

A Vital Community Link To National Clinical Research To Find New, Improved Treatments and Cures



The Institutional Review Board at Northridge Hospital reviews all clinical research.
 Top Row (L-R): Jay Udani, MD; Lisa K. Carothers, LVN, CCRC; Ronald Ziman, MD; Alan Holtzman, MD; IRB Chairman Xavier Caro, MD; Ethicist Miriam Cotler, PhD; Irene K. Weaver
 Seated (L-R): Kanchana Karunaratne; Roy Azarnoff, PhD; Ezekial Freed, MD; Earl Winter, PhD; Ivan Rokos, MD
 Not Pictured: Sheldon Davidson, MD; Pamela Davis, MD; Linda Fidell, PhD; Blair Galbreath, PharmD; Jan Seymour, D. Min, Chaplain; David Vukadinovich, JD, MPH; Megan Lundgren, MHA; Shant Boshnagian, IRB Coordinator

Groundbreaking medical advances are the result of new ideas and approaches developed through clinical research. Previously limited only to large university medical centers, research is now performed at top hospitals across the nation. Northridge Hospital Medical Center remains on the forefront of these latest research developments by participating in clinical research opportunities and partnering with the nation's most credible institutions.

"Every day, thousands of people volunteer to take part in clinical research trials. It is because of their willingness to participate in these studies that modern medicine is able to meet the challenge of continuing to find new, improved treatments and cures," said **Xavier Caro, MD**, Chairman of the Institutional Review Board (IRB) at Northridge Hospital. "For these patients, clinical trials offer the best, or even the only possibility for combating their disease. History has shown, however, that only by testing new ideas in humans can these laboratory findings reach their full potential."

The process that brings a new drug or treatment from the research laboratory to the marketplace is a long and thorough one. Even before any treatment is allowed to be tested on humans, it must first be shown to be safe and effective in laboratory studies. One of the most important steps in the development process is the clinical trial, with volunteers who receive medical therapy and are observed for its effects.

IRBs were established in the early seventies in response to the Federal government's call that a nation-wide network of committees be built to review all clinical research. The IRB

at Northridge Hospital ensures that the research meets the strictest of federal, state and hospital standards in addition to well-established ethical principles. All hospital clinical trials must first be approved by the IRB, which consists of physicians, administrators, ethicists, and knowledgeable members of the general public. All study participants are fully informed of possible risks and benefits, and sign an informed consent before they are accepted into a clinical trial.

CANCER PROGRAM CLINICAL RESEARCH
 At Northridge Hospital, physicians in the Leavey Cancer Center have a number of drug therapy protocols to offer their patients, through an affiliation with the Southwest Oncology Group (SWOG), a network consisting of almost 4,000 leading physicians at 283 top institutions throughout the United States and Canada. Northridge Hospital is also the only facility in the San Fernando Valley that is part of the University of California, Los Angeles (UCLA) Oncology Research Network, which authorizes the Hospital to conduct research with investigational agents that are usually only allowed through universities.

These affiliations enable Northridge Hospital to offer the treatments of tomorrow. "We actively seek clinical trials based on the prevalence of certain types of cancer in our community," says Oncologist **Sheldon Davidson, MD**. "Due to the number of cases we see each year, several protocols are being conducted in different types of cancer with particular interest in breast, lung and prostate cancer." Each cancer study seeks to answer scientific questions

and tries to find better ways to prevent, screen for, diagnose, or treat cancer. However, cancer studies are not the only area of special interest at Northridge Hospital.

THE ACCORD STORY
 "I think the ACCORD study is going to be a landmark study," says Ophthalmologist and former Medical Staff President **Leon Partamian, MD**. "This is a major study setting the next generation of guidelines for diabetes care, and it really asks a fundamental question which hasn't been answered before, namely, whether blood sugar control really prevents heart attacks, strokes and death in people with Type 2 diabetes," continues Primary Investigator and Cardiologist **Kevin Ariani, MD**.

EMERGENCY MEDICAL RESEARCH
 Equally excited about research is Emergency Department physician **Ivan Rokos, MD**. "We have a unique opportunity for clinical trials that investigate acute life-threatening emergencies. For instance, through a cooperative effort between the Emergency and Cardiology Departments at Northridge Hospital, patients can be enrolled into various national heart attack clinical trials that provide access to cutting edge medications. The goal is to restore blood flow in the blocked coronary artery as soon as possible and limit the injury to the heart muscle."



IRB Chairman **Xavier Caro, MD** and **Ivan Rokos, MD** discuss protocols for proposed clinical trials.

MAKING A DIFFERENCE
 Northridge Hospital is proud to have been part of the Randomized Trial of Letrozole in Postmenopausal Women after Five Years of Tamoxifen Therapy for Early-Stage Breast Cancer. Led by the National Cancer Institute of Canada Clinical Trials Group, and in collaboration with the North American Intergroup and the Breast International Group, this study is an excellent example of the success a clinical trial can have in changing the treatment protocols for future patients. This trial found that using letrozole therapy, after the completion of standard tamoxifen treatment, significantly improves disease-free survival.

Today, Northridge Hospital is conducting more than 50 studies in the areas of Cardiology, Diabetes, Gynecology, Sleep Disorders, and Oncology. For more information on clinical research visit the National Institutes of Health WebSite www.ClinicalTrials.gov or www.CenterWatch.com which lists national and international clinical trials. You can also log onto www.NorthridgeHospital.org/Research to learn more about current research at Northridge Hospital, call our Cancer Research Department at 818-885-5458 to learn about specific cancer trials or call 818-885-5391 to learn about other trials.



STAR Clinical Trial participant **Pat Villegas** of North Hills meets with **Sheldon Davidson, MD** at her six month follow up visit. Pat began the clinical trial in November 2001. In an effort to prevent breast cancer, the STAR Clinical Trial evaluates the use of drug therapy (Tamoxifen and Raloxifen) in postmenopausal women. It is one of the largest breast cancer prevention studies ever assembled in the Nation. This clinical trail is currently closed to new participants.

What is Clinical Research?

A clinical research trial is carefully supervised research that is done in humans prior to the approval of a drug or medical procedure.

Why participate in research at Northridge Hospital?

- An opportunity to accelerate the development and testing of promising new therapies
- Enjoy the opportunity to further science
- Access to new, still experimental medications
- Access to highly sought after physicians or specialists
- Give back to society

What are the PHASES of clinical trials?

- ➔ **PHASE I** trials involve a small number of people to test a new treatment that has already undergone rigorous laboratory testing.
- ➔ **PHASE II** trials involve a larger group of patients (100-300) and allows researchers to see if it is effective and to continue evaluation of its safety.
- ➔ **PHASE III** trials may involve over a thousand patients at several medical institutions to confirm its effectiveness, monitor side effects, compare it to standard treatment, and collect data to compare outcomes and make sure the treatment can be used safely.
- ➔ **PHASE IV** trials occur after the treatment is put on the market to monitor effects of long-term use and also to see how it affects certain population groups.

What information is included in an informed consent?

Informed consent is the process of learning the key facts about a clinical trial before deciding whether or not to participate. The research team gives you an informed consent form that includes details about the study, risks and benefits, purpose, duration, required procedures, and key contacts. The informed consent process continues throughout the study. You can leave a clinical trial at any time without penalty, even after signing the consent forms.