

OCG Template #103

NOTE: Highlighted text of this document has to be used as provided in your Institution's informed consent forms for the samples to be acceptable to the project

**OFFICE OF CANCER GENOMICS SUGGESTED LANGUAGE
FOR RETROSPECTIVE TISSUE COLLECTIONS
IN GENOMIC-SCALE PROJECTS**

Purpose of the Project

We would like to invite you to participate in a research project called **[Project Name]**. The purpose of the **[Project Name]** 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), 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 **[Project Name]** 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 **[Project Name]**. 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**

- You already have had surgery as a part of the medical treatment that you agreed upon with your doctor. During your surgery, cancerous/tumor tissue was removed. As usually happens, when your cancerous tissue was removed, very small amounts of nearby normal tissue were removed along with it. Your surgery

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was not part of the **[Project Name]** research project. For this research project, we seek permission to receive some of these cancerous and normal tissues.

- If a second type of normal tissue (e.g., blood) was collected from you before or after your surgery, we request permission to obtain some of this tissue and genetic material that already may have already been extracted from this tissue.
- If an adequate blood sample is not available for this project, we will collect a sample from you by drawing approximately 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 will also 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 or buccal (cheek swab) sample, and medical information will be labeled with a project-assigned ID.
- Only Dr. **[Physician Name]** at **[Institution Name]** 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. **[Physician Name]** will keep the information that matches the code to this traditionally-used identifying information in a safeguarded database. Only authorized people, who have specifically agreed to protect your identity, will have access to this database. All materials conveyed to the **[Project Name]** will be labeled with a project-assigned ID, removing traditionally-used identifying information, such as your name, address, phone number, or social security number. 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 that will process the samples and then send portions of your samples to different types of laboratories as part of this project. One type of laboratory will analyze your DNA by a method called sequencing. Other 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 obtained from analyses performed on 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 into 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 into a controlled-access database. The information in this database will be available only to researchers who have received approval from an NIH Data Access

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Committee. In gaining access to such information, researchers have to agree to use the data only for research projects and not to ever try to use it in order to identify the donor of the material. However, despite all of the safety measures that we will use, we cannot guarantee that your identity will never become known

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 Name] 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 will eventually 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. It is unlikely that you will be physically injured as a result of participating in this project. 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, and potentially to 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**

- If no blood sample is taken from you, there are no physical risks associated with this project.
- There are very few physical risks if a blood sample is taken from you. Possible side effects from drawing the blood sample include mild pain, bleeding, bruising,

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and infection at the site of 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 use many safety measures to protect your privacy. However, despite 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 (your name, address, telephone number, or social security number), technology may be developed 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 is also possible that there could be violations to the security of the computer systems used to store the codes linking your genetic and medical information back to you. Because some genetic variations can help to predict the current or future health problems of you and your relatives, this information may 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 could potentially 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 currently no federal law 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 remains anonymous. This signed consent form will be stored in a locked file that will be accessible only to a very small number of authorized personnel involved in this project. We will carefully follow the coding, storage, and release plan explained in the *Description of the Research* section on pages 1-3 of this document.

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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 [Project Name] website.

Alternatives to Participating in the Project

The alternative option is not to participate in this project.

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 laboratories and centers, and your information transferred to the appropriate databases, you will **not** be able to withdraw your information from this research project. However, you may be able to request the return or destruction of the tissue samples if you so desire.

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 cancerous 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 into 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-accessible databases will be used in this and in other research

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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 contacted in the future to see if I am willing to provide additional samples or follow-up information about my health or medical care if they are needed.

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

Your signature: _____

Date: _____

Signature of Doctor/Nurse/Other Witness _____

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