

Why is it important for me to consider donating my tissue for research?

A paper to help you understand how discoveries in medical research are applied to patient care.

Background

Tissue comes from people and is defined as a group of cells or fluids such as, muscle, organ, blood, etc. that perform a specific function. Tissue offers a means of diagnosing cancer and making appropriate treatment decisions for people. The tissue collected for staging and diagnosis may include a portion of the tumor taken, blood, urine, bone marrow, lymph nodes, fluid, sputum or excess normal tissue. Only residual tissue or tissue not needed for the patient's diagnosis and treatment is used for research purposes. Research on tissue may provide information that will help prevent, diagnose and treat cancer patients in the future.

Why should I consider donating my tissue for research?

Tissue is critical to the accurate diagnosis and staging of your cancer. It helps you and your doctor make appropriate treatment decisions giving you the best chance of disease-free survival. In addition to helping make decisions about your cancer treatment, the study and analysis of tissue by researchers could ultimately lead to scientific discoveries for the prevention, diagnosis and treatment of cancer patients in the future.

Scientific discoveries through tissue:

Learning how cells work, e.g., the role of estrogen receptors in breast cancer cells.

Through the analysis of tissue from breast cancer patients, scientists were able to identify that some breast cancer tumors had multiple estrogen receptors on their surface. This confirmed the theory that the body's own estrogen was "fueling" these estrogen receptor positive (ER+) tumors. Blocking the estrogen receptor with tamoxifen or decreasing the amount of hormones in the body with anastrozole could reduce the recurrence of cancer.

Finding targets for new drugs, e.g., gene overexpression in tumors. It was the identification of a biomarker for the overexpression of the gene Her2/neu in tumors that determined which women would benefit most from the new drug Herceptin.

Identifying causes of cancer. The information gained from the analysis of tissue samples may help identify the causes of cancer. Linking genetic factors and environmental exposures, such as, diet, culture, toxins, microorganisms and parasites, and life style choices. Information from tissue may help us understand how personal, familial and ethnic factors affect our susceptibility to diseases like cancer.

What are the risks to me in donating tissue?

Since the specimen sample or tissue is collected as part of the treatment process, the physical risks of donating tissue are minimal.

The social risks of donating tissue include:

- Loss of privacy – how researchers identify the medical information may allow others to know that information
- Breach of confidentiality – if researchers disclose medical information in a way you did not agree to, others may have access to that information and use it in a way that is harmful to you

What protections exist to ensure my privacy and the confidentiality of my medical information?

There are laws and regulations that govern how your tissue is collected and stored, the type of information researchers must provide to you before you agree to participate or donate tissue. There are also regulations about which medical information from your tissue may be provided to others and under what circumstances.

Common Rule and Privacy Rule

Two federal regulations specifically protect your privacy and confidentiality. The first is the Department of Health and Human Services (HHS) Federal Policy for the Protection of Human Subjects, also known as the "Common Rule". The Common Rule protects research participants from harm and requires that anyone who participates in federally funded research be treated with respect, justice and beneficence. The second is the HHS Standards for Privacy of Individually Identifiable Health Information, also known as the "Privacy Rule". The HHS Office for Human Research Protections has developed guidance for researchers and Institutional Review Boards (IRBs).

Institutional Review Boards

IRBs exist in every institution accepting federal funds to ensure that the rules and regulations pertaining to research with people are strictly followed. All drug research requires some level of IRB approval. The IRB analyzes whether the anticipated benefits of research are worth the risks. They protect you as a tissue donor by requiring your voluntary participation and full disclosure of research procedures, risks, rights, and responsibilities.

How does informed consent protect my privacy and confidentiality?

Federal laws and regulations require that people be fully informed of how their tissue will be taken and how it will be used. This process is called informed consent. Informed consent requires researchers to explain to you:

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- how the tissue will be collected and used in research;
- how medical information will be stored, and;
- what information will be provided to other researchers when they request your tissue to conduct their research.

The information should be explained to you by the research staff and written into an informed consent document signed by you and witnessed by a third party. The researcher conducting the study is responsible for providing the information to fully inform you of the risks and benefits of participation/donation in compliance with the federal laws and regulations. Your consent to participate in tissue donation for research should not be a requirement of participating in a clinical trial or research study to treat your cancer.

After a patient signs the informed consent document for the use of their tissue for research purposes, the tissue is collected and the residual tissue is sent to a tissue repository. This bank or repository may be located at a hospital or a central location and should meet certain standards. Researchers wanting use of this tissue must have IRB approval before requesting it from the bank. The donor may restrict the use of tissue to particular types of research, e.g., research specified in the consent, cancer research, other health related research.

Another federal regulation (HIPAA) requires that information sent electronically be stripped of any personal health information such as name, age, address, social security number, etc. One way of stripping the tissue of personal health information is to assign a code number to the tissue sample. If a researcher wants to link medical information with tissue at a later date they would have to gain permission to access the code.

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For more information, please see the following:

- Health Insurance Portability and Accountability Act (HIPAA) <http://www.hipaa.com/>
- NIH Office of Human Research Protections <http://www.hhs.gov/ohrp/>
- Belmont Report, <http://www.med.umich.edu/irbmed/ethics/belmont/BELMONTR.HTM>
- Moore Case, <http://www.forhealthfreedom.org/Publications/Informed/WhoOwns.html>
<http://www.bioethics.uu.se/chapters/JDRendtorff.pdf>
- National Bioethics Advisory Commission Report (1999) Research Involving Human Biological Materials: Ethical Issue and Policy Guidance, http://www.nlm.nih.gov/pubs/cbm/hum_exp.html
- National Dialogue on Cancer National Biospecimen Network Blueprint, http://ndoc.org/about%5Fndc/reports/pdfs/FINAL_NBN_Blueprint.pdf
- International Society for Biological and Environmental Repositories, <http://www.isber.org>