

The Third Annual Medical Research Summit

Tissue Banking and Repository Session

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“NCI/NAPBC Model Informed Consent for Future Research Use of Tissue”

Handout Materials

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NCI/NAPBC Model Informed Consent Documents

A consensus is emerging that consent beyond that contained in the general surgical consent is desirable for research use of prospectively identifiable specimens. The National Cancer Institute, together with the National Action Plan on Breast Cancer (NAPBC), developed a model informed consent document and an accompanying patient information sheet for use of specimens collected during routine medical care for future unspecified research¹. The consent form has been tested in 27 focus groups representing different socioeconomic levels, racial and ethnic groups, genders, and professional and patient groups. The documents are written for low literacy level.

The model informed consent and accompanying patient information sheet are designed to be used together. The patient information sheet helps to explain why and how tissues are used in research and should be given to the patient before asking the patient to sign the consent form. The documents can be downloaded from the Cancer Diagnosis Program, NCI website in HTML or PDF format and modified for use by research institutions collecting specimens for research purposes (<http://www-cdp.ims.nci.nih.gov/>). The documents can be tailored as appropriate for the anticipated research use of the specimens and as required by Institutional Review Boards.

References:

¹Taube, S.E., Barr, P., LiVolsi, V., Pinn, V. Ensuring the Availability of Specimens for Research. *The Breast Journal*, Vol. 4, Number 5, 1998; p. 391-395.

Name of Tissue Repository

address and phone number

Consent Form for Use of Tissue For Research

About Using Tissue for Research

You are going to have a biopsy (or surgery) to see if you have cancer. Your doctor will remove some body tissue to do some tests. The results of these tests will be given to you by your doctor and will be used to plan your care.

We would like to keep some of the tissue that is left over for future research. If you agree, this tissue will be kept and may be used in research to learn more about cancer and other diseases. Please read the information sheet called "How is Tissue Used for Research" to learn more about tissue research.

Your tissue may be helpful for research whether you do or do not have cancer. The research that may be done with your tissue is not designed specifically to help you. It might help people who have cancer and other diseases in the future.

Reports about research done with your tissue will not be given to you or your doctor. These reports will not be put in your health record. The research will not have an effect on your care.

Things to Think About

The choice to let us keep the left over tissue for future research is up to you. **No matter what you decide to do, it will not affect your care.**

If you decide now that your tissue can be kept for research, you can change your mind at any time. Just contact us and let us know that you do not want us to use your tissue. Then any tissue that remains will no longer be used for research.

In the future, people who do research may need to know more about your health. While the xyz may give them reports about your health, it will not give them your name, address, phone number, or any other information that will let the researchers know who you are.

Sometimes tissue is used for genetic research (about diseases that are passed on in families). Even if your tissue is used for this kind of research, the results will not be put in your health records.

Your tissue will be used only for research and will not be sold. The research done with your tissue may help to develop new products in the future.

Benefits

The benefits of research using tissue include learning more about what causes cancer and other diseases, how to prevent them, and how to treat them.

Risks

The greatest risk to you is the release of information from your health records. The xyz will protect your records so that your name, address, and phone number will be kept private. The chance that this information will be given to someone else is very small.

Making Your Choice

Please read each sentence below and think about your choice. After reading each sentence, circle "Yes" or "No". **No matter what you decide to do, it will not affect your care.** If you have any questions, please talk to your doctor or nurse, or call our research review board at IRB's phone number.

1. My tissue may be kept for use in research to learn about, prevent, or treat cancer.

Yes No

2. My tissue may be kept for use in research to learn about, prevent or treat other health problems (for example: diabetes, Alzheimer's disease, or heart disease).

Yes No

3. Someone from xyz may contact me in the future to ask me to take part in more research.

Yes No

Please sign your name here after you circle your answers.

Your Signature: _____ Date:

Signature of Doctor/Nurse: _____ Date:

Patient Information Sheet

How is Tissue Used for Research?

Where does tissue come from?

Whenever a biopsy (or surgery) is performed, the tissue that is removed is examined under the microscope by a trained doctor to determine the nature of the disease and assist with the diagnosis. Your tissue will always be used first to help make decisions about your care. After all tests have been done, there is usually some left over tissue. Sometimes, this tissue is not kept because it is not needed for the patient's care. Instead, a patient can choose to have the tissue kept for future research. People who are trained to handle tissue and protect the donor's rights make sure that the highest standards are followed by the xyz. Your doctor does not work for the xyz, but has agreed to help collect tissue from many patients. Many doctors across the country are helping in the same way. If you agree, only left over tissue will be saved for research. Your doctor will only take the tissue needed for your care during surgery.

Why do people do research with tissue?

Research with tissue can help to find out more about what causes cancer, how to prevent it, and how to treat it. Research using tissue can also answer other health questions. Some of these include finding the causes of diabetes and heart disease, or finding genetic links to Alzheimer's.

What type of research will be done with my tissue?

Many different kinds of studies use tissue. Some researchers may develop new tests to find diseases. Others may develop new ways to treat or even cure diseases. In the future, some of the research may help to develop new products, such as tests and drugs.

Some research looks at diseases that are passed on in families (called genetic research). Research done with your tissue may look for genetic causes and signs of disease.

How do researchers get the tissue?

Researchers from universities, hospitals, and other health organizations conduct research using tissue. They contact xyz and request samples for their studies. The xyz reviews the way that these studies will be done, and decides if any of the samples can be used. The xyz gets the tissue and information about you from your hospital, and sends the tissue samples and some information about you to the researcher. The xyz will not send your name, address, phone number, social security number, or any other identifying information to the researcher.

-see other side-

Will I find out the results of the research using my tissue?

No, you will not receive the results of research done with your tissue. This is because research can take a long time and must use tissue samples from many people before results are known. Results from research using your tissue may not be ready for many years and will not affect your care right now, but they may be helpful to people like you in the future.

Though research involves the test results of many different people, your biopsy result involves only you. Your doctor will give you the results of your biopsy when results are known. These test results are ready in a short time and will be used to make decisions about your care.

Will I benefit from the research using my tissue?

There will be no direct benefit to you because your tissue may not be used for some time after you donate it and because research can take a long time. However, it is hoped that the results of research on your tissue and tissues from other patients will provide information that will help other patients in the future. Your tissue will be helpful whether you have cancer or not.

Why do you need information from my health records?

In order to do research with your tissue, researchers may need to know some things about you. (For example: Are you male or female? What is your race or ethnic group? How old are you? Have you ever smoked?) This helps researchers answer questions about diseases. The information that will be given to the researcher includes your age, sex, race, diagnosis, treatments, and possibly some family history. This information is collected by your hospital from your health record and sent to xyz but without your name or other identifying information. If more information is needed, xyz may send it to the researcher.

Will my name be attached to the records that are given to the researcher?

No. Your name, address, phone number and anything else that could identify you will be removed before they go to the researcher.

How could the records be used in ways that might be harmful to me?

Sometimes, health records have been used against patients and their families. For example, insurance companies may deny a patient insurance or employers may not hire someone with a certain illness (such as AIDS or cancer). The results of genetic research may not apply only to you, but to your family members. For diseases caused by gene changes, the information in one person's health record could be used against family members.

How am I protected?

The xyz is in charge of making sure that information about you is kept private. The xyz will take careful steps to prevent misuse of records. Your name, address, phone number and other identifying information will be taken off anything associated with your tissue before it is given to the researcher. This would make it very difficult for any research results to be linked to you or your family. Also, people outside the research process will not have access to results about any one person which will help to protect your privacy.