



Affix Patient Label

Patient Name:

Date of Birth:

Informed Consent: Craniotomy for Tumor

This information is given to you so that you can make an informed decision about having a **craniotomy for a tumor**.

Reason and Purpose of this Procedure:

A craniotomy is an operation where an opening is made in the skull, or cranium. The goal of a craniotomy for tumor is to:

- Remove abnormal brain tissue for examination.
- Remove as much of a tumor as is safe.
- Remove part of the tumor to relieve pressure inside the skull.
- Reduce the amount of tumor to be treated with radiation or chemotherapy.

This surgery also:

- Relieves seizures due to pressure from the tumor.

Most craniotomies for brain tumor removal use a procedure called “image guidance.” This is a type of stereotactic, (image guided neurosurgery. The patient has an MRI or CT scan before surgery. This scan is used with a 3-dimensional neuro-navigation system. The surgeon uses a computer during surgery. He can see if instruments are on target, near critical parts of the brain that need to be preserved. He will know when the entire tumor that can be removed, has been removed.

Benefits of this Procedure:

You might receive the following benefits. Your doctor cannot promise you will receive any of these benefits. Only you can decide if the benefits are worth the risk.

- The tumor may be removed.
- A piece of the tumor will be sent to be analyzed which will help get a diagnosis and direct future treatment options
- A part of the tumor may be removed.
- Seizures may stop.
- A more direct chemotherapy access may be achieved.
- Your doctor can discuss further benefits with you. These will depend on your diagnosis and location of the tumor

General Risks of Procedures:

No procedure is completely risk free. Some risks are well known. There may be risks not included in the list that your doctor cannot expect.

- Small areas of the lungs may collapse. This would increase the risk of infection. This may need antibiotics and breathing treatments.
- Clots may form in the legs, with pain and swelling. These are called DVTs or deep vein thromboses. Rarely, part of the clot may break off and go to the lungs. This can be fatal.
- A strain on the heart or a stroke.
- Bleeding may occur. If excessive you may need a blood transfusion.
- Reaction to the anesthetic. The most common reactions are nausea and vomiting. In rare cases, death may occur. The anesthesiologist will discuss this with you.

Risks of this Procedure:

This surgery is safe and effective in most cases. The most common risks that require hospital admission are:

- (1) Infection (2%).

(2) Deep venous thrombosis (3%).

(3) Seizures (3%).

(4) Neurological damage after surgery is relatively rare (4%). This is usually temporary. Risks are higher with emergency surgery.

- **Balance problems.** or vertigo (dizziness). This may be from the tumor or from the surgery.
- **Brain injury.** This procedure could cause injury to the surrounding brain.
- **Death.** Death may occur during or soon after surgery.
- **Failure of the procedure.** Your condition may not improve.
- **Functional loss.** You may have problems chewing after surgery. You may have problems with strength, sensation, speech and language, memory, hearing or vision after surgery. This could be permanent or temporary
- **Hemorrhage.** Bleeding in the brain rarely occurs and may require further surgery.
- **Hydrocephalus.** The normal flow of spinal fluid around the brain may change. This may need more treatment, including surgery or placement of a drain.
- **Increased pain.** Pain or other symptoms may get worse after this procedure. You may have a headache for up to a month after surgery and occasionally for a longer period of time
- **Infection.** Infection may occur in the wound, either near the surface or deep within the tissues. This could include the bone. You may need antibiotics or further treatment.
- **Neurologic decline.** You may have weakness, numbness, and speech and memory problems after surgery. This could be from hemorrhage (bleeding) or cerebral edema (buildup of fluid that results in swelling and pressure on the brain).
- **Recurrence.** There is a chance that pain, numbness, weakness or other symptoms may come back. This may need more surgery. There is a chance that the tumor may return at the same or another site.
- **Seizure activity.** You may develop seizures.
- **Spinal fluid leakage.** A spinal fluid leakage may cause a spinal headache or need more surgery.

Risks Associated with Smoking:

Smoking is linked to an increased risk of infections. It can also lead to heart and lung complications and clot formation. Smoking has also been shown to slow down or stop the bone fusion.

Risks Associated with Obesity:

Obesity is linked to an increased risk of infections. It can also lead to heart and lung complications and clot formation.

Risks Associated with Diabetes or Immune System Compromise:

The risk of infection, slow wound healing and slow bone healing are increased in:

- Diabetes
- Chemotherapy or radiation therapy
- AIDS
- Steroid use

Risks Specific to You:

Alternative Treatments:

Other choices:

- Radiation therapy.
- Medical treatment. This may include diuretics, steroids and seizure medicine.
- Observation with neurological exams and imaging (CAT scan or MRI).
- Do nothing. You can decide not to have the procedure.

If you Choose not to have this Treatment:

- You may choose the alternative treatments listed above.
- The tumor may continue to grow. Your neurological function will decrease.
- The tumor may cause you to have seizures.
- The tumor may eventually cause death.

General Information

During this procedure, the doctor may need to perform more or different procedures than I agreed to.

During the procedure, the doctor may need to do more tests or treatment.

Tissues or organs taken from the body may be tested. They may be kept for research or teaching. I agree the hospital may discard these in a proper way.

Students, technical sales people and other staff may be present during the procedure. My doctor will supervise them.

Pictures and videos may be done during the procedure. These may be added to my medical record. These may be published for teaching purposes. My identity will be protected.

What is the Success Rate?

The success rate for a complete tumor resection depends on the type of tumor and its location. The size of the tumor may mean it is too risky to remove. It may be better not to injure normal brain tissue.



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Patient Name: _____	Date of Birth: _____

By signing this form, I agree:

- I have read this form or had it explained to me in words I can understand.
- I understand its contents.
- I have had time to speak with the doctor. My questions have been answered.
- I want to have this procedure: **Craniotomy for Tumor** _____
Location: _____
- I understand that my doctor may ask a partner to do the procedure.
- I understand that other doctors, including medical residents or other staff may help with procedure. The tasks will be based on their skill level. My doctor will supervise them.

Provider: This patient may require a type and screen or type and cross prior to procedure. If so, please obtain consent for blood/products.

Patient Signature: _____ Date: _____ Time: _____

Relationship: Patient Closest relative (relationship) _____ Guardian/POA Healthcare

Interpreter's Statement: I have interpreted the doctor's explanation of the consent form to the patient, a parent, closest relative or legal guardian.

Interpreter's Signature: _____ ID #: _____ Date: _____ Time: _____

For Provider Use ONLY:

I have explained the nature, purpose, risks, benefits, possible consequences of non-treatment, alternative options, and possibility of complications and side effects of the intended intervention, I have answered questions, and patient has agreed to procedure.

Provider signature: _____ Date: _____ Time: _____

Teach Back:

Patient shows understanding by stating in his or her own words:

_____ Reason(s) for the treatment/procedure: _____

_____ Area(s) of the body that will be affected: _____

_____ Benefit(s) of the procedure: _____

_____ Risk(s) of the procedure: _____

_____ Alternative(s) to the procedure: _____

OR

_____ Patient elects not to proceed: _____ Date: _____ Time: _____

(Patient signature)

Validated/Witness: _____ Date: _____ Time: _____