Appendix I – **Revision 1**

(original S0 version approved on Nov 05, 2014)

STUDY INFORMATION AND CONSENT to RESEARCH

TITLE: **Share the Journey Mind, Body and Wellness after Breast Cancer** (Breast Cancer Survivor Study)

PROTOCOL NO.: 201411020
WIRB® Protocol # 20142174

SPONSOR: Sage Bionetworks

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SUMMARY

You are invited to participate in a research study to understand variations in symptoms during recovery from breast cancer treatment. This study is designed for women between 18 and 80 years old with a history of breast cancer treatment and women without any history of cancer. Your participation in this study is entirely voluntary.

To be in a research study you must give your informed consent. The purpose of this form is to help you decide if you want to participate in this study. Please read the information carefully. You should not join the research study until all of your questions are answered. If you decide to take part in this research study, you will be given a copy of this signed and dated consent form. If you decide to participate, you are free to withdraw your consent, and to discontinue participation at any time.

Participating in a research study is not the same as receiving medical care. The decision to join or not join the research study will not affect your medical benefits.

PURPOSE OF THE STUDY

Women recovering from breast cancer treatment can have very different and more or less severe symptoms day to day. These symptoms affect quality of life and make managing recovery difficult. We would like to understand the causes of these symptom variations.

New technologies allow people to record and track their health and symptoms in real time. This study will monitor individual's health and symptoms using questionnaires and sensors via a mobile phone application. The data from many participants will be analyzed to better understand the differences in symptoms reported. We will also assess whether mobile devices and sensors can help better measure and manage these symptoms. You will have a unique account that you can use to review your own data and see how it fluctuates over time. Ultimately our goal is to learn with you how to improve quality of life after breast cancer treatment.

Your data, without your name, will be added to the data of other study participants and analyzed by the study team. Also, if you choose to, your study data (without your contact information) can be made available to other qualified researchers for this and future research. You will have a unique account that you can use to review your own data.

How long will I be in the research study?
We anticipate this study will last about six months, however the app can remain on your phone for multiple years, and you can keep using it to track your symptoms and review your data.

How many people will take part in this study?
We anticipate enrolling 20,000 subjects in this study.

PROCEDURES

What will you be asked to do?
If you decide to join the study you will need to download the free study application on your mobile device, register an account and confirm your agreement to participate in this study. Then, periodically we will ask you to answer questions and/or perform activities on your mobile phone. Your study data will include your responses to surveys and activities and some measurements from the phone itself about how you are moving and interacting with others.

- **Register to the study:** You will follow the prompts on the app to register an account and confirm your agreement to participate in this study. There will be an electronic consent process explaining the risks and benefits of using the app. The registration will include entering your name, email address, other general information about yourself and answer few questions to verify your eligibility. You can cancel the registration process at any time.

- **Health Surveys**: We will periodically ask you to answer questions about yourself, your medical history, and your current health. You may skip any questions that you do not wish to answer. We will ask you to rate your fatigue, thinking, sleep, mood and exercise performance on a scale of 1 to 5 daily. We will also ask you to answer brief weekly and monthly surveys about your symptoms to track any changes.
- **Activities**: Occasionally we may ask you to perform specific activities while using your mobile phone and record sensor data directly from your phone. For example, you may be asked to type a short journal entry, which will then be shared and analyzed for typing speed and accuracy as well as word usage. Additionally, you may be asked to provide data from third-party fitness devices (like the Fitbit or Jawbone Up) with your permission.

We will send notices on your phone asking you to complete these activities and surveys. You may choose to act at your convenience, (either then or later) and you may choose to participate in all or only in some parts of the study. These surveys and activities should take you about 20 minutes each week. You can adjust the app settings to turn on and off sending data at any time. Occasionally we may re-contact you to ask for your feedback about using the app and about the kind of questions included in the study.

What we will and will not do with the data?

- **Data processing**: We will electronically process your data and separate your account information (name, email, contact information, etc.) from your study data (your responses to surveys and the measurements from the phone itself when you perform activities). We will combine your coded study data (without your name) with those of other study participants. The combined data will be transferred electronically to Synapse (synapse.org), Sage Bionetworks' computerized research platform for storage and analysis.

- **Use in research:** The research team will analyze the combined data and report findings back to the community through Blog or scientific publications. Your coded study data (without your contact information) may also be used by other researchers and for research purposes beyond this study if you choose to share them more broadly. The Principal Investigator and Sponsor will have no oversight on the future use of the combined study data.

RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These risks, while very low, deserve careful thought and should still be contemplated prior to enrolling.

- This is not a treatment study and we do not expect any medical side effects from participating.

- Some survey questions may make you feel uncomfortable. Know that the information you provide is entirely up to you and you are free to skip questions that you do not want to answer.
- Other people may glimpse the study notifications and/or reminders on your phone and realize you are enrolled in this study. This can make some people feel self-conscious.
- Be safe – just as you would not text while driving, do not fulfill study activities while driving. Wait until you are in a safe place to perform the activities!
- We take great care to protect your information, however there is a slight risk of loss of privacy. This is a low risk because we separate your personal information (information that can directly identify you, such as your name or phone number) from the research study data to respect your privacy. However, even with removal of this information, experts in re-identification may be able to reverse our processes and/or attempt to re-identify an individual given enough cross-reference information about him or her.
- Accidental public disclosure may occur due to unintended data breaches including hacking or other activities outside of the procedures authorized by the study. In such a case, your data may be misused or used for unauthorized purposes.
- Data collected in this study will count against your existing mobile data plan. You may configure the application to only use WiFi connections to limit the impact this data collection has on your data plan.
- Participation in this study may involve risks that are not known at this time. You will be told about any new information that might change your decision to be in this study.

POTENTIAL BENEFITS
The goal of this study is to create knowledge that can benefit us as a society. The benefits are primarily the creation of insights to help current and future patients and their families to better detect, understand and manage their health. We will return the insights learned from analysis of the study data through the study website, blogs and/or research publications, but these insights may not be of direct benefit to you. We cannot, and thus we do not, guarantee or promise that you will personally receive any direct benefits from this study. However you will be able to track your health and export your data at will to share with your medical doctor and anyone you choose.

PAYMENT
You will not be paid for being in this study.

COSTS
There is no cost to you to participate in this study other than to your mobile data plan if applicable.

ALTERNATIVES
Since no medical treatments are provided during this study there are no alternative therapies. The only alternative is to not participate.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES
Because information about you and your health is personal and private, it generally cannot be used in a research study without your written authorization. If you sign this consent form, you will provide that authorization. You do not have to sign this form. But if you do not, you will not be able to participate in this research study.

What personal information will be used or disclosed? The information that may be used or disclosed in connection with this research study include your body height, weight, gender, age, ethnicity/race, health history, answers to study questions, and health information that may be discernible from your mobile phone's sensors. Your account information, study data and signed consent form may also be looked at and/or copied by designated personnel for regulatory and quality assurance.

Who may use and disclose my data and why? The study sponsor, investigators and study staff may use and disclose your data to do the research described above or as required by law (e.g. to see if the research was done right and/or to prevent possible injury to yourself or others).

Who May Receive or Use the Information? The parties listed in the preceding paragraph may disclose your health information as required by law to:

- The US National Institutes of Health, National Cancer Institute, Office for Human Research Protection, The Food and Drug Administration and other agencies as required,
- Governmental agencies in other countries,
- Western Institutional Review Board® (WIRB®) or other Institutional Review Board who watch over the safety, effectiveness and conduct of the research,
- Others, if the law requires

When will my authorization expire? Your authorization for the use and/or disclosure of your health information will expire December 31, 2060.

If you choose to withdraw from the research study, we will stop collecting your study data. At the end of the study period we will stop collecting your data, even if the application remains on your phone and you keep using it. If you were interested in joining another study afterward, we would ask you to complete another consent, like this one, explaining the risks and benefits of the new study.

CONFIDENTIALITY
We are committed to protect your information and keep your identity as confidential as possible, however total confidentiality cannot be guaranteed.

Except as required by law, you will not be identified by name or by any other direct personal identifier. The data collected through the app will be encrypted on the smartphone, transferred electronically and stored securely on the Synapse data repository and analysis platform using Amazon-Web Cloud Services.

Your contact information, including your name and e-mail address will be stored separately from the study data. We will use a random code number instead of your name on all your study data.. This code cannot be used to directly identify you. Information about the code will be kept in a secure system.
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We will NOT access your personal contacts, other applications, text or email message content, or websites visited. WE WILL NEVER SELL, RENT OR LEASE YOUR CONTACT INFORMATION

COMPENSATION FOR INJURY
THIS STUDY DOES NOT PROVIDE ANY COMPENSATION, HEALTH OR MEDICAL CARE TO PARTICIPANTS.

If you are injured as a direct result of your participation in this study, the Principal Investigator or the medical monitor and the research study staff will assist you in obtaining appropriate medical treatment. Your medical insurance, managed care plan, or other benefits program will be billed for this treatment. You will be responsible for any associated co-payments or deductibles as required by your insurance.

If costs of care related to such an injury are not covered by your medical insurance, managed care plan or other benefits program, you may be responsible for these costs. The sponsor will not routinely pay charges that your insurance does not cover. No payment is routinely available from the study sponsor.

VOLUNTARY PARTICIPATION AND WITHDRAWAL
Your participation in this study is voluntary. You do not have to sign this consent form. But if you do not, you will not be able to participate in this research study.
- You are not obligated to participate in this study.
- Your questions should be answered clearly and to your satisfaction, before you choose to participate in the study.
- You may decide not to participate or you may leave the study at any time.
- Your decision will not result in any penalty or loss of benefits to which you are entitled.
- You have a right to download or transfer a copy of all of your own study data.
- By agreeing to participate you do not waive any of your legal rights.

To withdraw from this study please contact the Dr. Andrew Trister by email BCSApp@sagebase.org or call +1-206-667-2103.

Although you can withdraw from the study at any time, you cannot withdraw the coded study data that have already been distributed. If you withdraw from the study, we will stop collecting new data, but the coded study data that you have already provided, and that have already been distributed will not be able to be destroyed or deleted.

The Study Principal Investigator or the sponsor may also withdraw you from the study without your consent at any time for any reason, including if it is in your best interest, you do not consent to continue in the study after being told of changes in the research that may affect you, or if the study is cancelled.

USE OF DATA FOR FUTURE RESEARCH

This study gives you the option to share your coded study data more broadly, with other researchers worldwide for use in this research and beyond to benefit future research. If you choose to share your data broadly,

your coded data (without your contact information) will be added to a shared study dataset on Synapse. This shared study dataset will be made available to qualified researchers who are registered users of Synapse and who have agreed to using the data in an ethical manner, to do no harm and not attempt to re-identify or re-contact you unless you have chosen to allow them to do so. No name or contact information will be included in this shared study dataset. Researchers will have access to the shared study data but will be unable to easily map any particular data to the identities of the participants. The Principal Investigator and Sponsor will have no oversight on the future use of the shared study data by other researchers

SOURCE OF FUNDING FOR THE STUDY

Sage Bionetworks designed this study in collaboration with advisors in breast cancer research. The study is sponsored by Sage Bionetworks with some funding from the Robert Wood Johnson Foundation (http://www.rwjf.org) and technical support from YMedia labs (http://www.ymedialabs.com/). Sage Bionetworks is a US-based non-profit research organization dedicated to the advancement of science through open research initiatives.

QUESTIONS and CONTACT INFORMATION

Please take all the time you need to review this study information and think about whether you would like to participate in this study. Do not hesitate to talk with family, friends and/or the study staff if you have any questions before you decide.

If after reading this document you would like more information, wish to provide us feedback or if you have new questions, concerns or complaints at any time before, during, or after the study, you can contact Dr. Stephen Friend, the study principal investigator or

Dr. Andrew Trister, the medical monitor by email at BCSApp@sagebase.org or call +1 206 667-2103.

Independent Contact: This study was reviewed and approved by the Western Institutional Review Board (WIRB). If you are not satisfied with how this study is being conducted, if you have questions about your rights as a research participant or if you have questions, concerns, input, or complaints about the research, please contact the Western Institutional Review Board (WIRB) to speak to someone independent of the research team:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, WA 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com.

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Thank you for taking the time to read and consider this information.

CONSENT
I have read about this research study (or it has been read to me). All my questions about the study and my part in it have been answered. I freely consent to be in this research study and I authorize the use and disclosure of my unnamed, coded data in electronic database(s) for use in research as indicated in the data sharing setting through the app preferences.

By signing this consent form I have not given up any of my legal rights.

YOUR SIGNATURE INDICATES THAT YOU HAVE READ AND UNDERSTAND THE ABOVE INFORMATION AND THAT YOU HAVE DECIDED TO PARTICIPATE BASED ON THE INFORMATION PROVIDED. A COPY OF THIS FORM WILL BE EMAILED TO YOU.

Data sharing preferences: Share broadly or Share sparsely

Name of adult participant: _____

Email: _____

Signature and Date: _____