Collection of Tissue Samples and Clinical Information for Research

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WHAT IS THE PURPOSE OF THE STUDY?:

The collection of human tissue samples is vital to medical research. Research with tissue can help scientists discover more about what causes diseases, how to prevent them, and how to cure them. Many different kinds of scientific research studies require the use of tissue. Researchers use tissue to help develop new tests to diagnose diseases, new drugs and new treatments. A tissue bank advances medical research by storing large quantities of human tissue samples and making them available to researchers. Likewise other body fluids such as blood, urine, and sputum can be used for research purposes. In order to best provide tissue, or other material derived from tissue, such as genetic information involving DNA and RNA, Maine Medical Center has established a tissue bank. The tissue contained in this bank is excess surgical tissue that otherwise would be discarded as medical waste.

Diseased tissue is different from normal tissue in ways that we don’t fully understand. Samples of diseased tissue from humans may provide better tools for scientific research than the cells grown in a laboratory. Research scientists may want to use some of your spare tumor tissue to grow in animal models. While they strive to avoid the use of animals wherever possible, for some studies growth of the cells in live animals may be very helpful in understanding human disease. If cells from your tumor grow well in animals, they may be treated with chemicals being considered for possible new treatments.

In some cases, part of your excess tissue sample may be divided into single cells and modified into a sample of special cells (called tumor stem cells). It is these cells research scientists want to use to grow in animal models. These cells may also be treated with chemicals being studied for possible new treatments. It is important to understand that tumor stem cells are not the same as embryonic stem cells (cells derived from human embryos).

Your donated tissue may be stored in ways that allow the cells to grow and multiply. These multiplying cells may form what is called a cell line. Cell lines can be used for multiple future research studies (eg, testing of new drugs). It is important to understand that cells from your tissue may be kept and grown in laboratories or in animal models for many years in the future.
Researchers may also look for biomarkers in your donated excess tissue and blood. Biomarkers are tiny molecules, including those called proteins, ribonucleic acid (RNA), and deoxyribonucleic acid (DNA). Your genes are made of DNA. Genes are inherited and they direct growth, development, and determine body characteristics. For example, some genes control the color of your hair or eyes. There are many differences in DNA from one person to another. These differences may affect a person’s chance of suffering from a particular disease or how their body responds to a particular drug. Your samples may be used for genetic research that will determine part of the structure of your DNA and be compared to your medical information. Researchers want to study how genetic variations are involved in disease pathways, and also how genetic differences may influence the way people respond to medication used in the treatment of a particular disease.

Researchers find medical information invaluable when trying to understand certain aspects of a particular tissue sample, and for comparing tissue samples to identify important similarities and differences within a disease. Maine Medical Center's tissue samples will be linked to a unique code. This coding process is done so that tissue samples can be linked to relevant information about a patient and their disease without identifying the patient by name, social security number or medical records number. Other researchers who do not require medical information will use anonymous samples that can not be traced back to a specific patient.

**WHAT IS INVOLVED IN THE STUDY?**

In treating your illness, your doctor will perform surgery which will include removing tissue for diagnostic and treatment purposes. The results of the tests done on this tissue will be given to you by your doctor and will be used to plan your care. There may be some tissue left over that would normally be discarded as medical waste. We would like your permission to collect, store and use some of this left over tissue for future medical research. **Your doctor will not take more tissue during your surgery than would normally be taken for your care. There will be no change in your treatment in connection with the collection and storage of the tissue.**

In addition you may be asked to contribute a blood sample. For the blood sample, a needle will be used to collect about 3-4 teaspoons of blood from a vein in your arm. You may agree to donate this blood sample or not as part of this project. Please initial your choice for donating blood.

I agree to donate_____________ (initial)
I do **not** agree to donate___________ (initial)

If you agree to participate, any tissue not used for your tests will be stored for future research. Maine Medical Center Tissue Bank staff will assign a code number to your tissue so that it can be linked with information from your medical record at Maine Medical Center, NorDx laboratory, and perhaps your outpatient medical record.
WHAT ARE THE RISKS? :

There is no discomfort to you as a result of storing leftover tissue for research. The tissue collected for research would normally be discarded. The choice to let us keep leftover tissue for research is entirely up to you.

There are minor risks and discomforts associated with blood sampling. This includes momentary pain and possible bleeding at the needle site. Occasionally a person feels faint or light headed when their blood is drawn. Rarely an infection develops. If this happens, it can be treated.

WHAT PRIVACY WILL I HAVE? :

To protect your privacy, your name and any other information that directly identifies you will be removed from your tissue and all information about your medical condition and history will be identified by a unique code number. The list of code numbers and corresponding names will be kept in a secure filing cabinet at the Maine Medical Center Tissue Bank with limited access to necessary Maine Medical Center staff only. The risk of jeopardizing your confidentiality is very low, but complete confidentiality can never be 100% guaranteed.

A Certificate of Confidentiality has been obtained from the National Institutes of Health (NIH). This is intended to further protect the confidentiality of information that we obtain about you. By having a Certificate of Confidentiality, researchers are not required to give information that can be used to identify you. For example, we cannot be forced to give information about you to insurance companies. We cannot be forced to give information about you to any civil, criminal, administrative, or legislative proceedings whether at the federal, state or local level. Rarely, representatives of the Department of Health and Human Services may review or ask for a copy of your study information to make sure federal requirements are being met. If this happens, we will provide your records. Please understand that this Certificate of Confidentiality does not prevent you from voluntarily giving this information to others.

Since no researcher who uses your tissue will have access to your identity, your name will not be used in any publication resulting from studies done on your tissue or in any publication related to the tissue bank. Likewise you will not be informed as to any results or outcomes of the research done on your tissues.

Information collected for this study is confidential. However, for purposes of assuring quality control and adherence to procedures, a certified auditor (third party) will periodically review the banking facilities, personnel, and records. In the course of such a review, the auditor may see your medical record. The auditor is required to strictly maintain confidentiality regarding any records reviewed.
WHO WILL BE ABLE TO USE MY TISSUE? :

The tissue collected and stored at Maine Medical Center may be made available to local researchers, other hospitals, universities, or other academic or commercial companies doing research. Commercial companies (and their affiliated companies) may be located both in the USA and in other countries around the world. Other companies working on behalf of a commercial company may also use your tissue and related medical information (for example a commercial company may hire another company to do lab tests). Your tissue may be used for a number of different research studies related to disease and you may not choose the type of research for which your tissue is used.

Funds received for tissue support the tissue bank and research within the community. All researchers who have access to Maine Medical Center Tissue Bank tissues are approved researchers who have obtained Institutional Review Board Approval for their research. The Institutional Review Board is a group of persons who are responsible for ensuring that your rights are preserved at all times, the tissue is properly collected and that there are procedures in place to protect your privacy.

WILL I BENEFIT BY PARTICIPATING? :

There will be no direct benefit to you, financial or otherwise, for donating a tissue sample. There are many possible benefits to society from research using these materials. Significant direct benefit to the Maine research community will include the possibility of increased research funding, access to more tissue for research, and the chance to collaborate with other large academic medical centers.

WILL THIS COST ME ANYTHING? :

There is no cost to you or your insurance for your participation. You will not be paid for the use of your tissue. As part of the research that is performed, some of your tissue may be used for the development of commercial products such as new drugs or tests. However, you will not receive any financial gain in any commercial development resulting from research that used your tissue.

Maine Medical Center and the researchers who use your tissue (for example those that work for a commercial company) provide no institutional benefit or financial compensation, including payment of expenses associated with medical treatment, or for an injury arising from or attributable to this research, but you do not give up any other legal rights by signing this form.
WHAT IF I CHANGE MY MIND OR DO NOT WANT TO PARTICIPATE? :

You may choose not to let us keep a part of your left over tissue for research. The decision to allow us to keep this tissue is entirely up to you.

If you choose not to participate, your medical care and treatment will not be affected and there will be no penalty or loss of benefits to which you are otherwise entitled.

If you decide to allow us to use your tissue and change your mind at any time you must notify Maine Medical Center Tissue Bank in writing. This request should be sent to: Michael A. Jones, M.D., Division of Pathology, Maine Medical Center, 22 Bramhall St., Portland, ME 04012. If there is any tissue remaining from your surgery that has not been distributed for use it will be discarded. Likewise any medical information that may have been collected will be destroyed. Once samples and related medical information are sent to a researcher, you will no longer be able to withdraw them.

PERMISSION TO USE OR RELEASE PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES:

As part of this research you are being asked to allow Maine Medical Center staff to collect health information about you that will be linked to your tissue and provided to the researchers using your tissue. The medical information collected will be information relevant to your tissue sample. It may include: your family background, and medical history, your current medical condition, medications, summaries of your hospitalization, surgery, pathology and laboratory reports. We may also look at your medical record in the future to see how you responded to your current illness and to see if any other medical conditions have occurred. This medical information will be stripped of all directly identifying information being transmitted for research purposes. This medical information provides researchers the information needed to understand how a disease develops over time, or how a disease responds to various treatments. It is also important so that researchers can decide the most appropriate use of your samples and to better understand any results. The information will be kept for an indefinite period of time.

Regulatory authorities and Institutional Review Boards (agencies that oversee research to protect patients) may also have access to your health information. These people may look at your health information to make sure the study has been done properly. They also want to make sure that your health information has been collected the right way, or for other reasons that are allowed under the law.

Your samples and health information may be transferred to researchers outside of the United States. The laws in other countries may not provide the same level of data protection and may not stop your study data (but not your identification) from being disclosed to others.
If you agree to take part in this research project, you are authorizing the release of your health information as part of this project. If you do not want to release your health information, you may choose not to take part in this research project (do not sign this form if you do not want to take part in this research project or you do not want Maine Medical Center to release your health information).

If you have any questions relating to this project or if you wish to report any research related injury, you are free to contact Michael Jones, M.D. (207-662-2959), Principal Investigator. If you have any question relating to human research at Maine Medical Center, you are free to contact the Research Compliance Office (207-885-8195), of the Maine Medical Center Institutional Review Board (which is a group of people who review the research to protect your rights).

I have read, or have had read to me, the above information before signing this consent form. I agree to participate in this research project. I also give you my permission to use or disclose my personal health information for the purpose of this research. I have been allowed to ask questions about my participation. My questions have been answered to my satisfaction.

Printed Name of Patient

______________________________
Signature of Patient or Authorized Representative         Date/Time

______________________________
Signature of Person Obtaining Consent                     Date/Time

A copy of this signed and dated consent will be given to you for your own records.