Basics of Consent

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Agenda

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- ✓ Fundamental Patient Consent Rights
- ✓ “Simple” versus “Informed” Consent
- ✓ Informed Consent Process
- ✓ Informed Refusal
- ✓ Risk and Liability
- ✓ Emergencies and Other Exceptions

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Fundamental Patient Consent Rights

- Every competent adult has a fundamental right of self-determination over his or her body.
- A person unable to exercise this right (a minor or incompetent adult) has the right to be represented by another person.

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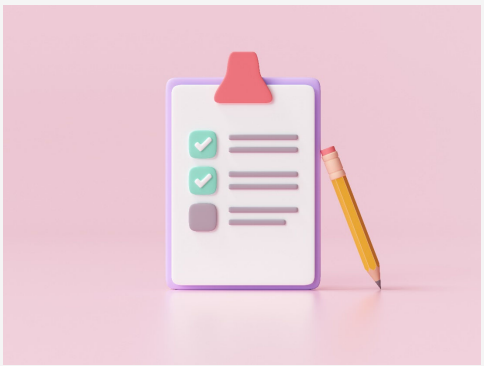
Fundamental Patient Consent Rights

Where can we find the authority on patient consent rights?

1. Federal law
2. State law
3. Federal guidance
4. State guidance
5. Common law (judicial decisions)
6. Standard of practice
7. Accrediting bodies
8. Hospital policies
9. All of the above



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Fundamental Patient Consent Rights

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Fundamental Patient Consent Rights

1. Federal Law → Patient Self-Determination Act (42 U.S.C. §§ 1395cc(f), 1396a(w))

2. State Law → Patients' Rights in General Acute Care Hospitals (22 C.C.R. § 70707)

3. Federal Guidance →

- Advance Directive (42 C.F.R. § 489.100)
- Advance Directives Requirements for Providers (42 C.F.R. § 489.102)
- Medicare & Medicaid Conditions of Participation for Hospitals: Patient's Rights (42 C.F.R. § 482.13)
- The patient has the right to formulate advance directives. (CMS State Operations Manual Appendix A-0132)

4. State Guidance → Information Regarding Patient's Rights; Duty of Hospitals (Cal. Health & Safety Code § 1262.6)

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Fundamental Patient Consent Rights (cont.)

5. Common Law →

- Simple Consent (Piedra v. Dugan (2004) 123 Cal. App. 4th 1483)
- Informed Consent (Cobbs v. Grant (1972) 8 Cal. 3d 22)
- No Consent is Battery (Perry v. Shaw (2001) 88 Cal. App. 4th 658)
- Battery Involves Intent to Injure (Ditto v. McCurdy (2007) 510 F. 3d 1070)
- "Battery" is a Question of Fact (Kaplan v. Mamelak (2008) 162 Cal. App. 4th 637)
- Withholding a Material Risk or Material Information May Be Fraud, Conversion, and Intentional Infliction of Emotional Distress (Hahn v. Mirda (2007) 147 Cal. App. 4th 740)

6. Standard of Practice → AMA Code of Medical Ethics Opinion 2.1.2

7. Accrediting Bodies → The hospital respects, protects, and promotes patient rights. (The Joint Commission Standard R.I.01.01.01)

8. Hospital Policies

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"Simple Consent" Versus "Informed Consent"

Common Procedure
- Simple Consent

Complicated Procedure
- Informed Consent

Cobbs v. Grant, 8 Cal.3d 229 (1972)
502 P.2d 1, 104 Cal.Rptr. 505

recuperation. Second, there is no physician's duty to discuss the relatively minor risks inherent in common procedures, when it is common knowledge that such risks inherent in the procedure are of very low incidence.[2] When there is a common procedure a doctor must, of course, make such inquiries as are required to determine if for the particular patient the treatment under consideration is contraindicated —for example, to determine if the patient has had adverse reactions to antibiotics; but no warning beyond such inquiries is required as to the remote possibility of death or serious bodily harm.

However, when there is a more complicated procedure, as the surgery in the case before us, the jury should be instructed that when a given procedure inherently involves a known risk of death or serious bodily harm, a medical doctor has a duty to disclose to his patient the potential of death or serious harm, and to explain in lay terms the complications that might possibly occur. Beyond the foregoing minimal disclosure, a doctor must also reveal to his patient such additional information as ***245** a skilled practitioner of good standing would provide under similar circumstances

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“Simple Consent” Versus “Informed Consent”

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Who decides what is a common procedure versus a complicated procedure?

1. CMS
2. State law
3. Hospital administration
4. Professional staff

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“Simple Consent” Versus “Informed Consent”

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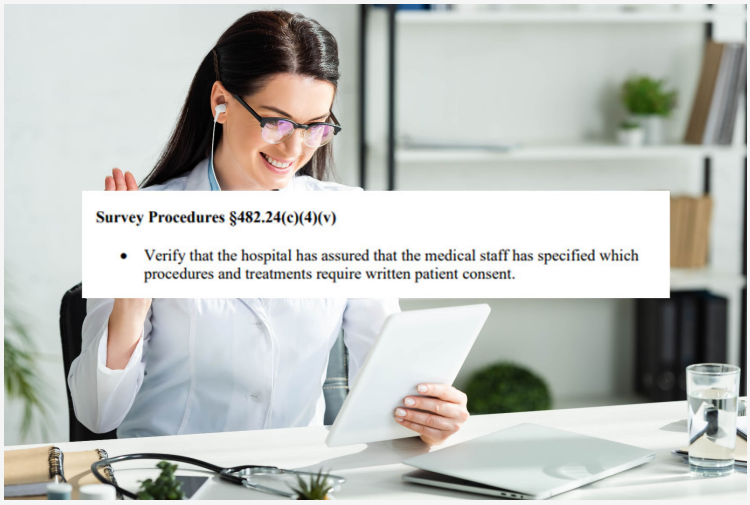

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Simple Consent

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What constitutes simple consent for common procedures?

FORM 8-1

Conditions of Admission

Patient's Name: _____

Consent to Medical and Surgical Procedures

I consent to the procedures that may be performed during this hospitalization or while I am an outpatient. These may include, but are not limited to, emergency treatment or services, laboratory procedures, X-ray examinations, medical or surgical treatment or procedures, telehealth services, anesthesia, or hospital services provided to me under the general and special instructions of my physician or surgeon. I understand that the practice of medicine and surgery is not an exact science and that diagnosis and treatment may involve risks of injury or even death. I acknowledge that no guarantees have been made to me regarding the result of examination or treatment in this hospital.

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Informed Consent

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Informed consent is required:

- ✓ If the nature of the treatment is complicated or invasive
- ✓ When the procedure involves material risks that are not commonly understood
- ✓ When required by law

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Informed Consent

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"Informed consent" is shorthand for a **process** that involves giving the patient information so the patient can make an informed decision — to accept or reject proposed treatment

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Informed Consent Process

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The informed consent process includes:

- A discussion with the patient/legal representative by the physician performing the procedure
- Documentation of the decision to consent to treatment or refuse treatment
  - Physician documentation: e.g., progress note evidencing discussion of risks, benefits and alternatives
  - Hospital documentation: completion of consent form
  - Witnessing of form by hospital personnel

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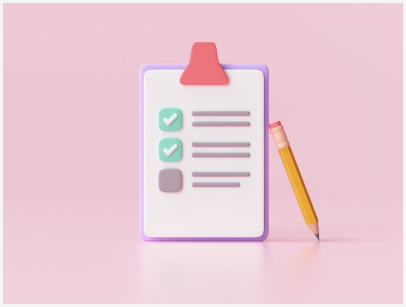
Informed Consent Process – The Explanation

Which of the following must be disclosed?

1. Nature and purpose of procedure
2. Likelihood of benefits, risks, complications and side effects of procedure
3. Small or remote risks
4. Possible alternative methods of treatment and their benefits/risks/complications/side effects (include risk of not receiving)
5. Potential problems during recuperation
6. Any potential conflicts of interest (research, financial)
7. Treatment that is illegal in CA, not recommended or unapproved
8. Any other info required by law



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Informed Consent Process – The Explanation

Must include these elements:

1. Nature and purpose of procedure
2. Likelihood of benefits, risks, complications and side effects of procedure
3. ~~Small or remote risks~~ (Scalere v Stenson)
4. Possible alternative methods of treatment and their benefits/risks/complications/side effects (include risk of not receiving)
5. Potential problems during recuperation
6. Any potential conflicts of interest (research, financial)
7. ~~Treatment that is not legal in California, not recommended, unapproved~~
8. Any other info required by law

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Informed Consent Process – The Explanation

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What information is sufficient?

- ✓ That information which would be considered significant by a reasonable person in the patient's position
- ✓ Supplemented by patient's unique concerns/condition (as known by the physician)
- ✓ May use patient information sheets
- ✓ Leave enough time before surgery for patient to ponder

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Informed Consent Process – The Explanation

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- Communicate (and document) significant risks, "including, but not limited to …"
  - Loss of life
  - Loss of limb, limb function
  - Risk of stroke, brain injury, loss of nerve function
  - Potential for hemorrhage, blood clots
  - Potential for allergic reaction
  - Blood loss necessitating transfusion
  - Infection
- Other, according to procedure: incontinence, impotence, infertility, paralysis, loss of vision, etc.

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Informed Consent Process

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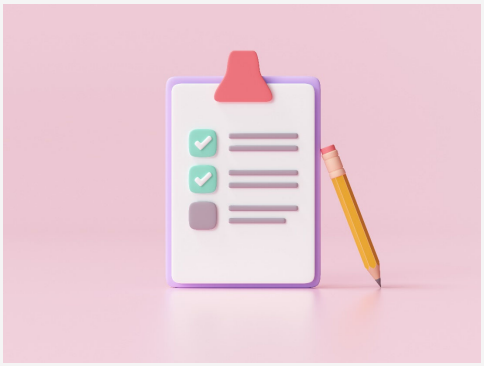
Who obtains consent?

1. Any physician
2. The physician performing the procedure
3. The treating nurse
4. The patient's decisionmaker or loved one



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Informed Consent Process

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- Generally, the physician who performs the procedure is responsible for obtaining the patient's consent.
- If a nonphysician will perform the procedure, then the ordering physician is responsible for obtaining consent.
- If more than one doctor is involved, they can determine together which one will obtain consent (or hospital policy may provide).
- **REMEMBER, PROCESS, NOT A FORM**

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Informed Consent Process – Physician Documentation

- Physician must document in the medical record discussion with patient
- There are many ways to write a progress note about consent
- Must be done before surgery or procedure
- Can be done in a summary or detailed way
- Patient information sheets can be useful for frequently performed procedures (e.g. “provided pt info sheet on c-section”)

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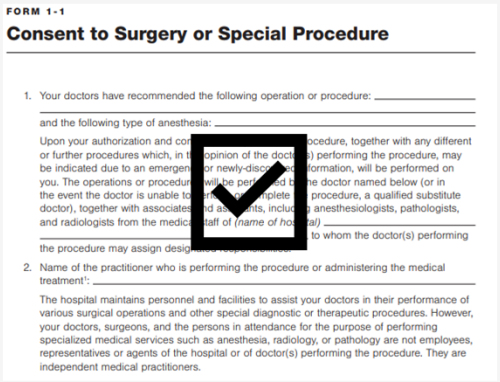
Informed Consent Process – Hospital Documentation

What is the Hospital’s responsibility in the consent process?

The Hospital verifies that the physician obtained informed consent, and this is well documented.



FORM 1-1

Consent to Surgery or Special Procedure

1. Your doctors have recommended the following operation or procedure: _____

and the following type of anesthesia: _____

Upon your authorization and co…ocedure, together with any different or further procedures which, in t…opinion of the doct…) performing the procedure, may be indicated due to an emergen… or newly-disco…formation, will be performed on you. The operations or procedur… will be per…ed b…e doctor named below (or in the event the doctor is unable to …mplete … procedure, a qualified substitute doctor), together with associates …d as…nts, includ… anesthesiologists, pathologists, and radiologists from the medica… staff of *(name of hos…tal)* _____ to whom the doctor(s) performing the procedure may assign desig…

2. Name of the practitioner who is performing the procedure or administering the medical treatment[1]: _____

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, representatives or agents of the hospital or of doctor(s) performing the procedure. They are independent medical practitioners.

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Informed Consent Process – Consent Form

CMS **requires** that the consent form contain at least:

- Name of hospital where treatment will take place
- Name of specific procedure to be performed (medical v. layperson description)
- Name of responsible practitioner who will perform procedure
- Statement that procedure, including anticipated benefits, material risks and alternative therapies have been explained (don't have to write all this on form – but how to prove later?)
- Signature of patient or patient's representative
- Date and time the form is signed by the patient

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Informed Consent Process – Consent Form

CMS's **optional** suggestions for a "well-designed consent form":

- Name of practitioner who conducted IC discussion
- Date, time and signature of witness to patient's signature
- List of material risks discussed
- Statement that other practitioners will be performing tasks w/i policy and skill set (required in first draft — ultimately taken out)
- Statement that non-physician practitioners who are participating in the procedure will stay within scope of practice

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Informed Consent Process – Consent Form

Are witnesses required to sign the consent form?

- There are no specific witnessing requirements for the consent form by CMS, CDPH, or TJC
- There is no need to notarize the consent form
- TJC will ask about witnessing and it is important for staff to know if witnesses are required and who can witness based on hospital policy
- Typical hospital personnel who act as witnesses are admitting staff, RNs and LVNs
- The purpose of the witness signature is to affirm that the patient (or legal representative) has the capacity to make a medical decision, understands that he or she is signing a consent to treatment form, and the signature belongs to the patient (or legal representative).
- The witness is not responsible for the content of the form.

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Informed Consent Process – Consent Form

How long is a consent form good for?

1. 24 hours
2. 6 months
3. Forever
4. 5 years
5. Depends

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Informed Consent Process – Consent Form

Generally, there is no strict rule on how long in advance of the procedure informed consent can or should be obtained. Although some procedures have specific requirements (e.g. sterilization). Otherwise, physician discretion and hospital policy govern.

As a general rule:

- The discussion should occur with sufficient time allowed for the patient to consider his/her decision
- If the patient evidences doubt or confusion, hospital personnel should contact physician to resolve issue

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Informed Consent Process – Consent Form

What if something changes?

- Consent effective until:
  - Revoked, or
  - Circumstances have changed, so as to materially affect the nature of the procedure or risks/benefits - for example, the patient's health has taken a turn for the worse since surgery was originally contemplated
- Then: the patient and doctor should discuss the planned procedure in light of any changes in the benefits, risks or alternatives
- Without documentation, it is almost impossible to prove the further discussion happened
- No need for multiple consent discussions/forms for repeat treatment – debridement, infusion therapy, etc. unless circumstances change as mentioned above

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Informed Refusal

- **Informed refusal is the flip side of informed consent, <u>but</u> also applies to simple and common procedures**

In Truman v. Thomas, the California Supreme Court held that the physician is responsible for assuring that the patient is aware of all the material risks that might result if the patient refuses to consent to not only complex procedures, but also to simple and common procedures if the risk could be significant

> **Truman v. Thomas, 27 Cal.3d 285 (1980)**
> 611 P.2d 902, 165 Cal.Rptr. 308
> Cal.Rptr. 505, 502 P.2d 1.) If a patient indicates that he or she is going to decline the risk-free test or treatment, then the doctor has the additional duty of advising of all material risks of which a reasonable person would want to be informed before deciding not to undergo the procedure. On the other hand, if the recommended test or treatment is itself risky, then the physician should always explain the potential consequences of declining to follow the recommended course of action.

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Risk and Liability

Failure to obtain consent = **battery**!

Failure to disclose nature of procedure, risks, alternatives = **negligence** (malpractice)!

Failure to obtain consent to hospitalization = **false imprisonment**!

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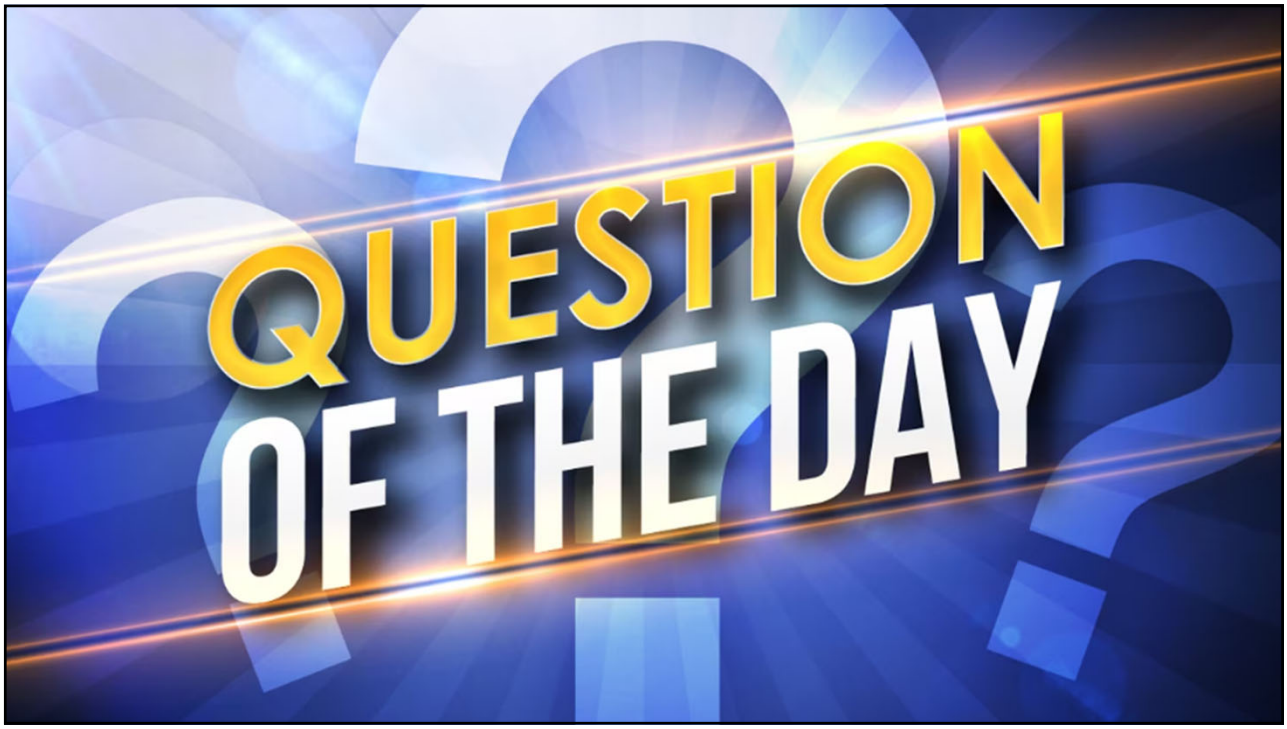

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TRUE OR FALSE?

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If two doctors agree that a patient would benefit from a particular procedure or treatment, the two doctors may consent on behalf of the patient?

FALSE

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Emergency Exception

What's an emergency?

- Immediate services are required for the alleviation of severe pain; or
- Immediate diagnosis and treatment of unforeseeable medical conditions are required, if such conditions would lead to serious disability or death if not immediately diagnosed and treated

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Emergency Exception

Express consent may not be required when there is an **EMERGENCY** and:

1. It's impracticable to obtain consent,
2. Patient mentally incapacitated,
3. No authorized representative available to consent, and reasonable efforts have been to made to contact; and
4. There is no prior refusal for specific treatment to treat emergency.

**CA BPC 2397 → immunity*

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Questions?

Raise your hand to ask a question.

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Thank you!

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