NCI Community Oncology Research Program – Kansas City (NCORP-KC)

Consent Form

Study Title for Study Participants: Collecting and growing patient tumor and blood cells from extra tissue to learn about cancer and test new drugs

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: Patient-derived Models Tissue Procurement Protocol for the National Cancer Institute (P9846)

Why is this study being done?

We are asking your permission to collect and store samples of your tumor and blood for research at the National Cancer Institute (NCI). The purpose of this research study is to collect samples so that NCI scientists can try to "grow" the tumor and blood cells in the laboratory to make new and better models to help them learn about cancer and to test new cancer drugs. Models are used to help understand the behavior of living tumor and blood cells outside the human body. Animals such as mice provide a living system in which to grow human cancer cells.

Collecting some of your medical information, such as what type of cancer you have, what cancer drugs you have taken, and whether or not your tumor responded to these drugs, is important for us to be able to analyze your samples and learn about cancer from them. For this reason we would like to know your age, sex, tobacco exposure history, race/ethnicity, and occupation.

We may also carry out a full genetic analysis of the tumor and blood samples to look for gene variations that may help us to understand the cancer in this way.

About 5000 people will provide samples for this research study. This is not a treatment study, and your willingness to take part in this study will in no way affect your ability to take part in any other research study for which you are being considered.

The results of research studies performed with these samples will be published in scientific journals, but your name or other personally identifiable information will not be disclosed. The results of the research studies will not be reported to you, your family, or your doctor.

Description of Procedures and Tests

What will happen if you take part in this research study?

Tumor samples can be collected when surgery is performed to remove a tumor as part of your treatment or you undergo a tumor biopsy as part of your care. No tissue biopsies are required to take part in this research study. We may request a small piece of extra tissue already taken as part of your clinical care or a clinical trial for research purposes unrelated to the primary research study.

Blood for research purposes may be drawn from either an arm vein or a central venous access device, if you have one. No more than 1 tablespoon (14 mL) will be collected at each collection time point.

How long will I be in the study?

If you agree to take part in this study, your involvement will last for length of time required to collect the samples and the required associated information about you and your samples. This process will only take a few hours to complete, and generally you will not be directly involved in the process. However, your samples and the materials and data derived from them will continue to be used over time, potentially for years to come.

What possible risks can I expect from taking part in this study?

Potential Risks Related to Donating Tumor and Blood Samples
The most common risks related to drawing blood from your arm are brief pain and possibly a bruise. Common side effects of a biopsy are a small amount of bleeding at the time of the procedure, pain at the biopsy site, which can be treated with regular pain medications, and bruising. Rarely, an infection can occur.

Potential Risks Associated With Gene Sequencing
We will also be performing a full genetic analysis on the tumor samples and blood of patients on this study. This analysis is investigational, and not approved or cleared by the US Food and Drug Administration (FDA), and is for research purposes only. We will only do this analysis after we have deleted all information that identifies the sample as belonging to you. Deleting your information is important because by sequencing your tumor and blood cells for gene variations, we may find information about your hereditary risk of developing disease, such as an increased risk of cancer or other serious illness. Because you share some genetic information with your children, parents, brothers, sisters, and other blood relatives, this information may also tell us about your blood relatives' risk of developing disease. This information could affect your ability or the ability of your family to purchase long term care insurance, disability insurance, and life insurance. Your privacy is very important to us. The best way to protect your privacy is to delete your personally identifiable information from your samples before we do these research tests. This means that we will not be able to tell which patients' tumors have gene variations. We will not know if a given tumor with or without a variation is yours, and therefore will not be able to give you any information we learn. If you have any questions about this, please ask your study team.

- **There also may be other privacy risks that we have not foreseen**

There are state and federal laws that protect against genetic discrimination. There is a new federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

For more information, please visit
http://www.genome.gov/Pages/PolicyEthics/GeneticDiscrimination/GINAInfodoc.pdf. A hard copy of the fact sheet can be provided to you on your request.

How will information about me be kept private?

All samples collected on this study will be assigned a unique code to protect your confidentiality. Only your clinical research team will be able to access your medical information. If you agree to allow us to save certain medical information for our research, your information will be kept in a computer database and "linked" with the unique code assigned to your samples. To help protect your privacy, your medical information will be "de-linked" before we perform detailed analysis of your samples so that we cannot connect the results back to you.

What possible benefits can I expect from taking part in this study?

There is no direct benefit to you from participating in this study. Information from this study may help scientists learn about cancer. This information could help future patients with cancer.

What are my other choices if I do not take part in this study?

You have the choice to not participate in this optional tissue collection study. There are similar gene tests that may be available as part of regular care. These tests may inform your doctor about features of your tumor that could guide your medical care. Depending on the kind of procedure used to obtain the tumor for this research there may be very little or no extra tissue available for testing the sample as part of your regular care without a new biopsy.

Can I stop taking part in this study?

Yes, you can decide to stop at any time. No further samples will be collected from you for this study. However, samples already donated will not be destroyed.

What are my rights in this study?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care that you are otherwise entitled to or any legal rights.

For questions about your rights while in this study, discuss with your study team or call the patient representatives at your local institution. _____ *(insert name of center)*

What are the costs of taking part in this study?

You will not have any additional costs for being in this research study. You will not be paid for taking part in this study.

What happens if I am injured or hurt because I took part in this study?

Because no medical procedure is being initiated as part of this study, no benefits or medical care are covered under this research study.

Who will see my medical information?

Your privacy is very important to us and the researchers will make every effort to protect it. Your information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you. Some of your health information, and/or information about your specimen, from this study will be kept in a central database for research. Your name or contact information will not be put in the database.

There are organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- The Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study.
- The Food and Drug Administration and the National Cancer Institute in the U.S., and similar ones if other countries are involved in the study.

Where can I get more information?

You may visit the NCI Web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Who can answer my questions about this study?

You can talk to the study doctor about any questions or concerns that you have about this study or to report side effects or injuries. Contact the study doctor(s) _____at _____ (insert telephone number).

Optional Sample Collections for Laboratory Studies

The samples collected for this study are for research purposes only and will not benefit you. If you agree to give samples, you will not be able to change your mind later about having your samples used for research "tests" in this study because the samples will be delinked and we will not be able to tell which samples are yours.

Please read the sentences below and think about your choice. Circle your choice of "yes" or "no" for each of the following studies.

I agree to have my blood collected and I agree that my blood sample and related information may be used for the research tests described above.

YES NO

I agree to have my tumor sample collected and I agree that my tumor sample and related information may be used for the research tests described above.

YES NO NOT APPLICABLE

Release

By signing this form you authorize NCORP-KC to access and obtain information that is required for the study. This may include your medical records, labs, radiologic films and reports and pathology specimens. This authorization to disclose your medical records shall not expire, even upon death, unless specifically revoked in writing by you.

You will get a copy of this form. If you want more information about this study, ask your study doctor.

My Signature Agreeing to Take Part in the Study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed copy of this form. I agree to take part in the tissue collection research studies where I circled "yes."

Participants Name_____

Participant's signature _____

Date of signature_____

Person Obtaining Consent _____

Person Obtaining Consents Signature_____

Date of Signature_____