University of North Carolina-Chapel Hill
Consent to Participate in a Research Study

Title of Study: Managing Uncertainty in Older Breast Cancer Survivors

Medical IRB Study # _____

Sponsors: National Cancer Institute, National Institute on Nursing Research

Principal Investigator: Merle H. Mishel, RN, PhD
UNC-CH Department: School of Nursing
Phone number: (919) 966-6610

Co-Investigators: Barbara Germino, RN, PhD, Michael Belyea, PhD, Iris Carlton-LaNey, PhD, Karen Gil, PhD, John Soltys, MD

You are being asked to take part in a research study. The investigators listed above are in charge of the study. Other professionals may help them or act for them.

What are some general things you should know about research studies?

Research studies are designed to gain scientific knowledge that may help other people in the future. You may or may not receive any direct benefit from participating. There may also be risks associated with participating in research studies.

Your participation is voluntary. You may refuse to participate, or may withdraw your consent to participate in any study at any time, and for any reason, without jeopardizing your future care at this institution or your relationship with your doctor. If you are a patient with an illness, you do not have to participate in research in order to receive treatment.

Details about this particular study are discussed below. It is important that you understand this information so that you can decide in a free and informed manner whether you want to participate. You will be given a copy of this consent form. You are urged to ask the investigators named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this research study is to learn whether a nursing intervention can help women who are surviving breast cancer manage the experience of survivorship more effectively.

How many subjects will participate in this study?
A total of 264 subjects at about 11 institutions will take part in this study. About 150 subjects from this institution are expected to participate.

How long will your participation last?
Your participation in this study will last for about 2 years.

What will happen if you take part in the study?
In addition to the usual care, you will be randomly assigned to 1 of 2 groups. Assignment to groups will be made by using a simple random procedure like flipping a coin. Using this procedure, you will have a 50% (1 out of 2) chance of receiving the nursing intervention.

If you are assigned to the **intervention group**, you will receive a set of audiotapes and a portable audiotape player to listen to them with. These audiotapes will help you to learn practical ways to deal with the times when you are uncertain about what will happen to you because of your cancer and the treatment you received. A nurse will call you 4 times over 4 weeks to help you learn the skills on the audiotapes. You will also receive a manual of written and audiotaped information which you can use to prevent and manage long-term side effects of your cancer treatment. The same nurse will also call you once a month for the first year you are in the study to talk about how you are using the tapes and manual to manage your cancer and its side effects. You will complete study questionnaires at 3 timepoints over 2 years.

If you are assigned to the **control group**, you will complete study questionnaires at 3 timepoints over 2 years. After you have completed the questionnaires at all 3 timepoints, you will receive the audiotaped and written materials which are part of the nursing intervention, without the nurse follow-up phone calls.

Everyone in the study will complete the questionnaire booklets, which ask you about your experiences and feelings related to being a cancer survivor. You will complete the questionnaires at 3 different times: when you first enter the study, 1 year later, and 2 years after you enter the study. It takes about 1-2 hours to answer the questions, and a data collector will come to your home to help you complete the booklet. If you get too tired or have too little time to complete all of the questions at one visit, you can complete them at shorter visits over 1-2 days. You may choose not to answer some or all of the

questions in the booklet. You can choose to fill out the questions yourself or have the data collector read the questions to you and fill in your answers in the booklet.

In addition to the information you give on the questionnaires, some information will be needed from your medical chart about the breast cancer treatment you received. A nurse working for our research study will get the necessary records from the hospital and/or physician's office where you were treated. If you were previously a subject in the Carolina Breast Cancer Study at UNC-Chapel Hill, we will get the information about your cancer treatment from their records.

What are the possible risks or discomforts?

Answering the questionnaires and listening to the tapes might cause you some uneasy feelings, like anxiety or tension, related to your experiences with breast cancer. You may choose to talk about these feelings with study personnel, or you may choose not to answer the questions that cause the negative feelings.

What are the possible benefits?

The benefits to you of participating in this study may be that you learn more about some of the issues related to being a breast cancer survivor and ways of dealing with these issues. It is also possible that even if you are not personally helped by being in this study, the information you provide will help health care professionals learn more about breast cancer survivors, and help develop useful nursing interventions for future breast cancer survivors.

If you choose not to participate, what other options do you have?

You do not have to participate in this research study.

What if we learn about new risks during the study?

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will your privacy be protected?

No subjects will be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-CH will take all steps allowable by law to protect the privacy of personal information.

Your records will be kept in a locked office. If you are in the intervention group, your phone calls with the nurse will be taped recorded with your permission, and all information on the tapes will be kept confidential. Tapes will be kept in a locked cabinet and identified only by a code number unrelated to your name.

Will you be paid for participating?
You will receive gifts worth about $20 each time you complete the study questionnaires**.**

Will it cost you anything to participate?
There are no costs to you for participating in this study.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or weren't available to study personnel, or because the entire study has been stopped.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have further questions, or if a research-related injury occurs, you should call Dr. Merle Mishel, RN, PhD, at 1-800-349-5858.

What if you have questions about your rights as a subject?
This research has been reviewed and approved by the Committee on the Protection of the Rights of Human Subjects (Medical IRB) at the University of North Carolina at Chapel Hill. If you have any questions or concerns regarding your rights as a research subject, you may contact the Chairman of the Committee at (919) 966-1344.

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Subject's Agreement:

I have read the information provided above. I voluntarily agree to participate in this study.

Signature of Research Subject	Date
Printed Name of Research Subject	
Signature of Person Obtaining Consent	Date
Printed Name of Person Obtaining Consent	