, so there is the risk that someone may recognize your voice. However, once the audio recordings are collected, each audio file will be coded. The recordings will be transcribed by the study staff and no names will appear in the written transcripts. The audio files will be stored in a secure database that will only be accessed by study staff and will be destroyed after the study.

E. MEDICAL RECORDS AND/OR CERTIFICATE OF CONFIDENTIALITY

This research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers may not disclose information or biospecimens that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, nor can the information or biospecimens be used as evidence, unless you have consented to this disclosure. Information or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research participants.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you are an MUSC patient you have an MUSC medical record. If you have never been an MUSC patient, a MUSC medical record will be created for the purposes of this study. Results of research tests or procedures will be included in your MUSC medical record. All information within your medical record can be viewed by individuals authorized to access the record. We will make every effort to keep confidential all research information in the medical record that identifies you to the extent allowed by law; however, there is the possibility that your research information will be disclosed.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. Examples of required disclosure include: child abuse and neglect, or harm to self or others.

Finally, a Certificate may not be used to withhold information from the federal government needed for auditing or evaluating federally funded studies or information needed by the U.S. Food and Drug Administration (FDA).

F. BENEFITS

There will be no direct benefit to you from participating in this study. However, it is hoped that the information gained from the study will help the investigator learn more about the impact of a mobile study app on the practice of YB to manage symptoms of breast cancer survivorship.

G. COSTS

There will be no cost to you as a result of participation in this study.

H. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be paid $75 at the first visit (week 1) and $125 at the last visit (week 12) (totaling $200) for participation in this study. If you do not complete the study, you will receive $75 for the first visit.

Payments that you receive from PranaScience for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from PranaScience reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

I. ALTERNATIVES

Your alternative is to not participate in this study.

J. DATA SHARING

Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The investigator, the sponsor or persons working on behalf of the sponsor and, under certain circumstances, the United States Food and Drug Administration (FDA), the National Institutes of Health, and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. No information about you that is collected as part of this research (whether or not it is identifiable) will be used or distributed for future research studies under any circumstances. If you prefer to be contacted by the study staff we will save your contact details to inform you about future studies or the current study's updates.

K. DISCLOSURE OF RESULTS

The study results will be published in peer-reviewed journals, and reported to the funding agency. After the study's completion if you would like to receive a copy of your own results, you can get the study data provided by you and any biomarker data from

your own biospecimens. This data will not contain any comparison of your data with other study groups or participants in the study.

L. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, your investigator and study staff will keep records of your participation in this study.

The health information PranaScience may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

Your investigator and study staff will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study who may become involved if it is relevant;
- Health insurer or payer in order to secure payment for covered treatment;
- Federal and state agencies and PranaScience committees having authority over the study such as:
    - The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or other governmental offices, such as a public health agency or as required by law.

Those persons who receive your health information may not be required by federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

Your health data will be used to conduct and oversee the research, including for instance:

- To see if the study app works and is safe.
- To compare the study app to other apps.
- For other research activities related to the study app.

You do not have to sign and date this consent and authorization form. If you choose not to sign and date, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study. You have the right to withdraw your authorization at any time. You can do this by giving written notice to your investigator at the address listed on the first page of this form. If you withdraw your authorization, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed and dated authorization from you.

M. SIGNIFICANT NEW FINDINGS

If there are significant new findings during the course of the study, you will be notified via the contact information you provided.

N. CLINICALTRIALS.GOV

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.

O. SPONSOR COMMITMENT

PranaScience Institute LLC (the “Sponsor”) is committed to teaching people to breathe better. The methods that the Sponsor uses are adopted from traditional breathing exercises published in the scientific literature, and are generally considered safe as there are no known adverse effects reported from the study exercises in the scientific literature. These breathing methods are modifiable to one’s comfort level. Certified instructors will work with the participants to teach the exercises. Please let the instructors know of any modifications that you would like to improve your practice. In the event of any adverse effects arising from the study exercises the Sponsor will take immediate steps as required by the IRB to make referrals to the investigator and social work support in the partnering institution.

P. COLLECTION OF SPECIMENS

There will be two time points at which your biospecimens will be collected, at week 1 and week 12 visits. In both visits fingernail clippings will be collected by regular self-grooming practice of clipping the fingernails using a nail clipper. In addition, two saliva

samples, before and after the study intervention, will be collected by passive drooling into a saliva collection tube. About 2 milliliters (half a teaspoon) of saliva will be collected at those times. These samples will be used for protein and cortisol estimation to understand if there are any biomarkers altered because of the study exercises. There will not be any genetic testing done in those biospecimens, and the remaining samples will be destroyed at the end of the study. The deidentified results of the study will be published in peer-reviewed journals, presented in scientific meetings, presented to the funding agency, and upon request by the participant their individual results will be provided.

Q. FUTURE CONTACT

The investigator in charge of this study might like to contact you in the future about other research opportunities. Please initial by your choice below:

____Yes, I agree to be contacted

____No, I do not agree to be contacted

R. VOLUNTARY PARTICIPATION / WITHDRAWAL

Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. However, please note that any information collected up to the point of your withdrawal cannot be removed from the study.

The investigator or the sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you;
- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- If the study is canceled; or
- For administrative reasons.

S. WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you have questions, concerns or complaints about the study, please contact the investigator at the telephone number listed on the first page of this consent document.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, contact:

- By mail:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free:** 877-992-4724
- or by **email:** adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00050387.

T. CONSENT AND AUTHORIZATION

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I do not give up any of my legal rights by signing and dating this consent document. I will receive a copy of this signed and dated consent document.

_____
Participant's Printed Name

_____ _____
Participant's Signature Date

_____
Printed Name of the Person Conducting the Consent Discussion

_____ _____
Signature of the Person Conducting the Consent Discussion Date