

Kansas City Clinical Oncology Program

Consent Form for Collaborative Cancer Genome Research Project

Collection of Samples for Z1031 Collaborative Cancer Genome Research Project

Purpose of the Project

As a participant in the Z1031 trial we would like to invite you to also take part in an additional research project that aims to document all the DNA changes that occur in breast cancer cells. You do not have to participate in this additional study if you do not want to. The reason for this additional request is to ask your consent to allow certain information from your DNA samples to be released anonymously into public databases. This should allow more discoveries to be made or for these discoveries to be made faster because more investigators have access to the data. Public release of your DNA sequences creates some potential privacy issues. If you do not sign this form all the DNA information derived from your samples will be kept securely in locked data bases and will not be released to the public and is covered by a certificate of confidentiality held by Washington University in St Louis and will not be released to the public.

The purpose of the 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). The purpose of this additional consent form is to clarify issues regarding the analyses we will conduct if you agree.

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. DNA can be sequenced so that the exact genetic code that you carry can be identified, and, using this technique we can detect cancer-specific DNA sequence changes. 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 the genetic changes that can cause cancer.

The 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. 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 Z1031 study records, it may be possible to identify the genetic changes that are associated with your particular type of cancer. 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. We also will combine genetic information with information that we have obtained from your progress on Z1031, such as the response to treatment and your long term health. With this knowledge, future treatments for breast cancer could become customized to a patient's unique genetic make-up.

Description of the Research

Coding of Tissue Samples and Medical Information

- Your tissues, blood sample, and medical information will be labeled with a code.
- Only ACOSOG will have the information that matches the code to traditionally-used identifying information, such as your initials, birth date or medical record number. ACOSOG 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 a storage facility, known as the ACOSOG Central Specimen Bank. 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 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. The purpose of making sequence and medical information available is so that they can be used by scientific researchers to study cancer and other diseases.
 - 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 the ACOSOG and NHGRI Data Access Committees.

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.

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, there are no plans for you to 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. If you are physically injured as a result of participating in this project, you will receive medical treatment. You and/or your insurance (health plan) will be charged for this treatment. The study will not pay for medical treatment.

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

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 have put in place, it is impossible to guarantee that links between you and the genetic information we have obtained 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 try and identify your sample from the publicly available information. 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, theoretically 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). We emphasize that and we will do everything we can to protect your private information. However because of the nature of the issues we feel that we should explain these issues to you carefully.
- 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 stress that we will make every attempt to protect your confidentiality and to make sure that your personal identity does not become known. 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.

Your medical records and study records are confidential but they may be disclosed if required by law.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include:

- The American College of Surgeons Oncology Group (ACOSOG);
- The local Institutional Review Board (IRB), a group of people who review the research study to protect your rights;
- U. S. Food and Drug Administration (FDA); and
- Government agencies including the Office of Human Research Protections (OHRP) and the National Cancer Institute (NCI). These agencies may review the research to see that it is being done safely and correctly.
- The Cancer Trials Support Unit (CTSU), a research group sponsored by the National Cancer Institute (NCI) to provide greater access to cancer trials
- NCI Central IRB, and Data Safety Monitoring Board (DSMB).

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 initials, birthdate or medical record number included in the publications. Some publications from this project will be found at the www.cancergenome.nih.gov.

Alternatives to Participating in the Project

The alternative option is not to participate.

Voluntary Participation

The choice to participate in this research by providing 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.** You may decide not to participate in this research or you may withdraw your samples without any penalty or loss of benefits to which you are entitled.

Withdrawal from the Project

You have a right to withdraw from the study before the samples have been distributed to the analysis laboratories. However, 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*].

Agreeing to Participate in the Project

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

- I voluntarily agree to provide cancer tissue and blood samples obtained during my participation in Z1031 to be used for the project described in this consent form. I have received a copy of this form.
- 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 re-contacted 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 _____