CANCER FACTS

National Cancer Institute • National Institutes of Health
Department of Health and Human Services

Cancer Studies at the National Institutes of Health Clinical Center: Questions and Answers

Key Points

- Everyone seen at the National Institutes of Health (NIH) Clinical Center is either being screened for or participating in a clinical trial (research study) (see Question 2).
- International patients can participate in clinical trials at the NIH Clinical Center if they meet the trial's specific medical eligibility requirements (see Question 3).
- As part of the Federal Government, the NIH Clinical Center provides treatment at no cost to the patient (see Question 4).
- The Pediatric Oncology Branch conducts clinical trials for a wide variety of childhood cancers at the NIH Clinical Center; the Neuro-Oncology Branch conducts trials related to brain tumors (see Question 9).

1. What is the National Institutes of Health (NIH) Clinical Center?

The NIH Clinical Center in Bethesda, Maryland, is a research hospital that is part of the NIH, the Federal Government's principal agency for biomedical research. Known as the Warren Grant Magnuson Clinical Center, this facility fosters the interaction between laboratory and clinical research. It supports studies conducted by the various components of the NIH.

National Cancer Institute (NCI) studies at the NIH Clinical Center are designed to test how well new medical treatments or other interventions work in people. Most of these studies test new methods for screening, prevention, diagnosis, or treatment of cancer.

2. Who can participate in NCI studies at the NIH Clinical Center?

Everyone at the NIH Clinical Center must be enrolled in a clinical trial. To enter a trial, each participant needs to meet specific medical eligibility requirements. The participant and/or the participant's health care provider are asked to provide detailed medical information.

Patients referred to a clinical trial may request to have their medical records from the NIH Clinical Center sent to their health care provider. However, medical records cannot be released without the patient's permission.

3. Can cancer patients who live outside the United States participate in NCI studies at the NIH Clinical Center?

Yes. Patients from other countries can participate in clinical trials at the NIH Clinical Center if they meet the trial's specific medical eligibility requirements. U.S. citizens and lawful permanent residents have priority for participation in these trials.

Patients from other countries can be accepted into clinical trials, but only if their admission would not result in denying admission to American citizens or lawful permanent residents (due to limitations of resources or funding). International patients planning to travel to the United States for cancer treatment should contact the U.S. Embassy or Consulate in their home country for visa eligibility and application procedures.

4. How much does it cost to participate in a clinical trial at the NIH Clinical Center?

As part of the Federal Government, the NIH Clinical Center provides treatment and clinical care at no cost to participants in clinical trials. U.S. citizens and lawful permanent residents may receive a stipend to help cover some of the costs of traveling to Bethesda for treatment and followup care. However, participants are responsible for all travel costs for the initial visit. Patients who live outside the United States are responsible for all travel costs, including the initial visit and all subsequent visits.

5. How can cancer patients enter a clinical trial at the NIH Clinical Center?

Interested cancer patients should first discuss their options with their health care provider. If a clinical trial at the NIH Clinical Center is an option, patients and their providers should follow the steps below:

- To find out whether a study is available for a specific type of cancer, patients and providers can call the NCI's Clinical Studies Support Center (CSSC) at 1–888–624–1937 weekdays between 9:00 a.m. and 5:00 p.m. Eastern time. The CSSC staff of oncology (cancer) nurses and information specialists can identify clinical trials that may be appropriate for the patient. CSSC staff can mail, e-mail, or fax information about these trials, such as the type of treatment

being offered, the type of patients eligible for the trial, and the telephone number for the research nurse or doctor in charge of the study. Information is also available online at http://ccr.cancer.gov/trials/cssc.

- Patients should review the information with their provider to decide which study, if any, to consider further. The provider or patient can then contact the NCI research nurse or doctor in charge of the study.

- Patients who meet the initial medical eligibility requirements may be asked to schedule an appointment at the NIH Clinical Center. During this appointment, patients learn more about the clinical trial and may also be asked to undergo some tests.

- Before agreeing to take part in the study, patients need to understand key information about the clinical trial, including details about the treatment, tests, and possible risks and benefits. After discussing all aspects of the study, patients receive an informed consent form to read and sign.

6. What is informed consent?

Making a decision about participating in a research study involves understanding the potential risks and benefits, as well as the participant's rights and responsibilities. During the informed consent process, the participant is told about the risks, benefits, rights, and responsibilities of participating. Next, the person is asked to sign an informed consent form, which is presented along with written information about the trial and other issues. The informed consent process, however, does not stop when the form is signed.

The process continues throughout the trial, providing participants with information that will help them decide whether to stay in the trial. Participants will have many opportunities to ask questions about the trial and about information that may be learned during the trial or from other research.

More information about informed consent can be found on the NCI's Web site at http://www.cancer.gov/clinicaltrials/conducting/informed-consent-guide.

7. What other safeguards are built in to the process to protect the participants' health, rights, and privacy?

Every effort is made to protect and promote the welfare of the patient and provide the best medical and nursing care. Research needs may require longer periods of hospitalization than would be expected in a general hospital. NIH Clinical Center patients also have more examinations and tests than are usually given, and followup examinations are often required because of the nature of the study.

As in any other hospital across the country, all patients at the NIH Clinical Center are protected by the Patient's Bill of Rights. This bill ensures that patients' medical records

remain private and are not disclosed or released without the patient's consent. In addition, each study is carefully reviewed for risks and merit by the NCI Institutional Review Board, which includes doctors, researchers, and community leaders. No test or treatment is ever given that is unnecessarily hazardous to the patient. The patient is always free to decline to participate in any aspect of the study at any time. Researchers will stop any trial if unexpected problems are noted.

8. Why are clinical trials important?

Studies of new treatment approaches may lead to the development of more effective cancer treatments, or treatments that have fewer side effects. If a new treatment proves effective in a study, not only does it benefit the study participants, but it can become a new standard treatment that may help many patients. Because of progress made through clinical trials, many people with cancer are cured and many others have longer, more comfortable lives. However, it is important to recognize that treatments under study do not always turn out to be more effective than the standard (established) treatment.

Studies that look at possible ways to prevent or delay cancer, or to improve the well-being of cancer patients, also make an important contribution. While these studies may not compare interventions, they do teach us about ways people might reduce their risk for cancer. They also provide insights into ways to improve the quality of life for people who have been treated for cancer.

9. What other services are provided at the NIH Clinical Center?

Two branches of the NCI that study specific types of cancer have their own contact points:

- **The Pediatric Oncology Branch** (POB) conducts clinical trials for a wide variety of childhood cancers (except brain tumors) at the NIH Clinical Center. To refer children, teenagers, or young adults, call the POB office at 1–877–624–4878 between 8:30 a.m. and 5:00 p.m. Eastern time. An attending physician will return the call, determine whether the patient is eligible for a research study, and help arrange the referral. More information about the POB can be found at http://home.ccr.cancer.gov/oncology/pediatric/ on the Internet.

  Attending physicians in the POB are also available to provide a second opinion. The patient, family member, or health care provider can contact the POB to talk about a diagnosis or treatment plan.

- **The Neuro-Oncology Branch** offers a large number of clinical trials as well as consultations for children and adults with brain tumors. Staff can provide a second opinion for doctors, patients, and family members who are interested in this service. Specialists can either evaluate the patient in person or review the patient's medical records and scans.

To find out more about this service, and what information is needed, contact the Neuro-Oncology Branch at 301–402–6298 between 9:00 a.m. and 5:00 p.m. Eastern time. The Neuro-Oncology Branch's Web site can be found at http://home.ccr.cancer.gov/nob/default.asp on the Internet.

More information about the NIH Clinical Center is available on the Center's Web site at http://www.cc.nih.gov/home.cgi on the Internet.

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Related Topics

Publications (available at http://cancer.gov/publications)

- Cancer Facts 1.2, *The National Cancer Institute Cancer Centers Program*
- Cancer Facts 1.4, *NCI's Clinical Trials Cooperative Group Program*
- Cancer Facts 1.21, *Care for Children and Adolescents with Cancer: Questions and Answers*
- Cancer Facts 2.11, *Clinical Trials: Questions and Answers*
- Cancer Facts 7.47, *How To Find a Doctor or Treatment Facility If You Have Cancer*

National Cancer Institute (NCI) Resources

Cancer Information Service (toll-free)

Telephone: 1–800–4–CANCER (1–800–422–6237)
TTY: 1–800–332–8615

Online

NCI's Web site: http://cancer.gov
LiveHelp, NCI's live online assistance:
https://cissecure.nci.nih.gov/livehelp/welcome.asp

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