

DISCLOSURE AND CONSENT - MEDICAL AND SURGICAL PROCEDURES

TO THE PATIENT: You have the right as a patient to be informed about your condition and the recommended surgical, medical or diagnostic procedure to be used so that you may make the decision whether or not to undergo the procedure after knowing the risks and hazards involved. This disclosure is not meant to scare or alarm you; it is simply an effort to make you better informed so you may give or withhold your consent to the procedure.

CONSENT FOR INTRAOPERATIVE NEUROPHYSIOLOGICAL MONITORING

I have been asked to carefully read all of the information contained in this consent form and to consider my consent to the intraoperative monitoring described below on behalf of UMC Health system. I have been told that I should ask questions about anything that I do not understand. (If the decision-maker signing this form is not the patient, references to “I,” “my” or “me” should be read as if referring to “the patient,” when applicable.)

I understand that the information about the procedure and testing described in this consent form, in addition to discussions with my physicians and any other written and/or audiovisual materials they may provide, is intended to help me make an informed decision whether to voluntarily undergo the testing proposed.

I understand that intraoperative neurophysiological monitoring has been requested by my surgeon and will be performed during the surgical procedure that is planned: _____.
The neurophysiologic monitoring will be interpreted in real-time during the procedure by a qualified Clinical Neurophysiologist.

Description of Procedure/Testing:

Intraoperative neurophysiological monitoring is performed during a variety of surgical procedures to measure the function of the brain, brainstem, cranial nerves, spinal cord, spinal nerve roots and peripheral nerves depending on the type(s) of testing performed and the surgery. Electrophysiological measurements provide information to the surgeon in the operating room that may assist in identifying neural structures, aid in performing the surgical procedure itself and in detecting and preventing injury to the nervous system.

Central and peripheral nervous system function is measured using electroencephalography (EEG, an electrical map of the brain), electromyography (EMG, measurement of electrical energy to the muscles) and/or evoked potentials (EP, stimulated electrical activity) recordings. The surgical procedure and the parts of the nervous system at risk will determine which of these tests will be monitored. In some cases, all of these will be recorded simultaneously.

After the induction of general anesthesia, but before the start of surgery, fine, sterile subdermal (under the skin) needle-pin electrodes will be placed and used as stimulating and recording devices. Baseline recordings will be made so that differences during the surgical procedure can be detected. Once the surgery has begun, recordings will be monitored continuously throughout the procedure and any significant changes will be reported to the surgical team by the Clinical Neurophysiologist. Prior to you awakening from anesthesia, all the electrodes will be removed.



Risks of Procedure/Testing:

1. Infection. Infection may occur at the site of electrode application in the skin. (Estimated risk <0.1%)
2. Burns. Burns and/or scabs at electrode site caused by the use of electrical equipment such as cautery or by a malfunction of the neurophysiological monitoring equipment (estimated risk <0.1%).
3. Hematoma. Because a needle is placed beneath the skin, blood may collect to form a hematoma (Bruise or blood clot) (Estimated risk <0.1%).
4. Neurologic loss. In rare cases, cranial or peripheral nerve damage may occur secondary to electrode placement and/or direct stimulation of the nerve. Symptoms can include weakness, numbness, disturbing sensations (tingling, burning, pins and needles) and pain (estimated risk <0.1%).
5. Device malfunction/failure. On rare occasions the equipment used for the collection of neurophysiologic data may malfunction or fail leading to no data collection during a portion of the procedure (estimated risk <0.1%).
6. Tongue lacerations. In cases where transcranial electrical stimulation is performed (motor evoked potentials), jaw movement may cause lacerations to the tongue (estimated risk <1.0%).
7. Seizure. In cases where transcranial (across the brain) or direct cortical (surface of the brain) stimulation is used, this stimulation can result in brief clinical seizure activity, which is immediately stopped by using interventions such as cold irrigation or medication (estimated risk <1.0%).
8. Needle Breakage. In rare instances the subdermal needle electrode can break off under the skin. If a needle breaks off it may or may not need to be removed. Your doctor will speak to you about the choices for treatment (estimated risk <0.1%).
9. False-Negative Results. On rare occasions, neurophysiological monitoring is unable to identify nerve tracts/tissue or detect neural injury. This can be due to preexisting disease and neurological deficits, unexpected or abnormal anatomy, and/or an error on the part of the monitoring team. These instances are called “false-negative” results (estimated risk <1.0%).
10. Other risks, if any: _____

Alternatives. I understand that I have the choice NOT to have intraoperative neurophysiological monitoring utilized during my procedure. Should I decide not to have intraoperative monitoring performed; I acknowledge that my physician(s) have discussed the risks associated with not having neurophysiological monitoring performed during the surgical procedure.

MY SIGNATURE BELOW ACKNOWLEDGES THAT:

1. I have read (or had read to me) and understand the statements that are set forth in this consent form. And I agree to discuss the benefits, risks and appropriateness of neurophysiological monitoring services with my physicians prior to surgery, that is, if I have not already done so.
2. A physician or physician’s representative has explained to me all of the information referred to in this consent form. I have had the opportunity to ask questions and my questions have been answered to my satisfaction.



Date _____

Resident and Nurse Consent/Orders Checklist

Instructions for form completion

Note: Enter “not applicable” or “none” in spaces as appropriate. Consent may not contain blanks.

- Section 1: Enter name of physician(s) responsible for procedure and patient’s condition in lay terminology. Specific location of procedure must be indicated (e.g. right hand, left inguinal hernia) & **may not be abbreviated.**
- Section 2: Enter name of procedure(s) to be done. Use lay terminology.
- Section 3: The scope and complexity of conditions discovered in the operating room requiring additional surgical procedures should be specific to diagnosis.
- Section 5: Enter risks as discussed with patient.
 - A. Risks for procedures on List A must be included. Other risks may be added by the Physician.
 - B. Procedures on List B or not addressed by the Texas Medical Disclosure panel do not require that specific risks be discussed with the patient. For these procedures, risks may be enumerated or the phrase: “As discussed with patient” entered.
- Section 8: Enter any exceptions to disposal of tissue or state “none”.
- Section 9: An additional permit with patient’s consent for release is required when a patient may be identified in photographs or on video.

Provider Attestation: Enter date, time, printed name and signature of provider/agent.

Patient Signature: Enter date and time patient or responsible person signed consent.

Witness Signature: Enter signature, printed name and address of competent adult who witnessed the patient or authorized person’s signature

Performed Date: Enter date procedure is being performed. In the event the procedure is NOT performed on the date indicated, staff must cross out, correct the date and initial.

If the patient does **not** consent to a specific provision of the consent, the consent should be rewritten to reflect the procedure that the patient (authorized person) is consenting to have performed.

For additional information on informed consent policies, refer to policy SPP PC-17.

Consent

<input type="checkbox"/> Name of the procedure (lay term)	<input type="checkbox"/> Right or left indicated when applicable
<input type="checkbox"/> No blanks left on consent	<input type="checkbox"/> No medical abbreviations

Orders

<input type="checkbox"/> Procedure Date	<input type="checkbox"/> Procedure
<input type="checkbox"/> Diagnosis	<input type="checkbox"/> Signed by Physician & Name stamped

Nurse _____ Resident _____ Department _____