Questions and Answers

1. What is The Cancer Genome Atlas?
The Cancer Genome Atlas (TCGA) is a large-scale collaborative effort by the National Cancer Institute (NCI) and the National Human Genome Research Institute (NHGRI) to systematically characterize the genomic changes that occur in cancer.

2. Why is TCGA important to the future of cancer research?
Our knowledge of the molecular bases of many cancers is improving daily. However, cancer is a complex disease and, in fact, may be unique in each cancer patient. Scientists expect that a deeper, systematic understanding of cancer genomics will provide important insights into the mechanisms responsible for the uncontrolled growth of cancer cells and their spread throughout the body.

The genomic information generated by TCGA could fuel rapid advances in cancer research and suggest new therapeutic targets. It could also suggest new ways to categorize tumors, which might allow clinical trials to focus on patients who are most likely to respond to specific treatments.

The TCGA will attempt to develop a comprehensive catalog, or atlas, of the many genomic changes that occur in cancers. These include chromosomal rearrangements, DNA mutations, and epigenomic changes (the chemical modifications of DNA or chromosomal proteins that can turn genes on or off without altering the sequence of "letters," or bases, in the DNA). It also could lead to new diagnostic tools to detect cancer earlier, new tests to help clinicians individualize treatments to each patient's cancer type, and, ultimately, new strategies for preventing cancer.

3. What will TCGA mean for cancer patients?
Discoveries in cancer genomics already have helped identify several new treatments that target cancer-related molecules. For example, Gleevec™ effectively treats chronic myelogenous leukemia, gastrointestinal stromal tumors, and several other cancers. Another product of cancer genomics research, Herceptin™, effectively treats about 20 percent of breast cancers with a specific genetic anomaly.

While these targeted treatments have performed impressively, the list of cancer drugs is still quite short. Researchers expect that developing an atlas of genomic changes in various tumors will identify new tumor-specific molecules, which could lead to new cancer drugs. It could also lead to new diagnostic tools to detect cancer earlier, new tests to help clinicians individualize treatments to each patient's cancer type, and, ultimately, new strategies for preventing cancer.

4. How is the TCGA different from the Human Genome Project?

The Human Genome Project (HGP), an international effort led in the United States by NHGRI and the Department of Energy, had the goal of providing a reference DNA sequence of the human genome. That goal was met in April 2003.

The HGP also drove major advances in DNA sequencing technology and laid the foundation for other genome-based research projects. One of these was the International HapMap Project, which recently produced a map of human genetic variations that is facilitating the search for genes involved in disease susceptibility.

TCGA is another genome-based research project made possible by the HGP. TCGA will build upon the reference human genome sequence and important advances in cancer research to characterize the many genomic alterations involved in cancer. While the HapMap focused on inherited factors in disease, most of the TCGA findings are expected to be gene mutations that arise in cells after a person is born. These socalled somatic, or acquired, mutations are not heritable. Most cancers acquire several somatic mutations before becoming threatening to health.

The ultimate aim of the TCGA is to provide researchers with a comprehensive atlas of cancer-associated genomic changes, along with other new tools and technologies that will lead to significant improvements in clinical care for cancer patients and those at risk for developing cancer.

5. What is the TCGA Pilot Project and how was it developed?

Compiling a complete atlas of the genomic changes in cancer is an ambitious venture requiring significant planning. NCI and NHGRI are taking a phased approach to ensure that the appropriate technologies, systems, and processes are developed and evaluated. The first phase is the 3-year TCGA Pilot Project, begun in December 2005. The pilot project will help assess the feasibility of a larger project to develop a complete cancer genome atlas. Only if the pilot project achieves its goals will the larger project move forward.

Major technical issues to be addressed by the TCGA Pilot Project include improving genome characterization and DNA sequencing technologies, developing standards and quality control criteria in biospecimen handling, improving data analysis accuracy, and evaluating the utility of the data produced by genomic analyses of tumor biospecimens.

In preparation for the TCGA Pilot Project, NCI and NHGRI convened a workshop in July 2005. The workshop was attended by some of the world's leading experts in cancer genomics, bioinformatics, gene expression technologies, and bioethics, as well as members of the patient advocacy community. Participants discussed the best approaches to characterizing the cancer genome, and information from this workshop helped guide the development of the pilot project.

6. What questions will the TCGA Pilot Project address?

The goal of the TCGA Pilot Project is to determine the feasibility of a large-scale effort to identify and catalog the genomic alterations found in all cancers. Because this initiative presents many technical challenges, specific benchmarks must be reached before TCGA receives the "green light" to widen its scope beyond the pilot phase. Important milestones for the TCGA Pilot Project include:

- identifying unique genomic alterations in a significant percentage of tissue samples from a few tumor types;
- differentiating tumor subtypes based on specific genomic alterations and/or molecular markers;
- identifying new cancer-related epigenomic alterations; and
- developing new and improved technologies and data analysis tools.

7. How will the TCGA Pilot Project be organized?

The TCGA Pilot Project will include five components:

- **Cancer Genome Characterization Centers (CGCC):** Using established technologies, these centers will analyze the genomic changes found in human tumors and identify interesting genomic regions for further characterization.

- **Genome Sequencing Centers (GSC):** Using high-throughput methods similar to those employed in the Human Genome Project, these centers will sequence the genes and other genomic targets identified by the CGCCs.

- **Human Cancer Biospecimen Core Resource:** This core will collect, process, and distribute cancerous and healthy control tissue samples to the CGCCs and GSCs.

- **Data Management, Bioinformatics, and Computational Analysis:** This component will develop methods for collecting, storing, and distributing the clinical and genomic data generated by the pilot project.

- **Technology Development:** Technological challenges presented by the TCGA Pilot Project include the need to improve the quality, throughput, and cost of gene expression and other molecular characterization methods; further decrease the costs of DNA sequencing while maintaining quality; improve the detection and throughput of technologies for detecting epigenomic changes, while also decreasing cost; and develop new and better methods of correlating disease state with genomic changes.

The individual components of the TCGA Pilot Project will be organized as a research network to foster interaction and collaboration among the participants, who will have a broad range of capabilities and expertise. The collaborative nature of the TCGA Research Network will be encouraged by collaborative management by NCI and NHGRI staff.

Please refer to TCGA: How Will It Work? for an illustrated explanation of the TCGA process.

8. How much will the TCGA Pilot Project cost and how will it be funded?

The TCGA will require considerable resources and preparation to address all of the technical and scientific issues. NCI and NHGRI have each committed $50 million for the 3-year TCGA Pilot Project.

The first year budget for the Cancer Genome Characterization Centers has been set at $11.7 million, with an additional $2 million for developing new technologies. The first year budget for the Genome Sequencing Centers has been set at approximately $16.7 million. Additional funds will be provided for the bioinformatics component and biospecimen core resource.

9. Why are NCI and NHGRI pursuing the characterization of the human cancer genome now?

At least three important advances suggest that now is the ideal time to launch a major human cancer genome effort. First, recent identification of genetic mutations linked to breast cancer, colon cancer, and many other cancers has led to the development of diagnostic tests that can point to the most effective treatment or prevention strategy. This has provided the "proof of concept" that comprehensive knowledge of the molecular origins of cancer can lead to more effective diagnosis, treatment, and prevention.

The second major advance is the availability of the human genome sequence generated by the Human Genome Project and the map of human genetic variations generated by the International HapMap Consortium. These reference sets will provide an excellent starting point for comparing the genomic data derived from various cancers.

Finally, technologies to sequence and analyze the genome have evolved rapidly. At the beginning of the Human Genome Project in 1990, the cost of sequencing was more than $10 per finished "letter," or base, of the DNA code. Today, the cost of sequencing is less than 2 cents per finished DNA base. Other high-throughput technologies for identifying genomic and epigenomic changes in the cancer cell have also been developed recently. TCGA will aim to build upon these advances and continue to drive the development and improvement of genomic sequencing and analysis technologies.

Together, these developments now make it possible to envision an effort to catalog the genomic changes associated with many known forms of cancer.

10. What are the major challenges faced by TCGA?

A major challenge for cancer research, especially for the molecular characterizations of cancer-associated changes, is the complexity of the disease, which is actually more than 200 diseases. Different cancer types originate from a wide range of genetic mutations and molecular mechanisms. A single cancer subtype can exhibit unique genomic characteristics through several stages of its progression, from pre-cancerous lesion to metastasis (the spreading of the disease from its site of origin to another part of the body). Any effort to understand cancer genomes in a comprehensive, systematic manner must address the technological hurdles of characterizing such a heterogeneous disease.

The technological challenges include the need to:

- improve molecular characterization methods (e.g., determining which genes are expressed at different levels in tumor cells compared with normal cells or how chromosomes are rearranged in tumor cells);
- improve the throughput of these methods;
- further decrease the costs of DNA sequencing;
- improve the detection of epigenomic changes; and
- develop new analytical methods to correlate disease state with the molecular characteristics of a cancer.

The bioinformatics challenges involve developing the best ways to collect, store, and distribute the clinical and genomic data generated by the project. Among the issues that need to be considered are:

- developing data standards and a uniform vocabulary for each new technology;
- establishing an informatics pipeline connecting all components of the project;
- creating portals for basic and clinical researchers around the world to easily access TCGA data; and
- ensuring that the confidentiality of clinical data is maintained.

Other challenges facing the TCGA include:

- establishing standard nomenclature and criteria for classifying cancer subtypes and stages;
- ensuring that important clinical data is linked to each biospecimen; and
- developing policies for data release, intellectual property protection, and informed consent from biospecimen donors.

11. What are the goals of the 3-year TCGA Pilot Project?
Using NCI's and NHGRI's existing infrastructure, knowledge, and resources, the TCGA Pilot Project will determine whether it is possible to cost-effectively characterize the genomes of a few cancer types and whether an atlas of all major cancer types is feasible. In addition, the project will support the development of new technologies.

12. How will the cancer types be chosen for the TCGA Pilot Project? *The Cancer Genome Atlas Biospecimen Selection Process describes the procedures by which the TCGA is selecting tumor and healthy control biospecimens for the Biospecimen Core Resource.*

In fall 2005, the National Cancer Institute issued a Human Cancer Biospecimen Collection Request for Information (RFI) to identify existing biospecimen collections that may be suitable for the TCGA Pilot Project. NCI and NHGRI program management staff will evaluate responses to the RFI from biorepositories on the basis of various criteria, such as biospecimen quality and quantity. Staff will also consult with the TCGA External Scientific Committee, a group of scientists, clinicians, patient advocates, and ethicists. Biospecimens that best match these criteria will be further selected on the basis of additional characteristics, such as which tumor types are most likely to yield genomic data that has the broadest clinical impact.

For updated information about the selection of the cancer types to be studied as part of The Cancer Genome Atlas Pilot Project, please click here.

13. How many genes will be sequenced in the TCGA Pilot Project and how will they be chosen?
The number of genes that will be sequenced will depend on the number of cancers analyzed, the number of samples per cancer, the number of genes that may be relevant to each cancer, and the size of the genes. The number of genes sequenced will likely increase as the pilot project moves forward.

14. What sort of genomic changes will the TCGA Pilot Project be looking for? What controls and procedures will be used to determine if such changes are real and if they play a key role in cancer?
The genomic analysis technologies that will initially be used in the TCGA Pilot Project will be determined on the basis of scientific peer review. It is likely that, from the start, technologies will be included that can identify regions of genetic deletions and amplifications, changes in gene expression levels, and DNA mutations. In addition, the pilot project will invest significant resources to improve throughput, decrease analysis cost, and develop new technologies, including better methods to detect epigenomic changes.

The exchange of resources and information will require experienced, hands-on management from NCI and NHGRI. In close collaboration with TCGA researchers, NCI and NHGRI program management staff will implement procedures for quality control and accuracy checks on materials used and data produced.

Since one of the major goals of the project is to demonstrate the technical feasibility of genomic characterization of cancer samples, benchmark levels of genomic abnormalities will be established. To help distinguish significant from insignificant genomic changes, researchers will correlate genomic changes with medical information associated with the biospecimens.

15. How will the success of the TCGA Pilot Project be measured?

The success of the TCGA Pilot Project will be determined based on its ability to demonstrate the technical feasibility and biological utility of the large-scale genomic characterization of cancer, while protecting patients' genetic privacy.
Criteria for feasibility of the large-scale effort will include:

- increased throughput and accuracy in genomic sequencing and characterization;
- improvements in data quality and analysis; and
- determination that the genomic data obtained is scientifically relevant to cancer research.

A committee of outside experts has been established as consultants to NCI and NHGRI on all aspects of the design and evaluation of the pilot project. The committee will work with NCI and NHGRI staff to evaluate progress and revise scientific strategies, as necessary, to meet pilot project goals and milestones.

16. How will the components of the TCGA Pilot Project be chosen? When will their selection be announced?

The TCGA Pilot Project will be supported by a combination of grants, cooperative agreements, and contracts. NCI and NHGRI have already issued a subset of the relevant Requests for Applications (RFAs) and Requests for Proposals (RFPs), and the remaining Requests will be issued within the next few months. The applications and proposals will be peer-reviewed by experts in the field.

17. When will TCGA results be made publicly available?

TCGA results will be made publicly available as the data are generated and validated. Web-based portals will allow academic researchers, biotechnology firms, pharmaceutical companies, and the general public to rapidly access this information.

Details of the data release policy will be developed during the planning and implementation of the pilot project. The policy will be designed to achieve the goals of rapid data availability, protection of the privacy of patient information, and appropriate handling of intellectual property.

Access to TCGA data will be modeled on successful data access policies developed by the Human Genome Project, the International HapMap Consortium, and the Encyclopedia of DNA Elements (ENCODE) project.

On May 9-10, 2006, NCI and NHGRI held a Data Release Workshop for the TCGA Project. Participants included representatives from genomic data production centers, bioinformatics data users, journal editors, cancer biologists, clinical researchers, patient advocates, pharmaceutical and biotechnology company representatives, intellectual property experts, and regulatory agency representatives. Workshop participants discussed methods for maximizing the release of data while ensuring patient privacy, optimizing intellectual property, and ensuring high data quality.

18. How will the ethical, legal, and social implications of the TCGA Pilot Project be addressed?

NCI and NHGRI recognize the importance of focusing early in the planning process on the ethical, legal, and social aspects of the project. As a result, the Ethics, Law, and Policy Group (ELP) was created to help NCI and NHGRI staff address the important issues that must be considered to make this project a success. ELP members represent the patient advocacy, scientific, clinical, ethics, and legal communities. The ELP is working on issues surrounding the informed consent process allowing for DNA sequencing from both cancer and normal tissues; collecting family, health, and medical records and linking these to biospecimens; and sharing TCGA data with researchers around the world. The ELP will also address unique data release and intellectual property issues.

19. Will any other organizations be involved in these efforts?

NCI and NHGRI are actively seeking partners from the public and private sectors, as well as international collaborators.

In addition, NCI and NHGRI are asking researchers to discuss the successes and challenges of similar efforts around the world. NCI and NHGRI program staff have met with scientists from the Wellcome Trust Sanger Institute, officials in the Wellcome Trust, and members of the European Commission to discuss their current activities in sequencing and analyzing cancer genomes. These discussions have provided valuable feedback to help guide the direction of the TCGA.

20. Where can I get more information?

For more information about The Cancer Genome Atlas, please visit the TCGA's Web site at http://cancergenome.nih.gov.

For more information about cancer, visit the NCI Web site at http://www.cancer.gov or call NCI's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237).
For more information about genetics and genomics, visit the NHGRI Web site at http://www.genome.gov.

21. How did NCI and NHGRI choose the cancer types to be studied as part of The Cancer Genome Atlas Pilot Project?

The Cancer Genome Atlas (TCGA) Pilot Project is a joint effort of the National Cancer Institute (NCI) and the National Human Genome Research Institute (NHGRI), both part of the National Institutes of Health (NIH). The TCGA project team, which is made up of staff from both institutes, selected the cancer types based on the availability of biospecimen collections that met TCGA's strict scientific, clinical, technical, and ethical requirements in three specific categories. (Please see criteria descriptions in Question and Answer 2.)

To identify the sources of biospecimens that qualified for study as part of TCGA Pilot Project, NCI issued a Request for Information (RFI) in the fall of 2005. Widely disseminated to the cancer research community, the RFI was designed to elicit responses from biorepositories that were collected using robust ethical, technical, biological, pathologic, and bioinformatic approaches.

The biospecimen collections identified in responses to the RFI were evaluated to identify those that were of the highest quality. It is important to note that "high quality" refers not only to biological quality of the samples, but also to the ethical and legal status of the samples and related clinical annotation (i.e., Institutional Review Board protocol review, appropriateness of the informed consent process, and presence or availability of Material Transfer Agreements), the quality of the associated data (e.g., the extent of donor clinical and biospecimen annotation), and the degree of process documentation (e.g., sample handling and storage protocol detail, and Quality Assurance and Quality Control systems). Additionally, TCGA needs at least 500 samples of any one cancer type for statistical purposes, and it is preferable that those samples derive from only one or two collections, to reduce variability.

The submissions were evaluated in a three-stage process. The primary criteria addressed minimal qualification requirements for the quality and quantity of the samples and the associated clinical information. Secondary criteria were then applied to effectively rank those tumor collections that met the primary criteria. Site visits to the biorepositories were then conducted by NCI and NHGRI staff. Critical factors for TCGA, such as timing, logistics, and the need for re-consent of patients, were factored into selection of the biorepositories to

be considered. Finally, the biospecimen collections that met the criteria for the first two stages of the process were further reviewed by an expert panel that included representatives from the surgery, research, pathology, bioethics, and patient advocate communities.

On the basis of all this information, TCGA Pilot Project team determined that the three biospecimen collections of tissue that met the selection criteria were: lung (squamous cell), glioblastoma (glioblastoma multiforme or grade IV astrocytoma), and ovarian cancers.

22. What were the primary and secondary criteria for selecting the cancer types to be studied by the TCGA Pilot Project?

The Primary Criteria included:

- **Quantity:** A biorepository must have at least 250 samples of the same cancer type, keeping in mind that two biorepositories may provide samples of the cancer type, each from a different patient. Combining samples of the same cancer type will provide a sufficient number of samples to ensure that findings from the pilot project are statistically significant.

- **Weight:** Each cancer sample must weigh more than 0.2 grams.

- **Cellular composition:** Each cancer sample must contain at least 80 percent viable cancer cells.

- **Matched germline DNA and "normal" tissue:** Each cancer sample must be accompanied by a sample of "normal" tissue, such as blood or adjacent non-cancerous tissue, from the same patient in order to compare the cancer cell genome with the genome of non-cancer cells. Finding genomic differences between cancer cells and non-cancer cells will indicate that the cancer-related genomic changes occurred during the lifetime of the patient and were not inherited.

- **Standardization:** All 250 samples of the same cancer type must be obtained as part of a clinical trial or from patients undergoing uniform treatment and follow-up according to a standard procedure. This criterion is required to ensure that all donors are as similar as possible in their clinical characteristics, their treatment, the manner in which investigators collected data about them, and their care follow-up.

- **Consent:** Patients who are living must have given permission to be re-contacted regarding the use of their donated samples, or the IRB can grant permission to recontact patients.

The Primary Criteria represented a "yes" or "no" response for which candidate biospecimen collections had to meet all requirements in order to be further considered for TCGA Pilot Project.

The candidate collections that passed the Primary Criteria were then ranked with a set of Secondary Criteria developed by Institute staff, with significant input from external experts.

The secondary criteria included both new questions and nuances of the primary criteria evaluated on a graded numerical scale, which resulted in a quantitative ranking of the remaining tumor collections.

The Secondary Criteria included:

- **Clinical trial protocol and donor enrollment:** Ranking value was increased by more consistent tissue donor clinical status, such as entry criteria (e.g., pathological stages), treatment regimen, standardized data collection and Quality Control audits, and follow-up. This category also placed value on accrual rates and the future ability to correlate molecular profile data with donor clinical data during the life time of TCGA.

- **Informed consent:** These criteria were designed to ensure the broadest ability to protect patient rights, especially privacy, in TCGA, since this project requires re-contacting donors and will generate individual genomic information on a larger scale than previously seen in most research projects.

- **Material Transfer Agreements (MTAs):** Collections were ranked on the basis of the institution's contractual policies and experience with distributing biospecimens for data generation.

- **Clinical data:** Several criteria were used to assess the quality of clinical data, especially its accessibility (e.g., is the information on paper or within an electronic database?), degree of standardization, and level of detail. Additional criteria evaluated the data in terms of compliance with patient confidentiality regulations (e.g., the Health Insurance Portability and Accountability Act of 1996).

- **Sample characteristics:** Biospecimen quality was evaluated and rated more highly if: the collection resulted from a relatively narrow range of pathological characteristics (e.g., tumor stage, grade, and histological type), donors had not yet been exposed to treatments that would alter molecular profiles of their cancers, the processing protocols for the specimens were consistent and well documented, and the biorepository management was demonstrated to be superior.

- **Quality Control (QC):** Biospecimen collections received additional value if the custodian biorepository had adopted formal protocols that include Quality Control analyses of both tissue and molecular extracts.

The NCI's Office of Cancer Genomics applied the Secondary Criteria to candidate biospecimen collections on the basis of RFI responses, follow-up meetings and calls with biorepository custodians, and site visits. In order of descending Secondary Criteria scores, the quantitatively ranked biospecimen sources were presented to the Biospecimen Expert Technical Panel (ETP) for review and comment.

23. What institutions will provide the biospecimens for the TCGA Pilot Project, and will the biospecimens be donated?

The three institutions that will donate all of the biospecimens to be studied as part of TCGA Pilot Project are:

- the brain tumor (glioblastoma) biospecimens will come from the MD Anderson Cancer Center in Houston, Texas;
- the lung cancer biospecimens will be donated by the Lung Cancer Tissue Bank of the Cancer and Leukemia Group B (CALGB) clinical trials group, which is housed at the Brigham and Women's Hospital in Boston, Mass; and
- the ovarian cancer biospecimens will be provided by the Gynecologic Oncology Group tissue bank at the Children's Hospital of the Ohio State University in Columbus, Ohio.

24. What organization will manage the TCGA Biospecimen Core Resource (BCR)?

The International Genomics Consortium of Phoenix, Ariz. was selected after a competitive process to establish and manage TCGA's BCR. The BCR will collect, store, process tissues, and distribute biomolecules from cancerous and normal samples to the Cancer Genome Characterization Centers and Genome Sequencing Centers for genomic analysis.

25. What was the rationale for the selection of the cancer types for the TCGA Pilot Project?

The goal of the TCGA Pilot Project is to determine the scientific, technological, and analytical feasibility of a larger-scale genome characterization and sequencing effort, which would ultimately look at the genomic changes in all types of cancer. Consequently, the project team chose the cancer types that provide TCGA with the greatest opportunities for developing, optimizing, and evaluating in an integrated manner, the cancer biology, technologies, production pipelines, and analytical methods designed to achieve the Pilot Project milestones.

Additionally, in terms of overall public health impact, it is estimated that 174,470 new cases of lung cancer will be diagnosed in the United States in 2006. Lung cancer is the major cause of cancer-related mortality in both men and women, with an estimated 162,460 deaths expected to occur in 2006. Brain tumors account for nearly 90 percent of all primary central nervous system tumors. It is estimated that 18,820 new cases of brain cancer will be diagnosed in the United States this year, and 12,820 patients will die from the disease.

Glioblastoma, also called glioblastoma multiforme or grade IV astrocytoma, is the most common and aggressive type of brain cancer and is usually fatal. An estimated 20,180 new cases of ovarian cancer, and an estimated 15,310 deaths from the disease are expected in the United States in 2006. Often detected late, ovarian cancer causes more deaths than any other cancer of the female reproductive system.

26. How can people with cancer benefit from the TCGA Pilot Project?

Many technical limitations currently limit the pursuit of studies to establish the genomic profiles of most types of cancer. For this reason, the TCGA Pilot Project has been designed to study three cancer types that hold the greatest promise for helping researchers understand how to design and conduct future studies involving a wide range of tumors.

As part of this process, TCGA will support the development of new technologies aimed at overcoming current limitations in genomic analysis techniques. Another important goal of the pilot project is to develop data analysis tools that will allow clinicians to use this new molecular information to better understand subtle differences between certain subtypes of cancer, how tumors develop and progress, and why some cancers respond to certain treatments and not others.

Ultimately, data from the TCGA Pilot Project will provide researchers and clinicians with an early glimpse of what promises to become an unprecedented, comprehensive "atlas" of molecular information describing the genomic changes in all types of cancer. One of the goals of the pilot project is to determine the validity of the technical approach and to determine if it can be applied to all the other cancers.

TCGA will ultimately enable researchers throughout the world to analyze and employ the data to develop a new generation of targeted diagnostics, therapeutics, and preventives for all cancers, and pave the way for more personalized cancer medicine.

27. As a cancer patient, can I participate in the TCGA Pilot Project?

Currently, there is no mechanism for an individual patient to directly participate in TCGA. The three cancers to be studied by the TCGA Pilot Project come from the previously established collections of three selected institutions. This is the best strategy for the pilot project because of the specific criteria for tissue samples (standardization, weight, etc.) that the project team determined are necessary in order to test the feasibility of using large-scale genome analysis technologies to find the important genomic changes involved in cancer. If TCGA is someday attempted on a larger scale, depending on the outcome of the pilot project, biospecimens will be prospectively collected as part of clinical trials. In fact, participating in well-designed clinical trials that ensure the collection and management of high-quality biospecimens, may help create additional collections of biospecimens for potential use in an expanded version of The Cancer Genome Atlas.

###