



Informed Consent and Informed Refusal: Obligation or Opportunity?

Daniel Rosenquist, MD

Susan Sgambati, MD, FACS, FASCRS

Patient Safety and Risk Management Conference

April 29, 2025

Is this informed consent?

FORM 1-2

INFORMED CONSENT TO SURGERY OR SPECIAL PROCEDURE

1. This form is called an "Informed Consent Form." It is your doctor's obligation to provide you with the information you need in order to decide whether to consent to the surgery or special procedure that your doctors have recommended. The purpose of this form is to verify that you have received this information and have given your consent to the surgery or special procedure recommended to you. You should read this form carefully and ask questions of your doctors so that you understand the operation or procedure before you decide whether or not to give your consent. If you have questions, you are encouraged and expected to ask them before you sign this form. Your doctors are not employees or agents of the hospital. They are independent medical practitioners.

2. Your doctors have recommended the following operation or procedure: _____ and the following type of anesthesia: _____

Upon your authorization and consent, this operation or procedure, together with any different or further procedures which, in the opinion of the doctor(s) performing the procedure, may be indicated due to any emergency, will be performed on you. The operations or procedures will be performed by the doctor named below (or, in the event the doctor is unable to perform or complete the procedure, a qualified substitute doctor), together with associates and assistants, including anesthesiologists, pathologists, and radiologists from the medical staff of (name of hospital) _____ to whom the doctor(s) performing the procedure may assign designated responsibilities.

3. Name of the practitioner who is performing the procedure or administering the medical treatment¹: _____

The hospital maintains personnel and facilities to assist your doctors in their performance of various surgical operations and other special diagnostic or therapeutic procedures. However, your doctors, surgeons and the persons in attendance for the purpose of performing specialized medical services such as anesthesia, radiology, or pathology are not employees or agents of the hospital or of doctor(s) performing the procedure. They are independent medical practitioners.

4. All operations and procedures carry the risk of unsuccessful results, complications, injury or even death, from both known and unforeseen causes, and no warranty or guarantee is made as to result or cure. You have the right to be informed of:

- The nature of the operation or procedure, including other care, treatment or medications;
- Potential benefits, risks or side effects of the operation or procedure, including potential problems that might occur with the anesthesia to be used and during recuperation;
- The likelihood of achieving treatment goals;
- Reasonable alternatives and the relevant risks, benefits and side effects related to such alternatives, including the possible results of not receiving care or treatment; and

1 CMS recommends that consent forms state, if applicable, that physicians other than the operating practitioner, including but not limited to residents, will be performing important tasks related to the surgery, in accordance with the hospital's policies (and, in the case of residents, based on their skill set and under the supervision of the responsible practitioner) and that qualified medical practitioners who are not physicians will perform important parts of the surgery or administration of anesthesia within their scope of practice, as determined under state law, and for which they have been granted privileges by the hospital.

A Story



Importance of Informed Consent

- Legal requirement
- Better health outcomes with chronic illness
- Better surgical outcomes
 - Less pain medicine
 - Decreased hospital stay
 - Quicker recovery
- Better compliance with treatment plans



Is a signature always required?

- **Express** consent: oral *or* written
- **Implied** consent: words *or* conduct by patient that led provider to believe patient was consenting
- Entry into progress notes
- More than just the form – teaching aids, models, drawings, etc.
- Ten-page forms?



Exceptions



- Emergency makes it impractical to obtain (reasonableness)
- Patient incapable: mental disability or infancy
- Where complete and candid disclosure might have detrimental effect on physical/psychological wellbeing of patient
- The procedure is simple and danger remote and commonly appreciated to be remote
- The physician does not know of risk and should not have been aware of it in exercise of ordinary care

What is the “standard”?

- Who decides?
- Know your state law
- Negligence



Negligent Consent



Failure to obtain the plaintiff's informed consent ***before*** the procedure



Under similar circumstances, a **provider in the community** would have obtained consent



That a patient **would not have undergone the procedure** had they been properly informed

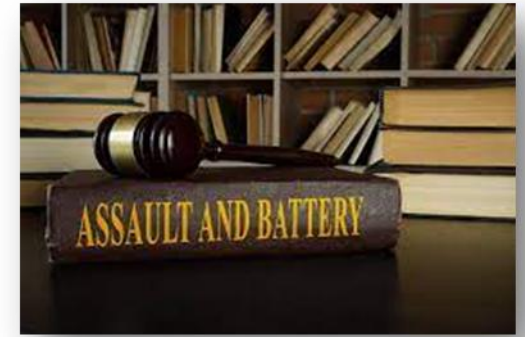


The lack of informed consent was the **proximate cause** of damages to the plaintiff



The **nature and extent** of that damage

Battery



- **Unless the patient consents**, any procedure involving contact with patient's body is battery, even when appropriate skill is used in treatment.
- If patient consents to a certain procedure and the physician **performs a different procedure**, without the patient's consent, the physician commits battery.
- No expert needed for battery claims.

Common Allegations

“Never saw the doctor”

“I was pushed into it”

“I was sedated”

“The doctor never went through the form”

“That specific risk wasn’t listed”

“The form wasn’t signed”

“The risks were minimized”

“They didn’t discuss the alternatives”

We've seen informed consent...

By the MA or
RN

Wrong
procedure

When patient
already
sedated

Minimized
risks

“Anything
can happen”

No signature
(witness *or*
patient)

Received
different
materials

Elements of Informed Consent



The nature of the illness, injury or condition



Nature of the treatment



Discussion of alternatives



Assessment of patient understanding



Exploration of patient preferences

Who can obtain consent?



- The provider performing the procedure
- Electronic signature caveats

Who can give consent?



- Capacity and competence
- Custody issues
- Assessment of understanding
- Goal of shared decision-making

Health Literacy



- 25% of adults function below 5th grade reading level
- Another 25% at or barely above that level
- Ask directed questions to make sure the patient understands

When to consent



- Procedures requiring local anesthesia
- Joint injection / aspiration
- Drugs
 - Anticoagulation
 - Biologic agents
 - Lamotrigine
- Allergy treatments

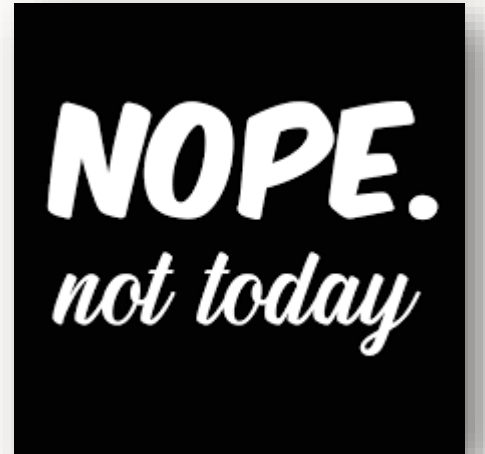
Informed Refusal



- Recommended procedures
- Recommended higher level of care: ER, hospital, specialist, etc.
- Note in chart vs. form

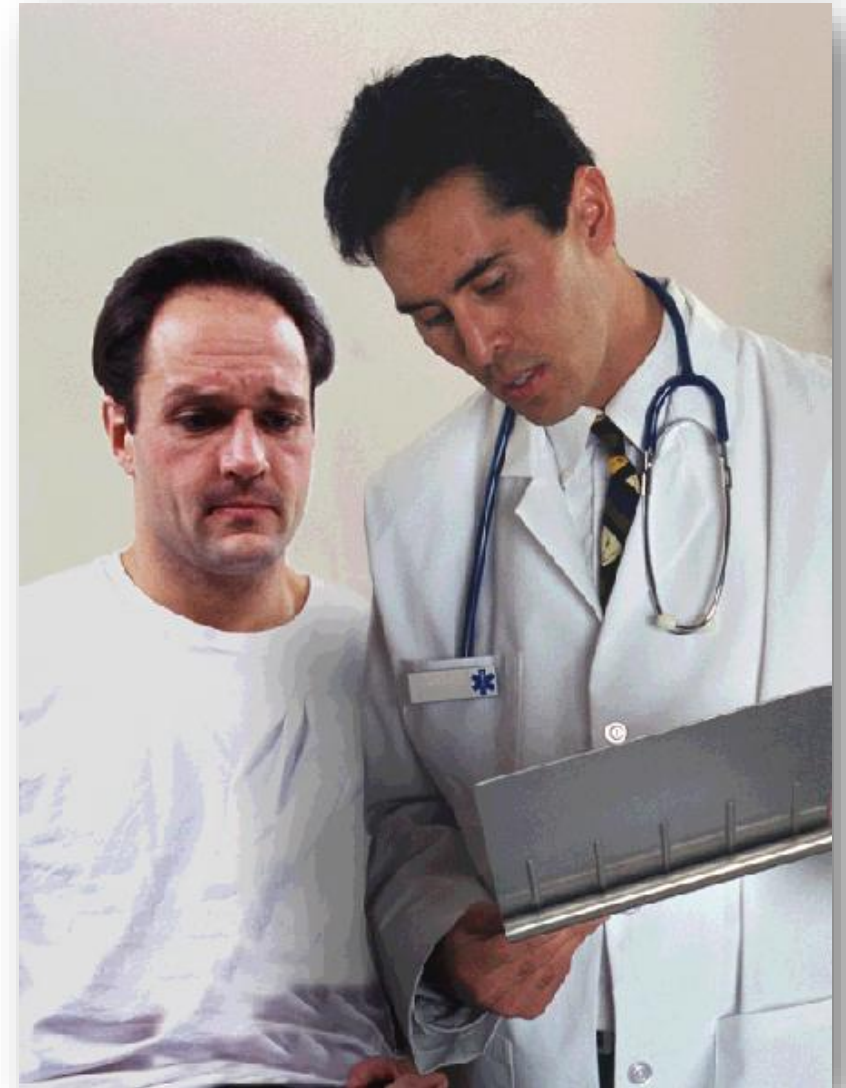
Elements of Informed Refusal

- Medical decision-making capacity
- Proposed treatment, test, medication
- Indications
- Benefits
- Risks
- Assumption of risk
- Can go to plan B, not an “all or nothing”



Shared Decision-Making Process

- Patient preferences
- Provider roles
 - education
 - guidance
 - exploration



Take-Home Points - Obligation

The documentation may defend against allegation – “process vs. paper”

The process cannot be delegated – must be performed by provider doing procedure

Document everything you did – discussion, pictures, models, etc.

Remember the elements

Determine capacity; assess understanding (teachback)

Take home points - Opportunity

Process enhances patient experience and outcomes

Get to shared decision-making

Prepares for possible disclosure process

Compliance

Applies to medical treatment as well



Thank you!

ssgambati@copic.com
drosenquist@copic.com