HELPFUL RESOURCES
If you have questions about Baylor’s clinical trials, please call:

Baylor Sammons Cancer Center at Dallas Access Center
(214) 820-3535

Baylor Patient Help Line
1-800-4BAYlOR

WEB SITE INFORMATION
BaylorHealth.com

Clinical Trials direct link:
BaylorHealth.com/Forms/Locations/BRI/Trials.aspx

FAQs about Clinical Trials:
clinicaltrials.gov/ct/info/resources

PATIENT SUPPORT SERVICES
Ernie’s Appearance Center
(214) 820-8282

Virginia R. Cvetko Patient Education Center
(214) 820-2608
The road to hope started here more than 30 years ago.

For those whose lives have been affected by cancer, Baylor Charles A. Sammons Cancer Center at Dallas is DEDICATED to GIVING YOU REASONS FOR HOPE.

We continue to make strides in cancer care through our ongoing commitment to prevention, screening, risk assessment, genetic counseling, research and clinical trials.

If you would like to make an appointment or ask questions, please call:

- **Baylor Sammons Cancer Center at Dallas Access Center**
  3049 Worth Street
  Sammons Tower, Suite 600
  Dallas, Texas 75246
  (214) 820-3535

- **Baylor Information Line**
  1-800-4BAYLOR (800-422-9567)
Clinical Trial Basics

WHAT ARE CLINICAL TRIALS (RESEARCH)?

A clinical trial is a medical research study to answer specific questions about drugs, medical devices, new therapies or new ways of using known treatments. Clinical trials are used to determine whether new drugs, devices or treatments are safe and effective. Carefully conducted clinical trials are the best way to determine whether therapies will work in people.

A clinical trial is one stage of the research process. The search for new medical solutions begins in the laboratory, where scientists first develop and test new ideas. If an approach seems promising, the next step may be testing using animals to see how it affects a living being. The therapies with the most promising laboratory results may be moved into clinical trials. During a trial, more and more information is gained about the potential new therapy, risks and how well it may or may not work.

WHY ARE CLINICAL TRIALS IMPORTANT?

Clinical trials contribute to knowledge and understanding about medical conditions. If a new drug, device or treatment proves to be effective in a study, it may become a new standard treatment that may help people in the future. Many of today’s most effective standard treatments are based upon previous
study results. Clinical trials may also answer important scientific questions and suggest future research directions. Because of progress made through clinical trials, many people have been treated for medical conditions and are now living longer, healthier lives.

WHAT HAPPENS IN A CLINICAL TRIAL?
The clinical trials process depends on the kind of trial being conducted. To help protect participants and produce sound results, clinical trials are done according to strict scientific and ethical principles.

Each clinical trial has a protocol that explains how it will work. The study’s investigator, usually a medical doctor, prepares the protocol that explains what will be done in the study and why. While clinical trials may have risks for the people who take part, each study also takes steps to protect participants.

WHAT ARE THE TYPES OF CLINICAL TRIALS?

- **Treatment trials** test new treatments, new combinations of drugs, or new approaches to surgery or radiation therapy.

- **Prevention trials** look for better ways to prevent disease in people who have never had the disease or to prevent a disease from returning. These approaches may include medicines, vitamins, vaccines, minerals or lifestyle changes.

- **Screening trials** test the best way to detect certain diseases or health conditions.

- **Quality of life trials (or supportive care trials)** explore ways to improve comfort and the quality of life for individuals with a disease or condition.

WHAT ARE THE PHASES OF CLINICAL TRIALS?
Each phase of clinical trials answers different questions.

- **Phase I** trials are the first step in testing in humans. In these studies, researchers evaluate safety, determine dosage and identify side effects. Because less is known about the possible risks and benefits in Phase I, these studies usually include only a small number of people.

- **Phase II** trials focus on learning whether the new treatment, drug or device is effective and to further evaluate its safety. In this phase, the study drug or treatment is given to a larger group of people than in Phase I.

- **Phase III** trials confirm the study drug or treatment effectiveness, monitor side effects, compare it to standard treatments and collect information that will allow the drug or treatment to be used safely. In Phase III trials, the study drug or treatment is given to large groups of people.

- **Phase IV** trials, also called post-marketing studies, are done to see how well the treatment works in a broader mix of subjects and to learn more about side effects and their frequency. As in Phase III, the Phase IV study drug or treatment is given to large groups of people.
Research at Baylor Dallas
(214) 820-3535

CONQUERING CANCER THROUGH RESEARCH
Our focus on developing novel and innovative therapies allows more people to live with and survive cancer. Because at Baylor, we’re dedicated to conquering cancer.

Currently, we have more than 150 clinical trials in progress to study ways to treat breast, bladder, colorectal, esophageal, kidney, lung, ovarian, pancreatic and prostate cancers, as well as melanoma, multiple myeloma, leukemia, lymphoma and others.

Physicians on the medical staff at Baylor Dallas lead and participate in many oncology research trials each year. The trials are conducted through Baylor Research Institute, Mary Crowley Cancer Research Centers, Texas Oncology and US Oncology.

Baylor Dallas participates in major multi-center trials conducted by groups such as the National Institutes of Health (NIH) Clinical Trials Network, the National Surgical Adjuvant Breast and Bowel Project (NSABP) the American College of Surgeons Oncology Group, and the Southwest Oncology Group. Clinical trials allow patients entry into clinical studies that could change how medicine is practiced in the future.

RESEARCH IN CANCER TREATMENT
Clinical investigators at Baylor Dallas conduct Phase I, II, and III clinical trials of investigational drugs to examine and compare the effectiveness of different drug regimens. Texas Oncology and US Oncology offer more than 40 research protocols at Baylor Sammons Cancer Center for first-line, second-line, and third-line therapy for patients with local and metastatic malignancies. Additional trials at Baylor Dallas explore the use of sentinel node biopsy in diagnosing and determining treatment for different types of cancer. Surgical studies are also testing the use of hepatic ablation of liver tumors and the use of intraperitoneal heated chemotherapy for advanced gastrointestinal and ovarian cancers. Baylor Dallas’ blood and marrow transplant team collaborates on national “mini-transplant” trials that employ lower dosages of chemotherapy and radiation than those doses given with conventional allogeneic adult stem cell transplants. Baylor Dallas is conducting a clinical trial in exercise and its effects and potential benefits for breast cancer patients.

Investigators at Mary Crowley Cancer Research Centers are exploring methods of transferring cancer-toxic and immune-stimulatory genes through viral vectors to cancer hidden throughout the body. They are also investigating mechanisms that lead to an immune reaction to cancer and are testing new classes of anticancer drugs. Investigators at Baylor Research Institute have shown that an immunologically based dendritic cell vaccine can specifically inhibit tumor growth in some patients with metastatic melanoma. This approach is being evaluated for other malignant diseases.

RESEARCH IN CANCER PREVENTION
Physicians on the medical staff at Baylor Dallas have participated in recognized NSABP studies such as STAR (Study of Tamoxifen and Raloxifene) for breast cancer prevention and SELECT (Selenium and Vitamin E Cancer Prevention Trial) for prostate cancer prevention. Baylor Dallas was one of four sites nationally studying fine-needle aspiration in high-risk women to identify precancerous breast cell changes. Also, Baylor Dallas has protocols focused on chemoprevention of colon cancer.

RESEARCH IN CANCER DETECTION
Studies with specific diagnostic protocols investigate the use of positron emission tomography (PET) in detecting esophageal cancer and endoscopic identification of pancreatic lesions, as well as diagnosing breast cancer and Computed Tomography (CT) screening for lung cancer.
Hereditary Cancer Testing and Counseling

If you know or suspect you have a family history of cancer, we offer risk assessment and genetic testing and counseling for breast, ovarian and colorectal cancers.

HEREDITARY CANCER RISK PROGRAM (HCRP)
(214) 820-9600

The Hereditary Cancer Risk Program adds an important dimension to breast and ovarian cancer patient care. This program offers patient education, testing, interpretation of genetic testing results, and discussion of breast and ovarian cancer risk management options.

Laboratory analysis of the BRCA1 and BRCA2 genes that contribute to breast and other types of cancer add to the resources used by professionals to develop risk assessment for individuals. A genetics counselor reviews and discusses the personal risk assessment, including a plan for prevention, to help each individual take steps to reduce the likelihood of developing cancer.

COLON CANCER GENETIC TESTING
(214) 820-2692

The colon cancer genetic testing program provides genetic counseling and testing for presymptomatic cancer genes that cause colon cancer. After a genetic mutation is identified in an individual, counseling and testing for other family members can determine the hereditary risk of colon and other related cancers.

COLON CANCER GENETIC TESTING CONTINUED

Lynch syndrome, or hereditary nonpolyposis colorectal cancer, is caused by a germline mutation in a DNA mismatch repair gene. It is now possible to identify the germline mutations in the causative genes of many affected families. Regular colonoscopy screening is recommended for those identified as being at risk.

Baylor Sammons researchers are examining how the DNA mismatch repair system is regulated and how agitations in this system may lead to cancer. They have found that chronic inflammation induces a derangement in DNA mismatch repair system function, predisposing inflamed tissues to the development of cancer. They have also found that there are characteristic “signature” mutations in cancers that develop in inflamed tissues and that the mismatch repair system has undergone an inappropriate “relaxation” in response to oxidative stress. Baylor Sammons researchers are working on ways to reverse this maladaptive tissue response.