UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN RESEARCH

CC# 164520: Sharing Clinical and Genomic Data in Cancer Research

This is a research study. The researcher, Eric Collisson, MD, or one of his associates from the UCSF Helen Diller Family Comprehensive Cancer Center will explain this study to you.

Medical research includes only people who choose to take part. Take your time to make your decision about participating. You may discuss your decision with your family and friends and with your healthcare team. If you have any questions, you may ask the researchers.

You are being asked to participate in this study because you have been diagnosed with cancer and your cancer has been characterized using advanced genomic techniques. You are also receiving treatment for your cancer at UCSF, and are being monitored by your care providers for the effects, positive and negative that this treatment has on your cancer and your overall health.

Why is this study being done?

The purpose of this study is to learn if people with cancer will provide informed consent to donate their clinical and genetic information about their cancer to a public data sharing project called the Cancer Gene Trust (CGT). Certain gene mutations in the DNA of cancers have been shown to predict how some patients will respond to some treatments, which is why you have had your cancer DNA tested. Improving our understanding how each genetic mutation or combination of mutations impact treatment will require collection of mutation data and detailed clinical information from hundreds, possibly thousands of people undergoing treatment. As part of this study the researches will also develop algorithms to automatically extract clinical and genomic data from patient records, de-identify it, and share it publicly with other researchers. By making these data quickly available to as many cancer researchers as possible, the study team hopes to support progress being made more rapidly.

The Cancer Gene Trust (CGT) is a pilot internet database designed to liberate clinical tumor data, especially molecular data, from medical institutions and other organizations worldwide and make it accessible for research use in real time. It will allow clinicians, researchers, and others to search cancer sequencing data and some clinical data in a secure, publicly open and available setting, to identify similar cases from around the world.

This study will be paid for by UCSF.

How many people will take part in this study?

Up to 99 people will be asked to take part in this research study. We will ask participants to continue donating their data until the research study ends.

What will happen if I take part in this study?

If you agree to participate, some or all of the following may happen.

A) We will collect clinical data about you and your cancer, including information about the type of cancer you have, how you were treated, and what happened as a result of that treatment. A complete list of items we will collect is in the appendix of this document, and we encourage you to review it.

B) We will collect data from genomic tests of your cancer performed at UCSF and outside labs, including the names of the mutated genes and the sequence of the building blocks that make up your cancer's DNA. We try to include only mutations that developed in your cancer, and to exclude mutations that you were born with from our data sharing activities. We may also share de-identified images (pictures) of what your tumor looks like under a high powered microscope and de-identified images from radiology tests (PET scans, CAT scans and MRI scans) that you undergo during your treatment.

C) We will make every attempt to remove any information that could enable someone to link your clinical records and genomic data to you or your family. We will do this by processing your clinical record with a software program that removes all information other than the data items listed in the Appendix. This is called "de-identifying" data. For example, the software will filter out your name and date of birth, but include diagnosis and information about your treatment. Similarly, the software will filter out genetic information you were born with, but include genetic information that is specific to your tumor.

   De-identified clinical records and genetic data will be made available to the research community by means of a database that is accessible freely, openly and publically through the internet. These de-identified records and data will be updated if you undergo additional procedures or treatments for your cancer.

D) Combining and analyzing your data and records with those of hundreds or thousands of other cancer patients may lead to new cancer treatments and clinical research studies. You may be asked to participate in one of these studies in the future. You can agree or decline.

How long will I be in this study?

You will be part of the study until the study ends or you decide to no longer participate.

Can I stop being in the study?

If you decide later that you do not want your health information to be used for future research, you can notify the investigator in writing at:

Eric Collisson, MD
University of California, San Francisco
1600 Divisadero St. Box 1705, San Francisco, CA 94143-1705

Data shared on the internet cannot be destroyed.

What risks can I expect from being in this study?

This is a “sharing” study in which we will make de-identified information about you, your cancer and your medical treatments for your cancer available on the internet. By making the information available to cancer researchers, and regularly updating it, we hope to speed the development of treatments for cancer, by learning on a large scale what works for people like you and what does not. The information will be available (in computer-readable format) to anyone with a computer and an internet connection. We cannot guarantee your privacy. It is possible that someone may figure out how to connect your de-identified data to you.

While we are making best efforts to filter out and not share any DNA mutations you were born with, if such sharing were to occur, there is a risk that taking part in this study may influence insurance companies and/or employers regarding your health. Such discrimination is illegal. 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. Federal and state laws in the United States forbid discrimination on genetic grounds. 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). Again, while such discriminatory practices are illegal, we cannot guarantee they will not occur.

Are there benefits to taking part in this study?

There will be no direct benefit to you from allowing your data to be stored and used for future research. However, if researchers find genetic changes in your cancer that may affect your treatment, they may contact UCSF and/or your doctor whose identity is part of the public information. UCSF will maintain a confidential code, effectively mapping your de-identified data back to you. Additionally, we hope to learn more about cancer and how to treat it.

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

You can choose not to participate in this study.

How will information about me be kept confidential?

Your signed consent form will be added to your UCSF medical record.

We will share your de-identified medical data (for example, diagnosis, radiology images, tumor genomics, treatment history, age at diagnosis) via the public Internet. We will never share your name, address, or phone number without your written permission. Qualified researchers worldwide may apply to access more detailed genetic and clinical data about you, in order to carry out further research. The study team will forward such requests to you for your consideration and facilitate introductions if you wish, but will not give advice as to how you should proceed in these cases.

The University of California may look at and/or copy your medical records for research, quality assurance, and data analysis.

Will I be paid for taking part in this study?

No, you will not be paid for donating your medical information. If the data or any new products, tests or discoveries that result from this research have potential commercial value, you will not share in any financial benefits.

What are the costs of taking part in this study?

You will not be charged for donating your medical information.

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

It is important that you tell your study doctor, Eric Collisson, M.D., if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him at 415-353-7151.

> **Treatment and Compensation for Injury:** If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California, depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415- 476-1814.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care in any way. You can still get your medical care from our institution.

Who can answer my questions about the study?

You can talk to the researchers about any questions or concerns you have about this study. Contact the researcher, Eric Collisson, M.D. or his associates at (415) 353-7151.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Institutional Review Board at 415-476-1814.

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OPTIONAL RESEARCH

Please note: This section of the informed consent form is about optional procedures that are being done with people who are taking part in the main study. You may take part in these optional procedures if you want to. You can still be a part of the main study even if you say "no" to taking part in any of these optional procedures.

Making Your Choice

Please indicate whether you agree to be contacted in the future below by putting your initials in the "Yes" or "No" box. You can still agree to donate your data even if you say "no" to being contacted in the future. If you have any questions, please talk to the researcher, or call our Institutional Review Board at 415-476-1814.

No matter what you decide to do, it will not affect your care.

1. Someone may contact me in the future to ask me questions about my health status.

YES	*NO*

2. Someone may contact me in the future to ask about participating in future research studies.

YES	*NO*

This is the end of the Optional Research section of the consent form.

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Appendix: Information that will and will not be shared as part of this study

	Information that **will** be shared	Information that will **not** be shared
Locations:	• Birth • Diagnosis • Residence • Death	• City or towns • Addresses
Dates	• Age at diagnosis • Year in which treatment began • Last patient contact • Age at time of Death	• Date of Birth • Date of Death
Durations	• Hospital admissions/discharges • Diagnostic procedures • Disease staging • Surgeries • Treatments • Recurrence	
Health	• Diagnosis • Diagnostic procedures • Disease staging • Presence of other diseases or conditions • Summary of previous treatments (including surgery, chemotherapy, radiation therapy, hormone therapy, and immunotherapy) • Summary of treatments • Summary of surgeries • Current health status • Cause of death • Tumor genetic data • Tumor imaging data	• Medical record number(s) • Health plan numbers • Photographs of your face • Physician name(s)

	• Photomicrographs of your tumor cells	
Demographic and Other	• Gender • Race/ethnicity • Religion	• Name • Phone numbers • Email addresses • Social Security number

Consent

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

Date	Participant's Signature for Consent
Date	Person Obtaining Consent
Date	Witness – Only required if the participant is a non-English speaker