

**ASSENT 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 (collection), where it can be used for future research projects. The samples and information 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 skin doctors (dermatologists) to classify spitzoid neoplasms. You have been asked to take part in this study because your dermatologist has discovered that you have a spitzoid neoplasm.

In order to decide whether or not you wish to donate your tissue samples and health information 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 process, you will be asked if you wish to take part. If you do, you will be asked to sign this form. Your parent/guardian will sign a separate form.

**How Your Tissue Sample Gets Into the Repository**

The tissue sample and health information 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 (procedure that involves removing cells from the skin) that has already been performed 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. If, after this tissue sample is taken, there is any more information from dermatology visits, the study doctor will look to see if there has been any change in the neoplasm. If there is any new information from a surgical procedure related to the neoplasm in question and an additional biopsy is taken, 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 if a committee at Yale (called the Yale Human Investigation Committee - HIC) gives them permission. (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.

### **Risks and Inconveniences**

Your body will not be harmed in any way if you agree to donate and store your tissue samples and health information 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. Sometimes surgical procedures are done as part of your regular care so that your doctor can watch for any changes in the spitzoid neoplasm.

It is unlikely that your information will be viewed by someone outside the research team but there is a risk of that you could be identified. We explain how your information is protected in the paragraphs below.

Some of the tests of the tissue sample will look for genetic information in the cells. This involves tracing how things are inherited (passed down through your family). If the genetic testing results are not de-identified and information about you is shared with others, the following can happen:

Risks to you may include trouble with insurance coverage, employment, or educational opportunities. Also, what we learn 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 private (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 rather not known.

### **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 health information into the repository.

Tissue samples and research data obtained from you for this research may be used to create an information system that could be licensed by Yale University as an invention (this is called a patent). 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 any money to you if this occurs. Your tissue samples and research data will not be sold.

### **Confidentiality**

All identifiable information gathered for this study will be kept confidential (private). It will be stored 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 approval to use your tissue samples and data will know your identity. Information and/or tissue samples may be shared with Yale researchers and other people within the Yale Medical Group, but it will be de-identified or assigned a special code (the code would link the results of the research 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 expose your identity unless you give permission to allow it.

Representatives from the HIC may inspect study records during review 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 health information 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 health information 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 health information you provided.

If you choose not to allow your information/samples to be stored and used, or if you take back 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.

**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.

**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 health information to the Spitzoid Neoplasm Repository. The general purposes of this donation, the details 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  
*Or*

\_\_\_\_\_  
Date Received

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Date