UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
PARENTAL OR LEGAL GUARDIAN CONSENT FOR MINOR CHILD TO BE A RESEARCH SUBJECT

Neurosurgery Tissue Bank

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, 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 child's leftover biological sample and review his or her 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 your child is scheduled to undergo brain, nerve or spinal surgery.

B. WHAT WILL HAPPEN

If you agree to allow your child to participate in this research, the following will happen:

1. After all routine tests required for your child's care are finished, instead of discarding his or her 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. 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 child's surgery during routine visits to the clinic. Blood volume drawn from pediatric patients weighing over 10 kilos (22 pounds) will be no more than 3 teaspoons (15 ml). This constitutes less than 5% of total blood volume according to weight and is less than what is allowed by Pediatric Clinical Research Center guidelines.*
- **Cerebrospinal fluid (CSF)**—The *CSF sample is drawn off by either lumbar or ventricular drains 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 your child's saliva. This collection would be performed during a routine clinic visit.
- **Buccal swab**—we may request your permission to collect cells from inside your child's 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 child's medical record, including things like age, sex, diagnosis, imaging studies and treatments received. We do not know for sure if information from your child's medical record will be used, but it might be used in research about brain tumors, epilepsy, developmental disorders or 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 the sample. These may include sequencing your child's sample and other genetic tests. This information will be associated with your child's sample in a way that does not allow researchers to identify your child. 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 child's medical information. However, your child's 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 child's clinical care may contact you to ask questions about your general health. Generally research done on your child's sample will not be of use to your child or affect your child's care in any way. However, in the rare event that such research reveals information that could be of use to your child's care in the future, the study leader may contact your child's 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 child's condition. However, under no circumstance will anyone uninvolved with your child's clinical care contact you in the future. Examples of situations where your child's clinician may contact you would be if your child might be a candidate for a new clinical trial relevant to your child's medical condition and based on specific research information learned about your child's 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 your child 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. The 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 your child (for example, diagnosis, treatments, age) to other scientists at UCSF and outside institutions, but your child's personal health information cannot be used for additional research without additional approval from the UCSF Committee on Human Research.

7. If your child has a brain tumor, we ask that you allow us to share a portion of your child's biospecimen along with non-identifying information (such as age, gender, diagnosis, treatment) with a larger national tissue bank called Children's Brain Tumor Tissue Consortium (CBTTC) Registry and Repository. This national bank is run by Children's Hospital of Philadelphia and will be managed similarly to our UCSF Neurosurgery Tissue Bank. The CBTTC Registry and Repository's main goal is to support future brain tumor research. They will perform some basic analyses like pathology review, molecular analysis, sequencing and genetic testing, establishment of cell cultures or cell lines. At this time we do not know all the studies that might be done with your child's biospecimen. Results from any analyses done on CBTTC biospecimens will NOT be shared with subjects, their family members, or treating physician(s). You can decide if you wish to participate in the CBTTC Registry and Repository by circling YES or NO on the signature page of this document.

If you are unsure about participation in this study, leave the CBTTC boxes unmarked. You may decide to participate later—up to 30 days after surgery. A separate consent form will be provided for this purpose.

If you decide to participate in the CBTTC Registry and Repository, your child may be asked to provide one or two additional blood samples in the future (each sample = 5 ml, about 1 teaspoon). The CBTTC blood samples will be drawn during routine clinic visits, in addition to any other blood draws required for your child's care. Additionally, if excess cerebrospinal fluid (CSF) from a clinically indicated procedure is available (range from 1ml (20 drops) to 10ml), we ask that this be shared with CBTTC as well.

Also, one or both of your child's biological parents may also be asked for a blood sample (5 ml, about 1 teaspoon) to store and use for future research. The parental blood samples are optional and not required for your child to participate in the study. A separate consent form will be provided for parental blood samples.

8. Your child's specimen and any information about your child 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 child's 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 child's 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 child's 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. Additionally, the risks of drawing blood include temporary discomfort from the needle stick and bruising; it could cause an infection although this is very unlikely.

Confidentiality: Information about your child will be handled as confidentially as possible. All records will be coded and maintained in a secured database. As with any use of electronic means to store data, there is a risk of breach of data security. PHI will be collected as part of the data elements and submitted to the CBTTC Operations Center at CHOP. PHI will include: Institutional medical record number (MRN), subject's date of birth (DOB), subject name and pathology case numbers. Data that contains these direct identifiers will not be transferred to the CBTCC registry/repository and will only be held by the operations center at Children's Hospital of Philadelphia. Only a non-identifying code number will be used to label biospecimens and associated information within the registry. Your child's name will not be used in any published reports about this study.

The UCSF Committee on Human Research and other UCSF personnel also may review or receive information about your child to check on the study. The research team will protect your child's 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 child's health information. However, despite these safeguards, participation in research may rarely involve a loss of privacy.

Genetic information that results from this study does not have medical or treatment importance at this time. However, there is a risk that information about taking part in a genetic study may influence insurance companies and/or employers regarding your child's health. To further safeguard your child's privacy, genetic information obtained in this study will not be placed in your child's medical record.

Taking part in a genetic study may also have a negative impact or unintended consequences on family or other relationships. If you do not share information about taking part in this study, you will reduce this risk. Although your name will not be with the sample, it will have other facts about you such as gender, age, race, ethnicity and diagnosis. These facts are important because they will help us learn if the factors that cause certain types of brain tumors to occur or get worse are the same or different based on these facts. Thus it is possible that study finding could one day help people of the same race, ethnicity, or sex as you. However, it is also possible through these kinds of studies that genetic traits might come to be associated with your group. In some cases, this could reinforce harmful stereotypes.

D. TREATMENT AND COMPENSATION

If your child is 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 costs, 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 your child from allowing his or her 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 allowing your child to participate in this research. You will not be paid for allowing your child to participate in this research. If any new products, tests or discoveries that result from this research have potential commercial value, you or your child will not share in any financial benefits.

G. ALTERNATIVES

If you choose not to allow your child to participate in this study, biological samples removed during his or her 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 will not change the care your child receives.

H. RIGHTS

Taking part in this study is your choice. You may choose either to take part or not to take part in the study for your child. No matter what decision you make, there will be no penalty to your child and your child will not lose any regular benefits. Leaving the study will not affect your child's medical care. Your child will still receive medical care from our institution.

In the case of injury resulting from this study, your child will not lose any of their legal rights to seek payment by signing this form.

I. WHERE TO GO WITH QUESTIONS

If you have any comments or concerns about participation in this study, you should first talk with Dr. Sabine Mueller, Director of UCSF Pediatric Brain Tumor Center at 415-502-7301. 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.

J. 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 allow your child to be in this study. Your choice will not affect your child's medical care in any way.

You may also withdraw your authorization for this study to use your child's biospecimen by contacting Dr. Anny Shai at 415-502-7796 to inform her of your decision.

Your signature below indicates you are willing to allow your child to participate in the research study as described.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about your child.

Indicate your willingness to participate in the CBTTC Registry and Repository below. If you are unsure about participation in this study, leave the CBTTC boxes unmarked. You may decide later—up to 30 days after surgery. A separate consent form will be provided for this purpose.

YES	Circle YES if you wish to participate in Children's Brain Tumor Tissue Consortium (CBTTC) Registry and Repository.
NO	Circle NO if do not wish to participate in CBTTC Registry and Repository

_____

Parent or Legal Guardian's Signature for Consent Date

_____

Signature of Person Obtaining Consent Date

_____

Print name Person Obtaining Consent

_____

Signature of Witness (only required if participant is a non-English speaker) Date

AND/OR

_____

Signature of Legally Authorized Representative Date

_____

Signature of Person Obtaining Consent Date

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
ASSENT TO BE A RESEARCH SUBJECT
Neurosurgery Tissue Bank

A. WHAT IS THIS STUDY ABOUT?

Dr. Nalin Gupta and Dr. Anu Banerjee, along with other doctors at UCSF Department of Neurological Surgery would like to learn more about brain, nerve, skull base and spinal tumors, epilepsy, developmental disorders and vascular malformations of the brain. Because I am having brain surgery, the doctors at UCSF would like to save a sample of my brain tissue. The brain tissue sample will be used to learn what makes tumors grow and how to stop them, or how to better treat epilepsy, developmental disorders and vascular malformations of the brain.

B. WHAT WILL HAPPEN IF I AM IN THE STUDY?

1. A small amount of my brain tumor tissue will be saved and stored in what is called a "Tissue Bank."
2. A small amount of my blood—about 2 teaspoons—will be taken at the time of surgery or during a clinic visit. This blood will be stored along with the tumor.
3. I may be asked to provide a small amount of saliva—about ½ teaspoon, or a swab of cells from inside my mouth will be taken and stored.
4. Information from my medical record such as my age, sex, diagnosis and treatment will be collected and stored.
5. Tissue samples from previous surgeries at other hospitals will be transferred to UCSF Tissue Bank.

C. WILL ANY OF THIS HURT?

The tissue and blood sample will be removed during surgery, while I am asleep. It will not hurt. If the blood is taken at an office visit it will involve a stick and will hurt the same as any routine blood draw. The saliva sample is given by spitting into a small plastic cup; cells from inside my mouth would be collected with a cotton swab -- both these procedures are painless.

D. WILL I GET BETTER IF I AM IN THIS STUDY?

No. Being in the study will not make me better or worse. But the doctors might find out something that will one day help other children with brain, nerve or spinal tumors, epilepsy, developmental disorders or vascular malformations of the brain.

E. WHAT ARE MY CHOICES?

Although my parent/guardian has said I can be in this study, I may also choose to be in the study or not. Nobody will get mad at me if I don't want to do this. If I decide to be in the study and I change my mind later, that is okay, too. I just have to tell Dr. Gupta or Dr. Banerjee.

F. WHAT IF I HAVE QUESTIONS?

I can ask Dr. Gupta or Dr. Banerjee, or the nurses who work with them, any questions about the study. I can ask now or later, or at any time I like.

This study has been explained to me by_____ and my questions were answered.

_____ _____
Patient's Signature Date

IRB# 10-01318

University of California San Francisco (UCSF Health)
Permission to Use Personal Health Information for Research

Study Title (or IRB Approval Number if study title may breach subject's privacy):

Neurosurgery Tissue Bank

Principal Investigator Name: Joanna Phillips, MD PhD

Sponsor/Funding Agency (if funded):

A. What is the purpose of this form?

State and federal privacy laws protect the use and release of your health information. Under these laws, the University of California or your health care provider cannot release your health information for research purposes unless you give your permission. Your information will be releasexd to the research team which includes the researchers, people hired by the University or the sponsor to do the research and people with authority to oversee the research. If you decide to give your permission and to participate in the study, you must sign this form as well as the Consent Form. This form describes the different ways that UCSF Health can share your information with the researcher, research team, sponsor and people with oversight responsibility. The research team will use and protect your information as described in the attached Consent Form. However, once your health information is released by UCSF Health it may not be protected by the privacy laws and might be shared with others. If you have questions, ask a member of the research team.

B. What Personal Health Information will be released?

If you give your permission and sign this form, you are allowing UCSF Health to release the following medical records containing your Personal Health Information. Your Personal Health Information includes health information in your medical records, financial records and other information that can identify you.

☒ Entire Medical Record	☐ Lab & Pathology Reports	☐ Emergency Dept. Records
☐ Ambulatory Clinic	☐ Dental Records	☐ Financial records
☐ Progress Notes	☐ Operative Reports	☐ Imaging Reports
☐ Other Test Reports	☐ Discharge Summary	☐ History & Physical Exams
☐ Other (describe):	☐ Consultation	☐ Psychological Tests

C. Do I have to give my permission for certain specific uses?

Yes.

☒ The research team will also be collecting information from your medical record that is marked by the check box. The following information will only be released if you give your specific permission by putting your initials on the line(s).

☐ I agree to the release of information pertaining to drug and alcohol abuse, diagnosis or treatment. _____(initials)
☐ I agree to the release of HIV/AIDS testing information._____ (initials)
☒ I agree to the release of genetic testing information._____ (initials)
☐ I agree to the release of information pertaining to mental health diagnosis or treatment._____ (initials)

D. Who will disclose and/or receive my Personal Health Information?

Your Personal Health Information may be shared with these people for the following purposes:

1. To the research team for the research described in the attached Consent Form;
2. To others at UC with authority to oversee the research
3. To others who are required by law to review the quality and safety of the research, including: U.S. government agencies, such as the Food and Drug Administration or the Office of Human Research Protections, the research sponsor or the sponsor's representatives including but not limited to the contract research organization (CRO), or government agencies in other countries.

E. How will my Personal Health Information be shared for the research?

If you agree to be in this study, the research team may share your Personal Health Information in the following ways:

1. To perform the research
2. Share it with researchers in the U.S. or other countries;
3. Use it to improve the design of future studies;
4. Share it with business partners of the sponsor; or
5. File applications with U.S. or foreign government agencies to get approval for new drugs or health care products.

F. Am I required to sign this document?

No, you are not required to sign this document. You will receive the same clinical care if you do not sign this document. However, if you do not sign the document, you will not be able to participate in this research study.

G. Optional research activity

☐ There are no optional research activities.

☒ The research I am agreeing to participate in has additional optional research activity such as the creation of a database, a tissue repository or other activities, as explained to me in the informed consent process, I understand I can choose to agree to have my information shared for those activities or not.

I agree to allow my information to be disclosed for the additional optional research activities explained in the informed consent process._____(initials)

H. Does my permission expire?

This permission to release your Personal Health Information expires when the research ends and all required study monitoring is over.

I. Can I cancel my permission?

You can cancel your permission at any time. You can do this in two ways. You can write to the researcher or you can ask someone on the research team to give you a form to fill out to cancel your permission. If you cancel your permission, you may no longer be in the research study. You may want to ask someone on the research team if canceling will affect your medical treatment. If you cancel, information that was already collected and disclosed about you may continue to be used for limited purposes. Also, if the law requires it, the sponsor and government agencies may continue to look at your medical records to review the quality or safety of the study.

J. Signature

<u>Subject</u>

If you agree to the use and release of your Personal Health Information, please print your name and sign below. You will be given a signed copy of this form.

_____

Subject's Name (print)--*required*

_____ _____

Subject's Signature Date

Parent or Legally Authorized Representative

If you agree to the use and release of the above named subject's Personal Health Information, please print your name and sign below.

_____

Parent or Legally Authorized Representative's Name (print) Relationship to the Subject

_____

Parent or Legally Authorized Representative's Signature Date

Witness

If this form is being read to the subject because s/he cannot read the form, a witness must be present and is required to print his/her name and sign here:

_____

Witness' Name (print)

_____ _____

Witness' Signature Date

Instructions for Researchers: Do not make any changes to this form other than the following items:

The IRB **will not** be confirming the accuracy of the information you complete on this form. The researchers are responsible for accurately completing the HIPAA Research Authorization as follows:

1. Page 1, Item B: Mark all sources of PHI that will be released
2. Page 2, Item C:
    a. Check the first box if any of the 4 categories of sensitive information will be collected
    b. Then, check the box ***only*** for each specific type of information that will be collected for this study
    c. Obtain the participant's initials ***only*** *for the specific types of information*
3. Page 3, Item G:
    a. Check one of the boxes indicating if there are optional research activities or not
    b. Obtain the participant's initial *only if the study involves optional research activity*
4. Page 3, Item J: Obtain the participant's name, signature, and date; *complete subsequent signature lines* ***if applicable***
5. Provide the subject with a signed copy of the form

Note: The Word document of this form allows you to check the boxes electronically. You can make a 'master version' of this form for this study with all pertinent boxes checked.

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

EXPERIMENTAL SUBJECT'S

BILL OF RIGHTS

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject I have the following rights:

1) To be told what the study is trying to find out,
2) To be told what will happen to me and whether any of the procedures, drugs, or devices is different from what would be used in standard practice,
3) To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me for research purposes,
4) To be told if I can expect any benefit from participating, and, if so, what the benefit might be,
5) To be told of the other choices I have and how they may be better or worse than being in the study,
6) To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study,
7) To be told what sort of medical treatment is available if any complications arise,
8) To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my right to receive the care I would receive if I were not in the study,
9) To receive a copy of the signed and dated consent form,
10) To be free of pressure when considering whether I wish to agree to be in the study.

If I have other questions I should ask the researcher or the research assistant. In addition, I may contact the Institutional Review Board, which is concerned with protection of volunteers in research projects. I may reach the committee office by calling: (415) 476-1814 from 8:00 AM to 5:00 PM, Monday to Friday, or by writing to the UCSF Human Research Protection Program, Box 0962, 3333 California St., Ste. 315, San Francisco, CA 94143.

Call 476-1814 for information on translations.