

CLINICAL TRIALS

INTRODUCTION

A clinical trial is a study conducted by cancer researchers to discover new methods for cancer prevention, diagnosis and treatment that are safe and effective. The drugs and procedures used in clinical trials have been researched in successful laboratory and/or animal studies. Each study comes with a unique set of rights and responsibilities and can also affect privacy concerns and insurance coverage.

What are the different types of clinical trials?

- Treatment Trials—test new ways to treat cancer.
- Prevention Trials—test ways to prevent cancer, to prevent cancer survivors from relapsing with the same type of cancer, and to prevent cancer patients and/or survivors from developing a new type of cancer.
- Screening Trials—look for the best way to find cancer, especially in its early stages.
- Quality of Life or Supportive Care Trials—discover ways to improve the quality of life and comfort level of cancer patients.
- Diagnostic Trials—study tests and procedures that will identify cancer more accurately.
- Genetic Studies—look at issue such as how genetic makeup can affect detection, diagnosis or response to cancer treatment.

What should I know before agreeing to participate in a clinical trial?

Before you make the decision to participate in a clinical trial, you must first determine the potential risks and benefits of the trial, as well as your rights and responsibilities as a participant. With that knowledge, your decision to participate in a clinical trial is referred to as informed consent. For more information, please see the Informed Consent section of this Cancer Guide.

What are the potential problems with the clinical trial process?

One possible problem that arises in clinical trials is the lack of informed consent by a participant. There are federal and state laws that regulate what constitutes informed consent (see the Informed Consent section of this Cancer Guide for more information). If these guidelines have not been strictly followed, the people in charge of the clinical trial could be liable for any damage caused by their failure to get informed consent from any and all participants.

Another potential problem with a clinical trial could involve the process used for the study itself. For example, the researchers conducting the clinical trial could perform a procedure incorrectly or the study itself could be inherently unsafe.

Privacy issues in clinical trials are also unique. While most studies mask patients' names, the records themselves can become part of the study. Because trials are research studies, complete confidentiality cannot be guaranteed. Be sure to ask your physician about any concerns you might have with regard to privacy.

Finally, clinical trial treatments may not be covered by your insurance policy. However, other means of funding may be available, and your physician and/or a hospital social worker should be able to help you locate appropriate funding.

HELPFUL RESOURCES:**National Cancer Institute**

1-800-4-CANCER

<http://www.cancer.gov/clinicaltrials>**American Cancer Society**

1-800-ACS-2345

<http://www.cancer.org>**THE FOLLOWING CLINICAL TRIAL REFERENCES ARE SUGGESTED BY THE AMERICAN CANCER SOCIETY:**

National Cancer Institute: Learning About Clinical Trials. National Cancer Institute. Available at: www.nci.nih.gov/clinicaltrials/learning

ECRI: Should I Enter a Clinical Trial? A Patient Reference Guide for Adults with a Serious or Life-Threatening Illness. ECRI; February 2002.

Available at: www.ecri.org/Patient_Information/Patient_Reference_Guide/prg.pdf

Coalition of Cancer Cooperative Groups. Most Cancer Patients Satisfied with Clinical Trial Experience, yet, few aware of Opportunity: study shows improved physician-patient communications could increase enrollment in cancer clinical trials [press release]. June 5, 2006. Available at: www.cancertrials.org/help/press/pressTemplate.jsp?ID=2120&VID=10009

Food and Drug Administration. Access to unapproved drugs. Available at: www.fda.gov/cder/cancer/access.htm

National Cancer Institute: Learning About Clinical Trials. National Cancer Institute. Available at: www.nci.nih.gov/clinicaltrials/learning

Pharmaceutical Research and Manufacturers of America (PhRMA) - Medicines in Development for Cancer. May 2005. Available at: www.phrma.org/files/Cancer%20Survey.pdf

Bennett C, Adams J, Knox K, et al. Clinical trials: Are they a good buy? *Journal of Clinical Oncology*. 2001;19:4330-4339.

Getz K, Borfittz D. *Informed Consent: The Consumer's Guide to the Risks and Benefits of Volunteering for Clinical Trials*. Boston, Mass: CenterWatch; 2002.