The Quilt Study is a new research project designed to investigate factors that may influence outcomes in women with breast cancer. Although most breast cancers are diagnosed in middle- and older-aged women, very little research has been done to explore why some of these women experience a recurrence of their cancer while others do not. To address this need, the National Cancer Institute has awarded investigators at the FHCRC a five-year grant to study factors that may affect the risk of recurrence in women diagnosed with breast cancer at ages 45-79. Specifically, this study seeks to:

- Determine if selected exposures and lifestyle factors, both before and after diagnosis, increase or decrease the risk of recurrence;
- Investigate how exposures before diagnosis relate to specific tumor characteristics as a means to identify biologic pathways of disease progression; and
- Evaluate how selected proteins and other factors in tumor tissue, such as estrogen and progesterone receptors (ER/PR), relate to the risk of recurrence.

The most effective way to meet the goals of this study is to build upon the wealth of information already collected in previous breast cancer risk factor studies. Therefore, we...
are combining the participants and the valuable information collected from them during three studies conducted at the Center between 1993 and 1999:

- The Electric Power and Risk of Breast Cancer Study (EMF)
- The Women’s Contraceptive and Reproductive Experiences Study (CARE)
- The Puget Sound Area Breast Cancer Evaluation Study (PACE)

Our name, the **Quilt Study**, represents the merging of eligible women from these three previous studies into a new, larger study group or “cohort.”

### Questions and Answers

Below, we address some of the questions you may have about the **Quilt Study**. However, please contact us at any time if you would like to discuss the study or your participation with an investigator or study manager (see back page for study contact information).

#### Why am I being asked to participate in this study?

The Quilt Study is asking women from the EMF, CARE, and PACE studies who were ages 45-79 when first diagnosed with breast cancer to participate in this new research project. Although there are over 2,300 women in this new cohort, your individual participation is vital to the success of the study. The participation of each woman fitting the eligibility criteria will strengthen our results and increase the validity of the study.

None of the steps our previous studies have taken toward a greater understanding of breast cancer would have been possible without each of our participants. We thank you for your past contributions and hope you will assist us in this new endeavor.

#### I haven’t had a recurrence. Am I eligible?

Yes! We need to collect information from women who have and have not experienced disease recurrence. This allows us to compare the characteristics of women who have had a recurrence of their breast cancer with those of women who have not had a recurrence. Our goal is to identify what characteristics or factors increase or decrease the risk of recurrence in this study group.

#### What will I be asked to do for the Quilt Study?

We are asking participants to complete two telephone interviews about two years apart, and to provide consent for review of medical records and collection of tumor tissue for analysis. While some of you gave consent for these activities in your original study, we may ask you to complete updated forms.

#### How long will the interviews take?

One average, the first interview should take about 50-70 minutes. Most of the questions in this interview are about events after your diagnosis, but some include the
time period up to five years before your diagnosis. We will recontact you about two years later to complete a second, shorter questionnaire covering the time since your first interview. The second interview should take only about 20 minutes to complete. The actual time it takes to complete your interviews will depend on your personal health history.

**What kinds of questions will you ask?**

The interview begins with questions about your breast cancer diagnosis, treatment, follow-up care, and cancer events since diagnosis. We then ask about aspects of your medical history and about use of several specific types of medication. Another series of questions relates to smoking and alcohol use and physical activity. We will also ask you to update your family health history and collect some information on your ancestry. Finally, there are several questions, such as access to health care, which will allow the study to evaluate the impact of such factors on risk of recurrence.

**What if I don’t want to answer a question?**

Participation in this study is completely voluntary. You may decline to answer any question the interviewer asks you, and you may end the interview or withdraw from the study at any time. You may also complete the interview, but decide against giving consent for other study activities such as tumor tissue collection or medical and pharmacy record review.

**Why do you want to review my medical and pharmacy records?**

Reviewing medical and pharmacy records for breast cancer treatment and general health information is one of the best ways we have of collecting data, and we can only do so with your consent. Medical records contain treatment details such as the specific drug names, dates, and dosages of chemotherapy administered, and the specifics of radiation treatment including type and dose of radiation that are very useful to this kind of research. We will also look at other health factors and medication use that, while not directly related to breast cancer care, may have an effect on the post-diagnosis course of the disease.

**What will you do with my tumor sample?**

With your consent, we will request a sample of your tumor tissue and the pathology report from the facility where they are stored. Tumor samples will be analyzed for proteins and other types of tumor features to further our understanding of their relation to risk of recurrence and/or treatment response. Also, tumor tissue will be reserved for additional testing as new tumor markers are identified.

**Will I benefit from participating in this study?**

While you will not benefit directly from participating in this study, your contributions will add to the knowledge of risk factors for recurrence, and could potentially lead to new strategies for reducing the risk of recurrence and progression. Information obtained by this study may help identify modifiable factors (things that can be changed) that could offer women additional means to reduce their risk of recurrence. Your participation in this study will have no effect on either your health or your medical care.

**Will I get results from this study?**

No individual results will be generated by this study. Your questionnaire and medical record information will be combined with that of the many other women in the study and only analyzed in a collective way. Analyses of tissue samples are performed in research labs, for research purposes only. Study samples are not collected, handled, processed, or tested in a manner suitable for use in individual medical decision-making. After the study is complete, the data analyzed, and the results published, we look forward to sending you a summary of the research findings.

**Will you keep my information confidential?**

All information you provide during your interview, the data we collect through medical and pharmacy record review, and any results of laboratory research testing will be kept strictly confidential as provided by law. Our focus is on population-level research and, therefore, analyses are only relevant at the group level. Results on any single individual will not be presented in any publication or presentation generated by this research.

Only investigators and study staff directly involved with the project will have access to research information that can identify you. As part of their responsibility to protect the rights of study participants, the staff of the FHCRC Institutional Review Office and the Office of Human Research Protection may have access to your research information. Karen Hansen, Director of the FHCRC Institutional Review Office, can answer any questions about your rights as a research participant. She can be contacted at 206-667-4867.
Contacting Us

We are happy to speak with you at any time. Here are several options for contacting study staff:

Phone: The study managers, Cecilia O’Brien and Anne Oswald can be reached by calling our main departmental phone line at 206-667-4630. We accept collect calls. Office hours are 8 am to 5 pm, Monday through Friday. Feel free to leave a message if calling after hours. Please state that you are calling regarding the Quilt Study, and leave your name, phone number, and the best time to reach you at that number.

E-mail: Study staff will monitor and respond to all e-mail messages sent to quilt@fhcrc.org.

Mail: Please address all correspondence to:

Quilt Study
Attn: Cecilia O’Brien
Fred Hutchinson Cancer Research Center
M4-C308
PO Box 19024
Seattle, WA 98109

We’re on the Web

The Quilt Study website (www.fhcrc.org/science/phs/quilt) will be updated as the study progresses. It includes an overview of the study, contact information, study newsletters, previously published articles from the EMF, CARE, and PACE studies, and links to other breast cancer sites our participants might find of interest.

Moving?

If you move at any time during the study, please call or e-mail us with your new address and phone number. Because interviews are done by telephone, even women who move out of the country can still participate!

The mission of the Fred Hutchinson Cancer Research Center is the elimination of cancer as a cause of human suffering and death. The Center conducts research of the highest standards to improve prevention and treatment of cancer and related diseases. The Center honors the contributions of study participants to its mission and commits to the highest standards of integrity and confidentiality.

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