OHSU Knight Cancer Institute Research Repository Consent Form

REPOSITORY TITLE: OHSU BioLibrary

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ABOUT RESEARCH REPOSITORIES

Generally, a research repository collects, stores and distributes human specimens (samples of blood, tissue, or body fluids) and/or data for use in future research projects. Storing and gathering lots of specimens and data together can help to conduct future research and avoid re-collecting specimens and data over and over again. With this stored information and samples, researchers may understand better how the human body works, develop new tests to find diseases, find new ways to treat diseases, or develop new products, such as drugs. When researchers collect and store many specimens and data together and use them for different kinds of research in the future, or share them with other scientists, this is called a research repository.

PURPOSE:
You are invited to be in this research repository because you have cancer or have had cancer, because you have a gene that might make it more likely for you to get cancer, because cancer runs in your family, or because you are a “normal control” (have no cancer).

The purpose of this repository is to create a collection of the following to be used for future research studies:

1. A bank of biological specimens, which may include tissue, blood and other body fluids, as well as DNA and RNA from these biological specimens.

2. A database containing clinical information including the results of tests for abnormal genes (mutations) in the specimens

3. A list of patients who have agreed to be contacted in the future for potential inclusion in clinical trials when eligibility has been established with collected genetic and health history information.

The overall goal of this repository is to support research to understand what causes cancer, and
how genes affect how cancer responds to different treatments. If a gene or genes that cause cancer can be found, the diagnosis and treatment of cancer may be improved. Genes are the units of DNA — the chemical structure carrying your genetic information — that determine many human characteristics such as the color of your eyes, your height, and whether you are male or female. Gene mutations are changes in the DNA that can make the gene not work right. Genetic testing refers to looking at genes and gene changes.

We plan to enroll approximately 1,000,000 participants in this repository at OHSU.

**PROCEDURES:**
If you take part in this repository, you are allowing us to:

- **Collect information contained within your medical records, including any health surveys and questionnaires:** OHSU is building a database that will be used for future research purposes. This database will contain information such as your health history, medical treatments, disease progression and quality of life. We will collect clinical information about the risk factors for, and the diagnosis and treatment of your cancer. This information will be used to study what you and other patients with cancer, or at risk for cancer, have in common. We will follow your clinical information for as long as this repository remains in progress and/or for the rest of your life.

- **Store and use excess tissue removed at the time of a surgical procedure:** If you have surgery to remove tissue as part of your standard care, usually there is a small amount of excess tissue that is also removed. This excess tissue is not needed for your clinical care and may be thrown away. We would like permission to store it for research instead. Your standard surgery will not be different if you agree to take part in this repository.

- **Collect and distribute “fresh” tissue from surgical specimens:** Some research requires tissue that has not been frozen or exposed to the preservatives usually used when collecting samples. This unmodified tissue is called “fresh” tissue. In addition to preserved samples obtained from surgical excess, we may also collect excess fresh tissue. However, the pathologist will always carefully determine what tissue is needed for your care and what can be given as excess. This will not alter your surgery, but may affect the pathologist’s ability to accurately diagnose your tissue (see RISKS AND DISCOMFORTS below).

- **Take samples of blood:** As part of your standard treatment, your treating physician will collect blood from your vein for clinical tests at regular intervals; sometimes weekly, monthly, or yearly. We would like to collect up to 3 ½ tablespoons of additional blood for future research purposes. Wherever possible, we will draw this blood at one or more of your regular clinical care blood draws. Blood collection may be arranged by placing an order in your medical record. Orders will be associated with this repository (OHSU BioLibrary) and include contact information for the study staff should you have questions.
- **Take samples of bone marrow:** Bone marrow may be obtained from a bone marrow aspirate procedure. As part of your standard treatment, your treating physician may order the collection of cells from fluid inside your bone (called a bone marrow aspirate). If this procedure is performed, we would like to collect up to approximately 1 tablespoon of additional fluid for future research purposes. The additional fluid may be collected each time you have a bone marrow aspirate performed. We will not ask you to undergo this procedure for research purposes only.

- **Collect other body fluids or samples:** We may collect additional samples, such as saliva, sputum, urine, feces, etc. As part of this protocol you may receive a saliva collection kit that can be used at home to collect a research saliva sample for this repository. All instructions for the collection and transport of fluids for this kit will be given to you.

- **Collect tissue samples from other clinical or research studies:** If you have participated in other clinical trials or research studies in the past, at OHSU or another institution, and tissue was collected, we are asking for permission for OHSU to have access to that tissue. Having a sample of your tissue from a past procedure can provide information about how your cancer has changed with time or responded to treatment.

- **Isolate genetic and other materials from your biological samples:** DNA, RNA, proteins and other materials may be isolated from your tissues and used for genetic testing.

- **Stay in touch with you:** As part of your standard medical care, you will probably see your doctor at least once per year to follow your health status, and to have routine blood tests. We may contact you or your doctor periodically to see how you are doing and to make sure we have accurate contact information for you and your doctor. We may also contact you or your doctor to see if you are interested in participating in a new study, or to discuss other matters associated with this repository.

You can ask questions about the repository at any time. If you have any questions regarding this repository now or in the future, contact a study coordinator at (503) 494-9648, option #1.

**SUBJECT ACCESS TO GENETIC TESTING RESULTS:**
We will not release test results to you directly because the meaning and reliability of these tests may be uncertain. However, you may choose to contact us (directly or through your physician) to request available testing results be sent to your care provider. Because genetic information is complex and sensitive, the results should be discussed with a genetic counselor or your care provider who can appropriately answer your questions and discuss concerns. Please be aware that by choosing to receive test results you may learn information that is upsetting or could impact you negatively. You may also need to have tests repeated in a non-research laboratory, in which case you would be responsible for all costs associate with any follow-up testing and medical care.
FUTURE STUDIES:
In the future, samples and information that we collect or generate may be given to other researchers as part of the search for causes and treatments of diseases. This may include, but is not limited to, information concerning HIV/AIDS, mental health, substance abuse or genetic information. Your authorization to use your health information will never expire unless you revoke it. The samples and clinical information will be labeled and stored as described in the CONFIDENTIALITY section. The clinical data, blood, tissue and body fluids you donate to this repository will be used to conduct future cancer research as long as it is available.

You will not be notified in the event that additional research is conducted, and no additional consent will be needed from you. You will not receive results generated from the future research done on your samples. Researchers conducting future studies will receive genetic information that is coded and does not include identifiers, unless they have special approval from an Institutional Review Board.

RISKS AND DISCOMFORTS:
If you take part in this repository, you may be exposed to the following risks:

- **For Genetic Testing:** A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination if you have already been diagnosed with the genetic disease being tested.

  Although we have made efforts to protect your identity, there is a small risk of loss of confidentiality. If the results of these studies of your genetic makeup were to be accidentally released, it might be possible that the information we will gather about you as part of this study could become available to an insurer or an employer, or a relative, or someone else outside the study. Even though there are certain genetic discrimination and confidentiality protections in both Oregon law and federal law, there is still a small chance that you could be harmed if a release occurred.

- **For Bone Marrow Aspiration:** Bone marrow samples will only be collected as part of a bone marrow aspiration performed for your clinical care. Bone marrow aspiration is a procedure for taking some cells from inside your bones. We will not request this procedure be performed solely to obtain a research sample. At the start of the procedure, an area of your skin (usually near your hip) will be numbed with a shot. The shot may cause a little pain. There is a rare chance of an allergic reaction to the numbing medicine, which can be serious and life-threatening. The medical team will be watching closely for signs of an allergic reaction and will provide emergency treatment if necessary. The bone marrow aspiration involves inserting a long needle into your bone to get the cells. Some people have moderate to severe pain when the bone marrow cells
are drawn out through the long needle. The procedure will be exactly the same as if you were not participating in the research, except that we will do an extra draw to collect a research sample. Your hip may hurt for about three to six days. There is a small chance you will get a bruise or an infection where the needle was inserted. You may bleed or have a scar. Your skin may temporarily itch where the needle was inserted. These problems are rare though and except for the pain during the extra draw, they are the same as if you weren’t participating in this research study.

- **For Blood Draw:** We may draw blood from a vein in your arm. You may feel some pain when your blood is drawn. There is a small chance the needle will cause bleeding, a bruise, an infection, or fainting. Wherever possible, this blood draw will occur at the time of a blood draw scheduled by your doctor, meaning you would not have an extra needle poke for this repository.

- **For Fresh Tissue:** It is our intent that any tissue collected for this repository will be an excess (or left over) of what was needed for your clinical care. As this tissue or fluid would normally be discarded this poses no additional risk to you. However, in the case of “fresh” tissue collections (see PROCEDURES above), the sample must be released to the research repository immediately after it is surgically removed. Fresh tissue that is released for research purposes is typically altered or consumed by research activities shortly after it is released, meaning it cannot be used for making a diagnosis of your condition. Because of this, there is a small risk that donating fresh tissue might result in your providers not being able to get a diagnosis for your condition. If you have concerns we encourage you to talk with your care provider(s).

**BENEFITS:**
You will not personally benefit from participating in this repository. However, by serving as a subject, you may contribute new information which may benefit patients in the future.

**ALTERNATIVES:**
You may choose not to participate in this repository.

**CONFIDENTIALITY:**
We will create and collect health information about you as described in the PURPOSE and PROCEDURES sections of this form. Health information is private and is protected under federal law and Oregon law. By agreeing to be in this study, you are giving permission (also called authorization) for us to use and disclose your health information as described in this form. The researchers, study staff, and others at OHSU may use the information we collect and create about you in order to conduct and oversee this repository and to conduct future research. We may continue to use and disclose your information as described in this form indefinitely.

We may release this information to groups who are involved in conducting or overseeing research, such as: the OHSU Knight Cancer Institute, the Oregon Clinical & Translational Research Institute (OCTRI), the OHSU Institutional Review Board (IRB), the National Cancer Institute (NCI), the National Center for Research Resources (NCRR), the Office for Human
Research Protections (OHRP), and others involved with the conduct of research. When we send specimens or information outside of OHSU, they may no longer be protected under federal or Oregon law. In this case, your specimens or information could be used and re-released without your permission.

We cannot guarantee total privacy, but efforts will be made to keep your personal information in our research records confidential. A code number will be assigned to you, your biological samples and genetic information, as well as to medical information about you. Only the approved study staff associated with this repository will be authorized to link the code number to you. Unless there is a scientific need for identified information, researchers and organizations who receive your samples or clinical information for research will be given only the code number, which will not identify you.

Your medical information will be kept in a password-protected online database, which is protected by OHSU firewalls, or it will be kept in a locked filing cabinet. Your samples will be kept in a locked laboratory at OHSU. Some of your biological samples may be sent to a non-OHSU laboratory for analysis.

Some of your medical or genetic information may be deposited into one or more online scientific databases. Some of these databases may be used by the public, and some of these databases may be restricted and can only be used by approved researchers. Your name and other information that could identify you will not be released into a scientific database.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. We can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. We will use the Certificate to resist any demands for information that would identify you, except as explained below.

- The Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

- The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of abuse and neglect of at-risk populations (such as children, elderly, or individuals with mental illness), or harm to self or others when reasonably suspected.

**COSTS:**
There will be no cost to you or your insurance provider for participating in this repository. You and your insurance will still be charged for the cost of procedures performed as part of your standard care. If your tumor is genotyped/sequenced as part of routine clinical care (and billed to you and your insurance carrier), the data generated from this analysis may be included in the repository. If procedures or genotyping are performed solely for research purposes, neither you
nor your insurance carrier will be charged.

There is no compensation provided to you for participating in this repository.

COMMERCIAL DEVELOPMENT:
You acknowledge that OHSU and their collaborators 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 organization. OHSU may bill such entities for costs related to collection, storage and retrieval of the samples and/or associated clinical and research data. Additionally, use of your samples and information might result in a discovery that could, in the future, be patented or licensed to a company, which could result in a possible financial benefit to that company, OHSU, and its researchers. There are no plans to pay you if this happens. You will not have any property rights or ownership or financial interest in or arising from products or data that may result from your participation in this study. Further, you will have no responsibility or liability for any use that may be made of your samples or information.

LIABILITY:
If you believe you have been injured or harmed while participating in this repository and require immediate treatment, contact your regular doctor or primary care physician.

If you are injured or harmed by the study procedures, you will be treated. OHSU does not offer any financial compensation or payment for the cost of treatment if you are injured or harmed as a result of participating in this research. Therefore, any medical treatment you need may be billed to you or your insurance. However, you are not prevented from seeking to collect compensation for injury related to negligence on the part of those involved in the research. Oregon law (Oregon Tort Claims Act (ORS 30.260 through 30.300)) may limit the dollar amount that you may recover from OHSU or its caregivers and researchers for a claim relating to care or research at OHSU, and the time you have to bring a claim. If you have questions on this subject, please call the OHSU Research Integrity Office at (503) 494-7887.

This federally funded study also does not have the ability to provide compensation for research-related injury. If you are injured or become ill from taking part in this study, it is important to tell your study doctor. Emergency treatment may be available but you or your insurance company will be charged for this treatment.

PARTICIPATION:
You do not have to join this repository. You do not have to allow the use and disclosure of your health information in the repository, but if you do not, you cannot be in the repository. If you do join, and later change your mind, you may quit at any time. This includes the right to withdraw your authorization to use and disclosed your health information. If you refuse to join or withdraw early from the repository, there will be no penalty or loss of any benefits to which you are otherwise entitled. Your clinical care will not be altered by your decisions regarding this repository.

If in the future you decide you no longer want to participate in the repository, contact any of the
staff listed on this document. We will remove your name from the repository list and no new
health information or specimens will be collected, stored, or used for any further research
projects. Any samples collected solely for research purposes will be destroyed.

Your request will be effective as of the date we receive it. However, health information collected
before your request is received may continue to be used and disclosed to the extent that we
have already acted based on your authorization. We may not be able to destroy samples that
have already been given to a researcher.

Contact one of the repository coordinators listed on this document at (503) 494-9648 for any
questions you may have about this repository. If you have any questions regarding your rights
as a research subject, you may also contact the OHSU Research Integrity Office at (503) 494-
7887.

You will be given any new information that may affect your wish to continue participation.

Your health care provider may be one of the study staff and/or a researcher utilizing this
repository, and as such is interested in both your clinical welfare and in the conduct of this
repository. Before entering this repository, or at any time, you may ask for a second opinion
about your care from another doctor who is in no way associated with this project. You are not
under any obligation to participate in any research project offered by your physician.

We will give you a copy of this signed consent form.