

Version	Version Release Date	Changes Made By
Initial	10.21.2019	HH
Edited	11.1.2019	DS
Edited	11.22.2019	HH
Edited	4.14.2022	RG

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 <u>ADVANCED MONITORING</u> <u>SERVICES, LLC/INTERPRETING PHYSICIAN ASSOCIATES, LLC.</u> 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 (IONM) 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 Interpreting Physician.

Description of Procedure/Testing:

IONM 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 surgery performed and the testing utilized during that procedure. 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 aid 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

Though their associated levels of risk are relatively low, please be informed that the following complications, injuries, symptoms, and/or conditions, among others, can occur in connection with these services:

- 1. <u>Infection</u>. Infection may occur at the site of electrode application in the skin.
- 2. <u>Burns.</u> 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.
- 3. <u>Hematoma.</u> Because a needle is placed beneath the skin, blood may collect to form a hematoma (bruise or blood clot).
- 4. <u>Neurologic loss.</u> 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.
- 5. <u>Device malfunction/failure.</u> 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.
- 6. <u>Tongue/Lip bruising or lacerations.</u> In cases where transcranial electrical stimulation is performed (motor evoked potentials), jaw movement may cause lacerations to the tongue.
- 7. <u>Seizure</u>. 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.
- 8 <u>Needle Breakage.</u> 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.
- 9. <u>False-Negative Results.</u> 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.
- 10. Other risks, if any:

<u>Alternatives.</u> I understand that I have the choice <u>NOT</u> 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.

<u>Assignment of Insurance/Third Party Benefits.</u> I authorize payment of medical benefits to Advanced Monitoring Services/Interpreting Physician Associates, for Intraoperative Neurophysiologic Monitoring and/or Clinical Neurophysiologic Diagnostic Testing. Further, I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits to include Medicare and Medicaid to either myself or to Advanced Monitoring Services/Interpreting Physician Associates.

I authorize any holder of medical information, including Advanced Monitoring Services/Interpreting Physician Associates, about me to release to the Centers for Medicare and Medicaid Services and its agents any information required to determine these benefits or the benefits payable for related services.



CONSENT FOR INTRAOPERATIVE NEUROPHYSIOLOGICAL MONITORING

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.
- 3. All blanks or statements requiring completion were filled in before I signed.
- 4. No guarantees or assurances concerning the results of the procedure(s) have been made. Although all reasonable efforts are taken to prevent injuries and the risk of injury from neurophysiological services is low, I assume all risks and fully release Advanced Monitoring Services, Inc., from any and all liability for any injury or damage caused by factors, acts, errors, and/or omissions under or committed by non-AMS employees and agents over whom AMS/IPA exercises no control or authority.
- 5. I am signing this consent voluntarily. I am not signing due to any coercion or other undue or improper factors beyond the control of AMS/IPA.
- 6. I hereby consent and authorize AMS/IPA and its employees and agents and/or those associates, assistants and other health care providers designated by my physician(s), to utilize intraoperative neurophysiological monitoring during my surgical procedure. I understand that during the course of the procedure, conditions may become apparent that require my physician(s) or their designees to request additional neurophysiologic monitoring procedures that they believe are medically necessary to achieve the desired benefits or for my well-being.

Date

Signature of patient or person authorized to consent for patient

Relationship to patient if signer is not patient

I acknowledge that I have explained to the patient, or the patient's representative, the benefits, risks, and possible complications that may be associated with neurophysiological monitoring services. I have given no guarantee or assurance as to the results that may be obtained.

Date

Signature of IONM Representative

Affix Patient Sticker