

**CONSENT AND RESEARCH AUTHORIZATION TO DONATE BIOLOGICAL TISSUE
SAMPLES AND RESEARCH DATA FOR FUTURE RESEARCH PURPOSES
YALE UNIVERSITY SCHOOL OF MEDICINE**

Title: Spitzoid Neoplasm Repository

Principal Investigator: Rossitza Lazova, MD

Funding Source: Department Funds (Yale University School of Medicine, Department of Dermatology)

Biological Tissue Sample and Research Data Donation

You are invited to donate tissue sample and/or fresh tissue from biopsies that have already been performed or will be performed for clinical purposes, as well as health information to a research tissue biospecimen and data repository, where it can be used for future research projects. The tissue samples and data collected in this repository will be used by researchers to study the biology, pathology and progression of certain skin tumors called spitzoid neoplasms. It is sometimes challenging for dermatologists and pathologists to classify spitzoid neoplasms. You have been asked to participate in this study because you have been diagnosed with a spitzoid neoplasm.

In order to decide whether or not you wish to donate your tissue samples and research data for future research, you should know enough about the risks and benefits to make an informed decision. This form gives you information about the research repository and how the tissue samples and data may be used. Once you understand the tissue sample and data donation and banking process, you will be asked if you wish to take part; if so, you will be asked to sign this form.

How Your Tissue Sample Gets Into the Repository

The tissue sample and research data that you donate for this research study will be sent to the Yale Dermatopathology Laboratory along with information about you which will be entered into a computer (the database) that is used for research purposes. If your tissue sample is currently stored at Yale Dermatopathology Laboratory it will be included in the study.

The following information about you will be entered into the database: name, age, medical record numbers, surgery date, clinical test results (such as MRI, lab tests, etc.), symptoms, risk factors and medical history. By signing this form, you agree to donate a tissue sample from a biopsy that has already been removed during a dermatology appointment (from the site on the skin where the spitzoid neoplasm is located) to Dr. Lazova in order to be studied further. The study doctors may perform tests on the tissue samples to understand the neoplasm cells better. They will look for specific markers and/or genetic links in the neoplasm cells. If, after this tissue sample is taken, there is any follow-up information from dermatology visits, the study doctor will look to see if there has been any change in the neoplasm. If there is any follow-up information from a surgical procedure related to the neoplasm in question and an additional biopsy is performed, the information and samples from this procedure will be collected.

How Your Tissue Samples and Research Data May Be Used for Future Research

The researchers who are responsible for entering and protecting your information in the database will use your information to study the biology, pathology and progression of certain skin growths called spitzoid neoplasms.

Whenever possible, the researchers will use your information in a de-identified manner. The term de-identified means that researchers will use your information without knowing your identity. In some cases they may use some identifying information about you for research purposes, subject to an approval process undertaken by the Yale Human Investigation Committee (HIC). (The HIC is an ethics committee that reviews, approves and monitors research on human subjects.) If any study data and/or tissue samples are shared with Yale researchers and collaborators within the Yale Medical Group, they will be de-identified or assigned a unique code (the code would allow results of the research to be linked back to you), unless permission is granted by the HIC to include specific identifiers.

Risks and Inconveniences

There are no physical risks to donating and storing your tissue samples and data for use in future research studies. We will not collect new tissue samples for research purposes. However, we will request tissue samples if you have any subsequent surgical procedures related to the neoplasm being studied. Surgical procedures are done as part of the clinical evaluation of spitzoid neoplasm so that the progress of the cells can be tracked.

In the unlikely chance that your information is viewed by someone outside the research team however, there is a risk of breach of confidentiality (see the Confidentiality section for an explanation of how your information is protected).

For research conducted on the genetic material that has not been de-identified, certain risks can arise if genetic information about you is made known to others.

Risks to you may include discrimination in insurance coverage, employment, or educational opportunities. Also, variation in some genes we will be studying may be shown at some point in the future to be related to illness. Since the results of these genetic tests may allow prediction of risk of illness in some cases, we will keep the results confidential (only scientists working on this research project will know the results). Family members may become aware of information related to the study and you, or that you may become aware of information about yourself or family members that you would have preferred not to know.

Due to the nature of this study and the existence of cases in the spectrum of Spitzoid neoplasms, which can be challenging to classify, there may be other opinions about your original diagnosis. The researchers may contact your physician if they believe that the research results might change the course of your treatment.

The research studies performed on your tissue biopsy material are for research purposes only and are not in any way a clinical examination. These studies are not designed to find abnormalities. The primary investigator, the lab, and the researchers are not responsible for providing a diagnostic evaluation of the biopsy material. If a gross misdiagnosis is identified using various research techniques, a dermatopathologist, a researcher, or another physician will be asked to review the relevant findings. Based on their recommendation (if any), the primary investigator will contact your physician and inform him/her of the finding. The investigators, the researchers, Yale Dermatopathology Laboratory, and Yale University are not responsible for any examination or treatment that you may receive based on these findings. The research results collected utilizing different techniques and via different studies performed using the tissue and biospecimen collection in the Spitzoid neoplasm repository are not parts of a clinical examination.

Benefits

You will not receive any direct benefit for donating your tissue samples and health information for future research use. We hope that the information we learn in future research studies will increase our knowledge of human health and that this information will lead to better diagnosis and treatment of spitzoid neoplasms in the future.

Economic Considerations

You will not receive any payments for donating your tissue samples and research data into the repository.

Tissue samples and research data obtained from you for this research may be used to establish a product or information system that could be patented and licensed by Yale University. If materials from the repository were shared with other investigators, the research and patenting might reach outside Yale University. In either case, there are no plans to provide financial compensation to you should this occur. Your tissue samples and research data will not be sold.

Confidentiality

All identifiable information that is obtained in connection with this research study will remain confidential. Information about you will be kept in password-protected computer and password-protected data files. Tissue samples will be stored in locked cabinets in a locked office. Only the members of the research repository staff and researchers who have received the approval of the HIC to use your tissue samples and data will know your identity. Study data and/or tissue samples may be shared with Yale researchers and collaborators within the Yale Medical Group, but it will be de-identified or assigned a unique code (the code would allow results of the research to be linked back to you) unless permission is granted by the HIC to include specific identifiers. When the results of future 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 HIC may inspect study records during auditing procedures. However, these individuals are required to keep all subject information confidential.

Voluntary Participation and Withdrawal

You are free to choose not to donate your tissue samples and data to research and if you do become a subject you are free to change your mind at any time, but the researchers may still use the information collected before you changed your mind in order to complete the research that has already started. The researchers will make your tissue samples and data anonymous by removing and destroying all identifiers and links to identifiers so that it can not be associated with you, but the researchers will not destroy the tissue samples or data.

If you choose not to allow your information/samples to be stored and used, or if you withdraw your permission, this will not harm your relationship with the study doctors, with Yale University or Yale-New Haven Hospital.

This form and your permission will never expire unless you change your mind and withdraw it. To withdraw your permission to use your information, please write to Dr. Rossitza Lazova at the Yale Dermatopathology Laboratory, 15 York Street, LMP5031, P.O. Box 208059, New Haven, CT 06520.

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 of information and/or specimens 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 information known as protected health information (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 signing this form, you give permission for the researchers to store and use and/or disclose the information in this research database. You have a right to refuse to sign this form. Your health care outside the study, the payment for your health care, and your health care benefits will not be affected if you do not sign this form. Information about you gathered during your clinical care or during this research study will not be placed into the research data repository described in this form or used for future research if you do not sign this form.

Authorization

I have read (or someone has read to me) this Consent and Authorization Form to donate tissue samples and research data for future research purposes and have decided to donate my tissue samples and data to the Spitzoid Neoplasm Repository. The general purposes of this donation, 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 my information. My signature also indicates that I have received a copy of this consent/authorization form.

May we contact you in the future for follow up: [] Yes [] No

Print Name of Subject

Address: _____

City:_____State: Zip Code:____

Signature of Subject

Date

Signature of Principal Investigator

Date Received

or

Signature of Person Obtaining Consent

Date