FOX CHASE CANCER CENTER
TEMPLE HEALTH

INFORMED CONSENT DOCUMENT

Enhancing Patient-Provider Communication in Breast Cancer
Phase III
Principal Investigator: Jennifer B. Reese, PhD

This is a research study. A representative from the research study team will explain this study to you. Research studies include only people who choose to take part. Please take your time to make your decision about taking part in this study. If you have any questions, you can ask the study team for more information.

You are being asked to take part in this research study because you have been diagnosed with breast cancer and are being followed by a Fox Chase clinician.

The sponsor of this study is the **American Cancer Society.**

Why is this research study being done?

This research is being done to test whether an educational video-based program is helpful at improving how breast cancer patients communicate with their providers about quality of life topics like menopausal and sexual health. Patients who are being seen in follow-up in the breast cancer clinics may join.

How many people will take part in this research study?

About **128** patients will take part in this phase of the research study.

What will happen if you take part in this research study?

If you agree to be in this study, you will be asked to do the following:

- Questionnaires: Complete 3 study surveys at different times
- Be assigned to one of two research study groups in which you will either (1) receive menopausal and sexual health resources or (2) view a brief communication video, described later on (called Starting the Conversation), and receive menopausal and sexual health resources.
- Audio record clinic visit communication: Allow us to audio record (tape) the communication that happens during a visit between you and your breast cancer provider.
- Medical Records Review: Allow us to look at your medical records to record details of your breast cancer and treatment history.

More information about what is involved in taking part in this study is described below.

Questionnaires

We are asking you to fill out questionnaires for this research study through the web, using a link available only to you. Paper questionnaires are available upon request. These questionnaires will ask about communication with your breast cancer provider(s), beliefs about communication,

your relationships, your physical and emotional well-being (mood), and sexual function and activity. We will ask you to fill out the first questionnaire immediately after electronically signing this consent form. We will ask you to fill out the second questionnaire immediately after your next clinic visit at Fox Chase. We will ask you to fill the third, and final, questionnaire out about two months from now.

You do not have to answer any questions in the surveys that make you uneasy. Whether or not you answer any question will not affect your medical care. We will keep all questionnaire answers secure, either electronically or in a locked file, to protect your privacy. Your doctor will not see or have access to the information you provide on your questionnaire.

Study Groups

You will be "randomized" into one of the following two research study groups: (1) Menopausal and Sexual Health Resource Guide, or (2) Menopausal and Sexual Health Resource Guide plus an educational video called Starting the Conversation. Randomization means that you are put into a group by chance. A computer program will place you in one of the research study groups. Neither you nor your clinician can choose the group you will be in. You will have an equal chance of being placed in either study group. If you are not assigned to the group that receives the educational video, you will be offered the chance to view it after your participation in this study is over.

(1) Menopausal and Sexual Health Resource Guide

If you are in group 1, you will receive the Menopausal and Sexual Health Resource Guide. The Resource Guide includes a list of links to websites that we have selected because they contain reputable and useful information about common menopausal and sexual health concerns for women with breast cancer. This list is organized by type of concern. The guide also lists information about resources available at Fox Chase for breast cancer survivors. You may use this resource guide at your leisure.

(2) Menopausal and Sexual Health Resource Guide + Educational Video (Starting the Conversation)

If you are in group 2, you will also receive the Menopausal and Sexual Health Resource Guide, as described above. As in group 1, you may use this resource guide at your leisure.

In addition, you will be sent a link to a brief educational video (called Starting the Conversation) and an accompanying workbook. To complete this part of the study, you will be asked to view the video completely and complete the accompanying workbook. It is recommended that you complete the workbook at the same time as you watch the video. The video will include detailed instructions for how to participate.

The Starting the Conversation video includes helpful tips and tools you can use to discuss menopausal and sexual health with your provider. It also includes brief activities that you will engage in so that you can learn skills to communicate more effectively about these kinds of issues.

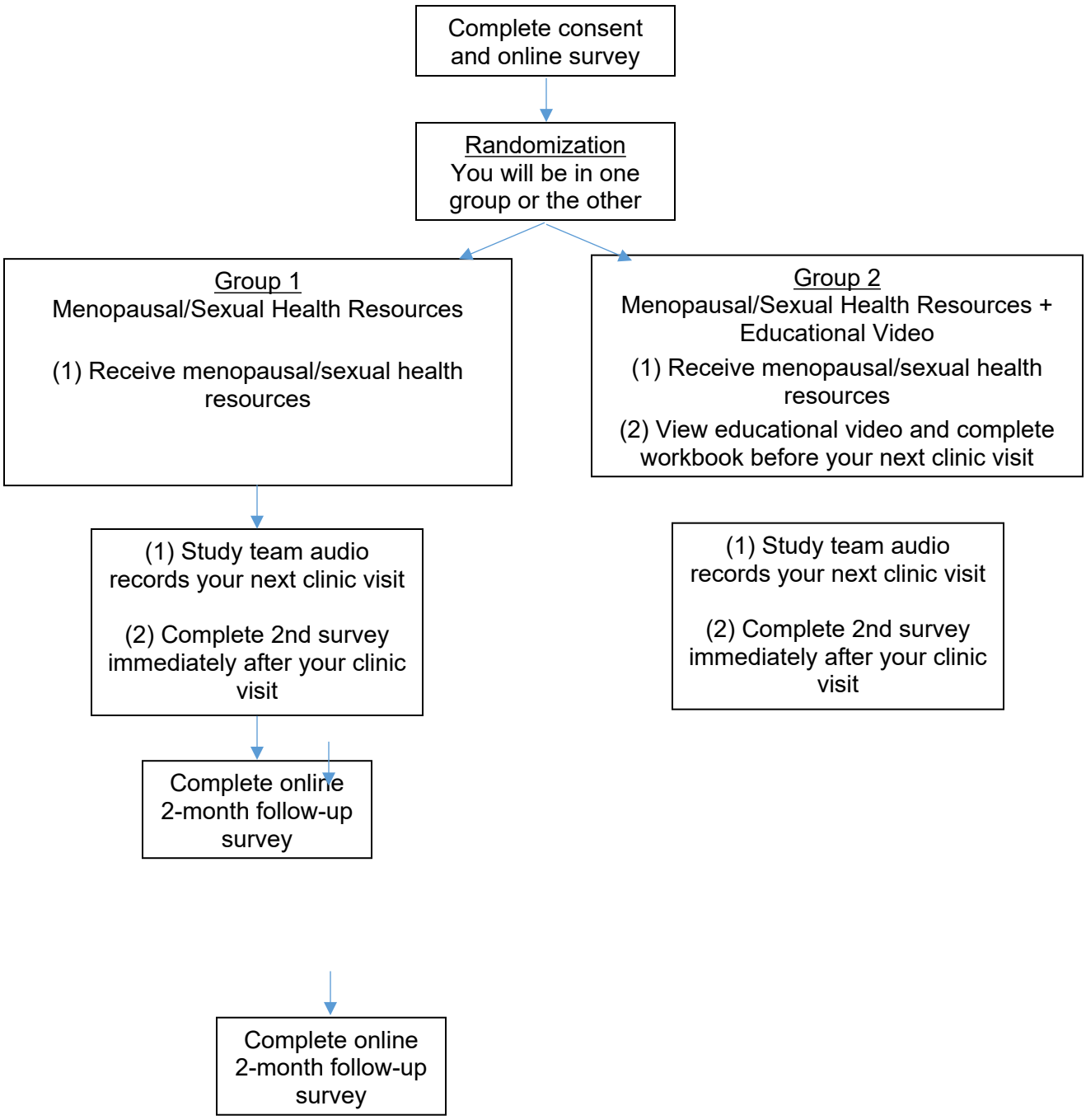
You will be asked to view the video and complete the workbook on your own before your next clinic visit. It should take you between 20 and 30 minutes to complete, and we ask that you try to complete it in one sitting if possible. You can use a preferred electronic device, such as a

computer, tablet, or smartphone, to watch the video. However, we recommend you use a larger sized device for ease of viewing, if possible.

Study Plan

Another way to find out what will happen to you during the research study is to read the chart below. Start reading at the top and read down the list, following the lines and arrows.

Keep in mind that although this chart says you will be assigned to a study group, you will be participating in this study by yourself.



Audio Record Clinic Visit Communication

Regardless of your study group, we will ask to audio record your next clinic visit between you and your breast cancer provider. *By electronically signing this consent form, you are consenting to let us audio record your next clinic visit with your breast cancer provider.* We will use the audio recording to measure the way you and your provider communicate with each other. This will help us learn about the best ways to enhance patient-provider communication about quality of life topics. The provider visit is part of your standard care. The recording will include the entire length of your visit with your provider. This recording will become a part of your confidential research record – not your medical record – and will not be accessible to anyone other than the members of the research team.

Medical Records Review

We will record certain aspects of your medical history from your medical records that are relevant to this study. This includes: types and dates of surgery(ies) and treatments, medications, and health status. The information we obtain through your medical record will be noted in a database that is separate from your medical record. Any identifying information will be removed. This information will become a part of your confidential research files.

How long will you be in the research study?

You are being asked to be in this study for about 3 months.

Can you stop being in the research study?

Your participation is completely voluntary. You can agree to be in the study now and change your mind later.

- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.
- If you leave the study early, Fox Chase may use or give out your health information that it already has if the information is needed for this study or any follow-up activities.

What side effects or risks can you expect from being in the research study?

There is a small risk that you will feel uncomfortable answering survey questions or participating in the program, or that you may get bored during the questionnaire completion. You do not have to answer any question you do not want to answer.

We will make every effort to keep the information you provide in this study confidential. However, there is a risk that information about you could become known to people outside of this study. To protect against this, the following steps have been taken:

- All information gathered during this study will be kept in locked cabinets or in electronic databases that are password-protected.
- The study team will delete your name and other information that might identify you or the other participants, to the extent possible.
- All audio recordings will be destroyed when the study is completed or later, if necessary for regulatory compliance.

Are there benefits to taking part in the study?

Participating in the study may or may not help you directly. You may learn helpful information through participating but there are no guarantees.

If you take part in this study, the information you provide will help inform educational programs for other breast cancer patients and survivors in the future.

What other choices do you have if you do not take part in this research study?

You do not have to join this study. Whether you decide to join or not join this study, your care at Fox Chase Cancer Center will not be affected.

Will your information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- American Cancer Society
- The National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people
- Fox Chase Cancer Center and its Institutional Review Board

A description of this study will be available on *http://www.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 study and its results. You can search this website at any time.

You will be given a separate form to review regarding the steps we will take to guard your privacy as part of your participation in the research study. By electronically signing that additional authorization, you will be providing your consent to use and disclose information described in that form connected with your participation in this research study.

What are the costs?

There are no costs to you for participating in this study.

Will you be compensated?

You will receive $20 after completing each of the three questionnaires for this study, for a total of $60. You will be compensated in the form of gift cards.

What are your rights if you take part in this research study?

Taking part in this research study is your choice. You may choose either to take part or not to take part in the research study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care if you are a patient here at Fox Chase Cancer Center. You can still get your medical care from our institution.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by electronically signing this form.

Who can answer your questions about the research study?

If you have questions about:	Please Call:
This study	Dr. Jennifer Barsky Reese 215-214-3223
If you have a concern or complaint	Director, Risk Management 215-728-2591
Your rights as a research participant while you are on this study or after the study ends	Institutional Review Board 215-214-3754

Where can you get more information?

You may call the National Cancer Institute's Cancer Information Service at:

1-800-4-CANCER (1-800-422-6237)

You may also visit the NCI Web site at http://cancer.gov

- For NCI's general information about cancer, go to: http://cancer.gov/cancerinfo/

Future Research

We would also like your permission to contact you about other studies that you may be eligible for in the future directly (i.e., without first consulting your treating provider). Please initial on only one line:

_____**Yes**, I may be contacted directly in the future about other studies related to breast cancer and quality of life.

_____**No**, I do not want to be contacted directly about other studies.

Consent

By signing below, you tell us that you have gotten all of the information you need; that you have received clear answers to your questions, and that you agree to take part in the research study. You will receive a copy of this form. You may also request a copy of the research plan.

_____	_____	_____
Signature of Participant	**Print Name of Participant**	**Date**
_____	_____	_____
Signature of Person Obtaining Consent	**Print Name of Person Obtaining Consent**	**Date**

By signing this form the person obtaining consent indicates that the research participant has been fully informed of all aspects of the research study.

"Temple Health refers to the health, education and research activities carried out by the affiliates of Temple University Health System, Inc. and by Temple University School of Medicine."