

Cancer Clinical Trials

Key Points

- Clinical trials are research studies that involve people and test new ways to prevent, detect, diagnose, or treat cancer and other diseases (see Question 1).
- Every clinical trial has a protocol that describes what will be done in the trial, how the trial will be conducted, and why each part of the trial is necessary (see Question 6).
- National and international regulations and policies have been developed to protect the rights, safety, and well-being of people who take part in clinical trials and to ensure that trials are conducted according to strict scientific and ethical principles (see Question 7).
- Informed consent is a process through which people learn the important facts about a clinical trial to help them decide whether or not to take part in it, or whether to continue participating in it (see Question 8).
- Many states require that insurance companies cover the costs of routine care for people taking part in a clinical trial. In other states, voluntary agreements between the states and insurance companies include such a provision. However, coverage varies by state, by health insurance plan, and by type of clinical trial (see Question 14).

1. What are clinical trials, and why are they important?

Clinical trials are research studies that involve people. These studies test new ways to prevent, detect, diagnose, or treat diseases. People who take part in cancer clinical trials have an opportunity to contribute to scientists' knowledge about cancer and to help in the development of improved cancer treatments. They also receive state-of-the-art care from cancer experts.

2. Are there different types of cancer clinical trials?

Yes. Cancer clinical trials differ according to their primary purpose. They include the following types:

- **Treatment.** These trials test the effectiveness of new treatments or new ways of using current treatments in people who have cancer. The treatments tested may include new drugs or new combinations of currently used drugs, new surgery or radiation therapy techniques, and vaccines or other treatments that stimulate a person's immune system to fight cancer. Combinations of different treatment types may also be tested in these trials.
- **Prevention.** These trials test new interventions that may lower the risk of developing certain types of cancer. Most cancer prevention trials involve healthy people who have not had cancer; however, they often only include people who have a higher than average risk of developing a specific type of cancer. Some cancer prevention trials involve people who have had cancer in the past; these trials test interventions that may help prevent the return (recurrence) of the original cancer or reduce the chance of developing a new type of cancer.
- **Screening.** These trials test new ways of finding cancer early. When cancer is found early, it may be easier to treat and there may be a better chance of long-term survival. Cancer screening trials usually involve people who do not have any signs or symptoms of cancer. However, participation in these trials is often limited to people who have a higher than average risk of developing a certain type of cancer because they have a family history of that type of cancer or they have a history of exposure to cancer-causing substances (e.g., cigarette smoke).



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- **Diagnostic.** These trials study new tests or procedures that may help identify, or diagnose, cancer more accurately. Diagnostic trials usually involve people who have some signs or symptoms of cancer.
- **Quality of life or supportive care.** These trials focus on the comfort and quality of life of cancer patients and cancer survivors. New ways to decrease the number or severity of side effects of cancer or its treatment are often studied in these trials. How a specific type of cancer or its treatment affects a person's everyday life may also be studied.

3. Who sponsors clinical trials?

Government agencies, such as the National Cancer Institute (NCI) and other parts of the National Institutes of Health (NIH), the Department of Defense, and the Department of Veterans Affairs, sponsor and conduct clinical trials. In addition, organizations or individuals, including physicians, academic medical centers, foundations, volunteer groups, and biotechnology and pharmaceutical companies, also sponsor cancer clinical trials.

NCI sponsors a large number of clinical trials each year, and it has developed a variety of programs to make cancer clinical trials widely available in the United States and elsewhere. These programs include the following:

- The **Clinical Trials Cooperative Group Program**, which brings researchers, cancer centers, and doctors together into cooperative research groups. These groups work with NCI to identify important questions in cancer research and to design and conduct clinical trials that involve patients at multiple locations to answer those questions. Cooperative groups are located throughout the United States and in Canada and Europe. For more information, refer to the fact sheet *NCI's Clinical Trials Cooperative Group Program* at <http://www.cancer.gov/cancertopics/factsheet/NCI/clinical-trials-cooperative-group> on the Internet.
- The **Cancer Centers Program**, which provides support to research-oriented institutions that have been recognized as NCI-designated Cancer Centers or Comprehensive Cancer Centers because of their scientific excellence. More information is available through the program's Web site at <http://cancercenters.cancer.gov> on the Internet or from the National Cancer Institute-Designated Cancer Centers Database, which is available at https://cissecure.nci.nih.gov/factsheet/FactSheetSearch1_2.aspx on the Internet.
- The **Community Clinical Oncology Program (CCOP)**, which makes clinical trials available in a large number of communities across the United States. Through the CCOP, local hospitals throughout the country affiliate with an NCI-designated Cancer Center or Clinical Trials Cooperative Group, which makes it easier for doctors at those hospitals to offer their patients participation in an NCI-sponsored clinical trial. Consequently, patients do not have to travel long distances or leave loved ones to take part in an NCI-sponsored trial. The **Minority-Based Community Clinical Oncology Program (MBCCOP)** focuses on encouraging minority populations to take part in cancer clinical trials. It is important for members of these populations to participate in cancer clinical trials to determine which cancer treatments are most effective for people with different ethnic and racial backgrounds. More information about the CCOP and MBCCOP can be found at <http://dcp.cancer.gov/programs-resources/programs/ccop> on the Internet.
- The **NCI Community Cancer Centers Program (NCCCP)**, which is a program testing the concept of a national network to expand cancer research and deliver the latest, most advanced cancer care to more Americans in their home communities. One of the goals of the NCCCP is to increase patient participation in clinical trials in community settings. More information about the NCCCP is available at the program's Web site at <http://ncccp.cancer.gov> on the Internet.
- The **Specialized Programs of Research Excellence (SPOREs)**, which bring together scientists and researchers to design and implement research programs, including clinical trials, to improve the prevention, detection, diagnosis, and treatment of specific types of cancer. More information about SPOREs is available at <http://spores.nci.nih.gov/index.html> on the Internet.
- The **National Institutes of Health Clinical Center**, which is a research hospital located in Bethesda, Maryland. Trials at the Clinical Center are conducted by the components of NIH, including NCI. The NCI fact sheet *Clinical Trials Conducted by the National Cancer Institute's Center for Cancer Research at the National Institutes of Health Clinical Center* has more information about the Clinical Center. This fact sheet is available at <http://www.cancer.gov/cancertopics/factsheet/NCI/clinical-center> on the Internet.

4. Where do cancer clinical trials take place?

Cancer clinical trials take place in cities and towns across the United States and in other countries. They take place in doctors' offices, cancer centers and other medical centers, community hospitals and clinics, and veterans' and military hospitals. A single trial may take place at one or two specialized medical centers only or at hundreds of offices, hospitals, and centers.

5. Who manages clinical trials?

Each clinical trial is managed by a research team that can include doctors, nurses, research assistants, data analysts, and other specialists. The research team works closely with other health professionals, including other doctors and nurses, laboratory technicians, pharmacists, dietitians, and social workers, to provide medical and supportive care to people who take part in a clinical trial.

The research team closely monitors the health of people taking part in the clinical trial and gives them specific instructions when necessary. To ensure the reliability of the trial's results, it is important for the participants to follow the research team's instructions. The instructions may include keeping logs or answering questionnaires. The research team may also seek to contact the participants regularly after the trial ends to get updates on their health.

6. What are eligibility criteria, and why are they important?

Every clinical trial has a protocol, or action plan, that describes what will be done in the trial, how the trial will be conducted, and why each part of the trial is necessary. The protocol also includes guidelines for who can and cannot participate in the trial. These guidelines, called eligibility criteria, describe the characteristics that all interested people must have before they can take part in the trial. Eligibility criteria can include age, sex, medical history, and current health status. Eligibility criteria for cancer treatment trials often include the type and stage of cancer, as well as the type(s) of cancer treatment already received.

Enrolling people who have similar characteristics helps ensure that the outcome of a trial is due to the intervention being tested and not to other factors. In this way, eligibility criteria help researchers obtain the most accurate and meaningful results possible.

7. How is the safety of clinical trial participants protected?

National and international regulations and policies have been developed to help ensure that research involving people is conducted according to strict scientific and ethical principles. In these regulations and policies, people who participate in research are usually referred to as "human subjects."

Clinical trials that are conducted or supported by agencies of the U.S. Federal Government or that evaluate new drugs or medical devices that are subject to regulation by the U.S. Food and Drug Administration (FDA) must be reviewed and approved by an Institutional Review Board (IRB). The IRB reviews all aspects of a clinical trial to make sure that the rights, safety, and well-being of trial participants will be protected. The IRB must also review ongoing trials at least yearly and, based on those reviews, can decide whether the trial should continue as initially planned or if changes should be made to improve participant protection. An IRB can stop a clinical trial if the researchers are not following the protocol or if the trial appears to be causing unexpected harm to the study participants.

An IRB must have at least five members, including one scientist, one person who is not a scientist, and one person who is not affiliated with the institution where the trial is taking place and who is not an immediate family member of someone who is affiliated with that institution. The nonscientist and the nonaffiliated member can be the same person. IRBs can also include doctors, nurses, social workers, chaplains, patient advocates, and other health care or community professionals. All members of an IRB are required to be educated about the IRB's purpose, functions, and responsibilities, as outlined in Federal regulations. Trials taking place at multiple locations can involve multiple IRBs.

In addition, some clinical trials, especially phase III clinical trials (see Question 9), use a Data and Safety Monitoring Board (DSMB) to monitor the safety and progress of the trials. In contrast with IRBs, each trial has only one DSMB.

A DSMB is a committee of doctors, statisticians, and others who are independent of the people, organizations, and institutions that are sponsoring, organizing, and conducting the clinical trial. Similar to IRBs, DSMBs review the progress of a clinical trial and participant safety, but they also review data on the effectiveness of the trial interventions. DSMB members are experts in clinical research and clinical trials. They ensure that trial data are complete, and they can stop a trial early if safety concerns arise or if an answer to the main research question is obtained earlier than expected. Stopping a trial early because the main research question has been answered may make it possible for people who are not in the trial to get access to an effective intervention sooner. DSMBs have scheduled meetings to review clinical data, and their meeting minutes or recommendations are forwarded to the IRBs.

8. What is informed consent?

Informed consent is a process through which people 1) learn the important facts about a clinical trial to help them decide whether or not to take part in it, and 2) continue to learn new information about the trial that helps them decide whether or not to continue participating in it.

During the first part of the informed consent process, people are given detailed information about a trial, including information about the purpose of the trial, the tests and other procedures that will be required, and the possible benefits and harms of taking part in the trial. Besides talking with a doctor or nurse, potential trial participants are given a form, called an informed consent form, that provides information about the trial in writing. People who agree to take part in the trial are asked to sign the form. However, signing this form does not mean that a person must remain in the trial. Anyone can choose to leave a trial at any time—either before it starts or at any time during the trial or during the follow-up period. It is important for people who decide to leave a trial to get information from the research team about how to leave the trial safely.

The informed consent process continues throughout a trial. If new benefits, risks, or side effects are discovered during the course of a trial, the researchers must inform the participants so they can decide whether or not they want to continue to take part in the trial. In some cases, participants who want to continue to take part in a trial may be asked to sign a new informed consent form.

9. What does a trial's "phase" mean?

New interventions are often studied in a stepwise fashion, with each step representing a different "phase" in the clinical research process. The following phases are used for cancer treatment trials:

- **Phase 0.** These trials represent the earliest step in testing new treatments in humans. In a phase 0 trial, a very small dose of a chemical or biologic agent is given to a small number of people (approximately 10-15) to gather preliminary information about how the agent is processed by the body (pharmacokinetics) and how the agent affects the body (pharmacodynamics). Because the agents are given in such small amounts, no information is obtained about their safety or effectiveness in treating cancer. Phase 0 trials are also called micro-dosing studies, exploratory Investigational New Drug (IND) trials, or early phase I trials. The people who take part in these trials usually have advanced disease, and no known, effective treatment options are available to them.
- **Phase I (also called phase 1).** These trials are conducted mainly to evaluate the safety of chemical or biologic agents or other types of interventions (e.g., a new radiation therapy technique). They help determine the maximum dose that can be given safely (also known as the maximum tolerated dose) and whether an intervention causes harmful side effects. Phase I trials enroll small numbers of people (20 or more) who have advanced cancer that cannot be treated effectively with standard (usual) treatments or for which no standard treatment exists. Although evaluating the effectiveness of interventions is not a primary goal of these trials, doctors do look for evidence that the interventions might be useful as treatments.
- **Phase II (also called phase 2).** These trials test the effectiveness of interventions in people who have a specific type of cancer or related cancers. They also continue to look at the safety of interventions. Phase II trials usually enroll fewer than 100 people but may include as many as 300. The people who participate in phase II trials may or may not have been treated previously with standard therapy for their type of cancer. If a person has been treated previously, their eligibility to participate in a specific trial may depend on the type and amount of prior treatment they received. Although phase II trials can give

some indication of whether or not an intervention works, they are almost never designed to show whether an intervention is better than standard therapy.

- **Phase III (also called phase 3).** These trials compare the effectiveness of a new intervention, or new use of an existing intervention, with the current standard of care (usual treatment) for a particular type of cancer. Phase III trials also examine how the side effects of the new intervention compare with those of the usual treatment. If the new intervention is more effective than the usual treatment and/or is easier to tolerate, it may become the new standard of care.

Phase III trials usually involve large groups of people (100 to several thousand), who are randomly assigned to one of two treatment groups, or “trial arms”: 1) a control group, in which everyone in the group receives usual treatment for their type of cancer, or 2) an investigational or experimental group, in which everyone in the group receives the new intervention or new use of an existing intervention. The trial participants are assigned to their individual groups by random assignment, or randomization. Randomization helps ensure that the groups have similar characteristics. This balance is necessary so the researchers can have confidence that any differences they observe in how the two groups respond to the treatments they receive are due to the treatments and not to other differences between the groups.

Randomization is usually done by a computer program to ensure that human choices do not influence the assignment to groups. The trial participants cannot request to be in a particular group, and the researchers cannot influence how people are assigned to the groups. Usually, neither the participants nor their doctors know what treatment the participants are receiving.

People who participate in phase III trials may or may not have been treated previously. If they have been treated previously, their eligibility to participate in a specific trial may depend on the type and the amount of prior treatment they received.

In most cases, an intervention will move into phase III testing only after it has shown promise in phase I and phase II trials.

- **Phase IV (also called phase 4).** These trials further evaluate the effectiveness and long-term safety of drugs or other interventions. They usually take place after a drug or intervention has been approved by the FDA for standard use. Several hundred to several thousand people may take part in a phase IV trial. These trials are also known as post-marketing surveillance trials. They are generally sponsored by drug companies.

Sometimes clinical trial phases may be combined (e.g., phase I/II or phase II/III trials) to minimize the risks to participants and/or to allow faster development of a new intervention.

Although treatment trials are always assigned a phase, other clinical trials (e.g., screening, prevention, diagnostic, and quality-of-life trials) may not be labeled this way.

10. Are placebos used in cancer treatment clinical trials?

The use of placebos as comparison or “control” interventions in cancer treatment trials is rare. If a placebo is used by itself, it is because no standard treatment exists. In this case, a trial would compare the effects of a new treatment with the effects of a placebo. More often, however, placebos are given along with a standard treatment. For example, a trial might compare the effects of a standard treatment plus a new treatment with the effects of the same standard treatment plus a placebo.

11. What are some of the possible benefits of taking part in a clinical trial?

The benefits of participating in a clinical trial include the following:

- Trial participants have access to promising new interventions that are generally not available outside of a clinical trial.
- The intervention being studied may be more effective than standard therapy. If it is more effective, trial participants may be the first to benefit from it.

- Trial participants receive regular and careful medical attention from a research team that includes doctors, nurses, and other health professionals.
- The results of the trial may help other people who need cancer treatment in the future.
- Trial participants are helping scientists learn more about cancer (e.g., how it grows, how it acts, and what influences its growth and spread).

12. What are some of the potential harms associated with taking part in a clinical trial?

The potential harms of participating in a clinical trial include the following:

- The new intervention being studied may not be better than standard therapy, or it may have harmful side effects that doctors do not expect or that are worse than those associated with standard therapy.
- Trial participants may be required to make more visits to the doctor than they would if they were not in a clinical trial and/or may need to travel farther for those visits.
- Health insurance may not cover all patient care costs in a trial.

13. What are correlative research studies, and how are they related to clinical trials?

In addition to answering questions about the effectiveness of new interventions, clinical trials provide the opportunity for additional research. These additional research studies, called correlative or ancillary studies, may use blood, tumor, or other tissue specimens (also known as “biospecimens”) obtained from trial participants before, during, or after treatment. For example, the molecular characteristics of tumor specimens collected during a trial might be analyzed to see if there is a relationship between the presence of a certain gene mutation or the amount of a specific protein and how trial participants responded to the treatment they received. Information obtained from these types of studies could lead to more accurate predictions about how individual patients will respond to certain cancer treatments, improved ways of finding cancer earlier, new methods of identifying people who have an increased risk of cancer, and new approaches to try to prevent cancer.

Clinical trial participants must give their permission before biospecimens obtained from them can be used for research purposes.

14. Who is responsible for the costs of care for people taking part in a clinical trial?

The costs of care for people participating in a clinical trial fall into two general categories: 1) routine care costs and 2) research costs. Routine care costs are costs associated with treating a person’s cancer whether or not they are in a trial. These costs are usually covered by health insurance, but requirements vary by state and type of health plan. Research costs are costs associated with conducting a clinical trial; these costs may include the costs of extra doctor visits, extra tests, and procedures that are required for the trial but would not be part of routine care. Research costs are usually covered by the organization that sponsors the trial.

It is important to investigate how the costs of care will be covered before joining a clinical trial. Many states require that insurance companies operating in those states cover routine care costs; in other states, voluntary agreements between the states and insurance companies include such a provision. In states without these requirements or agreements, health plans may not cover routine care costs for people taking part in cancer treatment trials if the interventions being tested are considered experimental or investigational. States also vary in their requirements for covering costs associated with participation in cancer screening and prevention trials. Anyone thinking about taking part in a clinical trial should discuss cost coverage issues with representatives of their health plan. In some cases, it helps to have someone from the research team talk with the health plan’s representatives.

State laws and voluntary agreements, and health plans in states without laws or agreements, may list certain criteria that a trial must meet before routine care costs can be covered. For example: 1) the trial must be conducted or approved by specific organizations; 2) there must be a “reasonable expectation” that the treatment being tested in the trial will be at least as effective as the current standard of care; 3) the costs of treatments in the trial must not be substantially higher than the costs of treatments that are usually considered standard; and 4) the trial must focus on a type of cancer for which no standard

treatment is available. In addition, the hospital or treatment facility and its medical staff may have to meet a health plan's qualifications for performing certain specialty procedures, such as bone marrow transplants, if they are required as part of the trial.

More information about insurance coverage can be found on NCI's Clinical Trials and Insurance Coverage Web page at <http://www.cancer.gov/clinicaltrials/learning/insurance-coverage> on the Internet.

More information about state requirements and voluntary agreements can be found on NCI's Web site at <http://www.cancer.gov/clinicaltrials/developments/laws-about-clinical-trial-costs> on the Internet.

Some Federal programs help pay the costs of care in clinical trials:

- Medicare reimburses patient care costs for its beneficiaries who participate in clinical trials designed to diagnose or treat cancer. Information about Medicare coverage of clinical trials is available at <http://www.medicare.gov> or by calling Medicare's toll-free number for beneficiaries at 1-800-633-4227 (1-800-MEDICARE). The toll-free number for the hearing impaired is 1-877-486-2048. Also, the NCI fact sheet *More Choices in Cancer Care: Information for Beneficiaries on Medicare Coverage of Cancer Clinical Trials* is available at <http://www.cancer.gov/cancertopics/factsheet/support/medicare> on the Internet.
- Beneficiaries of TRICARE, the Department of Defense's health program, can be reimbursed for the medical costs of participating in NCI-sponsored phase II and phase III cancer treatment and cancer prevention (includes screening and early detection) trials. Additional information is available in the NCI fact sheet *TRICARE Beneficiaries Can Enter Clinical Trials for Cancer Prevention and Treatment Through a Department of Defense and National Cancer Institute Agreement*. This fact sheet can be found at <http://www.cancer.gov/cancertopics/factsheet/NCI/TRICARE> on the Internet.
- The Department of Veterans Affairs (VA) allows eligible veterans to participate in NCI-sponsored prevention, diagnosis, and treatment studies nationwide. All phases and types of NCI-sponsored trials are included. The NCI fact sheet *The NCI/VA Agreement on Clinical Trials: Questions and Answers* has more information. It is available at <http://www.cancer.gov/cancertopics/factsheet/NCI/VA-clinical-trials> on the Internet.

15. What happens when a clinical trial is over?

After a clinical trial is completed, the researchers look carefully at the data collected during the trial to understand the meaning of the findings and to plan further research. After a phase I or phase II trial, the researchers decide whether or not to move on to the next phase or stop testing the intervention because it was not safe or effective. When a phase III trial is completed, the researchers analyze the data to determine whether the results have medical importance and, if so, whether the tested intervention could become the new standard of care.

The results of clinical trials are often published in peer-reviewed scientific journals. Peer review is a process by which cancer research experts not associated with a trial review the study report before it is published to make sure that the data are sound, the data analysis was performed correctly, and the conclusions are appropriate. If the results are particularly important, they may be reported by the media and discussed at a scientific meeting and by patient advocacy groups before they are published in a journal. Once a new intervention has proven safe and effective in a clinical trial, it may become a new standard of care.

The FDA Amendments Act of 2007 requires that researchers report the "basic" results of clinical trials that tested FDA-regulated and FDA-approved chemical or biologic agents or medical devices in ClinicalTrials.gov (<http://www.clinicaltrials.gov>), a publicly accessible database maintained by the U.S. National Library of Medicine (NLM). Basic trial results, which include the following items, must be submitted whether or not the results are published in a peer-reviewed scientific journal.

- Demographic and baseline information about the participants.
- The progress of the participants through each stage of the trial (e.g., the number of participants who left the trial and at which stage).

- Results for the primary and secondary outcomes (also called endpoints) measured in the trial (e.g., tumor response, disease-free survival, overall survival, quality of life, etc.).
- A point of contact for the trial (to obtain additional information about the trial and its results).

More information about the ClinicalTrials.gov results database is available at <http://www.clinicaltrials.gov/ct2/info/results> on the Internet.

NLM's Web site also has an FAQ that lists other ways to find clinical trial results. This FAQ can be found at <http://www.nlm.nih.gov/services/ctresults.html> on the Internet.

16. Where can people find more information about clinical trials?

People interested in taking part in a clinical trial should talk with their health care provider.

Information about cancer clinical trials is also available from NCI's Cancer Information Service (CIS). CIS information specialists use NCI's Web site, located at <http://www.cancer.gov> on the Internet, to identify and provide detailed information about clinical trials that are currently accepting patients. NCI's Web site contains updated information about NCI-sponsored clinical trials and many other clinical trials conducted by independent investigators at hospitals and medical centers in the United States and around the world, as well as trials sponsored by pharmaceutical companies.

People also have the option of searching for clinical trials on their own. The clinical trials search form on NCI's Web site is located at <http://www.cancer.gov/clinicaltrials/search> on the Internet. Another resource is NLM's ClinicalTrials.gov (<http://www.clinicaltrials.gov>), which lists clinical trials for a wide range of diseases and conditions, including cancer.

NCI's Web site further contains educational materials about clinical trials, articles about recent clinical trial results, and information for research teams about conducting clinical trials. These resources can be accessed by visiting <http://www.cancer.gov/clinicaltrials> on the Internet.

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Related NCI materials and Web pages:

- National Cancer Institute Fact Sheet 1.4, *NCI's Clinical Trials Cooperative Group Program* (<http://www.cancer.gov/cancertopics/factsheet/NCI/clinical-trials-cooperative-group>)
- National Cancer Institute Fact Sheet 1.13, *TRICARE Beneficiaries Can Enter Clinical Trials for Cancer Prevention and Treatment Through a Department of Defense and National Cancer Institute Agreement* (<http://www.cancer.gov/cancertopics/factsheet/NCI/TRICARE>)
- National Cancer Institute Fact Sheet 1.17, *The NCI/VA Agreement on Clinical Trials: Questions and Answers* (<http://www.cancer.gov/cancertopics/factsheet/NCI/VA-clinical-trials>)
- National Cancer Institute Fact Sheet 1.22, *Clinical Trials Conducted by the National Cancer Institute's Center for Cancer Research at the National Institutes of Health Clinical Center* (<http://www.cancer.gov/cancertopics/factsheet/NCI/clinical-center>)
- National Cancer Institute Fact Sheet 2.13, *Donating Tissue for Cancer Research: Biospecimens and Biorepositories* (<http://www.cancer.gov/cancertopics/factsheet/information/donating-tissue-research>)
- National Cancer Institute Fact Sheet 8.14, *More Choices in Cancer Care: Information for Beneficiaries on Medicare Coverage of Cancer Clinical Trials* (<http://www.cancer.gov/cancertopics/factsheet/support/medicare>)
- National Cancer Institute-Designated Cancer Centers Database (https://cissecure.nci.nih.gov/factsheet/FactSheetSearch1_2.aspx)
- *Participating in a Trial: Questions to Ask Your Doctor* (<http://www.cancer.gov/clinicaltrials/learning/questions-to-ask-about-participating>)
- *Protecting Participants in Clinical Trials* (<http://www.cancer.gov/clinicaltrials/digestpage/protecting-participants>)

- *Taking Part in Cancer Treatment Research Studies*
(<http://www.cancer.gov/clinicaltrials/Taking-Part-in-Cancer-Treatment-Research-Studies>)

How can we help?

We offer comprehensive research-based information for patients and their families, health professionals, cancer researchers, advocates, and the public.

- **Call** NCI's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237)
- **Visit** us at <http://www.cancer.gov> or <http://www.cancer.gov/espanol>
- **Chat** using LiveHelp, NCI's instant messaging service, at <http://www.cancer.gov/livehelp>
- **E-mail** us at cancergovstaff@mail.nih.gov
- **Order** publications at <http://www.cancer.gov/publications> or by calling 1-800-4-CANCER
- **Get help** with quitting smoking at 1-877-44U-QUIT (1-877-448-7848)

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