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CONSENT FORM FOR DEEP BRAIN STIMULATION SURGERY FOR PARKINSON'S DISEASE

Name of the Patient: _____
Age : _____
Gender: _____
Hospital No.:_____

AFFIX PATIENT LABEL HERE

One of the doctors in my treatment team, Dr……, has explained to me, and with my consent, to my family members, in detail regarding my disease (Parkinson's disease) and its various treatment options available to me. We fully understand that Parkinson's disease is not a curable disease as of now. Moreover, we understand that its gradual and relentless worsening course cannot be altered by any of the treatment modalities currently available (Medical or surgical, including DBS).

We have been told that all the treatment modalities available now (medical as well as surgical) aim to control symptoms and improve quality of life, rather than to provide a cure or prevent the disease from worsening over time. The doctor has also explained to us (me and my family) that as the disease gradually worsens over time, a stage will be reached at which further modifications of medical treatment fail to provide a satisfactory quality of life improvement.

My doctors have explained to us that Deep Brain Stimulation (DBS) is a surgical option which can be considered at that stage, for improving symptoms and quality of life. The doctor has explained to us in detail the advantages and disadvantages of this surgery, surgery- and stimulation-related risks, costs, potential recurring costs, and limitations. The lifelong precautions to be followed after surgery have also been explained. A brochure on various aspects of the surgery, in English / Malayalam (also published on the SCTIMST website), has been given to us. Our native language is Malayalam / ……and we can understand ……. ……well. The doctor explained all the aspects to us in …… ……..A person who speaks our native language,…… ……translated all the facts into our language for us and helped us clear all our doubts.

My family members and I fully understand the following

1. Why DBS surgery has been suggested to me (disabling mobility-related OFF time symptoms and fluctuations in symptom control to prolong ON period; and to control the involuntary movements)
2. Expected improvement with surgery; potential risk of not getting the expected improvement or no improvement at all. We understand that this is a functional neurosurgical procedure, and its outcome depends on many factors, known and unknown, and may therefore not be predictable. We acknowledge the fact that the degree of improvement obtained may vary from patient to patient.
3. Risk of loss of clarity of speech with DBS, and the limitations for "axial" symptoms (Balance dysfunction is very unlikely to improve with surgery and could worsen minimally with DBS; "Freezing" of gait may not improve satisfactorily and could worsen in future from disease progression. Freezing of gait may not show sustained response to DBS)
4. We fully understand and acknowledge the following limitations of DBS surgery, which the treating doctors have explained to us in great detail: (1) Inability to arrest or modify the progression of the brain changes underlying Parkinson's disease, resulting in potential future appearance and worsening of DBS-refractory

Signature of the patient / LAR: _____

symptoms - like "freezing" of gait, falls, difficulties in speech, difficulties in swallowing, memory and intellectual dysfunction, psychiatric and behavioural disturbances etc; (2) inability to control most "non-motor" symptoms of Parkinson's disease- like intellectual disturbances, memory dysfunction, psychiatric symptoms (depression, behavioural changes, hallucinations, impulse control disorders, other psychiatric symptoms), sleep disturbances, constipation, difficulties in urinary bladder control, and other "autonomic" symptoms and (3) recurring expenses including the need to replace DBS neurostimulator periodically and costs involved. We understand that the improvements in quality of life obtained with DBS are not permanent and will gradually wane off with time.

5. The surgery-related complications were explained to us in detail, and we understand and acknowledge all of them, including but not limited to (1) epileptic seizures (2) bleeding into / around the brain or cavities inside the brain. We know that such bleeding could occur in 1-2 % of patients undergoing surgery and could result in permanent handicaps, dependency or death) (3) Implant infections, which could occur in 4-8% of all operated patients. We understand that, despite all the precautions (as explained by the doctors), infections can occur. We also understand that infections may necessitate surgical removal of DBS hardware, in part or in full, and that implants removed for infection are generally not reusable. We have been informed that such implant removals are not covered by the warranty or any compensation schemes, and we will have to bear the financial burden. We also understand that implant infections can sometimes turn life-threatening, leading to meningitis or other brain infections. (4) Stroke happening around the period of surgery (5) Anaesthesia-related complications which include chest infections, cardiac arrest or heart attack (6) Other complications like clotting of blood in lower limb veins, leading to "pulmonary embolism," (sudden blockage of blood flow to lungs which could be life-threatening) and post-operative behavioural and psychiatric problems resulting from brain injury and swelling

6. We were explained the details of the surgical procedure and that the surgery is best performed in the awake state. We understand that various tests are performed during surgery to ensure the correct placement of the leads in the brain. The need for a good level of co-operation from the patient's side for accurate lead placement has been communicated to us.

7. We understand that lead malposition (unsatisfactory positioning of the wires carrying current into the brain) can occur as a known complication of DBS surgery, in some patients, despite maximal efforts from the doctor's side to avoid this. If a lead is not positioned well, it may need to be removed and may be unusable.

8. We understand that if the doctors, during surgery, find that the correct position to place the lead is not obtained despite one or two trials, the surgery will be abandoned. Abandonment of the surgery could also occur if the doctors find signs of complications during the surgery (such as reduced responsiveness or fluctuations in blood pressure). We understand that the payment for the consumable items used for the patient till the point of abandoning the surgery will be charged to us if this happens.

9. We have been informed regarding the post-surgery care and programming of DBS. We know that a temporary worsening of symptoms, lasting a few weeks to 3-4 months, can occur in many patients, resulting from mild brain injury and brain swelling, which can occur even with an otherwise uncomplicated surgery.

10. We have been explained, and we acknowledge the fact that all patients do not respond equally to DBS surgery. We also know that some patients may need repeated programming visits to get the best benefits out of surgery.

11. We have been clearly explained the precautions to be followed strictly to prevent implant infections. We know that immediate reporting to the hospital is of paramount importance for salvaging the implants if signs of infection occur.

12. The doctors have explained to us that patients with DBS will need regular follow-up and lifelong specialised care, in view of the presence of a specialised and continuously working electronic equipment in the body. The precautions to be followed lifelong - especially during surgical and radiological procedures and during air travel, etc., have been explained to us.

Signature of the patient / LAR: _____

13. We understand that there are different types of Neurostimulators, including rechargeable and non-rechargeable ones, and implants made by different manufacturers. We have been informed about the features of each type. We have been informed about long-life (up to 25 years) neurostimulators and stimulators capable of adaptive stimulation. We understand that we have to choose the type of stimulator based on the information provided by doctors and our preferences. We understand and acknowledge that the lifetime of non-rechargeable stimulators will vary widely depending on each patient's electrical energy requirement and, in some cases, can be significantly shorter than expected. We have made the choice ourselves after considering these aspects. We have opted for ……

14. We have been informed regarding the manufacturer- provided warranty and its clauses, and purely technical problems occurring for the implants or accessories (like recharger or patient's programmer) will be dealt with by the manufacturing company as per warranty clauses. That infectious and peri-operative surgical complications will not be covered under the warranty has been explained to us clearly.

The added risk factors in the patient have been explained, viz. (Tick whichever is applicable and cancel whichever is not)

☐ Prominent freezing of gait whose response to DBS may not be satisfactory in many patients

☐ History of psychiatric symptoms, which will need close follow-up after surgery and could flare up in the initial period after surgery

☐ Presence of early memory and intellectual changes, which is very likely to worsen over time and offset the improvements obtained with DBS in quality of life

☐ History of coronary artery disease and use of blood thinners (antiplatelet drugs) – we understand that DBS surgery will need a more prolonged withdrawal of blood thinner drugs (than other types of surgery) and the risks of cardiac events, stroke, etc. resulting from the same.

☐ Presence of high blood pressure, increasing the risk of surgical complications, particularly bleeding into the brain and stroke during/after surgery

☐ Presence of diabetes, which increases risk of surgical complications, including infections

☐ Relatively advanced age, and presence of significant brain shrinkage (atrophy). We understand that this can cause malposition of leads and poor response to DBS and also increase risk of other surgical complications.

☐ Others (please add): _____
_____
_____

Signature of the patient / LAR: _____

AFFIX PATIENT LABEL HERE

We have fully understood the above points, clarified our doubts and after understanding the pros, cons, limitations, surgical risk, cost and need for long-term specialised care, we give our consent to go ahead with DBS surgery in the patient, ……. With hospital number…….

	Name	**Signature / Thumb impression**	**Date**	**Time**
Patient / Authorised relative (LAR)	Relationship with patient (if LAR):		DD/MM/YYYY	HH:MM AM/PM
Witness (Relative) if available			DD/MM/YYYY	HH:MM AM/PM
In the presence of Dr.			DD/MM/YYYY	HH:MM AM/PM

Signature of the patient / LAR: _____