mHealth Behavioral Cancer Pain Intervention for Medically Underserved Patients

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Informed Consent Form Document

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DUKE UNIVERSITY HEALTH SYSTEM

Consent to Participate in a Research Study
mHealth behavioral cancer pain intervention for medically underserved patients

CONCISE SUMMARY
This study is being done to test a Pain Coping Skills Training protocol that can be delivered to previously treated breast cancer patients in their community-based oncology clinic through the use of technology such as a mobile phone or tablet/computer. There is a critical need for additional ways to manage pain in cancer patients who live in medically underserved communities. We aim to develop a Mobile Health Pain Coping Skills Training (mPCST) protocol for breast cancer survivors with persistent pain that will produce significant improvements in pain, pain disability, fatigue, physical disability, and adherence to post-treatment lifestyle recommendations that are impacted by pain (i.e., daily activity, self-monitoring of symptoms). Participants will be randomized (like the flip of a coin) to receive a Mobile Health Pain Coping Skills Training (mPCST) or mHealth-Education (mHealth- Ed) intervention. You may find that participating in the Mobile Health Pain Coping Skills Training (mPCST) intervention reduces your physical disability and improves your physical activity and symptoms of pain, fatigue, and stress. The mHealth-Education (mHealth-Ed) intervention focuses on general health education intervention that focuses on improving overall health.

The greatest risks of this study include the possibility of loss of confidentiality.

If you are interested in learning more about this study, please continue to read below.

You are being asked to take part in this research study because you have been diagnosed and treated for breast cancer. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor 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. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

Tamara Somers, PhD, will conduct this study and it is funded by the National Institutes of Health (NIH). They have paid for the study team to perform this research and these funds may reimburse part of Dr. Somers' salary.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, you will not have a different medical doctor. Your regular doctor will continue to be your doctor throughout the time that you are in the study. A member of the study team may be in contact with your doctor throughout the time you are in the study and afterwards, if needed.

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WHY IS THIS STUDY BEING DONE?
The purpose of this study is to evaluate two different programs to help breast cancer survivors with persistent pain in their home clinic through the use of technology such as a mobile phone. One program focuses on Mobile Health Pain Coping Skills Training (mPCST) protocol that may produce significant improvements in pain, pain disability, fatigue, and physical disability. The other program focuses on mHealth-Education (mHealth- Ed) which involves pain education, healthy lifestyle information and improving overall health.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 190 people will take part in this study.

WHAT IS INVOLVED IN THE STUDY?
If you agree to be in this study, you will be asked to sign and date this consent form.

You will then complete questionnaires using a smart phone, over the telephone or paper/pencil. The questions will ask about your symptoms (pain, fatigue, and stress), physical functioning and activity, and how you think and feel about your symptom and cancer experience. We expect these questions to take about 25 minutes to complete.

In addition, you will be randomized (like flipping a coin) into one of two groups. Mobile Health Pain Coping Skills Training (mPCST) or mHealth-Education (mHealth- Ed).

Group 1. Mobile Health Pain Coping Skills Training (mPCST): you will participate in a mobile Pain Coping Skills Training Program (mPCST) that is delivered to you via videoconferencing on a tablet/computer. Participating in mPCST will involve four 50-minute individual intervention sessions conducted over the course of 8 weeks with tele-video-conferencing at your community-based clinic. The therapist delivering the intervention will be at Duke University Medical Center, and you will be in your community clinic. Your sessions will be audio recorded and will be reviewed by Dr. Somers and her research staff to better help the development of Mobile Health Pain Coping Skills Training. The audio recording will occur through a local program at Duke and the videoconferencing platform will not have access to the audio recording.

Group 2. MHealth-Education (mHealth- Ed) you will participate in a mHealth-Education (mHealth- Ed) that is delivered to you via videoconferencing on the tablet/computer. Participating in mHealth will involve four 50-minute individual intervention sessions conducted over the course of 8 weeks with tele-video-conferencing at your community-based clinic. The therapist will be delivering the intervention at your community clinic. Your sessions will be audio recorded and will be reviewed by Dr. Somers and her research staff to better help the development of Mobile Health Pain Coping Skills Training. The audio recording will occur through a local program at Duke and the videoconferencing platform will not have access to the audio recording.

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If needed, you will also be loaned a smartphone to take home with you. A study team member will instruct you on how to use and care for the smartphone. You will also be provided with written instructions and given a number that you can call for assistance with your smartphone. The smartphone will be programmed with a mobile application designed solely for this study. The mobile application will provide you with access to session content information and other study materials. You will be asked about your use of the coping skills, and to use the study mobile application on the smartphone between sessions to report information about your symptoms and your skills practice experience. We ask that you use the smartphone for study related purposes only. You will be asked to provide your name, date of birth and e-mail address when creating your personal account for the study app. We ask that you use the smartphone for study related purposes only.

You will be asked to complete a post-treatment assessment immediately following your final study intervention session and a follow-up assessment three and six months later. You will be asked to return the iPhone after completing the study procedures. This will be the last thing you will be asked to do for this study.

HOW LONG WILL I BE IN THIS STUDY?
You will be in the study for approximately 8 months. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled.

WHAT ARE THE RISKS OF THE STUDY?
The risks associated with this study are minimal and rare. There is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions. Discussing stressors associated with your symptoms may be upsetting. You also have the option of not discussing concerns you find upsetting. You will be provided with a smartphone if needed. You should not use the smartphone for personal use (e.g., internet searching, texting, emailing, phone calls, storing personal contacts, downloading mobile apps) during the study. If you are loaned a Duke iPhone for use during this study and you use it for non-study related reasons, this could add your personal information onto the device and potentially result in it being sent to unauthorized persons. The device will be preset with security settings. Please do not alter these during the course of the study. When you return the device at the end of the study, the device will be cleaned to remove any of your personal information. If the device is lost or stolen during the course of the study, please contact the study team immediately. There is some risk of loss of confidentiality due to the use of videoconferencing to conduct the intervention sessions. You may stop your participation in this study at any time.

Risks Specific to Mobile Apps: Information collected by mobile applications or 'apps' is subject to their terms of use, which you should read carefully. Many apps claim that they are very secure, compliant with federal privacy regulations, and used and tested by other academic centers. However, any mobile app that is downloaded carries potential security risks, and Duke cannot guarantee that these mobile

apps are free of risk. Some apps may be able to perform hidden functions or may have security flaws that allow unauthorized access to information. We are unable to fully tell you what information these mobile apps are able to access or change on your device (phone/tablet) or what information from your device may be stored outside of Duke. You are encouraged to limit personal identifiers you enter into mobile applications (particularly your name, date of birth, address, place of employment, and other details that could allow someone to identify you) only to those that you wish to voluntarily share with others. These apps may send/receive information with other mobile apps, including social networking apps or websites (for example, Facebook). If you give permission for this, the terms of use for those apps/websites apply and you should read them carefully.

It is recommended that you run a current operating system (OS) on your device, review the privacy/security settings often, and restrict any unnecessary access. These applications may run in the background of your device. Mobile apps may have unanticipated impact on the operations of your device (e.g., battery drainage). If you do not have an unlimited data/text plan, you may incur additional charges. At the conclusion of the study, we will provide you instructions on how to remove the mobile app from your device.

We are not asking you to make any health decisions based on the use of these mobile apps. You should discuss health decisions directly with your healthcare provider.

As with all technology, we ask you to wait until you are in a safe environment, use good judgment and follow prevailing laws. Do not perform study-related activities while you are driving.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, there may be direct benefits to you. You may find that your participation in the study intervention reduces your physical disability and improves your physical activity and symptoms of pain, fatigue, and stress. We also hope the information learned from this study will benefit other patients with cancer.

WHAT ALTERNATIVES ARE THERE TO PARTICIPATION IN THIS STUDY?
All participants in this study will receive standard of care therapy as an alternative to this study. Standard of care is referral for behavioral pain management or psychological services as clinically indicated.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Duke University Health System (DUHS). For records disclosed outside of DUHS, you will be assigned a unique code number. The key to the code will be kept in a locked file in Dr. Somers's office located at 2400 Pratt Street, 7th Floor, Room 7046,

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Durham, NC, 27705. All audio recordings will be stored on an encrypted laptop and will be available only to authorized study personnel as necessary to review the content of the sessions. All audio recordings will be destroyed at the end of the study.

Your records may be reviewed in order to meet federal or state regulations. Reviewers may include the Duke Office of Audit, Risk and Compliance, Duke University Health System Institutional Review Board, and Duke Cancer Institute. If your research record is reviewed by this group, they may also need to review your entire medical record. If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by the federal privacy regulations.

The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2) you have consented to the disclosure, including for your medical treatment; or
3) The research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

As part of this study, Dr. Somers and her study team will ask you to complete assessments. Results of the assessments done solely for this research study and not as part of your regular care will not be included in your medical record.

The study results will be retained in your research record for at least six years after the study is completed. At that time either the research information not already in your medical record will be destroyed or information identifying you will be removed from such study results at DUHS. Any

research information in your medical record will be kept indefinitely.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your identity will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS TO YOU?
There will be no costs to you as a result of being in this study.

WHAT ABOUT COMPENSATION?
Participants will receive $30 for completing each of the four study assessments. Total compensation may be up to $120. If you choose to withdraw from the study, you only will receive compensation for the parts of the study that you completed.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center or your local community hospital emergency room in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury. For questions about the study or research-related injury, contact Dr. Somers at (919) 416-3408 during regular business hours or by page at 919-970-5202.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes except to keep track of your withdrawal.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Somers in writing and let her know that you are withdrawing from the study. Her mailing address is Tamara Somers, PhD, 2400 Pratt Street, 7th Floor, Room 7046, Durham, NC, 27705.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

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If you choose to withdraw from the study, your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your samples or data, we will no longer be able to identify and destroy them.

A description of this clinical trial will be available on https://clinicaltrials.gov/ as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Somers at 919-416-3408 during regular business hours and 919-970-5202 after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at 919-668-5111.

STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time