NATIONAL CANCER INSTITUTE FactSheet

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

Key Points

- The National Institutes of Health (NIH) Clinical Center is devoted exclusively to clinical investigation. Unlike most hospitals, the Clinical Center does not routinely provide standard diagnostic and treatment services. Admission is selective; patients are chosen by Institute physicians solely because the patient has an illness being studied by one or more of the Institutes (see Question 1).
- 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).
- There is no charge for medical care received at the NIH Clinical Center (see Question 4).
- Health care providers may identify available trials and corresponding study team contact information on the Internet. Providers and patients may also call the Clinical Trials Referral Office to find out if a clinical trial is available for a specific type of cancer (see Question 5).

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

The NIH Clinical Center in Bethesda, Maryland, is the research hospital for the NIH, the Federal Government's principal agency for biomedical research. The NIH Clinical Center is actually made up of two centers: the Warren Grant Magnuson Clinical Center and the Mark O. Hatfield Clinical Research Center. The NIH Clinical Center as a whole promotes translational research—that is, the transformation of scientific laboratory research into applications that benefit patient health and medical care. At the Center, patient care units are in close proximity to cutting-edge technologies and laboratories doing related research. This "bench-to-bedside" approach facilitates interaction and collaboration among clinicians and researchers. The Clinical Center supports clinical trials conducted by the 27 Institutes and Centers of the NIH, including the National

Cancer Institute (NCI). More information about the NIH Clinical Center is available on the Center's Web site at http://clinicalcenter.nih.gov on the Internet.

2. Who can participate in NCI cancer clinical trials at the NIH Clinical Center?

To enter a trial, each prospective 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. Because participant safety is of the highest concern, the NCI principal investigator and the research team make the final decision about enrolling a person during the screening visit.

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

Yes. People from other countries can participate in clinical trials at the NIH Clinical Center if they meet the trial's specific medical eligibility requirements. Due to limitations on resources and funding, however, U.S. citizens and lawful permanent residents have priority for participation in these trials.

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. Participants must pay for their own travel to the United States, and they must have a place to stay while they are in the United States.

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

There is no charge for medical care received at the NIH Clinical Center. Participants will be responsible for costs for travel to their initial screening visits. In most cases, once a participant is enrolled in a trial, NCI will pay for the transportation costs for all subsequent trial-related visits for participants who do not live in the local area. In addition, these participants will receive a small per diem for food and lodging expenses if they are being treated as outpatients. However, it is important for participants to maintain current health insurance for medical care required outside of the trial.

Participants who live outside the United States are responsible for all travel costs to the United States, including the initial visit and all subsequent visits.

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

Health care providers can make referrals by following the procedures outlined below:

- Identify trials appropriate for the patient by reviewing the trial information available at http://bethesdatrials.cancer.gov/clinical-research/index.asp on the Internet.

- Contact a member of the research team listed on the trial summary of a particular trial to discuss a screening visit, or to request more information.

Or

- Call the Clinical Trials Referral Office (CTRO) at 1–888–624–1937 weekdays between 9:00 a.m. and 5:00 p.m., Eastern time, to find out whether a clinical trial is available for a specific type of cancer. Individuals who live outside of the United States may contact the CTRO by e-mail at ncicssc@mail.nih.gov.

    - The CTRO staff will conduct a trial search and assist in the preliminary evaluation of eligibility, based on the patient's medical information provided.

    - The CTRO staff may either forward the prospective participant's information to the research teams of appropriate trials, or provide the patient or health care provider with contact information for appropriate investigators.

If the patient is eligible for a trial, the research team will call the health care provider or patient to discuss procedures further. Before enrolling in a clinical trial:

- Patients should review the information with their health care provider to decide which study, if any, to consider further.

- 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 trial, 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 trial, patients receive an informed consent form to read and sign.

6. What is informed consent?

Informed consent is an ongoing process during which information is presented that enables a person to decide voluntarily whether to begin or to continue to participate in a clinical trial. During the informed consent process, the participant is told about the purpose of the trial, the risks and benefits, the procedures, the schedule, the alternatives to participation, and other important details of the study. Once a person decides to enter a trial, he/she is asked to read, sign, and date an informed consent document. This document contains a summary of the clinical trial and explains the rights of the participant. The participant should be given a copy of the signed document.

The informed consent process does not stop when the informed consent document is signed, but continues throughout the trial. Participants are given any information

necessary to help them decide whether to stay in the trial. Participants 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 on the Internet.

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

Every effort is made to protect and promote the welfare of the participant, and to provide the best medical and nursing care possible. Research needs may require longer periods of hospitalization than would be expected for standard treatment. NIH Clinical Center participants may also have more examinations and tests than are usually given, and follow-up examinations are often required because of the nature of the studies.

All participants at the NIH Clinical Center are protected by the Patient's Bill of Rights. This bill ensures that medical records remain private and are not disclosed or released without the participant's consent. In addition, each trial is carefully reviewed for risks and merit by the NCI Institutional Review Board (IRB), which includes doctors, researchers, and community leaders. IRBs check to see that the trial is well designed, legal, and ethical; does not involve unnecessary risks; and includes safeguards for patients. No test or treatment is ever given that is unnecessarily hazardous to the participant. The participant is always free to decline to participate in any aspect of the study at any time. Researchers will stop any trial if unexpected problems arise.

8. How is the referring health care provider kept informed of patient care and progress during the trial?

The NCI and the referring health care provider coordinate patient care. The NCI principal investigator discusses the trial and treatment with the patient's health care provider upon receiving a referral. Once a patient is enrolled in a trial, the investigator will send updates and test results at regular intervals.

NCI encourages health care providers to continue open communication with their patients throughout the clinical trial. Patients are encouraged to share their clinical trial experience with their health care providers. Referring health care providers are welcome to call the NCI research team at any time to discuss patient treatment plans and care.

9. 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 clinical trial, not only does it benefit the trial participants, but it can become a new standard of care that may help other people with cancer. Due to 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 treatment.

Trials that look at new ways to detect, prevent, or delay cancer, or to improve the well-being of cancer patients also make an important contribution. The results from these studies can help reduce deaths from cancer by identifying better ways to find cancer early, when it is usually easier to treat, and by finding ways to reduce the risk of developing cancer. They also provide insights into ways to improve the quality of life for people who are being or have been treated for cancer.

10. What other services are provided by NCI at the NIH Clinical Center?

The following branches of NCI study specific types of cancer at the Clinical Center, provide various types of support and care, and have their own contact information:

- **The Pediatric Oncology Branch (POB)** conducts clinical trials for a wide variety of childhood cancers at the NIH Clinical Center. To refer children, teenagers, or young adults, the patient's health care provider should contact the POB office at 1–877–624–4878 between 8:30 a.m. and 5:00 p.m., Eastern time. The attending physician will discuss the case with the patient's health care provider, determine eligibility for treatment under a clinical protocol, and help arrange the referral. Once the patient has been accepted for evaluation, a social worker from the POB will contact the family and provide information on the study, as well as details about travel and lodging. 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 (NOB)** offers 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 301–594–6767 or 1–866–251–9686 (toll-free) between 9:00 a.m. and 6:00 p.m., Eastern time. The Neuro-Oncology Branch's Web site can be found at http://home.ccr.cancer.gov/nob on the Internet.

- **The Immunotherapy Service of the Surgery Branch** conducts clinical trials for melanoma. The patient, family member, or health care provider can get information about these studies by calling the Immunotherapy Referral Office at 1–866–820–4505 or 301–451–1929 between the hours of 8:30 a.m. and 5:30 p.m., Eastern time. A member of the study team is available to discuss open studies for

which the patient may be eligible. If a patient is thought to be eligible, their health care provider will be asked to send medical records and scans. A screening visit is scheduled only after all the information is received and reviewed. The Surgery Branch does not offer consultations or second opinions for patients. More information about the Surgery Branch can be found at http://ccr.cancer.gov/labs/lab.asp?labid=93 on the Internet.

- **The Urologic Oncology Branch** offers consultations for patients who have been diagnosed with renal or localized prostate or bladder cancer and who have not had surgery. Health care providers and patients may call 301–496–6353 between the hours of 7:30 a.m. and 5:00 p.m., Eastern time. After speaking with the physician, the patient may be asked to come in for a screening visit. Surgery and/or referral to clinical studies will be offered if appropriate. More information about the Urologic Oncology Branch can be found at http://ccr.cancer.gov/labs/lab.asp?labid=92 on the Internet.

- **The Thoracic Group of the Surgery Branch** conducts clinical trials for esophageal cancer, lung cancer, pleural mesothelioma, and lung metastasis. Patients and health care providers may call 301–451–1233 between 6:00 a.m. and 2:30 p.m., Eastern time, to receive information about available trials and eligibility requirements. Messages can be left 24 hours a day. Consultations and second opinions may be offered to patients and health care providers. If a patient is interested in participating in a trial, all medical records must be sent to the team. The patient's case will then be reviewed by a physician on staff and, if the patient is thought to be a likely candidate, a screening visit will be scheduled. Additional information about the Surgery Branch can be found at http://ccr.cancer.gov/labs/lab.asp?labid=93 on the Internet.

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Related Resources

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

- National Cancer Institute Fact Sheet 1.2, *The National Cancer Institute Cancer Centers Program*
- National Cancer Institute Fact Sheet 1.21, *Care for Children and Adolescents With Cancer: Questions and Answers*
- National Cancer Institute Fact Sheet 1.4, *NCI's Clinical Trials Cooperative Group Program*
- National Cancer Institute Fact Sheet 2.11, *Clinical Trials: Questions and Answers*
- National Cancer Institute Fact Sheet 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://www.cancer.gov
LiveHelp, NCI's live online assistance:
https://cissecure.nci.nih.gov/livehelp/welcome.asp

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