

University of California, Los Angeles

CONSENT TO PARTICIPATE IN TISSUE BANKING (Parental Consent/Youth Assent)

(In the statements below the word "you" refers to you or your child or ward)

Research Title: Rare Brain Disease Tissue Bank

INTRODUCTION

You are asked to participate in a research study conducted by Gary W. Mathern, MD from the Division of Neurosurgery/Department of Surgery at the University of California, Los Angeles (Principal Investigator). The Rare Brain Disease Tissue Bank would like to store brain tissue left over after your surgery, blood, saliva and cerebrospinal fluid (CSF) for research. You have been asked to participate because you have a brain disease or disorder that is considered to be rare. A rare disease, also referred to as an orphan disease, is any disease that affects a small percentage of the population – typically populations smaller than 200,000.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to collect brain tissue obtained at surgery, blood, saliva and available cerebrospinal fluid for storage in the tissue bank. All of these materials will be sent to the Rare Brain Disease Tissue Bank at the University of California, Los Angeles (UCLA). The tissue and fluids collected will be stored and may be used in research to learn more about your disease or disorder. Your biological samples may be used in research directed at understanding any inherited or other causes of your brain disease. To accomplish this, a blood or saliva sample may be collected from each member of your family that might carry the affected gene. If additional family members wish to bank biological samples, such as blood or saliva, they will need to sign separate informed consent forms. These additional samples will be stored along with your samples for research.

WHAT WILL HAPPEN IF MY CHILD TAKES PART IN THIS RESEARCH STUDY

If you volunteer to participate in tissue banking you do not have to do anything other than agree to allow your brain tissue, blood, saliva and available CSF that are removed during your surgery to be stored in the Rare Brain Disease Tissue Bank. In summary if you agree to participate, the following will happen to you:

1. Left over brain tissue and any available cerebrospinal fluid (CSF) will be collected during surgery. The amount of tissue removed during surgery will not be increased for tissue banking. The brain tissue and CSF will be gathered while you are under anesthesia during your surgery. If available, CSF will be collected during surgery and not by lumbar puncture. Your participation in tissue banking will not cause any additional risks or discomfort other than what you would normally experience as part of your surgery.
2. A blood sample (approximately 3 tablespoons) will be drawn from a vein in your arm during surgery.
3. A saliva sample (approximately 2 tablespoons) will be collected from you using a specialized saliva collection kit.
4. You will sign a release to allow your medical records to be forwarded to the Rare Brain Disease Tissue Bank where all personally identifiable information will be removed. Your donated material will be assigned a unique identification number to maintain your privacy.

ARE THERE ANY POTENTIAL RISKS OR DISCOMFORTS THAT MY CHILD CAN EXPECT FROM THIS STUDY?

We will be storing brain tissue that is left over from your brain surgery. Your decision to provide material to the Rare Brain Disease Tissue Bank will not increase the amount of tissue being removed at the time of your surgery. The tissue and brain fluid will be removed while you are under anesthesia. The amount of blood removed will be proportional to your weight. The brain tissue, blood and cerebrospinal fluid removed will not interfere with your medical treatment. Therefore, the banking of your donated material will not cause any additional risks or discomfort to you other than what you would normally experience as part of your planned surgery.

All personally identifying information will be removed from your donor records. Your donated material and associated medical records will be assigned a unique patient identification code. There is a risk for a breach in confidentiality even though procedures are in place to minimize this risk.

ARE THERE ANY POTENTIAL BENEFITS TO MY CHILD IF HE OR SHE PARTICIPATES?

Participation in tissue banking will not help you directly but may help people in the future who have a similar rare brain disease or disorder.

ARE THERE ANY ANTICIPATED BENEFITS TO SOCIETY IF HE OR SHE PARTICIPATES?

It is hoped that accumulating specimen from rare brain diseases and disorders will spur future research that will improve understanding of rare brain diseases and lead to better treatment in the future for patients who suffer from similar conditions.

WHAT ARE THE ALTERNATIVES TO PARTICIPATION?

Donation of your tissue and fluid is completely voluntary. Whether or not you agree to donate your tissue and biological fluid to the Rare Brain Disease Tissue Bank will not affect your medical or surgical treatment.

WILL MY CHILD BE PAID FOR PARTICIPATING?

There is no payment for donating your specimen to the tissue bank

WHAT IS MY FINANCIAL OBLIGATION?

Neither you nor your insurance company will be billed for your participation in tissue banking.

WILL MY CHILD BENEFIT FROM POSSIBLE COMMERCIAL PRODUCTS?

All donated samples will be stored at the Rare Brain Disease Tissue Bank at the University of California, Los Angeles. Your samples will be owned by the Rare Brain Disease Tissue Bank, or by a third party designated by the tissue bank (such as another university or private company). If a commercial product is developed from future research derived from your samples, the commercial product will be owned by the Rare Brain Disease Tissue Bank or its designee. You will not profit financially from such a product.

WILL INFORMATION ABOUT MY CHILD AND HIS OR HER PARTICIPATION BE KEPT CONFIDENTIAL?

The only people who will know that you donated samples to the tissue bank are the tissue bank coordinator, principal investigator and, if appropriate, your physicians and nurses. No information about you, or provided by you will be disclosed to others without your written permission, except:

- If necessary to protect your rights or welfare (for example if you are injured and need emergency medical care); or
- If required by law

Authorized representatives of the UCLA office of Human Research Protection Program may need to review records of individual subjects. As a result, they may see your name, but are bound by the rules of confidentiality not to reveal your identity to others.

When the results of future research are published or discussed in conferences, no information will be included that would reveal your identity. The brain, blood, CSF and saliva samples we receive will be assigned a code that will prevent others from knowing your identity. Only the tissue bank coordinator under the supervision of the tissue bank principal investigator will have access to the code. All coded information about you is kept in locked cabinets and only specific persons who are part of the tissue bank will have access to the cabinets.

WHAT IF MY CHILD DECIDES NOT TO PARTICIPATE IN TISSUE BANKING?

Your participation in tissue banking is VOLUNTARY. If you choose not to participate, that will not affect your relationship with UCLA (or UCLA Medical Center), or your right to health care or other services to which you are otherwise entitled. If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without prejudice to your future care at UCLA.

CAN THE INVESTIGATOR WITHDRAW MY PARTICIPATION IN THIS STUDY?

The investigator may withdraw you from participating in tissue banking if circumstances arise which warrant doing so. The investigator, Dr. Gary Mathern will make the decision and let you know if it is not possible for you to continue.

WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?

If you have any questions about the research, please feel free to contact:

Gary W. Mathern, MD; Reed Neurological Research Center, Room 2123, 710 Westwood Plaza, Los Angeles, CA 90095. Telephone: 310-825-7961

WHAT ARE MY CHILD'S RIGHTS IF HE OR SHE TAKES PART IN THIS STUDY?

You may withdraw your consent at any time and discontinue participation without penalty. You are not waiving any legal claims, rights or remedies because of your participation in tissue banking. If you wish to ask questions about your rights as a tissue bank participant or if you wish to voice any problems or concerns you may have about tissue banking to someone other than the researchers, please call the Office of the Human Research Protection Program, UCLA, 11000 Kinross Avenue, Suite 102, Box 951694, Los Angeles, CA 90095-1694.

SIGNATURE OF TISSUE BANK DONOR

I have read (or someone has read to me) the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given a copy of this form, as well as a copy of the Subject's Bill of Rights.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBES.

Name of Tissue Bank Donor

Signature of Tissue Bank Donor

Date

Name of Legal Representative

Signature of Legal Representative

Date

SIGNATURE OF INVESTIGATOR/STUDY COORDINATOR

I have explained the research to the subject, and answered all of his/her questions. I believe that he/she understands the information described in this document and freely consents to participate.

Name of Investigator/Study Coordinator

Signature of Investigator/ Study Coordinator

Date (must be the same as subject's)