Because of research, we have better and more effective breast cancer drugs and therapies than ever before. As a result of these newer treatments, survival rates have increased, quality of life has improved, and treatment side effects are fewer for thousands of women with breast cancer. Many of these drugs and therapies would not be available today if it were not for cancer research programs and cancer patients willing to participate in clinical trials. Some women feel that participating in a clinical trial gives them an opportunity to help other women with breast cancer through the knowledge gained from the study.

**What is a Clinical Trial?**

A clinical trial is a research study designed to answer one or more questions about how a certain drug, treatment or medical device affects a disease such as breast cancer. Clinical trials are available for prevention, treatment and symptom management of breast cancer.

Breast cancer clinical trials can be sponsored by the National Cancer Institute, cancer cooperative groups, nonprofit organizations, pharmaceutical companies and device companies. Most breast cancer clinical trials offered through Sutter Health are sponsored by the National Cancer Institute or a pharmaceutical company.

In cancer care, treatment clinical trials examine the current standard of care and what researchers are hoping will be more effective. Placebos are never used unless the standard of care is observation, meaning that no other treatments are recommended (just follow-up with your doctor).

**Is Participating in a Clinical Trial Right for Me?**

The treatment you receive during a clinical trial may benefit you. Newer therapies may lead to better results. On the other hand, they may not be any better, or even as good as, standard therapies already available.

Participating in a clinical trial will require some extra time on your part. The research team will want to monitor you closely during the trial and collect follow-up information. This care is in addition to the care you will continue to receive from your oncologist and medical team.

**Am I Eligible for a Clinical Trial?**

Not everyone is eligible to participate in every clinical trial. Each clinical trial has criteria about who can participate. Criteria includes factors such as the stage of your cancer, previous treatment history and other medical conditions. These factors are called eligibility requirements. They are used to ensure that researchers will be able to answer the questions they plan to study. Your doctor and/or clinical research team will determine if you are eligible for a clinical trial after a physical examination and a review of your health history and medical records.
Considering a Clinical Trial

If you are eligible for a clinical trial, members of your research team will meet with you to discuss the details of the study. They will review a document called an informed consent.

The consent form will answer a number of questions, including:

- What is the purpose of the clinical trial?
- How long will the trial last?
- What is required of you to participate in this study?
- What treatments or drugs will you receive during the trial?
- What treatments, tests and/or procedures will be required during the study? How many and how often?
- Which treatments, tests, medications and/or procedures will be paid for?
- What are the risks and benefits of participating in this research study?
- What are all the treatment options, if you do not participate in a trial?

Voluntary Participation

Participation in clinical trials is always voluntary. You will not be enrolled in a clinical trial without your permission. You give permission to participate in a clinical trial by signing the informed consent form. You can change your mind about participating in the clinical trial at any time after signing the informed consent form. To stop your participation in a study, talk to your research team.

More Information on Clinical Trials

For more information on government-sponsored National Cancer Institute (NCI) trials, you can contact the NCI at 1-800-4-CANCER or you can find a comprehensive list of NCI-sponsored studies at https://clinicaltrials.gov. You can search for clinical trials available within the Sutter Health network at https://www.sutterhealth.org (look for the Research section). You can also ask your doctor or health care team for specific information regarding clinical trials available in your area.

The information in this section is not meant to replace the individual attention, advice, and treatment plan of your oncologist and medical team.

You will be given time to read this document and talk it over with your doctor, family or friends before deciding if you want to participate. The informed consent process continues as long as you are involved in the study. You will be notified of any modification, new information, or changes that may affect your participation.