THE ASSOCIATION OF OTOLARYNGOLOGISTS OF INDIA

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CONSENT FORM FOR MUCORMYCOSIS SURGERY

HOSPITAL REG. NO: _____

NAME OF THE HOSPITAL:

NAME OF THE PATIENT: **AGE/SEX:**

ADDRESS:

The person giving consent has / does not have, the capacity and competence to give consent.

I, ………………………………………………………………. the undersigned give consent willingly for myself / my patient for the required procedure with sound mental state without any Coercion, Undue Influence, Fraud, Misrepresentation or Mistake of Facts.

DIAGNOSIS: SINONASAL/ ORBITAL / CEREBRAL MUCORMYCOSIS

Mucormycosis is a life threatening invasive fungal infection which affects starting from the Nose and Paranasal Sinuses to Palate, Orbit, and to Brain. Surgical and medical management both are equally necessary to control the spread of the disease. Surgical management is necessary to reduce the fungal load after which medical management will be required on a long-term basis.

NAME OF THE PROCEDURE:

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NATURE OF THE PROCEDURE WITH EXPECTED OUTCOME AND LIKELIHOOD OF SUCCESS:

Good / Fair / Bad

The procedure will be performed Endoscopically and / or Externally.

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RISKS OF THE PROCEDURE:

There are risks and complications with this procedure. They include but are not limited to the following

General Risks:

- Bleeding could occur and may require a return to the operating room, especially if the patient is on blood thinning drugs.
- Infection can occur, requiring antibiotics and further treatment.
- Increased risk in obese people of wound infection, chest infection, heart and lung complications, and thrombosis (DVT).
- Cardiac arrest and death as a result of this procedure is rarely possible.

Specific Risks:

- Bleeding: This may occur either at the time of surgery or in the first few weeks after surgery. Excessive Bleeding at the time of surgery may be due to injury to some major blood vessel and may even require termination of the procedure and nasal packing. Injury to some major blood vessel can even cause Orbital Hematoma. Bleeding after surgery may require packing of the nose under local anesthesia or may require another operation to stop the bleeding. A blood transfusion may be necessary depending on the amount of blood lost.
- Eye injury: Injury can be caused to extraocular eye muscles. This may lead to bruising or swelling around the eye. Rarely, permanent damage causing double vision or partial or complete loss of vision can occur.
- Infection of the nose and sinuses: Usually temporary but will require antibiotic therapy
- CSF leak, Meningitis, Brain abscess may occur if there is damage to the Brain during surgery.
- Damage to the Nasolacrimal duct which can cause tearing of the eye.
- Perforation in septal wall and Crusting of the nasal cavity.
- Allergic reaction to medications.
- Cardiac arrest and Death as a result of this procedure is rarely possible.

SPECIFIC RISKS IF ANY FOR THIS PARTICULAR PATIENT:

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ALTERNATIVE TREATMENT TO THIS PROCEDURE:

There is no alternative treatment to this procedure. Surgical treatment is necessary to decrease the fungal load. Only Medical treatment will not be sufficient to treat the disease completely.

I ACKNOWLEDGE THAT THE DOCTOR HAS EXPLAINED:

- My medical condition- I/my ……………………………………………………… am / is suffering from Mucormycosis which is a life threatening invasive fungal infection of the Nose and Paranasal sinuses and can extend to palate, Orbit and even Brain.
- The proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- The anesthetic required for this procedure. I understand the risks of anesthesia explained to me by doctor and that also includes the risks specific to me.
- My prognosis, and risks of not having the procedure. If I/my patient ………………………………………………………………………………………… do not undergo this surgery the fungal infection will rapidly spread even within hours in some cases to the adjacent structures like Orbit and Brain and may cause either blindness or even death.
- Need for multiple surgeries or staged surgeries as per the patient's overall condition and extent of the disease.
- There are many chances of recurrence of surgery which might need further medical or surgical management again.
- Facial cosmetic disfigurement can occur secondary to surgery which might require further prosthetic surgery.
- Depending on the extent of the disease this procedure may also require Orbital exenteration and Dental extraction if needed to avoid the progression of disease.

- The procedure may include a blood transfusion if required.
- There can be a need for prolonged hospitalization, Tracheostomy and Assisted Ventilation if necessary.
- I have been explained that excessive bleeding, infection, cardiac arrest, pulmonary embolism, and complications like this can arise suddenly and unexpectedly while undergoing operative procedure or anesthesia.
- I give consent for any change in anesthesia or surgery at the time of surgery.
- During surgery suspected body tissues could be removed for histopathological examination.
- I have been made aware that after the above operation and anesthesia some complication may arise, and I believe that to avoid such complications if any appropriate care is needed it shall be taken by the surgeon and anesthetist or any other doctor suggested by them.
- That there is an ICU in the hospital and treating Doctor will shift patient there in case of any complication and take appropriate care/ That there is no ICU in this hospital but this hospital has a tie up with ……………………………………………….. Hospital which has ICU set up and patient will be shifted there in case of any complication so that appropriate care can be taken of.
- I have been explained that after surgery I might need to take some medications which will also include Anti-Fungal treatment either orally and/or intravenously for a particular period of time as per my medical condition and as per prescribed by doctors depending on availability of all necessary drugs. After surgery I will have to regularly follow up with my doctor as per his orders.
- During my stay in hospital all aseptic precautions will be taken by the hospital but still I have chances of acquiring any kind of infection including COVID-19.
- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedures and its risks and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
- I understand I have the right to change my mind at any time, including after I have signed this form but preferably following a discussion with my doctor.
- I understand that images or video footages may be recorded as a part of or during my procedure.
- I accept that medicine is not an exact science and understand that no guarantees can be given to the results even after complete removal of the disease and understand these limitations.
- I have read the above writing; the above writing has been read out to me and explained to me in …………………………………….the language by the interpreter………………….....................which I understand.

- I request DR. ………..………………………….to perform the above-mentioned procedure.

Declaration by Doctor:

I declare that I have explained the nature and consequences of the procedure to be performed, and discussed the risks that particularly concern the patient.

I have given the patient an opportunity to ask questions and I have answered these.

DOCTOR	**PATIENT**
NAME:	NAME:
SIGN:	SIGN:
DATE/TIME:	DATE/TIME:

WITNESS 1	**WITNESS 2**
NAME:	NAME: