

**AUTHORIZATION FOR DONATION OF EXCESS TISSUE
YALE UNIVERSITY SCHOOL OF MEDICINE**

Title:

Principal Investigator:

Funding Source:

Tissue Donation

You are invited to donate any tissue left over from your surgery to a research tissue bank where it can be used for future research projects. The tissue collected in this bank is used by Yale University researchers to do *[Specify use, e.g., cancer research, and bank, if tissue is for a specific bank.] [Alternatively, choose more general language: a broad range of medical research, such as methods for improving the diagnosis and treatment of human diseases, and fundamental studies exploring new areas of biology, physiology, anatomy, biochemistry, biotechnology, biomedical engineering, and informatics.]*

In order to decide whether or not you wish to donate your tissue, you should know enough about its risks and benefits to make an informed decision. This form gives you information about the research bank and how the tissue is used. Once you understand the tissue donation and banking process, you will be asked if you wish to participate; if so, you will be asked to sign a form prior to surgery.

How the Tissue Gets Into the Bank

Tissue which is removed during surgery is sent to the Yale University Pathology Laboratory Critical Technologies Program where any tests that your doctor has requested will be done. The results of these clinical tests will be sent to your doctor, who will discuss the results with you.

Any tissue left over will be sent to the tissue bank along with the following information about you: your name, the name of your physician, the date of your surgery and your clinical and tissue diagnosis, medical record number, date of birth, race, and gender. In most cases, the researchers who use your left over tissue will not know whose tissue it is. In some cases, they may get some identifying information about you for research purposes. But before they can do so, an ethics board, which is known as an Institutional Review Board, or IRB, must approve the release of any identifying information about you. At Yale, the IRB is known as the Human Investigation Committee (HIC), the committee that reviews, approves and monitors research on human subjects and human tissue.

Risks and Inconveniences

There are no known risks associated with donating your tissue for research. You will not be required to give any more tissue than that which will be taken during your surgery. We will first make sure that there is enough tissue available so that all the tests required by your doctor can be done. If you choose not to donate your tissue, it will be discarded.

Benefits

You will not receive any direct benefit from donating your tissue to the bank. We hope that the information learned in future research studies will increase our knowledge of human health and disease, and that this information will lead to better treatments.

Economic Considerations

You will not receive any payments for donating your tissue to the research bank. Your tissue will only be used for research and will not be sold. The information we get from your sample may help to develop new products in the future, but you will not get paid.

Confidentiality

All identifiable information that is obtained in connection with your tissue will remain confidential. *[Specify provisions for maintaining confidentiality: e.g., replacing subject names with code numbers, limiting access to study information to designated research team members, maintaining study records in locked files or password-protected computer files.]* Members of the research tissue bank staff will know which tissue is yours. Researchers who have received the approval of the HIC to use your tissue with some information that identifies you will know your identity. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent is obtained.

Representatives from the Department of Health and Human Services, as well as the HIC, may inspect study records during auditing procedures. However, these individuals are required to keep all donor information confidential.

Voluntary Participation and Withdrawal

You are free to choose not to donate your tissue to research and if you do become a donor, you are free to change your mind at any time and ask that your tissue be removed from the bank and destroyed. The researchers may still use the information collected before you changed your mind in order to complete the research that has already started.

If you choose not to donate or if you withdraw your permission it will not harm your relationship with your own doctors or with Yale University or Yale-New Haven Hospital.

Your permission will never expire unless you change your mind and withdraw it. To withdraw your permission to use your information, please write to *[Study-specific contact, or General contact: Director of Critical Technologies, Yale University Pathology Department, Room 140 Brady Memorial Laboratory, 310 Cedar Street, P.O. Box 208023, New Haven, CT 06520-8023]*.

Questions

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this donation and the consent form carefully – as long as you feel is necessary – before you make a decision.

Privacy Rights

The health-related information that we gather about you in this study is personal. The researchers are required by law to protect the privacy of the information known as protected health information or PHI. All reasonable efforts will be made to protect the confidentiality of your PHI, which may be shared with others to support this research, to conduct public health reporting, and to comply with the law as required. Despite these protections, there is a possibility that information about you could be used or disclosed in a way that it will no longer be protected.

By agreeing to donate tissue, you give permission for the researchers to use and/or disclose the information for this research bank. You have a right to refuse to donate. Your health care outside the study, the payment for your healthcare, and your healthcare benefits will not be affected if you do not agree to donate tissue. If you do not agree to donate, your tissue will not be banked for research purposes.

Authorization

I have read (or someone has read to me) the Authorization for Donation of Excess Tissue and have decided to donate my tissue to the Yale Pathology Tissue Bank. Its general purposes, the particulars of my involvement and possible hazards and inconveniences have been explained to my satisfaction. By signing below, I give permission for the described uses and disclosures of information. My signature also indicates that I have received a copy of the consent/authorization form. I do not give up any of my legal rights by signing this form.

CHECK ONE:

I wish to donate my leftover tissue to the Yale Pathology Department for research

I do not wish to donate my leftover tissue to the Yale Pathology Department for research

Signature of Subject or Personal Representative Date

Print Name of Subject or Personal Representative Description of Representative's Authority

Signature of Person Obtaining Consent Date

If you have further questions about this project, or if you have a research-related problem, you may contact the principal investigator, [Name of Principal Investigator], at [Phone Number of PI]. If you have any questions concerning your rights as a research subject, you may call the Yale Human Investigation Committee at (203) 785-4688. If after you have signed this form you have any questions about your rights, please contact the Yale Privacy Officer at 203-436-3650.

THIS FORM IS NOT VALID UNLESS THE FOLLOWING
BOX HAS BEEN COMPLETED IN THE HIC OFFICE

<p>THIS FORM IS VALID ONLY THROUGH: _____</p> <p>HIC PROTOCOL NO. _____</p> <p>INITIALED _____</p>
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