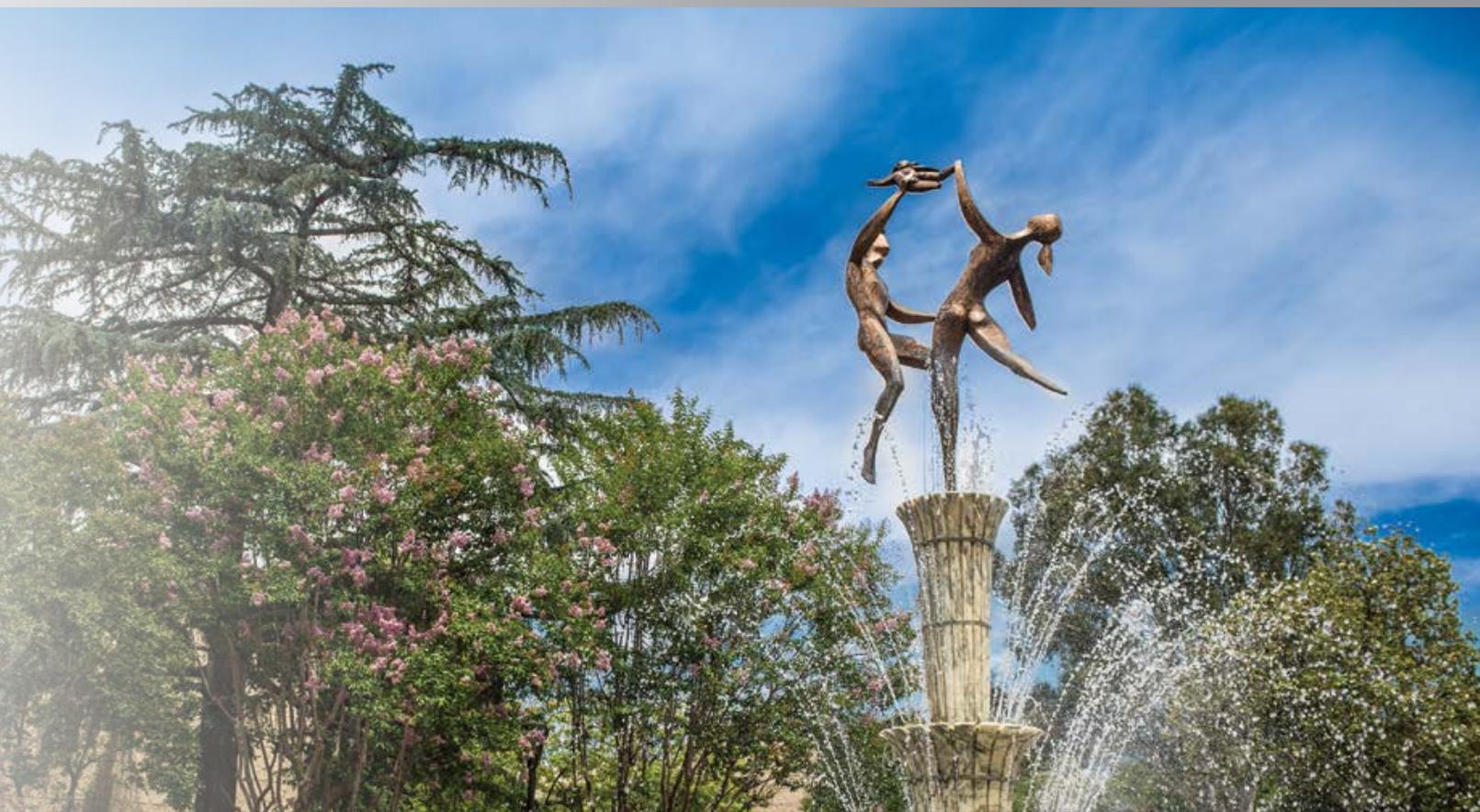


“Participating in a clinical trial offers an opportunity for patients to take active roles in their health care.”

— BMT Survivor

CHAPTER 17



Participation in Clinical Trials

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Participation in Clinical Trials

What you Might Like to Know about How to Volunteer for a Clinical Trial

Clinical trials are an essential step in developing new and better treatments for cancer. Clinical trials are very carefully designed medical studies that help, doctors, nurses and researchers provide new understanding and better treatments for cancer.

City of Hope has a long and successful history of advancing cancer treatment by taking laboratory and research discoveries to develop effective medications or treatments. Results of these studies have led to significant improvements in cancer treatments and patient care.

Each trial involves a patient, a physician, a medical organization and frequently a government agency or private company that sponsors the research. City of Hope currently conducts many promising and innovative clinical trials through its involvement in the National Comprehensive Cancer Network (NCCN). City of Hope conducted over 300 clinical trials in 2014. Over the years these clinical trials help to improve and redefine treatments, outcomes and care standards for patients in the United States and in other countries as well.

Clinical trials are very carefully designed research studies, in which patients voluntarily participate to help discover and test new methods of prevention, screening, diagnostics, treatment, symptom management and survivorship or quality-of-life factors for cancer patients. Clinical trials are conducted in four different phases with each phase serving a specific purpose to researchers.

Participating in a clinical trial offers an opportunity for patients to take active roles in their health care. By partnering with the research team to improve treatments, clinical trial participants have the chance to make a difference in their own lives and those of patients and families that follow them. Since you are at City of Hope, you may be participating in a clinical trial or know of someone who has.

Participation in clinical trials is always voluntary. Patients may decide to participate to help advance medical treatment or the clinical trial may offer a newer treatment that is not available as a standard care. Selection of patients for eligibility for a clinical trial is based on "inclusion" and "exclusion" criteria for a specific study. For example, eligibility may be based the type of cancer, the stage, genetic markers or previous treatments.

Patient safety in clinical studies is taken very seriously by the medical team and organizations like City of Hope. Participation is also guided by extensive federal regulations on the protection of patients in clinical trials. All participants in clinical trials must go through an informed consent process. The informed consent provides information on the study purpose, potential risks, benefits and treatment alternatives verbally, in written materials and in face-to-face meetings.

Patients who decide to participate sign the informed consent document but may still decide to not participate at any time during the study without compromising their medical care.

Additionally, federally conducted clinical studies of a drug, biological product or medical device regulated by the Food and Drug Administration must be reviewed, approved and monitored by an institutional review board (IRB). An IRB is made up of physicians, researchers and members of the community. Its role is to make sure that the study is ethical and the rights and welfare of participants are protected.

Every clinical study is led by a principal investigator, who is most often a medical doctor, although other health care professionals or researchers can be principal investigators. Clinical studies generally have a research team that may include doctors, nurses, social workers, statisticians and other health care professionals.

To Learn More about Clinical Trials

If patients or families would like to know more about clinical trials at City of Hope, they can ask always their doctors or members of their health care team.

Reliable online resources for clinical trials can be found on the U.S. National Institutes of Health website www.clinicaltrials.gov/ct2/about-studies/learn or the City of Hope website at www.cityofhope.org/clinical-trials.