

**THE CANCER GENOME ATLAS (TCGA)  
SUGGESTED LANGUAGE  
FOR PROSPECTIVE COLLECTIONS  
July 17, 2006**

**Purpose of the Project**

We would like to invite you to participate in a research project called The Cancer Genome Atlas (TCGA). The purpose of the TCGA project is to discover genetic changes associated with cancer. This should lead to better ways to prevent, detect, and treat cancer and, perhaps, other diseases as well. This project is being sponsored by the National Cancer Institute (NCI) and the National Human Genome Research Institute (NHGRI). The NCI and the NHGRI are both part of the government agency known as the National Institutes of Health (NIH).

Body tissues are made up of cells. Cells contain DNA, which is part of your unique genetic material that carries the instructions for your body's development and function. Cancer can result from changes in a person's genetic material that cause cells to divide in an uncontrolled way and, sometimes, to travel to other organs. Currently, researchers and doctors know some of the genetic changes that can cause cancer, but they do not know all of the genetic changes that can cause cancer.

The TCGA project is designed to identify most of the genetic changes that can cause cancer in people. Therefore, we would like to study the genetic material from your cancer tissue as part of the TCGA. We will compare the genetic material from your cancer tissue to the genetic material from your normal tissue to find the differences that exist. By combining this information with information from your medical records, it may be possible to identify the genetic changes that are associated with your particular type of cancer. We will perform this same process with many (hundreds of) other people who have agreed to participate in this research project. By studying many different kinds of cancer in this way, we expect to identify most of the genetic changes associated with different kinds of cancer. Since we also will combine genetic information with information from medical records, such as the responses of different kinds cancers to different treatments, this project could lead to more knowledge about why certain cancers respond differently to treatments. With such knowledge, future treatments potentially could become customized to a patient's unique genetic make-up.

**Description of the Research**

**Collection of Samples and Medical Information**

- Your scheduled surgery is part of the medical treatment that you agreed upon with your doctor. Your surgery is not part of the TCGA research project. During surgery, cancer tissue will be removed. Usually, when cancer tissue is removed, very small amounts of nearby normal tissue also are removed. We will receive some of these cancer and normal tissues following your surgery.

- We also will collect a second type of normal tissue (blood) from you by drawing about 4 tablespoons of blood from a vein in your arm.
- If you object to having blood drawn, we will collect normal tissue from you by swabbing cells from the inside of your cheeks.
- We also will collect information from your medical records, including your age, ethnic background, diagnosis, disease history, medical treatments, and response to treatments.

#### **Coding of Tissue Samples and Medical Information**

- Your tissues, blood sample, and medical information will be labeled with a code.
- Only Dr. \_\_\_\_\_ at (Institution) will have the information that matches the code to traditionally-used identifying information, such as your name, address, phone number, or social security number. Dr. \_\_\_ will keep the information that matches the code to this traditionally-used identifying information in a safeguarded database. Only very few, authorized people, who have specifically agreed to protect your identity, will have access to this database. All other researchers and personnel, including those who will be working with your samples and medical information, will not have access to any of the traditionally-used identifying information about you.

#### **Storage and Release of Samples and Medical Information**

- Your coded tissue samples will be sent to an NCI-sponsored storage facility, currently known as the Biospecimen Core Resource (BCR). The samples will be processed there and portions of your samples then will be sent to different types of laboratories as part of this project. One type of laboratory will analyze your DNA by a method called sequencing. Other types of laboratories will study your samples by different methods. The remaining portions of your samples will be stored in the BCR for an unlimited period of time for future use in research related to cancer or, perhaps, in other research projects.
- Information from analyses of your coded samples and your coded medical information will be put into databases along with information from the other research participants. These databases will be accessible by the Internet.
  - Anonymous information from the analyses will be put in a completely public database, available to anyone on the Internet.
  - Your coded medical information and information from more detailed analyses of your coded samples will be put in a controlled-access database. The information in this database will be available only to researchers who have received approval from an NIH Data Access Committee.

*Please note that traditionally-used identifying information about you, such as your name, address, telephone number, or social security number, will NOT be put into either the public or controlled-access databases for this project.*

#### **Recontact**

- In the future, we may want to obtain additional samples or follow-up information about your health or medical care. Should this be needed, a person from (Institution) will contact you to ask whether you would be interested in participating in this additional research.

## **Financial Compensation/Costs**

You will not be paid to participate in this project. Your tissue samples and your medical information will be used only for research purposes and will not be sold. It is possible that some of the research conducted using your samples or information eventually will lead to the development of new diagnostic tests, new drugs or other commercial products. Should this occur, you will not receive any part of the profits generated from such products.

You will not incur any expenses from participating in this project. The chance that you will be physically injured as a result of participating in this project is very small. However, if you are physically injured as a result of participating in this project, emergency medical treatment for your research-related injury will be provided to you at no cost.

## **Potential Benefits of Participating in the Project**

You should not expect to personally benefit from this research. The main reason you may want to participate is to help researchers and health professionals around the world to better understand the causes of cancer and other diseases so that they can find better ways to prevent, detect, treat, and cure such illnesses. We hope that you will feel good knowing that you may be helping future cancer patients as well as patients with other diseases.

## **Potential Risks of Participating in the Project**

### **Physical Risks**

- There are very few physical risks associated with this project. Possible side effects from drawing the blood sample include mild pain, bleeding, bruising, and infection at the site of the needle insertion. Fainting or light-headedness can sometimes occur, but usually last only a few minutes.

### **Psychological or Social Risks Associated with Loss of Privacy**

- Your privacy is very important to us and we will use many safety measures to protect your privacy. However, in spite of all of the safety measure that we will use, we cannot guarantee that your identity will never become known. Although your genetic information is unique to you, you do share some genetic information with your children, parents, brothers, sisters, and other relatives. Consequently, it may be possible that genetic information from them could be used to help identify you. Similarly, it may be possible that genetic information from you could be used to help identify them.
- While neither the public nor the controlled-access databases developed for this project will contain information that is traditionally used to identify you, such as your name, address, telephone number, or social security number, people may develop ways in the future that would allow someone to link your genetic or medical information in our databases back to you. For example, someone could compare information in our databases with information from you (or a relative) in

another database and be able to identify you (or your relative). It also is possible that there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information to you.

- Since some genetic variations can help to predict the future health problems of you and your relatives, this information might be of interest to employers, health providers, insurance companies, and others. Patterns of genetic variation also can be used by law enforcement agencies to identify a person or his/her relatives. Therefore, your genetic information potentially could be used in ways that could cause you or your family distress, such as by revealing that you (or a relative) carry a genetic disease or by leading to the denial of employment or insurance for you (or a relative).
- There also may be other privacy risks that we have not foreseen.

While we believe that the risks to you and your family are very low, we are unable to tell you exactly what all of the risks are. There are some state laws that protect against genetic discrimination by employers or insurance companies, but there is no federal law yet that prohibits such discrimination. We believe that the benefits of learning more about cancer and other diseases outweigh these potential risks.

## **Confidentiality**

We will make every attempt to protect your confidentiality and to make sure that your personal identity does not become known. This signed consent form will be stored in a locked file that will be accessible only to a very small number of authorized people involved in this project. We will carefully follow the coding, storage, and release plan explained in the *Description of the Research* section on pages 1 and 2 of this document.

To help us protect the confidentiality of your information, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, we cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. We will use this Certificate to resist any demands for information that would identify you, with the following exceptions.

- The Certificate cannot be used to resist a request for your information from the United States Government when the information is to be used for auditing or evaluation of federally funded projects or for information that must be disclosed to meet the requirements of the federal Food and Drug Administration (FDA).
- The Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. Also, if you have given written consent to an insurer, employer, or other person to receive research information, then we may not use the Certificate to withhold that information.

## **Project Results**

Your individual results from this research project will not be given back to you or put into your medical records. If research from this project is published in professional journals, there will be no traditionally-used identifying information, such as your name, address, telephone number, or social security number, included in the publications. Some publications from this project will be found at the [www.cancergenome.nih.gov](http://www.cancergenome.nih.gov) website.

## **Alternatives to Participating in the Project**

The alternative option is not to participate.

## **Voluntary Participation**

The choice to participate in this research by donating your tissues and medical information is completely up to you. **No matter what you decide to do, your decision will not affect your medical care.**

## Withdrawal from the Project

Once your coded samples have been distributed to the participating research centers and your information transferred to the databases, it will not be possible for you to withdraw your samples or your information from this research project.

## Contact Information

If you have any questions about the project or your participation, [*please use specific institutional language here, but do not automatically promise ability to withdraw*].

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## Agreeing to Participate in the Project

To participate in this research, you must agree to **ALL** of the following statements:

- I voluntarily agree to donate cancer tissue and normal tissue to be used for this and for other research projects.
- I agree to release information from my medical records for this and for other research projects.
- I agree to have my coded genetic information and coded medical information placed in databases accessible by the Internet, as described in the *Storage and Release of Samples and Medical Information* section on page 2 of this document.
- I understand that my coded genetic information and coded medical information in the Internet databases will be used in this and in other research projects.
- I understand that there is a risk that someone in the future might be able to use information in these databases to identify me or possibly my relative(s).
- I agree to be recontacted in the future to see if I am willing to provide additional samples or follow-up information about my health or medical care.

Please sign your name here if you agree with the above six statements.

Your signature: \_\_\_\_\_

Date: \_\_\_\_\_

Signature of Doctor/Nurse/Other Witness \_\_\_\_\_