Informed Consent Document

Study Title: Communication App to Manage Symptoms and Improve Adjuvant Endocrine Therapy Adherence for Women With Breast Cancer

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Main Consent Form

TITLE: Communication App to Manage Symptoms and Improve Adjuvant Endocrine Therapy Adherence

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1. INTRODUCTION:

You are being given the opportunity to participate in this research study. The purpose of this consent form is to help you decide if you want to be in the research study. This consent form may contain words that you do not understand. Please ask the study doctor or the study staff 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. Please tell the study doctor or study staff if you are taking part in another research study.

We are conducting a research study to learn how technology may improve medication adherence and the quality of care provided to women with breast cancer. This study is a collaboration between the West Cancer Center and the University of Tennessee Health Science Center. You are being invited to participate in this study because you are a West Cancer Center patient with an early stage diagnosis of breast cancer. Your views and experiences are extremely valuable.

Approximately 375 subjects will participate in this research study at the following three locations of the West Cancer Center: EAST MEMPHIS, 7945 Wolf River Blvd., Memphis, TN 38138; MIDTOWN, 1588 Union Avenue, Memphis, TN 38104; and DESOTO, 7668 Airways Blvd., Southaven, MS, 38671.

Your participation in this study will last 12 months, and follow-up information will be collected every 6 months for up to 36 months.

2. PROCEDURES TO BE FOLLOWED:

If you choose to participate, you will be contacted by a West Cancer Center staff member to schedule an in-clinic visit after you fill your first prescription for an adjuvant endocrine therapy (AET) cancer medication, like Tamoxifen or an aromatase inhibitor. During this visit, a West

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Cancer Center staff member will enroll you in the study and provide you with an electronic pillbox to monitor your AET use. You will also be randomly assigned (like the flip of a coin) into one of three study groups. You have an equal chance of being assigned to each group. The investigator will not be the person who decides which you receive.

Group 1: Study participants in this group will complete an online survey at the beginning of the study and twice more during the study period (every 6 months) and use an electronic pillbox for AET medication for 12 months.

Group 2: Study participants in this group will complete an online survey at the beginning of the study and twice more during the study period (every 6 months) and use an electronic pillbox for AET medication for 12 months. Participants in this group will also have access to a web-based app and receive weekly reminder text messages to use the app.

Group 3: Study participants in this group will complete an online survey at the beginning of the study and twice more during the study period (every 6 months) and use an electronic pillbox for AET medication for 12 months. Participants in this group will have access to a web-based app and receive weekly reminder text messages to use the app. In addition to weekly reminder text messages, participants in this group will also receive weekly text messages.
Study participants will be asked to:

- Answer a series of questions in an online survey that will take approximately 15 minutes
- Use an electronic pillbox daily for AET medication only
- Use a mobile device or computer to access a web-based app and receive weekly study-related text messages (Group 2 and 3).

Responses from participants who use the mobile app will also be monitored by healthcare providers for "early warning alerts" related to your symptom management and use of AET medications as prescribed by your doctor. Upon receiving an alert, a clinic nurse or your oncologist will contact you by phone to discuss any current health issues or problems you may be experiencing.

All participants will be asked to return the electronic pillbox device after 12 months by either:

1. Dropping off the device at any West Cancer Center clinic location.
2. Using packaging provided by us to drop off the device at any Fedex station.

All groups will continue to receive standard care for management of medications and symptoms. Your medication use is part of standard care. All of the procedures described in this consent form are for research purposes.

If you choose not to participate in this research study, you will still receive the best treatment option for your disease after talking with your doctor.

3. RISKS ASSOCIATED WITH PARTICIPATION:

Questionnaires/Surveys
Some of the survey questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions, and you may take a break at any time during the study.

There is a risk that your private identifiable information may be seen by people not involved in the research (such as if a researcher's computer is stolen or an electronic database is hacked). However, we will use very careful security measures (such as locks on file cabinets, computer passwords, etc.) to minimize the chance that any unauthorized persons might see your confidential information.

The research may involve risks to which are currently unforeseeable. You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

You should report any symptoms that may require immediate attention directly to your healthcare provider or the appropriate emergency treatment facility even if you have reported your symptoms using the web-based app. Use of the web-based app in this study should not take the place of any communication with your care team that would have occurred if the app was not available.

4. BENEFITS ASSOCIATED WITH PARTICIPATION:

Your participation in this study may help you better manage your mediaction. Also, the results of this study may help patients like you in the future through the development of new ways to improve patient-provider communication, quality of life, and health outcomes.

5. ALTERNATIVES TO PARTICIPATION:

You do not have to participate in this study. You will continue to receive medical treatment for breast cancer whether or not you participate in the study.

You will not have to undergo any of the procedures described in this consent form which are for research purposes. Taking medication for your condition is standard care and not a research procedures.

6. CONFIDENTIALITY:

Research records
All your paper research records will be stored in locked file cabinets and will be accessible only to research personnel and those entities named below in this section, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).

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All your electronic research records will be computer password protected and accessible only to research personnel and those entities named below in this section, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).

Medical Records
Information about your participation in this study or the results of procedures performed in this study will be placed in your medical record; as such, this information could be made available to your employer or insurer.

Presentations/Publications
While overall findings of this research study might be provided in publications or presentations about this research, they will not be discussed in a way that would allow you to be individually identified as a participant.

Authorization to Use and Disclose Protected Health Information for Research Purposes
Under federal privacy regulations, you have the right to decide who can review and copy your identifiable health information (called "protected health information" or PHI). PHI collected in this study may include information such as:

- Past and present medical records
- Records about your study visits
- Records about phone calls made as part of this research
- Research records

By signing this consent form, you are giving your permission for the study doctor and the study staff to get your PHI from your doctor and/or facilities where you have received health care. They may also share your PHI with:

- The Institutional Review Board (IRB) at the University of Tennessee Health Science Center
- Department of Health and Human Services (DHHS) or other government agencies
- Methodist Healthcare-Memphis Hospitals
- West Clinic

Your PHI will only be used and/or given to others:

- To do the research
- To study the results
- To see if the research was done correctly

Your PHI will be used until the study is completed.

You may withdraw or take away your permission to use and disclose your PHI at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you may not be able to stay in the study.

When you withdraw your permission, no new PHI will be gathered after that date. However, information that has already been gathered may still be used. The federal regulations allow you to review or copy your PHI that is used in this study.

7. COMPENSATION AND TREATMENT FOR INJURY:

You are not waiving any legal rights or releasing the UTHSC, The West Cancer Center / Methodist Healthcare, or the agents of either, from liability for negligence. In the event of physical injury resulting from research procedures, the UTHSC and The West Cancer Center / Methodist Healthcare do not have funds budgeted for compensation for medical treatment. Therefore, the UTHSC and The West Cancer Center /Methodist Healthcare do not provide for treatment or reimbursement for such injuries.

If you are injured or get sick as a result of being in this study, you and/or your insurance will be billed for the costs associated with this medical treatment.

No compensation will be available to you for any extra expenses that you may have as the result of research related physical injuries, such as additional hospital bills, lost wages, travel expenses, etc.

No compensation will be available to you for any non-physical injuries that you may have as a result of research participation, such as legal problems, problems with your finances or job, or damage to your reputation.

8. QUESTIONS:

Contact Dr. Ilana Graetz at [redacted] if you have questions about your participation in this study, or if you have questions, concerns, or complaints about the research.

If you are injured or get sick as a result of being in this study, call Dr. Gregory Vidal at [redacted] at his office immediately. The study doctor will provide acute medical treatment, and will provide you with a subsequent referral to appropriate health care facilities.

You may contact Cameron Barclay, MSA, UTHSC IRB Director, at 901-448-4824, or visit the IRB website at http://www.uthsc.edu/research/compliance/irb/ if you have any questions about your rights as a research subject, or if you have questions, concerns, or complaints about the research.

9. PAYMENT FOR PARTICIPATION:

If you complete all study-related activities, you will be paid $180 in online merchant credit at the end of the 12-month study period.

- You will receive a $60 credit for the first 6 months.

  - Pillbox use ($35 max): There will be a deduction of $1 for every 5-day period if you do not charge your pillbox.
  - Survey at 6 months ($25 max): There will be a deduction of $1/day after a 14-day grace period
- You will receive a $120 credit for the second 6-month period.
  - Pillbox use ($35 max): There will be a deduction of $1 for every 5-day period if you do not charge your pillbox.
  - Survey at 12 months ($25 max): There will be a deduction of $1/day after a 14-day grace period.
  - Pillbox Return ($60 max) at the end of month 12
    - $30 + a $30 bonus if returned within 30 days
    - $30 + a $20 bonus if returned within 60 days
    - $30 + a $10 bonus if returned within 90 days
    - $30 if returned between 3-24 months

If you choose to complete brief follow-up surveys starting at 18-months, you will be paid an additional $10 in online merchant credit every time you complete a new survey (every 6 months for up to 36 months). We will deduct $1/day after 14-day grace period for each survey.

10. COSTS OF PARTICIPATION:

There are no costs to you for participating in this study. This study is being funded by a grant from the National Institute of Health.

11. VOLUNTARY PARTICIPATION AND WITHDRAWAL:

Your participation in this research study is voluntary. 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.

Deciding to not take part in this research study will not change your regular medical care in any way. If you decide to stop taking part in this research study, you should tell your study doctor, and any information that you have already provided will be kept in a confidential manner.

Your participation in this research study may be terminated by the investigator or the sponsor without regard to your consent for the following reasons:

- If the investigator decides it is in your best interests
- If the study is no longer being funded

12. FUTURE CONTACT:

If we lose contact with you during the study for any reason (your phone number changes; your physical or email address changes; you are not responding to our attempts to contact you about your continued participation; etc.), we will attempt to find you or make contact with you in the following ways:

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- The phone number(s) you provided to us will be called, but if you are not the person who answers, we will not say the title of the study or the fact that you are/were participating in a study.
- Certified mail will be sent to you requesting that you call us.
- A letter will be sent to the address(es) you provided to us, but neither the return address nor any markings on the envelope will identify the title of the study or the fact that you are/were participating in a study.

Put your initials on one of the lines below:

_____We CAN attempt to find/contact you in the above ways.

_____We MAY NOT attempt to find/contact you in the above ways.

Sometimes we wish to keep your contact information, medical diagnosis, and other health information in order to contact you in the future and tell you about other studies in which you might be eligible to participate.

Put your initials on one of the lines below:

_____We CAN keep your contact information and health information to ask you about participating in future studies.

_____We MAY NOT keep your contact information and health information to ask you about participating in future studies.

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13. CONSENT OF SUBJECT:

You have read or have had read to you a description of the research study as outlined above. The investigator or his/her representative has explained the study to you and has answered all the questions you have at this time. You knowingly and freely choose to participate in the study. A copy of this consent form will be given to you for your records.

_____ _____ _____
Signature of Research Subject (18 years +) **Date** **Time**

_____
Printed Name of Adult Research Subject

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

_____
Printed Name of Person Obtaining Consent

In my judgment, the subject has voluntarily and knowingly given informed consent and possesses the legal capacity to give informed consent to participate in this research study.

_____ _____ _____
Signature of Investigator **Date** **Time**