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Cancer Clinical Trials at the NIH Clinical Center

Key Points

- The NIH Clinical Center is devoted exclusively to clinical investigation. NIH physicians only accept patients for clinical trials who have an illness being studied by one or more of the Institutes and meet the trial's specific medical eligibility requirements (also called eligibility criteria).
- Health care providers and patients can identify available trials and the study team contact information through NCI's clinical trials search form or by calling the Clinical Trials Referral Office to find out if a clinical trial is available for a specific case.
- There is no charge for medical care received at the NIH Clinical Center.

1. What is NCI's Center for Cancer Research (CCR)?

The Center for Cancer Research (CCR) is NCI's program at the National Institutes of Health (NIH) campus in Bethesda, Maryland. The CCR is home to more than 250 scientists and clinicians who work in intramural research. CCR's investigators include basic, clinical, and translational scientists who work together to advance our knowledge of cancer and AIDS and to develop new therapies against these diseases. CCR investigators collaborate with scientists at more than 20 NIH Institutes and Centers, as well as with scientists in academia and industry.

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

The NIH Clinical Center in Bethesda, Maryland, is the research facility 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 CCR.

The NIH Clinical Center is devoted exclusively to clinical investigation. Unlike most facilities, the Clinical Center does not routinely provide standard diagnostic and treatment services. NIH physicians accept patients for clinical trials if the patient has an illness being studied by one or more of the Institutes and the patient meets the trial's specific medical eligibility requirements (also called eligibility criteria). More information about the NIH Clinical Center is available at http://clinicalcenter.nih.gov.

3. Why are clinical trials important?

Clinical trials are the way in which new and more effective cancer treatments are discovered and proven. If a new treatment proves effective in a clinical trial, it benefits the trial participants and can also 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 living longer. However, it is important to recognize that treatments under study do not always turn out to be more effective than the standard treatment. More information about clinical trials, including questions people can ask their

doctor or nurse before deciding to enter a trial, can be found in the NCI fact sheet *Cancer Clinical Trials*, which is available at http://www.cancer.gov/cancertopics/factsheet/Information/clinical-trials.

4. What are eligibility criteria?

To enter a clinical trial, each prospective applicant must meet specific requirements, called eligibility criteria. Eligibility criteria are an important part of each clinical trial's protocol or action plan. The criteria vary from study to study and may include age, gender, medical history, and current health status. Treatment studies often require that patients have a particular type and stage of cancer. Eligibility criteria help ensure the participants' safety. For example, some people have other health problems that could be made worse by the treatment being studied. The qualifications also help researchers achieve accurate and meaningful results.

5. How can patients take part in a clinical trial at the NIH Clinical Center?

Health care providers and cancer patients can initiate the process to join a trial by performing a search themselves or by calling the Clinical Trials Referral Office (CTRO) directly to see if a study is available.

- Identify trials appropriate for the patient by reviewing the trial information available at http://bethesdatrials.cancer.gov/clinical-research/index.asp or by using NCI's clinical trials search form at http://www.cancer.gov/clinicaltrials/search.

- 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 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 the United States may contact the CTRO by e-mail at ncicssc@mail.nih.gov.

- The CTRO staff will transfer the caller to the appropriate referral specialist based on the patient's diagnosis. The CTRO staff will also provide contact information for the primary referral specialist and any additional referral specialist(s) who may be able to assist in finding an appropriate trial. If the patient is eligible for a trial, the research team will call the health care provider or patient to discuss next steps.

- Patients who meet 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.

The following NCI branches study specific types of cancer at the Clinical Center, provide various types of support and care, and may be contacted directly:

- **The Medical Oncology Branch and Affiliates** conducts trials for patients with a variety of cancers. The patient, family member, or health care provider can receive information about these studies by calling the Medical Oncology Referral Office at 1–866–611–6310 or 301–451–1228 between the hours of 9:00 a.m. and 5:00 p.m., Eastern time. Messages may be left if lines are busy or after hours. A member of the referral team will 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, including scan images and pathology materials. A screening visit is scheduled after appropriate medical information is received and reviewed. Consultations or second opinions for patients who are not eligible for trials may be provided at the discretion of the investigator.

  Additional information about the Medical Oncology Branch and Affiliates can be found at http://ccr.cancer.gov/labs/lab.asp?labid=753.

- **The Neuro-Oncology Branch (NOB)** offers clinical trials as well as consultations for patients 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.

Consultations for pediatric patients are available and may be requested by contacting the NCI Pediatric Oncology Branch at 1–877–624–4878 (see below).

To find out more about this service and what information is needed, contact the NOB at 301–594–6767 or 1–866–251–9686 (toll-free) between 9:00 a.m. and 6:00 p.m., Eastern time. More information about the NOB can be found at http://home.ccr.cancer.gov/nob.

- **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://pediatrics.cancer.gov/.

  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 Radiation Oncology Branch (ROB)** designs and conducts pre-clinical and clinical research on the biologic and therapeutic effects of radiation therapy. The clinical trials that the ROB develops and conducts involve novel technology and/or imaging-based approaches to radiation therapy treatment. Within ROB, computed tomography and magnetic resonance (MR) image fusion is a routine part of a patient's treatment plan. The ROB also provides treatment via radiosurgery, intensity-modulated 3–D conformal radiotherapy, real-time dose measurement, brachytherapy, and MR-guided procedures.

  To find out more about current clinical trials in the ROB, patients and health care providers can call 301–451–8905 or 301–496–5457. More information about the ROB can be found at http://ccr.cancer.gov/labs/lab.asp?LabID=52.

- **The Surgery Branch** offers trials in the following areas:

  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.

  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.

- **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.

6. 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.

7. 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. Once a participant is enrolled in a trial, NCI will pay for transportation for 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 that is required outside of the trial or that is provided away from the Clinical Center.

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.

8. How are the participant's health, rights, and privacy protected?

Every effort is made to protect and promote the welfare of the participant and to provide the best medical and nursing care possible.

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. The purpose of the trial, the risks and benefits, the procedures, the schedule, the alternatives to participation, and other important details of the study are explained to the patient. If 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.

More information about informed consent can be found at http://www.cancer.gov/clinicaltrials/patientsafety/informed-consent-guide.

In addition, 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.

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

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.

Related Resources

- *A Guide to Understanding Informed Consent* (http://www.cancer.gov/clinicaltrials/patientsafety/informed-consent-guide)
- *Cancer Clinical Trials* (http://www.cancer.gov/cancertopics/factsheet/Information/clinical-trials)
- *Care for Children and Adolescents with Cancer* (http://www.cancer.gov/cancertopics/factsheet/NCI/children-adolescents)
- *How To Find a Doctor or Treatment Facility If You Have Cancer* (http://www.cancer.gov/cancertopics/factsheet/Therapy/doctor-facility)
- *National Cancer Institute: Clinical Trials at NIH in Bethesda, Maryland* (http://bethesdatrials.cancer.gov/information-and-resources/handbook-2007.pdf)
- *NCI's Clinical Trials Cooperative Group Program* (http://www.cancer.gov/cancertopics/factsheet/NCI/clinical-trials-cooperative-group)
- *Taking Part in Cancer Treatment Research Studies* (http://www.cancer.gov/clinicaltrials/Taking-Part-in-Cancer-Treatment-Research-Studies)
- *Targeted Cancer Therapies* (http://www.cancer.gov/cancertopics/factsheet/Therapy/targeted)
- NCI-Designated Cancer Centers (with contact information for patient referrals) (http://www.cancer.gov/researchandfunding/extramural/cancercenters)