

**THE CANCER GENOME ATLAS (TCGA)
SUGGESTED INFORMED CONSENT LANGUAGE
FOR PROSPECTIVE COLLECTIONS
2011**

Purpose of the Project

We would like to ask your permission to include you 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 knowledge 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 US 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 causes 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 them.

The TCGA project is designed to try to identify all of the genetic changes that can cause cancer in people. Therefore, since you are having surgery to remove a cancer, we would like to study the genetic and biochemical material from your cancer tissue as part of the TCGA. We will compare the genetic and biochemical material from your cancer tissue to the genetic and biochemical 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 also volunteered to be 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 will combine genetic and biochemical information with information from medical records, such as how cancers respond to different kinds of treatments, this project could lead to more knowledge about why certain cancers respond differently or don't respond at all. With such knowledge, future treatments could become customized to a patient's unique genetic make-up.

Description of the Research

We are requesting your permission to use your cancer tissue, some of your normal tissue, and information from your medical records in this study. The following sections describe how your tissue samples and information will be collected and studied if you give us permission to include you in this study.

Collection of Your 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, and usually, when cancer tissue is removed, very small amounts of nearby normal tissue also are removed. After the pathology department takes the tissue they need for your diagnosis, we will receive some of the extra cancer and normal tissues that would normally be thrown away.

- 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 some normal tissue from you by swabbing cells from the inside of your cheeks or saliva from which genetic material can be collected.
- 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 Your Tissue Samples and Medical Information

- Your tissues, blood sample, and medical information will be labeled with a code number.
- 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.

Analysis of Your 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 other biochemical material from your samples by different methods. The remaining portions of your samples, if any, 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 samples and your medical information will be put into databases along with information from the other people who volunteered for this project. These databases will be accessible by the Internet in two ways:
 - Some of the results from the analysis will be mixed with results from other participants and put in a completely public database, available to anyone on the Internet. This information will not be specific to you or any other participant.
 - The other database is private, and will include person-by-person coded genetic, biochemical and medical information. The results in this database

will be available to the global biomedical research community, but the access is controlled. Only researchers who have received approval from an NIH Data Access Committee will be authorized to access this database.

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 more information about your health or medical care. Right now, we are just asking your permission to recontact you if this should be needed. If you say yes, a person from (Institution) would contact you in the future to ask whether you would be interested in participating in this additional research.

Payment and 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 costs 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.

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 lasts 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 measures 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. In 2008, the federal government established the Genetic Information Nondiscrimination Act (GINA), a law that prohibits genetic discrimination in employment and health insurance. It is important to note that while this law protects you from certain kinds of genetic discrimination, there are exceptions. For example, GINA does not apply to employers with fewer than 15 employees. Additionally, this law does not protect you from genetic discrimination in life, disability, or long-term care insurance. [Note to PI/IRB: insert state/local laws reference that may offer additional protections to safeguard patients' genetic information and prevent genetic discrimination.]

Keeping Your Information Confidential

We will make every attempt to protect the confidentiality of your information. 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.

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 order, 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, it will not include traditionally-used identifying information, such as your name, address, telephone number, or social security number. Some publications from this project will be found at the www.cancergenome.nih.gov website.

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.**

Alternatives to Participating in the Project

The alternative option is not to participate.

Withdrawal from the Project

You may stop being part of this research project at any time and for any reason. If you wish to withdraw, please contact the person named below. If you withdraw, we will stop collecting any of your information and will no longer distribute your samples to anyone – they will be discarded. However, please understand that, even if you do withdraw, once your samples have been distributed to the participating research centers and your information transferred to the databases, it will not be possible to discard your samples or remove your information from this research project.

If you withdraw from this project, it will in no way affect the care you receive from this hospital.

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*].

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 *Analysis of Your 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 _____