INFORMED CONSENT IN YOUR ASC

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While ASCs require that the patient gives an informed consent, the process actually begins in the surgeon's office.

Informed consent is a process rather than "the" form that we are all so focused on getting signed. The goal of the informed consent process is to enable the patient/patient representative to make an informed, and educated, decision to undergo the proposed procedure. Below, a list of considerations—such as the initial conversation, obtaining vs. witnessing consent, signatures needed, time limits, and withdrawal of or inability to give consent—necessary for achieving that goal.

START WITH THE SURGEON

The surgeon gives information to the patient about the diagnosis, the procedure that s/he is recommending, and the risks, alternatives, and benefits of that procedure. The following elements should be included in any conversation about risks, benefits, and alternatives:

- Language the patient/patient rep can understand
- Disclosure of any serious risk of injury
- Disclosure of any risk of death
- Generally, *no* requirement to disclose "minor" risks not likely to occur
- Generally, *no* requirement to disclose alternative treatments not recommended for that patient
- Time involved for procedure and recovery
- Ride home with responsible adult
- Restrictions on resuming normal activities
- Requirements for follow-up care

The consent form we ask the patient to sign in the ASC merely documents that the informed consent process has occurred and that the patient elects to proceed with the procedure as proposed.

SIGNING OFF

The facility consent form should have verbiage acknowledging that the patient has received information to give consent, but an ASC consent should also include items such as consent for observers, consent to photography, consent to release specimens, etc., if applicable.

As we all know, we live in a litigious time. The informed consent process, when conducted appropriately, provides a legal defense. If the patient has acknowledged that they understand the procedure, risks, benefits, and alternatives, some amount of legal protection is present to mitigate lack of informed consent claims and battery claims. If an informed consent is not

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obtained, the surgeon and ASC face the probability of a negligence or battery claim.

One common misconception we see in ASCs is the requirement that the physician's consent form needs to be sent to the ASC or that the surgeon needs to sign the ASC facility consent. Neither of these is accurate unless your particular state requires it.

WITNESSING

In the ASC, the consent form should be witnessed. The witness is merely witnessing that the patient is signing the form. A licensed person does not need to be the witness. The facility consent discussion should be in a private location and before the patient has received any sedation.

The patient should be asked to state the procedure to the staff member and the staff member should ask if the patient has any questions. The important issue here is that if a patient has ANY unanswered questions or concerns, they should not sign the form until the physician has addressed all concerns. Always keep in mind the difference between *obtaining* consent and *witnessing* consent.

INABILITY TO GIVE CONSENT

Many of our ophthalmic patients are elderly with many of the co-morbidities that accompany aging. What do you do if a patient is not able to give consent? For example, they may be in a skilled nursing facility and not have family in the area, or they may be disoriented only occasionally and have not yet appointed a medical power of attorney. The best-case scenario is that the patient has a legal guardian or a designated medical power of attorney who can give consent for the procedure.

The more challenging situation is when the patient has not yet appointed a surrogate and they are not able to give an informed consent. The elderly in our current population are frequently mobile and may not have identified a local individual. Several states are responding to this. Florida, for example, has a list of proxies the facility can use. North Carolina is passing the Two Physician Rule, whereby two physicians can attest to the patient's need for a procedure. The key is to know what your state will allow.

If none of these options is available to the patient, they will need to go through the court-appointed guardianship process.

TIME LIMITS

Is there a time limit on consent? Unless your state has specific requirements regarding time, there is not a time limit for your practice or the ASC in which you perform surgery. However, you must keep in mind that if the patient's health has changed in a way that would alter the risks, benefits, and alternatives to the procedure, the informed consent process should be updated.

WITHDRAWAL

Patients are able to withdraw consent at any point during the process. Be sure to document conversations leading up to the withdrawal of consent. If the patient has been sedated, ensure you follow your policy on leaving against medical advice (AMA). Have a form for the patient to sign indicating they or their surrogate are aware they are leaving against medical advice.

BOTTOM LINE

Ensuring your staff has a complete understanding of the informed consent process will contribute to patient safety and mitigate legal claims should they occur. ***AE***

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