LEGACY HEALTH SYSTEM
Tumor Sample Consent Form

TITLE: Collection of Tissue, Blood and Other Specimens from Patients with Cancer for Legacy Tumor Bank

PRINCIPAL INVESTIGATORS: Katherine Morris, MD (503) 413-5409
Juhua Chen, MD, PhD (503) 413-5381

PURPOSE:

Doctors at Legacy Health System study normal cells and cancer cells to better understand what causes cancer and how best to treat it. To study these cells we need to have human tissue, body fluids, and blood.

During your treatment for cancer a procedure/operation to remove tumor tissue or body fluids with cancer cells in them may be done. We are asking your permission to collect some of your specimen after all the necessary tests have been performed on it. We also want to collect blood. The collected specimens will be stored in a Legacy laboratory in our tumor bank. A tumor bank is a protected place to store cancer specimens so they can be studied to learn more about cancer. No extra specimens other than the blood will be taken for this bank. The specimens will be used for research studies to help us better understand cancer.

Information about your diagnosis, any prior cancer history, treatment and your response to treatment, as well as limited demographic information will be obtained. In addition, the investigators will ask the established Legacy Cancer Registry or your treating physician for updates on your survival on a quarterly basis. This information may be important for the research studies that will be done using your specimens. All of this information will be kept in strictest confidence; we will use it only for cancer research. Your name will not be used in any report or publication.

This study will only be conducted in the Legacy Health System and will involve approximately 100-300 patients a year.

PROCEDURES:

The specimens will be taken at the time of your procedure or operation. NO additional tissue will be taken from you for the purposes of this tumor bank. The specimen that contains the tumor tissue will first be taken to the Pathology Department. Diagnostic tests will be done on the tissue. IF any tumor or normal tissue remains after the tests are complete, a piece of this will be taken for the registry. If body fluids (from your abdomen, lung, spine or a cyst) are removed as part of your cancer care, we may take some after the necessary diagnostic tests have been done.

If you have already had a procedure or operation in which a tumor was removed, and there is tissue available, you may give your permission at this time to have it collected and placed in the tumor bank.

If you chose to take part, a blood sample will also be taken from the intravenous (IV) catheter in your hand or arm. If we are unable to get blood through the intravenous catheter, the blood for the tumor bank will be taken at the time of other blood draws necessary for your care. There will be no extra needle sticks to obtain blood for the tumor bank. The amount of blood we collect for the tumor bank will not be more than 50 cc (about 3-4 tablespoons).

Taking part in the tumor bank will involve no extra time on your part.

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The specimens collected for the tumor bank will be used by the investigator listed on this form (or designated colleagues) for studies of cancer. Samples of your cells may be given to researchers outside of this institution as part of the research. These will be coded so that access to identifying information about you is protected.

Your doctors may be contacted to check on your health and whether or not the cancer has returned.

RISKS AND DISCOMFORTS:

The only risk associated with this registry is that there could be a breach of confidentiality. All personal medical information about you and any information obtained from future studies of your tissue will be strictly guarded. Your name and identity will be used only for data collection for this tumor bank and will not be disclosed to a third party outside of the Legacy Health System. However, if unauthorized persons obtained information about you that we have collected for this tumor bank, it could affect your insurability or employability, and could release information about the risk of future development of disease in you, some of your relatives, or in your future children. We will take all precautions possible to avoid this from happening.

BENEFITS:

Taking part in this research will not benefit you directly; however, what we learn may help others in the future.

ALTERNATIVES:

You may choose not to take part in this tumor bank.

COSTS:

You will be billed for all procedures associated with your clinical care. There will be **no** cost to you for any procedures required for the tumor bank. You will not be paid or given any other award for taking part.

PROPERTY DONATION:

By agreeing to take part, you allow the use of your samples for the research described in the PURPOSE section of this document. In addition, you agree that Legacy Health System may make any lawful use of your samples, including, but not limited to, future research studies, destroying them, or transferring them to a public or private entity.

Samples obtained from you for this tumor bank may be used to make a discovery that could be patented or licensed to a company. There are no plans to pay you if this occurs. However, if Legacy Health System ever provides your samples to anyone else for research or commercial use, it will do so in such a way as to protect your privacy and confidentiality as stated in the CONFIDENTIALITY section of this document.

PARTICIPATION:

Katherine T. Morris, MD, (503) 413-5409, has offered to answer any other questions you may have about this tumor bank. If you have any questions regarding your rights as a research subject, you may contact the Legacy Health System Institutional Review Board at (503) 413-2474. You may choose not to take part, or you may withdraw from this study at any time without affecting your relationship with or treatment at the Legacy Health System.

If in the future you decide you no longer want to take part in this tumor bank, we will destroy all identifying information and will not use your tissue in any future research. However, if your tissue samples are already being used in an on-going research project and if their withdrawal jeopardizes the success of the entire project, we may continue to use them until the project is completed.

You will be given a copy of this consent form for your records.

Your signature below indicates that you have read this consent form and agree to take part in this tumor bank.

CONFIDENTIALITY:

Every effort will be made to keep your registry records private. All others, including employers, insurance companies, personal physicians, and relatives will be refused access to the information and to the samples, unless you provide written permission, or unless

we are required by law to do so. Anything that can identify you will be kept in private, protected files. A code number will be assigned to you, your tissue samples, and information about your medical history. Only the investigator named on this consent form will be authorized to link the code number to your name. The link of your code number to your name or any other identifying data will be stored in the established secure Legacy Cancer Registry database. Other investigators, who may receive a sample of your tissue for research purposes will be given only the code number that will not identify you or any of your relatives.

Any future research done on any of the samples must be designed in a way that protects your privacy and presents research results and data anonymously. The Institutional Review Board must also monitor it.

Authorization to Use and Disclose Protected Health Information

By signing this consent, you allow Legacy Health System to use and disclose your Protected Health Information (PHI) solely for the purposes of the tumor bank, with protections as detailed above. PHI includes any portion of your medical records that could be used to identify you such as name, address, telephone number, or date of birth.

Your permission to use your PHI for the purposes of this tumor bank will not end unless you change your mind. You may cancel your permission to use your PHI for this tumor bank at any time by sending a written notice to:

Principal Investigator: Dr. Katherine Morris
Address: Legacy Holladay Park Medical Center
Clinical Research and Technology Center
P.O. Box 3950
Portland, Oregon 97208
Phone: 503 413 5409

However, if you revoke this authorization, you may no longer be able to participate in the tumor bank. In addition, even if you change your mind, the information already obtained by Legacy Health System may be used and disclosed as permitted by this authorization and this informed consent.

14. Contacts

If at any time following consent for this tumor bank, you think that you have not been adequately informed as to the risks, benefits, alternative procedures, or your rights as a research subject; or you feel under pressure to take part against your wishes, you can contact Legacy Health System's Research Regulatory Specialist. The Research Regulatory Specialist will be available to speak with you during weekday work hours (8:30 a.m. to 5:00 p.m.) at (503) 413-2474.

The subject has been informed of the (1) nature and purpose of the procedures described above including any risks involved in participating in this tumor bank; and (2) of how his or her Protected Health Information may be used or disclosed. The subject has been asked if any questions have arisen regarding these procedures and the subject's privacy rights, and these questions have been answered to the best of the Legacy Health System's ability. A copy of this Compound Consent has been provided to the subject.

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Date Investigator's Signature or Designee

I have been informed about the procedures, risks, and benefits of participating in the registry and agree to participate. I know that I am free to withdraw my consent and to quit the registry at any time. I have read and understand the terms of this Consent Form and I have had an opportunity to ask questions about the registry and to discuss the registry with my doctor and other health care providers and my family and friends. I also have had the opportunity to ask questions about the use and disclosure of my Protected Health Information and my privacy rights. I hereby knowingly and voluntarily authorize Legacy health System to use and disclose my Protected Health Information in the manner described in this Consent Form. <u>I understand that I may decline to participate in this registry. I further understand that if I choose to participate, I may withdraw from the registry at any time. My decision not to participate in this registry or my decision at any time to withdraw from this registry will not cause me any penalty or loss of benefits that I am otherwise entitled to enjoy.</u>

____________________ _________________________________

Date Subject's Signature