A. PURPOSE AND BACKGROUND

The Neurosurgery Tissue Bank of the UCSF Department of Neurological Surgery is collecting biological samples from surgeries for removal of brain, nerve, skull base, and spinal tumors and procedures for treatment of epilepsy, developmental disorders and vascular malformations.

If you let us, we would like to store some of your leftover biological sample and review your medical record for future research. We would also like to obtain a blood sample, and/or a small sample of normal muscle or skin, and/or a sample of cerebrospinal fluid (CSF). In some circumstances, we may also request permission to collect a sample of saliva or cells from inside your mouth.

You are being asked to participate in this research because you are scheduled to undergo brain, nerve or spinal surgery.

B. WHAT WILL HAPPEN

If you agree to be in this research, the following will happen:

1. After all routine tests required for your care are finished, instead of discarding your leftover biological sample we will save it in what is called a “Tissue Bank” for possible future research. In addition, some normal tissue may be collected at the time of surgery or during a routine clinic visit. These normal tissues are:
   - **Normal muscle or skin**—a sliver of normal muscle or skin (the size of a grain of rice). *The muscle or skin will be removed from the site of the existing surgical excision.*
   - **Blood**—the blood sample will generally be drawn through lines already in place for the surgical procedure, but we also ask your permission to draw another blood sample either before or after your surgery during routine visits to the clinic. *Blood volume drawn from adult patients will be less than 3 tablespoons (50 ml).*
   - **Cerebrospinal fluid (CSF)**—*The CSF sample is drawn off by either lumbar or ventricular drains and otherwise discarded as a normal part of the surgical procedure.* Volumes range from 1 ml (20 drops) to 10 mls.
   - **Saliva**—we may request your permission to collect approximately ½ teaspoon of saliva. This collection would be performed during a routine clinic visit.
   - **Buccal swab**—we may request your permission to collect cells from inside your mouth. This safe, non-invasive collection would be performed during a routine clinic visit.

Normal tissue, blood and CSF samples will be collected only if this will not cause any additional risk, discomfort or pain besides what is normally expected from a surgical procedure.

2. We will also collect and save information from your medical record, including things like age, sex, diagnosis, imaging studies and treatments received. We do not know for sure if information from your medical record will be used, but it might be used in research about brain, nerve, skull base, spinal tumors and procedures for treatment of epilepsy, developmental disorders and vascular malformations.

3. As part of the storing of your tissue we may perform a series of tests to look at proteins, DNA, and RNA in your sample. These may include sequencing your sample and other genetic tests. This information will be associated with your sample in a way that does not allow researchers to identify you. The results of these tests may be provided along with the tissue to researchers at this institution or those who are collaborating with our
researchers. This testing information will be stored in a secure database which authorized researchers may access along with your medical information. However, your personal health information cannot be used for additional research without additional approval from the UCSF Committee on Human Research.

4. In the future, someone associated with your clinical care may contact you to ask questions about your general health. Generally, research done on your sample will not be of use to you or affect your care in any way. However, in the rare event that such research reveals information that could be of use in the future, the study leader may contact your physician with this information. Your physician would then make a decision about whether to contact you concerning this new information or with a recommendation to perform additional testing related to your condition. However, under no circumstance will anyone uninvolved with your clinical care contact you in the future. Examples of situations where your clinician may contact you would be if you might be a candidate for a new clinical trial relevant to your medical condition and based on specific research information learned about your research sample.

5. We may request that you allow transfer of tumor tissue samples removed during prior surgical procedure(s) performed at other institutions. The hospital where you may have had previous surgical procedures(s) will be asked to send paraffin-embedded tissue blocks (or microscopic glass slides prepared from the tissue blocks), along with a copy of the corresponding pathology report, to the UCSF Neurosurgery Brain Tumor Research Tissue Core. The Tissue Core will prepare a number of tissue sections and tissue “roll-ups” from the paraffin tissue blocks and store them for the following intended uses:

- Pathology re-review at UCSF or a collaborating site
- Comparison of pathology from past and present surgeries
- Molecular and genetic tests that may predict treatment effect
- Developing techniques that may become available in the future
- Research that might lead to new and more effective treatments

Afterwards, the paraffin tissue blocks will be returned to the originating hospital. Any tissue sections and tissue “roll-ups” prepared from the blocks will be kept until it is used up or destroyed.

6. We may transfer biological samples and/or cell lines created from it, along with certain medical information about you (for example, diagnosis, blood pressure, age) to other scientists at UCSF and outside institutions, but your personal health information cannot be used for additional research without additional approval from the UCSF Committee on Human Research.

7. Your specimen and any information about you will be kept until it is used up or destroyed. It may be used to develop new drugs, tests, treatments or products. In some instances these may have potential commercial value. If you decide later that you do not want your sample and information to be used for future research, you can contact Dr. Anny Shai, Neurosurgery Tissue Bank Manager at 415-502-7796, and inform her of your decision. We will destroy any remaining identifiable sample and information if it is no longer needed for your care. However, you will not be able to withdraw samples that have already been used in research or have any control of research results that may have already been generated from your tissue.

**C. RISKS**

**Physical:** There will be no additional risk due to the removal of biological samples for the Neurosurgery Tissue Bank. Patients will receive care appropriate for recovery from the surgical procedure.

**Confidentiality:** Information about you will be handled as confidentially as possible. All records will be coded and maintained in a secured database. Your name will not be used in any published reports about this study. Only a non-identifying code number will be used in any reports or publication resulting from this study. Data gained from genomic characterization and analyses of your biological sample may eventually become available on the Internet. Although this public data will never include information traditionally used to identify you—such as your name,
address, telephone number, or social security number—it is possible that genetic information could one day be used to identify you or your family members.

The UCSF Committee on Human Research and other UCSF personnel also may review or receive information about you to check on the study. The research team will protect your personally identifiable health information as described in this consent form. The University of California complies with the requirements of Health Information Portability and Accountability Act (HIPAA) and its privacy regulations, and with all other applicable laws that protect the confidentiality of your health information. However, despite these safeguards, participation in research may rarely involve a loss of privacy.

D. TREATMENT AND COMPENSATION

If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical cost, or covered by the University of California, depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Committee on Human Research at 415-476-1814.

E. BENEFITS

There will be no direct benefit to you from allowing your biological sample to be used for research. However, we hope we will learn something that will help in the treatment of future patients.

F. FINANCIAL CONSIDERATIONS

You will not be charged for being in this research. You will not be paid for being in this research. If any new products, tests or discoveries that result from this research have potential commercial value, you will not share in any financial benefits.

G. ALTERNATIVES

If you choose not to participate in this study, biological samples removed during your surgery that are not needed for diagnosis will be thrown out and no additional normal skin, muscle, blood, CSF, saliva or buccal swabs will be removed for research purposes. Choosing not to participate in the study will not change the care you receive.

H. WHERE TO GO WITH QUESTIONS

If you have any comments or concerns about participation in this study, you should first talk with Dr. Nicholas Butowski Director of Division of Translational Research in Neuro-Oncology; phone number 415-353-7500. If for some reason you do not wish to do this, you may contact the Committee on Human Research, which is concerned with the protection of volunteers in research projects. You may reach the committee office between 8:00 and 5:00, Monday through Friday, by calling (415) 476-1814, or by writing: Committee on Human Research, Box 0962, University of California, San Francisco; San Francisco, CA 94143.
I. CONSENT

You will receive a copy of this consent form and the Experimental Subject's Bill of Rights brochure. PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to choose whether or not to be in this study. Your choice will not affect your medical care in any way. You may also withdraw your authorization for this study to use your personal health information by contacting Dr. Anny Shai at 415-502-7796 to inform her of your decision.

Your signature below indicates that you are willing to participate in the research study as described. You will also be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

Subject’s Signature for Consent: ____________________________ Date ____________________________

Signature of Person Obtaining Consent: ____________________________ Date ____________________________

Printed name of Person Obtaining Consent: ____________________________

AND/OR:

Signature of Legally Authorized Representative ____________________________ Date ____________________________

Signature of Person Obtaining Consent ____________________________ Date ____________________________