DEEP BRAIN STIMULATION (DBS)

Informed Consent Document

Form No: AOF-023	**Rev. No / Date:** 2026 v09 / 10.07.2026

PATIENT PROTOCOL NO		DATE	
TURKISH ID / PASSPORT NO		DATE OF BIRTH	
PATIENT'S FULL NAME		SEX	
DIAGNOSIS			

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1. Dear Patient,

It is your most natural right to be informed about your medical condition and about all medical / surgical treatments and diagnostic procedures recommended to you for the treatment of your illness. After learning the benefits and possible risks of medical treatments and surgical interventions, it is again your own decision to consent or not to consent to the procedure to be performed. The purpose of this explanation is not to frighten or worry you, but to involve you more consciously in the decisions to be made about matters concerning your health. If you wish, all information and documents concerning your health can be given to you or to a relative you deem appropriate. Although this form has been designed to meet the needs of most patients under many circumstances, it should not be considered a document containing the risks of all forms of treatment. Depending on your personal health condition, your physician may give you different or additional information. After learning the benefits and possible risks of diagnosis, medical treatment and surgical interventions, it is your own decision to accept or not to accept the procedures to be performed. Except in situations of legal and medical necessity, you may refuse to be informed or may withdraw your consent at any time. This form has been prepared to inform you about the risks of the surgery and about alternative treatment methods. Please read this form completely and carefully, and sign this consent form only after you have read it and all your doubts regarding the procedure in question have been resolved by the physician.

2. General Information About the Disease and Its Treatment

Deep brain stimulation (DBS) is a surgical method applied to reduce the complaints (tremor, spasm, immobility, involuntary movements, etc.) in Parkinson's disease, essential tremor (shaking), dystonia and similar movement disorders that do not respond adequately to medication therapy or in which the side effects of the medications have become pronounced. The procedure consists of the attachment of the stereotaxy (fixation) device to the head, followed by the determination of the coordinates of the target region by magnetic resonance (MR) and/or computed tomography, and the placement of a stimulating electrode into the targeted nucleus deep in the brain. In order to confirm that the targeted deep area has been reached accurately, a mapping method called microelectrode recording (MER) is most often used; in this way it is confirmed whether the targeted area has been reached, and the procedure is continued. The placed electrode is connected, by means of a connector (extension cable),

to a programmable battery (neurostimulator) to be placed on the chest wall, and it is a completely reversible procedure after the removal of the system. Your doctor, after evaluating your condition in detail, has decided on the most appropriate surgical treatment method for you and has recommended this approach to you. Depending on the type of your disease and your complaints, one or more of the following interventions may be applied:

Placement of a Stimulating Electrode into the Thalamic Region and of a Battery into the Chest Wall for Tremor: This intervention is applied to eliminate the complaint of tremor that does not respond to medication therapy. It consists of the attachment of the stereotaxy device, followed by the determination of the coordinates by magnetic resonance (MR) and, after the placement of an electrode into the VIM region of the thalamus, the connection of the electrode by means of a connector to a programmable battery to be placed on the chest wall, and it is a completely reversible procedure after the removal of the system.

Placement of a Stimulating Electrode and of a Battery into the Chest Wall for Spasm, Involuntary Movements and Immobility: This intervention is applied in cases of Parkinson's disease dominated by the complaints of spasm, involuntary movements and immobility that do not respond to medication therapy, in order to eliminate the symptoms. It consists of the attachment of the stereotaxy device, followed by the determination of the coordinates by magnetic resonance (MR) and, after the placement of an electrode into the Globus Pallidus region, the connection of the electrode by means of a connector to a programmable battery to be placed on the chest wall, and it is a completely reversible procedure after the removal of the system.

Placement of a Stimulating Electrode into the Subthalamic Region and of a Battery into the Chest Wall: This intervention is applied in cases of Parkinson's disease that do not respond to medication therapy, in order to eliminate the symptoms. It consists of the attachment of the stereotaxy device, followed by the determination of the coordinates by magnetic resonance (MR) and, after the placement of an electrode into the subthalamic region, the connection of the electrode by means of a connector to a programmable battery to be placed on the chest wall, and it is a completely reversible procedure after the removal of the system.

Creation of a Lesion for Spasm, Involuntary Movements and Immobility: In some cases, in Parkinson's disease dominated by the symptoms of spasm, involuntary movements and immobility that do not respond to medication therapy, in order to eliminate the complaints, the attachment of the stereotaxy device, followed by the determination of the coordinates by magnetic resonance (MR) and the irreversible creation of a lesion by the radiofrequency method in the Globus Pallidus region, may be applied.

Creation of a Lesion in the Subthalamic Region: In some cases, in cases of Parkinson's disease that do not respond to medical treatment, in order to eliminate all the symptoms, the attachment of the stereotaxy device, followed by the determination of the coordinates by magnetic resonance and the irreversible creation of a lesion by the radiofrequency method in the subthalamic region, may be applied.

3. Alternatives to the Surgery, If Any

As alternatives to the surgery, I have considered the following options:

As explained to me verbally by my doctor, accepting all risks and not having this surgery,

Follow-up by means of medical medication therapy and periodic radiological/neurological examinations,

Trying to reduce the complaints by means of medication therapy and the rearrangement of the medication scheme,

Irreversible lesion surgery by the radiofrequency method (pallidotomy, thalamotomy, subthalamotomy),

Vagal nerve stimulation,

Stereotactic radiosurgery (Gamma Knife) (targeted radiation therapy),

Other possible treatment options...

I have also evaluated the other treatment methods explained to me by my doctor. The advantages and disadvantages of these alternative methods have also been explained to me by my doctor.

4. Expected Benefits of the Surgery

It is an improvement in the patient's current neurological condition and complaints. The surgery is performed to eliminate the complaints and with the expectation of preserving or improving the function of the nervous system. The aim of this surgery is the treatment of the disease and the preservation, as far as possible, of the neurological functions. It is intended that the neurological deficits present before the surgery (paralysis-loss of strength-numbness-loss of reflexes-urinary incontinence, etc.) and complaints such as tremor, pain-spasm be completely relieved by the surgical treatment to be applied, or that their worsening be halted. I am aware that there is no guarantee that the results of this procedure will be good or that the complaints will be completely eliminated, but I accept the intervention.

5. Estimated Duration of the Surgery

The duration of the procedure to be performed may vary according to the condition of the disease and of the patient, and is on average 2-6 hours. In addition, the procedures to be performed on patients before and after the surgery by the anesthesia doctors are not included in this duration. The procedure may take longer than the stated duration depending on the condition of the case. Your doctor will give you detailed information at the end of the procedure.

6. Risks and Complications of the Surgery

In addition to the benefits of the surgical procedure to be performed, there are also risks that may arise.

Anesthesia risk: There are risks during and after local and general anesthesia procedures (due to the position given to the patient during the surgery). In addition, in every form of anesthesia and in sedation, there are also complications and harms that may occur due to the medications. The anesthesia procedure to be applied and the related risks and complications have been explained to me, and I approve the recommended procedure in this regard.

Bleeding: Although very rare, I am aware of the existence of a risk of bleeding, which may be severe, during or after my surgery. In case of bleeding, additional treatment or blood transfusion may be needed. In such a case, I approve the necessary blood transfusion and other treatments. Some medications that I use and/or that need to be used during my treatment may increase the risk of bleeding through drug interactions and/or side effects. In some cases, it may be necessary to use blood-thinning medications earlier than expected, and this may also increase the risk of bleeding. During or after the surgery, bleeding may occur in the region where the lesion was created or the electrode was placed. If the bleeding grows, it may pose a danger to life.

Blood clot formation: Blood clots may form after any type of surgery. Clots forming in the bleeding area may obstruct blood flow and lead to complications such as pain, edema, inflammation or tissue damage. If the use of blood thinners is discontinued, the risk of clotting may increase.

Postoperative Neurological Deterioration: Due to problems such as bleeding at the surgical site, brain edema (pressure on the brain as a result of fluid accumulation) or vasospasm (narrowing of the vessels), nervous system functions may deteriorate after the surgery.

Injury to the Brain Tissue: There is a possibility that the surgery will cause injury to the normally functioning brain tissue around the damaged brain tissue. The effect that this damage will have on the patient varies according to the location of the damaged region.

Respiratory problems: After the surgery, respiratory distress, which is usually temporary, or pneumonia may be seen. Pulmonary embolism (obstruction of the vessels of the lungs) may be seen.

Cardiac complications: The surgery carries a low risk of leading to an irregular heart rhythm or a heart attack.

Death: There is also a risk of death during or after the Parkinson's surgery. Sometimes more severe reactions such as an asthma attack, sudden drop in blood pressure, shock, having a seizure or respiratory-cardiac arrest may be seen. A very small portion of the patients in whom these findings are seen may die.

Failure of the surgery: There are the risks that, after the surgery to be performed, the placed electrodes may not be in the planned region or, even if they are, may remain insufficient, that the placement of additional electrodes may be needed, that the electrode may break or become stuck while being removed; and that in such a situation it may be necessary to remove the electrode under operating-room conditions.

Renal failure due to the use of contrast material may develop. The majority of the failure that occurs is temporary. In a very small portion of patients, permanent renal failure and treatment may be required.

Increase in the complaint of pain: Although rare, the complaint of pain may increase after the surgery.

Infection: Infection may occur at the skin incision site as well as in the surgical field, and even in the bone within the surgical field. Risks related to infection include meningitis (inflammation of the membranes surrounding the brain and spinal cord) and empyema-abscess formation (accumulation of pus).

I have also understood the possibility that, during my surgery, in the face of an unexpected situation such as bleeding, injury to an adjacent tissue or organ, etc., my doctor may perform other procedures required for my health apart from the planned procedure, and I approve this.

Nerve root injury: Nerve root injury may cause pain in the leg, weakness in the relevant muscle groups, and sensory disturbances in the relevant dermatomes (nerve areas).

Spinal cord injury: Although very rare, paralysis due to spinal cord injury may occur during the surgery.

Risk of cerebrospinal fluid leakage: After the surgery, cerebrospinal fluid may leak from the wound site to the outside. For the treatment of this, a spinal (spinal cord) catheter or an additional intervention aimed at repairing the same wound site again may be required.

Recurrence, Residue: After the surgery, the symptoms may reappear and additional surgery may be required.

Seizure Activity: Abnormal electrical activity may arise in the brain, and this may lead to epileptic (seizure) attacks.

Hydrocephalus: After the surgery, the intracranial cerebrospinal fluid circulation pathways may become obstructed and the placement of a device called a shunt may be required.

Cerebral Vasospasm (narrowing of the vessels): In patients with hemorrhage, or after bleedings that may occur during surgery, before or after the surgery, a regression in nervous system functions may occur due to ischemia in the brain (impairment of the brain's nourishment).

Neuropsychological Disorders: After the surgery, there is a possibility, albeit low, of loss of intellectual (mental) capacity or of depression.

Stroke (Paralysis): Although rare, weakness in the arm and/or leg may develop during/after the surgery following the lodging of air or a clot into the brain from the veins. Additional treatment may be required.

Not Benefiting from the Surgery: The surgical intervention to be performed may not ensure the improvement of all or some of the complaints.

Undesired situations are seen in 3-10 out of 100 patients. The mortality rate is lower than that of alternative surgical procedures (5-10 in 1000 patients).

I have understood and accept all the risks written above that may occur during and after the surgical procedure to be performed on me.

7. Consequences to Be Faced If the Surgery Is Not Performed

The patient's current complaints and clinical condition may not improve, and there may be a worsening. In movement disorder diseases with a chronic and progressive course, the complaints (tremor, spasm, immobility, involuntary movements, etc.) may increase over time and carrying out the activities of daily living may become progressively more difficult.

8. Important Characteristics of the Medications to Be Used

If you have a previously identified drug allergy, you must inform your physician and your nurse about this. During your current treatment process, medications appropriate to the patient's medical condition (painkillers, antibiotics, medications supporting the circulation and the heart, blood products, fluid therapies, medications specific to your disease) will be given according to the reason for your admission or newly developing conditions. During the use of medications, side effects may emerge and cause damage to the heart, kidneys and other organs. New medications will be added to the treatment to correct organ damage. ANTIEPILEPTIC MEDICATION: After brain surgeries, seizure-preventing medications called antiepileptics are used to prevent epileptic seizures. PROPHYLAXIS: Before and after your surgery, appropriate protective antibiotic therapy is applied with the aim of reducing the risk of surgical site infection. USE OF BLOOD-THINNING MEDICATION: If you are using anticoagulant, blood-thinning medications, different medication therapies or blood products may be given to you to counteract the effects of these medications. INTRACRANIAL MASS, HYDROCEPHALUS, HEMORRHAGE CASES: Medications (antiepileptic medications) may also be given to lower the pressure in the brain (intracranial pressure) and the blood pressure; to prevent spasm (narrowing) in the vessels and seizures. In the presence of brain edema and progressive clinical symptoms, anti-edema medications may be used. HEMORRHAGED CASES-VASOSPASM: In case vasospasm-narrowing of the vessels develops after the treatment, medications supporting the circulation may be used to keep the blood pressure high. These medications may disturb the water-salt balance and may damage the heart, kidneys and other organs. PITUITARY INVOLVEMENT: Due to the pituitary gland being affected during the surgery, appropriate medications may be used to maintain the body's water and salt balance. The medications used may also cause disturbances in the body's hormonal balance. INTENSIVE CARE-DELIRIUM: In elderly patients and during prolonged intensive care stays, for psychological symptoms that may emerge in patients, mental health-regulating medications recommended by a psychiatrist may be used. These medications may damage the heart, kidneys and other organs. SHUNT INFECTION, EVD: As a result of a CSF infection, it will be necessary to start appropriate antibiotics recommended by infectious diseases. Among these treatments, the method in which medications are applied into the brain ventricles by means of an EVD, expressed as intraventricular treatment, may also be used. In addition to these, medications related to anesthesia are used. The general anesthetic medications given during the surgery may have toxic (poisonous) effects / side effects on organs such as the lungs, heart, brain, kidneys and liver. For this reason, DANGER OF DEATH may arise. I have informed my doctor about all my known allergies. I have also informed my doctor about the prescription medications I use, over-the-counter medications, herbal medicines, dietary supplements, illegal drugs, alcohol and narcotics/intoxicants. The effects of the use of these substances before and after the surgery have been explained to me by my doctor and recommendations have been made. During my stay in the hospital, I have received information about the important characteristics of the medications to be used for diagnosis and treatment (what they are used for, their benefits, their side effects, how they are to be used).

9. Lifestyle Recommendations Critical for Patient Health

Tobacco and Tobacco Products: It has been explained to me that smoking tobacco and tobacco products (cigarettes, waterpipe, cigars, pipe, etc.) before or after my surgery may cause my recovery process to be prolonged. Anesthesia risks are higher in patients who smoke; death due to anesthesia is seen more frequently. If you smoke, you should know that the success of the treatment/surgery will be lower than the general success average.

Follow your doctor's recommendations (exercise, nutrition program, etc.) and, if applicable, do not neglect your outpatient clinic check-up on the date requested of you.

I have received information about what I need to do regarding my lifestyle after my treatment/surgery (diet, bathing, medication use, mobility status and/or restriction status).

10. Patient-Specific Section

*The patient's individual specific circumstances are recorded at the end of the form under **Section 14 — Signatures**.*

11. How to Access Medical Assistance on the Same Matter When Needed

Not accepting the application of the treatment/surgery is a decision you will make of your own free will. If you change your mind, you may personally reapply to our hospital/hospitals capable of performing the treatment/surgery in question.

I have received information about how to access medical assistance on the same matter when needed (my own physician, a different physician, the clinic where I was treated, and in emergencies, 112).

12. Permissions

I authorize the Head of the Surgical Team, Responsible Specialist Doctor **Dr. Özgür Akşan**, and his team to perform my surgery.

I understand that this intervention is performed with the aim of eliminating my complaints and with the intention of preserving or improving the function of the nervous system. I confirm that my doctor has explained all the information above, that I have understood this information, and that all my questions regarding this intervention have been answered. Therefore, I give my consent for **DEEP BRAIN STIMULATION (DBS) — MOVEMENT DISORDERS / PARKINSON'S SURGERY** and for all different or additional surgeries and additional treatment interventions deemed necessary by my doctor.

Use of tissue: Any tissue not required for medical diagnosis may be used for medical research within the framework of ethical rules. I give my consent to the use of any tissue, medical device or body parts that may have been removed during the surgical procedure.

Medical research: I give my consent to the review of clinical information from my medical records for the advancement of medical study, medical research and doctor training, provided that confidentiality rules are observed.

Photography/Observers: I consent to the photographing or video recording of the surgery to be performed for scientific, medical or educational purposes, provided that the images do not reveal my identity.

13. Consent Verification

- I know the alternative treatment methods and their risks.
- I know the risks and side effects of the intervention.
- I know the possibility of success and failure.
- I know what may happen if I am not treated.
- I understand that the procedure to be performed may not carry a guarantee of cure.
- I have understood everything that has been told to me.
- My doctor has answered all my questions.
- My doctor has explained to me what is written here, item by item, in a clear, understandable and explanatory manner that I can comprehend.
- I know the meaning of the Informed Consent form.
- I have been informed about the approximate cost of the treatment.
- I am making my decision of my own free will.

I had enough time before the intervention to obtain a second opinion within a reasonable period.
I have read and understood the content of the Informed Consent form.
All the blanks on this form were filled in before I signed it, and I have received a copy.

Signatures

A) Patient-Specific Conditions

The patient writes in their own handwriting any personal conditions (allergies, medications, previous surgeries, etc.). If there are none, writing "NONE" is sufficient.

B) Handwritten Declaration

The patient writes the following sentence in their own handwriting:

"I have read this form carefully, I have been informed about DEEP BRAIN STIMULATION (DBS), my questions have been answered, and I consent to this procedure of my own free will."

C) Signatures

	Full Name	Signature	Date / Time
Patient			
Patient's Legal Representative / Relative (Relationship: .....)			
Head of Surgical Team, Responsible Specialist	**Dr. Özgür Akşan**		