

# Obtaining and Verifying Informed Consent

**Purpose of risk management recommendations**

OMIC regularly analyzes its claims experience to determine loss prevention measures that our insured ophthalmologists can take to reduce the likelihood of professional liability lawsuits. OMIC policyholders are not required to implement risk management recommendations. Rather, physicians should use their professional judgment in determining the applicability of a given recommendation to their particular patients and practice situation. These loss prevention documents may refer to clinical care guidelines such as the American Academy of Ophthalmology’s *Preferred Practice Patterns*, peer-reviewed articles, or to federal or state laws and regulations. However, our risk management recommendations do not constitute the standard of care nor do they provide legal advice. Consult an attorney if legal advice is desired or needed. Information contained here is not intended to be a modification of the terms and conditions of the OMIC professional and limited office premises liability insurance policy. Please refer to the OMIC policy for these terms and conditions.

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To honor the patient’s right to make decisions about health care, ensure patient understanding, and prevent allegations of lack of informed consent, follow these risk management guidelines.

**Obtaining informed consent**

* In general, the health care provider performing the diagnostic procedure or surgery must obtain informed consent for it. The duty to obtain informed consent cannot be delegated.
* Informed consent begins as an **oral agreement** between the ophthalmologist and the patient **reached after a discussion**. The discussion includes the condition, recommended treatment or procedure, and the risks, complications, benefits, and alternatives. The discussion should include the consequences of refusing the recommended treatment or procedure.
* If the patient has any known risk factors that increase the likelihood of complications, side effects, or poor outcome, the ophthalmologist should discuss these with the patient.
* The informed consent discussion should take place when the patient is awake and aware, free from the effects of any medication that could interfere with the patient’s ability to participate in the decision-making process.
* For elective surgeries, the discussion should take place before the day of the surgery whenever possible. Some patients who had surgery the same day as the informed consent discussion have later sued for lack of informed consent, arguing that they were coerced into having the procedure and did not have time to weigh the risks and benefits. If the patient cannot be seen until the day of surgery (e.g., the patient lives far away), but the type of surgery is already determined, taking a few extra steps will facilitate patient understanding and ensure that consent is informed and voluntary.

	+ - Obtain information—from the referring physician or directly from the patient per telephone or questionnaire—about the patient’s medical and ocular health to rule out contraindications to the procedure and screen for conditions that could affect the safety of the surgery or anesthesia (e.g., significant coronary artery disease, need for anticoagulants, etc.).
		- Send the patient an unsigned copy of the procedure-specific form along with other educational information and ask the patient to review the materials.
		- At the time of the preoperative visit and consent discussion, address any questions or concerns, and ask the patient to sign the form.

**Documentation of the informed consent discussion**

* Document the discussion in the patient’s medical record and, if used, on the informed consent document itself (see below, “Verification of informed consent”).
* If the discussion took place in a language other than English, document the language used, and the name and relationship of any translator.
* Include specific questions or concerns raised by the patient, along with the answers.
* In addition to documenting that the discussion took place, ask the patient to sign a consent form (see below, “Verification of informed consent” and “Signature rules”).
* Document any materials the patient was given or shown explaining the procedure or treatment, such as a copy of a procedure-specific consent form, pamphlets or brochures, educational materials, or videos.

**Verification of informed consent: the role of the consent form**

* An informed consent form serves to document and verify that the informed consent discussion between the ophthalmologist and the patient took place. It is not a substitute for the informed consent discussion.
* To promote patient understanding, and to document the content of the discussion, OMIC strongly recommends using a procedure-specific consent form that explains the patient’s ophthalmic condition as well as the risks, benefits, and alternatives of the procedure the patient will undergo. See our website at [www.omic.com](http://www.omic.com) for a list of available forms.
* Keep the original document in the patient’s record.
* Send a copy, along with your preoperative orders, to the ambulatory surgery center or hospital.
* Offer patients a copy, noting in the record, "Patient given/offered signed copy of consent form." Encourage patients to review the form at home with their family members, and to call if they have any questions.
	+ Many patients do not remember all that the physician told them about their condition or the proposed procedure.
	+ Reviewing the form at home helps ensure that the patient understands the procedure and its risks and will significantly assist OMIC to defend the physician in the event of a malpractice lawsuit.
	+ There is no evidence to suggest that patients who are given a form will be "scared off" from needed treatment or be "reminded to sue" if something goes wrong. Rather, informed patients are better able to participate in their care and follow instructions. They also appreciate the opportunity to review the information with family members. Finally, it is more difficult for patients to claim they did not understand the risks when they are provided with a signed document that lists them.

**Signature “rules”**
Asking patients to sign consent forms serves both to document that the oral agreement has been reached, and to verify patient agreement and understanding. There are several important rules to apply when requesting the patient's signature on a consent form:

* The document should not be signed until after the patient and ophthalmologist have first discussed the risks, benefits, and alternatives of the procedure.
* Only the ophthalmologist performing the surgery can obtain the patient's oral consent. Some practices ask patients to review the consent form again after the discussion before signing it, and then have a staff member obtain the patient’s signature.
* As a rule, the physician is not required to sign the form.
* Any member of the physician's staff can be authorized to obtain the patient's signature on the consent form.
* As a risk management measure, instruct staff members to ask patients what procedure will be done and why before asking them to sign the form.
* If the patient does not appear to understand, instruct staff members to inform you so that you can discuss the procedure again and clear up any confusion or misunderstanding. Document that you discussed the procedure again with the patient, and that the patient appeared to understand and signed the consent.
* Do not ask patients to sign forms if the patient is even mildly sedated.
* It is best not to present the form or seek a signature when the patient is dilated. Plaintiffs have successfully challenged the validity of the informed consent by proving that the patient’s eyes were dilated before they were asked to sign the form.
* If the patient’s eyes are dilated, read the form to the patient and family members, if present, and then ask the patient to sign it. Document the name and title of the person who read the document out loud and note that the patient had an opportunity to have questions answered before signing. Family members and staff should sign that they witnessed the reading of the form and the patients’ signature.
* Although witnesses to signatures are helpful, they are not required in most jurisdictions and their absence would not necessarily invalidate the consent or its evidentiary value.

**General consent forms used by ambulatory surgery centers and hospitals**

* Ambulatory surgery centers (ASC) and hospitals need to verify that the informed consent discussion took place between the ophthalmologist and the patient before allowing the procedure or surgery to take place. The ASC or hospital cannot obtain the patient’s informed consent; only the ophthalmologist can do that. The facility’s role in informed consent is limited to verifying that the informed consent discussion took place. Ask the surgeon to fax a copy of the informed consent document along with the preoperative orders.
* ASCs and hospitals have a separate duty to obtain what is known as general consent for the care and treatment provided at their facility by their employees and other providers. ASCs and hospitals often use a single form to both verify that the informed consent discussion took place and to obtain general consent for care rendered at their facility. The patient is usually given this form to sign by a facility employee during the registration or admission process.

**Need confidential risk management assistance?**

OMIC-insured ophthalmologists, optometrists, and practices are invited to contact OMIC’s Risk Management Department at (800) 562-6642, option 4, or at riskmanagement@omic.com.