SCHOOL OF MEDICINE & DENTISTRY

Department of Neurosurgery

UNIVERSITY of ROCHESTER MEDICAL CENTER

MEDICINE of THE HIGHEST ORDER

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CONSENT FORM

Department of Neurosurgery Brain Tissue Bank
University of Rochester Medical Center

Principal Investigator: **Kevin A. Walter, MD**

Co-PI: **Eleanor Carson-Walter, PhD**

If you are an authorized representative, the use of the word "you" in this consent form refers to your loved one.

Introduction

This consent form describes a research study and what you may expect if you decide to participate. You are encouraged to read this consent form carefully and to ask the person who presents it any further questions you may have before making your decision whether or not to participate.

You are being asked to participate in this study because you are scheduled to undergo intracranial surgery (i.e. brain surgery), which will include the removal of a small portion of your brain tissue.

This form describes the known possible risks and benefits of the study. You are completely free to choose whether or not to participate.

Purpose of Study

The purpose of the study is to collect and store brain tissue and a small sample of blood from a large number of individuals for future research purposes. The tissue and blood will be used by investigators at the URMC for studies to better prevent, detect, diagnose, monitor and treat diseases of the brain and central nervous system (CNS), including, but not limited to, benign and malignant brain tumors, Alzheimer's disease, epilepsy and stroke.

Description of Procedures

If you decide to participate in this study, you will undergo the following procedures that are not part of your standard medical care:

1. At the time of your surgery, we will collect 10cc (2 teaspoonfuls) of blood. Blood is normally drawn during operative procedures for clinical monitoring. The blood saved in this study will be residual (leftover) blood from those

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blood draws that would normally be discarded. The blood sample will be stored in the brain tissue bank for future analysis.

2. At the time of your surgery, a small piece of your brain tissue will be frozen and/or chemically preserved in paraffin (a type of wax) and saved indefinitely. The piece of tissue that is saved represents material that would normally be discarded. The way your surgery is performed is not altered **in any way** by saving a piece of the tissue once it is already removed.
3. We will create a research record (code) for each tissue piece that details your clinical diagnosis.
4. The brain and blood samples will be stored in the neurosurgery labs of URMC under the immediate supervision of Dr. Eleanor Carson-Walter, Ph.D., an investigator on this study.
5. The samples will be used to assist investigators (including those listed on page 1 of this form and others in the URMC community who receive approval) to analyze diseased and normal brain tissues and blood samples for biological clues as to what causes these diseases, how to detect and treat them and how tissues respond to the current treatments available. Sometimes, approved investigators might share material with their colleagues at outside institutions. Again, any material provided to investigators outside the URMC will be completely de-identified, with **no** way to link your samples to your name or identifying information. Banked tissue material and blood will **not** be sold.

Risks of Participation

The possible risks of this study may be due to breach of confidentiality.

Benefits of Participation

You will receive no direct benefit from taking part in this research project.

Number of Subjects

There will be 500 subjects enrolled locally, at an expected rate of 100-150 per year.

Duration of the Study

After your surgery, you will not be required to do anything further for this study. Your tissue and blood will be kept indefinitely, but your active participation will be complete after your surgery.

Costs

There will be no additional cost to you to participate in this study. You and/or your insurance company will be responsible for the costs of your routine care, including surgery.

Payments

You will not be paid for participating in this study.

Circumstances for Dismissal

It is possible that you may be removed from the research project by the researchers if, for example, your tissue sample was too small or too degraded (of too poor a condition) to be helpful to the researchers.

Confidentiality of Records and HIPAA Authorization

While we will make every effort to keep information we learn about you private, this cannot be guaranteed. Other people may need to see the information. While they normally protect the privacy of the information, they may not be required to do so by law. Results of the research may be presented at meetings or in publications, but your name will not be used.

The federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information about you that we either create or use as part of the research. This permission is called an Authorization. We will use your research record, as well as medical information from your hospital and/or other (e.g. physician's office) records. The information that will be recorded will be limited to data such as your sex and age, and medical information concerning the results of your clinical diagnosis and treatment to date, the results of your surgery or biopsy and the results of your clinical follow-up.

We will use your health information to conduct the study and to determine research results. Health information is used to report results of research to sponsors and federal regulators. It may be audited to make sure we are following regulations, policies and study plans. Strong Health policies let you see and copy this information after the study ends, but not until the study is completed. If you have never received a copy of the Strong Health HIPAA Notice, please ask the investigator for one.
To meet regulations or for reasons related to this research, the study investigator may share a copy of this consent form and records that identify you with the following people: The Department of Health and Human Services and the University of Rochester.

If you decide to take part, your Authorization for this study will not expire unless you cancel (revoke) it. The information collected during your participation will be kept indefinitely. You can always cancel this Authorization by writing to the study investigator. If you cancel your Authorization, you will also be removed from the study. However, standard medical care and any other benefits to which you are otherwise entitled will not be affected. Canceling your Authorization only affects uses and sharing of information after the study investigator gets your written request. Information gathered before then may need to be used and given to others.

As stated in the section on Voluntary Participation below, you can also refuse to sign this consent/Authorization and not be part of the study. You can also tell us you want to leave the study at any time without canceling the Authorization. By signing this consent form, you give us permission to use and/or share your health information as stated above.

Contact Persons

For more information concerning this research or if you believe that you have suffered a research related injury, please contact: Kevin A. Walter, MD, at (585) 276-3581.

If you have any questions about your rights as a research subject, or any concerns or complaints, you may contact the Human Subjects Protection Specialist at the University of Rochester Research Subjects Review Board, Box 315, 601 Elmwood Avenue, Rochester, NY 14642-8315, telephone (585) 276-0005, for long-distance you may call toll-free (877) 449-4441. You may also call this number if you cannot reach the research staff or wish to talk to someone else.

Voluntary Participation

Participation in this study is completely voluntary. You are free not to participate or to withdraw at any time, for whatever reason, without risking loss of present or future care you would otherwise expect to receive. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner. If you withdraw consent, no additional use of any of your banked tissue material or blood will be made, although we cannot guarantee complete destruction of these materials, as they might already have been accessed and analyzed for approved research purposes.

Signature/Dates

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I will receive a signed copy of this form for my records and future reference.

Study Subject: _____ Print Name

Study Subject: _____ Signature

_____ Date

Authorized Representative Print Name: _____

Authorized Representative Signature: _____

Relationship to Subject: _____

Person Obtaining Consent

I have read this form to the subject/authorized representative and/or the subject/authorized representative has read this form. I will provide the subject/authorized representative with signed copy of this consent form. An explanation of the research was given and questions from the subject/authorized representative were solicited and

answered to the subject's/authorized representative's satisfaction. In my judgment, the subject/authorized representative has demonstrated comprehension of the information.

_____ Print Name and Title

_____ Signature

_____ Date