Cancer Research Study

What if I agree to participate and change my mind later?
If you decide you no longer want to participate, you will need to notify the Yale Principal Investigator in writing and your specimens and data will not be used for further research.

Mailing Address:
Lajos Pusztai, MD, DPhil
Yale Cancer Center
PO Box 208327, New Haven, CT 06520
Phone: (203) 737-8309

The stored tissue and associated data will be destroyed. However, deidentified samples, which have been distributed to other researchers, research results, and information generated before your withdrawal cannot be located and will not be discarded.

Will I learn the findings from my samples?
In general, we do not plan to contact you or your doctor about research findings from your samples or put the findings in your medical record.

What are the risks of participating?
There is no physical risk involved with banking leftover tissues.

There is a risk that, despite our efforts, your personal information could be revealed to others. Genomic data (i.e. DNA sequences) from cancer and normal tissues that researchers may place in scientific databases could reveal genetic relationships between individuals and could even identify a person.

Germline genomic information may cause concern, including discrimination by others, including employers and insurance companies, and psychological distress. There is a federal law called the Genetic Information Nondiscrimination Act of 2008 (GINA), which makes it illegal to use genetic information to make decisions about your eligibility for health insurance or your health insurance premium, contribution amounts, or coverage terms. GINA makes it illegal for employers with more than 15 employees to discriminate against you based on your genetic information.

Will I benefit from participating?
Participating is not likely to help you but what we learn could help future patients. Research using your specimens may lead to the development of new tests, new therapies or products that are sold. You will not receive any money from such sales.

Will it cost me anything to participate?
No. There are no costs involved for you.

What if I have questions?
If you have any questions, please talk with your doctor first or contact Yale Cancer Center at (203) 785-5702. If you have questions about your privacy rights, please contact the Yale Privacy Officer at (203) 432-5919. You can also contact the Principal Investigator of this research, Dr. Lajos Pusztai at (203) 737-8309 or the Yale University Institutional Review Board (IRB) at (203) 785-2190.

Researchers at Yale University and Yale New Haven Health System want to learn as much as possible about the causes of cancers, leukemias, and other diseases, and find new ways to treat them.
Cancer Research Study

What is research?
Research is the process of creating new knowledge. Clinical and medical research discovers new knowledge about diseases to find better treatments and to develop new diagnostic tests.

What is the purpose of this research?
The goal of this research is to create new knowledge about cancer and diseases of the blood by studying medical records and leftover tumor tissue samples, including biopsy material, saliva, blood, and other body fluids collected during tests and procedures performed as part of your routine care. Leftover tissues (also called specimens) are biological material that remain after the routine clinical tests requested by your doctor have been completed.

Why am I being asked to participate in this research?
You are being asked to participate because
- You currently have, or have had cancer in the past; or
- You are thought to have an increased risk for developing cancer; or
- You have a blood disease; or
- You have a disease that can be treated with bone marrow transplantation; or
- You are planning to donate bone marrow for transplantation.

What research will be done with my samples and medical records, and the samples and medical records of other people?
Scientists will study cancer and normal cells in the samples and look for information in the medical record to learn about how cancers start, grow and spread, and how they respond to therapy.
Scientists may also study what causes blood diseases and how bone marrow cells affect patients who undergo a bone marrow transplant.

What is the purpose of this research?

Will the research involve genetic testing?
Yes, the research will involve genetic testing, which is sometimes called DNA testing, of your cancer and normal tissues. Genes are biological material in cells that is passed from parents to a child. Blood relatives share genes. Genes are responsible for many aspects of your health, and genes may influence whether you develop certain diseases and how you respond to drugs.

What can happen if your sample is used for research?

Who will use my samples and look at my medical records?
Your tissue samples are being collected for research. Your deidentified samples and deidentified data will be available to researchers at Yale University and Yale New Haven Health System (YNHHS), and researchers may share samples, findings from samples, and facts from medical records with researchers and organizations other than Yale and YNHHS.

How will my personal information be protected?
We emphasize that when researchers study your tissues or medical data, your name and any information that might be used to identify you, as defined by the Health Insurance Portability and Accountability Act (HIPAA) of 1996, will be removed.

Results and data from the research may also be deposited in scientific databases open to other researchers. When data are placed into databases, all patient identifiers are removed and therefore cannot be linked to a specific person. Your name and identifiers will never be released in publication or to researchers outside of Yale.

Local, national, and international authorities involved in the oversight of research have the right to inspect our records, and this may involve looking at records that include your name.

Your specimens and your data will never be sold. There is a possibility that tissue obtained from you in this research may be used to establish a cell line that could be patented and licensed, or lead to development of products that will be commercialized. If this happens, there is no plan to share any financial gain with you. Research using your specimens may lead to the development of new tests, new therapies, or products that are sold. You will not receive any money from such sales.

Do I have to agree to all of these in order to participate?
Yes, but participation is entirely voluntary. If you agree to participate, you can change your mind at any time. Whether you agree to participate or not, your care and your relationship with your doctors, the hospital, and all the staff will not be affected in any way.

What will my participation involve?
- We ask your permission to study tissue and blood samples leftover from past and future procedures you undergo as a part of your routine care.
- We ask your permission to look at your medical records now and in the future to learn about your health.
- This study does not involve any extra, additional procedures for you.
- You may be contacted in the future for additional information.

By signing this document, I agree that:
Researchers may study tissue samples leftover from procedures I have undergone or will undergo in the future as a part of my routine care and can look at my medical records now and in the future to learn about my health.

Therefore, I am agreeing to:

Print Participant name

Print name of legally authorized Representative (If applicable)

Participant Medical Record number

Today’s date

Today’s date

Today’s date

Today’s date

Today’s date

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Patient ID Barcode

or

Print name of legally authorized Representative (if applicable)

Print Participant name

Participant date of birth

Participant Medical Record number

Print name of Translator

Participants Medical Record number

By signing this document, I agree that:

I have translated the above informed consent as written and assisted the people in obtaining and providing consent by translating all questions and responses during the consent process for this participant.

TRANSLATOR

If a Translator/Interpreter is Required

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Print name of Translator

Translator signature

Today’s date

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Will the research involve genetic testing?

Yes, the research will involve genetic testing, which is sometimes called DNA testing, of your cancer and normal tissues. Genes are biological material in cells that is passed from parents to a child. Blood relatives share genes. Genes are responsible for many aspects of your health, and genes may influence whether you develop certain diseases and how you respond to drugs.

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Results and data from the research may also be deposited in scientific databases open to other researchers. When data are placed into databases, all patient identifiers are removed and therefore results cannot be linked to a specific person. Your name and identifiers will never be released in publication or to researchers outside of Yale.

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/ / 

Participant date of birth

/ / 

Participant Medical Record number

Print name of legally authorized Representative (If applicable)

/ / 

Participant (or Representative) signature 

/ / 

Today’s date

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