YAKIN DOĞU ÜNİVERSİTESİ HASTANESİ

PATIENT INFORMED CONSENT FORM FOR GLAUCOMA SURGERY

Patient's Name - Surname:	**Gender: □ F □ M**
Patient ID No:	**Date of Birth:**
Father's Name:	**Identity Number:**

Dear Patient/ Patient Relative,

It is your natural right to be informed about all medical/surgical treatment and diagnosis methods regarding your medical situation and your disease. Approving or declining medical and surgical procedures that will be conducted after learning about their benefits and potential risks is your own decision.

The aim of this explanation is not to scare or worry you; it is to collaborate with you on the decisions that will be made regarding your health in a more informed manner. You can request any documentation related to your health; all medical information and documents can be given to you or a relative deemed appropriate by you.

This form has been prepared to provide you with adequate information about the benefits and potential risks of the treatment/intervention and alternative treatment methods proposed by your physician. Please read this form thoroughly and carefully. Once you have read all the information, do not hesitate to ask any questions you may have regarding medical procedures, and sign this consent form after all your concerns have been alleviate and you are fully satisfied with the information provided by your physician.

PATIENT INFORMED CONSENT FORM FOR GLAUCOMA SURGERY

1. PRE-DIAGNOSIS / DIAGNOSIS: GLAUCOMA

GENERAL INFORMATION ABOUT YOUR DISEASE

Glaucoma (high eye pressure) is a disease that leads to loss of vision when the optic nerve is damaged by elevated intraocular pressure. Fluid produced by the eye normally flows throughout the inside of the eye and it is drained through the drainage system. Thus, intraocular pressure remains at normal levels. Intraocular pressure increases due to some factors that prevent the discharge of the produced intraocular fluid. If the trabecular canals of the drainage system are blocked, or the system is not functioning well, the fluid is built up in the eye and leads to elevated intraocular pressure, which in turn damages the optic nerve. In general, eye pressure below 21 mm Hg is normal. Although glaucoma is usually caused by elevated eye pressure due to fluid buildup in the eye, which may damage the optic nerve, it may develop when eye pressure is normal. Damage to the optic nerve is closely associated with high intraocular pressure, if not diagnosed and treated, glaucoma can lead to severe loss of vision leading to blindness. It is not possible to reverse the optic nerve damage caused by glaucoma. However, the progression of the damage to the optic nerve can be curbed when a decrease in intraocular pressure is achieved.

2. PROPOSED TREATMENT: TRABECULECTOMY or SETON (TUBE) SURGERY

3. IF IT IS A SIDED APPLICATION:

Right ☐ Left ☐ Both sides ☐ Stage: ……

4. ANAESTHETIC ADMINISTRATION: Not required ☐ Required ☐

During this procedure, the area around your eye is numbed with local anesthesia. In some cases, general anesthesia is required. Patients with any systemic disease such as heart disease, respiratory tract disease, and Diabetes Mellitus (DM) are at greater risk of complications associated with drugs used for anesthesia. Very rarely, life-threatening conditions and death may occur due to the medication and anesthesia. During local anesthesia administration, a stinging sensation, pain, and bleeding may occur at the site where the local anesthetic agent is administrated. Although it is very rare, significant damages that threaten the body health, vision, and eye due to the drugs used for local

anesthesia can be encountered.

5. USE OF BLOOD AND BLOOD PRODUCTS:

If blood and blood products are required to be used for the procedure, the patient is provided with information about the issue and asked for consent.

6. RISKS OF THE RECOMMENDED TREATMENT:

Complications such as hypotony, choroidal detachment, macular edema, and malignant glaucoma may rarely occur due to a sudden and excessive decrease or increase in intraocular pressure during surgery. Some postoperative complications may rarely occur after the glaucoma surgery. Complications such as intraocular fluid leakage from the incisions made during the surgery, changes in the intraocular pressure (increase or decrease), intraocular infection, decrease in vision, cystic formation or loss of function in the surgically created pouch to drain intraocular fluid, cataract, and excessive increase in intraocular pressure due to the deflection of the fluid in the anterior part of the eye to the posterior may occur after the surgery. The procedure can be performed under sedation/general/local/topical anesthesia. Although it is very rare, complications associated with local anesthesia may include ocular injury, injury to vessels at the back of the eye, damage to the optic nerve with an anesthetic agent, allergic reaction to the anesthetic drug, and bleeding at the back of the eye. As in all surgical procedures, very rare complications associated with general anesthesia such as deterioration in heart, lung, and brain functions can be encountered. Very rarely some complications may be life-threatening and fatal. Although it is very rare, significant damage to the general body-health, vision, and eye may occur. We recommend that you get information from the anesthesiologist about the risks of general anesthesia.

7. INDIVIDUAL RISKS

After you consent to have this surgery, the following risks and complications related to your personal characteristics may occur.;

.....

.....

8. INTENDED POTENTIAL BENEFITS FROM THE RECOMMENDED TREATMENT

Glaucoma surgery may help reduce the intraocular pressure and stop the damage caused by glaucoma.

9. POSSIBILITY OF SUCCESS OF THE RECOMMENDED TREATMENT

Glaucoma surgeries are effective procedures for reducing intraocular pressure and preserving vision. The long-term success rate of glaucoma surgeries is over 80%.

10. POSSIBLE ALTERNATIVE TREATMENT(S)

Glaucoma is treated by lowering intraocular pressure. Treatment options other than surgery include prescription eye drops, oral medicines, and laser treatment. The use of medication is lifelong. Possible side effects of medication for glaucoma include difficulty breathing, slowed heart rate, lower blood pressure, fluid collection in the yellow spot of the eye, mood changes, and fatigue. Lowering eye pressure with laser therapy can be useful in cases where eye pressure is mild, or when the patient cannot tolerate medication for glaucoma.

11. WHAT THE PATIENT SHOULD DO / CONSIDER DURING THE RECOVERY PERIOD

Do not eat or drink anything at least 5 hours before the operation. You will be discharged on the same day of the surgery or the next day following the surgery. However, this period can be prolonged to several days. If you are discharged on the same day of the procedure, have someone drive you home since you may be drowsy due to anesthesia.

You can have liquid foods 3 hours after the surgery, and you can switch to a normal diet after 12 hours. Do not take a bath for the first 3 days. Wash your hands with soap and warm water and dry them with a paper towel before using eye drops. Use your medicines regularly and on time as prescribed and recommended to you. Do not ignore your checkups and dressings. You will be able to resume your normal activities in a couple of days. Your doctor will tell you when to return to work.

12. POSSIBLE CONSEQUENCES OF REJECTING THE RECOMMENDED TREATMENT

1. Glaucoma may progress further and damage to the optic nerve may increase, causing an increase in intraocular pressure and a painful reaction.
2. Painful attacks leading to more serious visual loss may occur over time.
3. As a consequence, vision may decrease further and permanently; complete loss of vision

is also possible.

THE SCOPE OF THE RECOMMENDED INTERVENTION, AND CONSENT

- ✓ I have been verbally informed in detail about the treatment proposed by my physician. I have read all pages of this form and fully understood the information provided. All my questions concerning the recommended treatment have been fully answered to my satisfaction.
- ✓ I consent to the use of blood and blood products in the case of an emergency and/or an unexpected situation.
- ✓ Since this process may have an educational role in the training of medical/paramedical personnel, I consent to the participation of students and/or technical personnel in the process with the purpose of improving medical training and/or product use. Additionally, I know that the procedure can be photographed or videotaped if necessary. I consent to any photographing or videotaping of the procedure, and the use of these recordings for scientific purposes provided my identity is kept confidential.
- ✓ My doctor informed me that in situations that are foreseen or unexpected, additional medical intervention can be required. I fully understand and consent that if necessary, additional medical procedures, which have not been identified in this form may be applied to me by my physician and his/her team only to prevent serious harm to my health, and for life-saving purposes.
- ✓ It may be necessary to use medical devices such as X-ray, imaging, ultrasonography, scintigraphy, computed tomography, magnetic resonance, etc. during the interventions; I know that some of these devices/applications may expose me to rays that could cause adverse effects on my health, and I consent to the use of these medical devices if necessary.
- ✓ I have been informed about the average cost of the recommended intervention.

Being aware of my right to object to the scientific examination, storage, use, or destruction of tissues/organs, their images, or tissue/cell cultures to be removed in any way during the applications that may be made regarding my health, I give my authority and consent.

. I …….., have read and fully understood the content of this form. In full consciousness, I hereby consent to the treatment that will be provided by the Near East University Hospital doctors under the authority, management, and supervision of Dr. …… and the care

that will be provided by other health providers.
I consent to the use of medication, tests, and interventions required for the treatment of my disease.

Signature: Date: Time:

If consent is taken from a Legal Representative;
The proximity of the Legal Representative: .....
Reason for having a Legal Representative;
□ Patient is unconscious □ Patient is younger than 18 □Patient unable to make a decision
□ Emergency

Witness (if possible, someone that is not a hospital staff member):

Name & Surname: Signature: Date: Time:

The Informing Physician:
Name-Surname: Signature: Date: Time:

The translator (if necessary):
Name-Surname: Signature: Date: Time:

The patient informed consent form is signed personally by

- The competent patient who is 18 years of age or older
- The legal representative of the patient and the patient who is between 15-18 years of age
- The legal representative of the patient who is unconscious, younger than 15 years of age, unable to make a decision, and in emergency medical situations