

Molecular Classifications of Cancer **Consent and Authorization Document**

Background


You are invited to participate in research that will help understand, treat, and prevent cancer. Your tissues contain information that is important for cancer research and medicine. You were selected as a possible participant because you will be undergoing a surgical procedure for removal of tissue or because your body fluid (e.g. blood) is needed to find differences between individuals with and without cancer. You may also have been selected as a possible participant because you are being treated at the University of Utah Hospital or Huntsman Cancer Hospital or clinics. Cancer develops due to mistakes in your cells that cause them to behave abnormally. By studying your cells and comparing them to cells from other people, researchers are able to discover differences that account for why some people survive cancer and others do not. Sometimes people are born with mistakes in their cells that make them more likely to get cancer compared to other people. Looking at cells to see if you were born with a risk for developing cancer is called genetic testing. If you were born with a risk for developing cancer, your children may also be at risk for getting cancer. Please take time to read the following information carefully and discuss it with friends and relatives if you wish. Ask us if there is anything that is not clear or if you would like more information. Philip Bernard, M.D. is the Principle Investigator for this study.

Study Procedure

If you decide to be in this study and you are undergoing an operation, some of the tissue that is normally taken out as part of your surgery will be saved. No additional tissue will be removed and there will be no additional risk to you beyond the usual risks of the operation. If your doctors feel that removal of your tissue for this project will adversely effect your treatment, then no tissue will be taken. If you are undergoing surgery or are being recruited as a control subject, we may collect a urine sample (about 1 cup) and a blood sample (about 4 tablespoons). Sample collections may be done prior to your surgery or during follow-up visits. Your saved tissue may also be used to grow more cells. If you have been selected as a possible participant and had tissue removed as part of a prior procedure, we may also request to use that tissue for this study. Your tissue will be looked at in many different ways, some of which are considered genetic testing.

Risks

If blood is drawn, there may be slight discomfort or bruising from the needle stick site in your arm. You may experience psychological distress, such as anxiety. Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. It is unlawful to use genetic testing for job discrimination or insurance purposes in Utah. For your protection, confidential information relating to your identification will be kept separate from the biological information we learn about your tissue. Investigators will use the results of this study for research and will not include them in your medical record. Since it may be harmful to share information before we know exactly what it means, you will not be told about results that are considered genetic testing. To protect yourself from possible harm due such things as extra blood drawing, extra x-rays, interaction of research drugs, or other problems, it is best to talk to your doctor before starting other research studies.

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Benefits

We cannot and do not promise that you will directly benefit from being in this study. Cancer is a major health problem throughout the world. Information we learn from your tissues may help prevent and treat cancer in the future.

Alternative Procedures

You may choose not to participate in this study or choose to participate by donating only body fluid.

Confidentiality

We will keep all research records that identify you private to the extent allowed by law. Records about you will be kept on computers protected with passwords. Only those who work with this study will be allowed access to your information. However, representatives from the Food and Drug Administration and the National Institutes of Health may inspect and/or copy the records that identify you. Results of the study may be published; however, your name and other identifying information will be kept private. In order to participate in this study we may require the use of your social security number.

Person to Contact

If you have any questions or concerns, you can contact Philip Bernard, M.D. at anytime by calling either 801-581-5353 (office) or 801-339-0978 (pager).

Institutional Review Board

If you have questions regarding your rights as a research subject, or if problems arise which you do not feel you can discuss with the Investigator, please contact the Institutional Review Board Office at (801) 581-3655.


University's Liability Statement

If you are injured from being in this study, the University of Utah can give you medical care. This medical care will be given to you immediately for emergency problems. The University will not charge you for this medical care, but we will bill your insurance company if you have insurance. If you sign this document you are not giving up your right to take legal action against the University or other companies involved with this research.

The University of Utah is a part of the government. If you are injured in this study, and want to sue the University or the doctors, nurses, students, or other people who work for the University, special laws may apply. The Utah Governmental Immunity Act is a law that controls when a person needs to bring a claim against the government, and limits the amount of money a person may recover. See Section 63-30d-101 through 63-30d-904 of the Utah Code.

Voluntary Participation

Your participation is voluntary and you may choose not to participate in this research. If you decide to participate, you have the right to refuse to allow your tissues to be studied at any time. Withdrawal of consent will not cause prejudice to you or affect your medical care.

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Unforeseeable Risks

In addition to the risks listed above, there may be risks which are currently unforeseeable.

Right of Investigator to Withdraw

The researchers may remove you from this study. Reasons to remove you from the study include the following:

- If saving tissue for research could interfere with your medical care
- If your medical care requires steps that prevent the research study from being followed

Costs to Participants and Compensation

You will not be charged any money to be in this study. You will not be paid for being in this study.

New Information

Sometimes during the course of a research project, new information becomes available about the treatment/drug that is being studied. Since this study is independent of any treatments you may receive, the discovery of new treatments should not affect your decision to continue in this study. Any new findings developed during the research that relate to your willingness to continue participation will be provided.


Number of Participants

Approximately 1000 patients from The University of Utah Hospital and Huntsman Cancer Center will be enrolled into this research study each year.

Authorization for Use of Your Protected Health Information

Signing this document means you allow us, the researchers in this study, and others working with us to use information about your health for this research study. You can choose whether or not you will participate in this research study. However, in order to participate you have to sign this consent and authorization form. If you choose to participate in this study, we may use the following information:

- Personal Information
 - o Name, Age, Address, Telephone number, E-mail, Social Security Number (SSN)
- Medical System Identification
 - o Medical Record Number (MRN), Surgical Pathology Number (SP#)
- Clinical Information:
 - o Surgery Reports, Pathology Reports, Medical/Oncology Reports, Radiology Reports
 - o Current and past medical conditions, medications, operations and therapies
 - o Genetic and environmental risks for cancer
 - o Length of cancer remission and overall outcome

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- Family medical history

Your medical information will be accessed through secure electronic connections to the University of Utah Data Warehouse, the Utah Cancer Registry (or Tumor Registry), and the Utah Population Database. All information which is collected about you during the course of the research will be kept strictly confidential. If we share your information with anyone outside the University of Utah Health Sciences Center you will not be identified by name, social security number, address, telephone number, or any other information that would directly identify you, unless required by law.


Others who will have access to your information for this research project are the University's Institutional Review Board (the committee that oversees research studying people) and authorized members of the University's workforce who need the information to perform their duties (for example: to provide treatment, to ensure integrity of the research, and for accounting or billing matters).

You may revoke this authorization. **This must be done in writing.** You must either give your revocation in person to the Principal Investigator or the Principal Investigator's staff, or mail it to Philip Bernard, M.D., Huntsman Cancer Institute, Room 3345, 2000 Circle of Hope, Salt Lake City, UT 84112-5550. If you revoke this authorization, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

You have a right to information used to make decisions about your health care. However, your information from this study will not be available during the study; it will be available after the study is finished. This authorization does not have an expiration date.

Tissue Banking

To protect your privacy as a patient in this study, you have choices for us to keep your tissues and the results. To be in this study you can choose to have your tissue kept for the study and not be contacted in the future, or you can choose to be in this study and be contacted in the future so that we may inquire about your health and notify you about other studies that may help your treatment. Either choice you make, all tissues will be assigned a number that allows test results to be matched to a particular tissue. The number protects your privacy by allowing your name to be removed from your tissue and your results. The number can also be used to match your tissue and results to your medical information, while still keeping your personal and medical information private. All information that could be used to directly identify you will be removed from your tissue and research results. The match between your private information and tissue or research results will be kept in a computer that is password protected. Sometimes, the match will be used to update information. Afterwards, the matching information will again be removed.

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Please read each sentence below, think about your choice, and mark "YES" or "NO". No matter what you decide to do, your decision will not affect your medical care.

May The University of Utah or its research partners keep your sample(s) for cancer research and link your personal and medical information with your sample(s)?

YES, my sample(s) may be used for cancer research in this study and other future studies and my medical information and personal identifiers can be associated with my sample(s). All information will be kept secure and confidential.

NO, I would not like to participate in this study.

May The University of Utah or its research partners contact you in the future to inquire about your health and notify you about other studies (e.g., clinical trials) that may help your treatment?

YES, I would like to be contacted in the future.

NO, I would not like to be contacted in the future.

If you granted permission for the sample(s) to be used in future research by the University of Utah or its research partners, the Institutional Review Board will review and approve each new project. The Institutional Review Board may require that you be contacted for your permission prior to the use of the sample(s) in a new project if it determines new consent is required for your protection. You have the right to withdraw your consent in the future. You would need to notify the investigator of your decision.

Consent

I confirm that I have read and understand this consent and authorization document and have had the opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. I understand that sections of any of my medical notes may be looked at by responsible individuals from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. I will be given a signed copy of the consent and authorization form to keep.

I agree to participate in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.

Participant's Name


Participant's Signature

Date

Name of Person Obtaining Authorization and Consent

Signature of Person Obtaining Authorization and Consent

Date

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