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Legal Considerations of Medical Informed Consent

I Agree


Roadmap

- What is Informed Consent?
- Capacity & Barriers
- Setting Differences
- Types of Consent
- Documentation – Requirements & Recommendations
- Patient Safety Issues
- Battery-Malpractice Concerns

Officer Arrests Utah Nurse

SALT LAKE CITY — A Utah police officer whose rough arrest of a hospital nurse has drawn condemnation, put the woman in handcuffs even after investigators told him not to worry about getting a blood sample he was seeking from a patient, the chief said Friday.

Officers initially wanted the sample as a routine part of a car crash investigation, but after Salt Lake City Police detective Jeff Payne was told he'd need a warrant or formal consent to get it, he arrested Nurse Wubbels.



NBC News, Sep 9, 2017. <https://www.nbcnews.com/news/health/officer-arrested-utah-nurse-after-he-was-told-let-her-4830023>



Officer Arrests Utah Nurse


Why is Consent Required?
Who can give Consent?



What is your Role?
What should you do?




What is Informed Consent?




Common Misunderstandings

- Consent that is not “fully” informed is not informed consent.
- Consent is not a piece of paper. (It is a process.)
- A signature on a form is not informed consent.
- “Consenting a patient” is impossible. (It is the patient that must consent, not you.)
- The purpose of informed consent is to protect the Patient. (It is not for the benefit of the Doctor.)




What is Informed Consent?

- The **PROCESS** of communication between a patient and physician that results in the patient's authorization or agreement to undergo a specific medical intervention (American Medical Association 1998)



What is Informed Consent?


- *It is NOT only a signature or a piece of paper.*
- Failure to obtain informed consent renders a physician liable for negligence or battery and constitutes medical malpractice



What is Informed Consent?

- The Supreme Court of Pennsylvania held that only the physician performing the procedure should be involved in the discussions with patients about whether to have surgery, the risks, and the alternatives.
- A physician's duty to provide information to a patient sufficient to obtain his/her informed consent is non delegable by the physician.

Shinal v. Toms M.D., June 2017




When is it Required?

- In most institutions it is required prior to:
 - Surgery/Procedures
 - Anesthesia
 - Other invasive or complex medical or radiologic procedures

*Laws vary from state to state about exactly when and how formal informed consent must be provided.




Capacity & Barriers




Capacity & Barriers

Capacity means a person's ability to understand the nature and consequences of a decision and to make and communicate a decision, and includes in the case of proposed health care, the ability to understand its significant benefits, risks , and alternatives.



Capacity & Barriers


- Things that MAY or MAY NOT influence capacity:
 - IQ, Intelligence Level
 - Mental illness (Legal Competence)
 - Dementia
 - Severity of illness
 - Fear, Apprehension
 - Age (Minor, Advanced)



Capacity & Barriers

Patient Factors:


- Low health literacy
- Limited English proficiency
- Cognitive impairments
- Confusion about the purpose of consent process
- Feeling of intimidation, stress or time pressure



Capacity & Barriers

Provider Factors:


- Lack of time for up-front patient education
- Overly complex or overly broad written materials
- Lack of support with interpreters
- Wrong assumptions about patient comprehension




Capacity & Barriers

Poorly Written Forms [Bottrell et al 2000]

- Analysis of 540 informed consent forms from 157 hospitals
 - Only 26% included all of the following elements (Nature of procedure, Risks, Benefits, Alternatives)
 - Less than 50% of the forms provided specific information about risks
 - Alternatives were noted only in 57% of forms




Setting Differences



Setting Differences


- Research
- Hospital
- Ambulatory
- Emergency
- Clinic
- Behavioral Health



Setting Differences – ASC

CFR §416.40 Condition for Coverage:
Compliance With State Licensure Law


- The ASC must comply with State licensure requirements.



Setting Differences - ASC

§416.47 Condition for Coverage: Medical Records
The ASC must maintain complete, comprehensive, and accurate medical records to ensure adequate patient care.


- §416.47(b)(7) Documentation of properly executed informed patient consent



Setting Differences - ASC

Interpretive Guidelines: §416.47(b)


- The medical record must contain all of the required elements listed in the regulation.



Setting Differences - ASC

Interpretive Guidelines: §416.47(b)


- Documentation of a properly executed informed patient consent. A well-designed informed consent process would most likely include a discussion of the following elements:



Setting Differences - ASC

Interpretive Guidelines: §416.47(b)

- A description of the proposed surgery, including the anesthesia to be used;
- The indications for the proposed surgery;
- Material risks and benefits for the patient related to the surgery and anesthesia, including the likelihood of each, based on the available clinical evidence, as informed by the responsible practitioner's clinical judgment;
- Treatment alternatives, including the attendant material risks and benefits

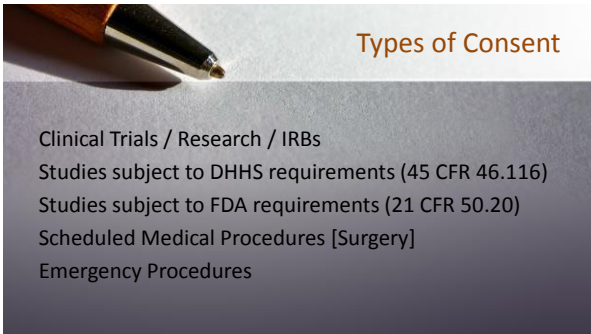


Setting Differences - ASC

Interpretive Guidelines: §416.47(b)

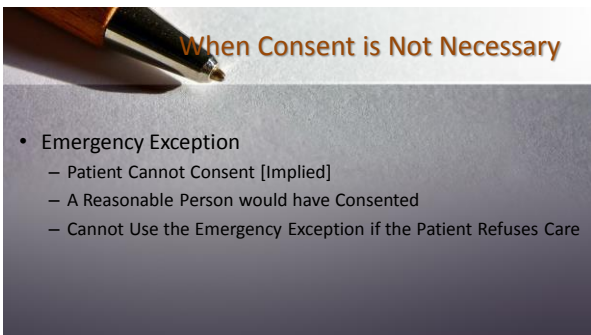
- Who will conduct the surgical intervention and administer the anesthesia;
- Whether physicians other than the operating practitioner will be performing important tasks related to the surgery. .
- Whether, as permitted by State law, qualified medical practitioners who are not physicians will perform important parts of the surgery or administer the anesthesia, and if so, the types of tasks each type of practitioner will carry out; and that such practitioners will be performing only tasks within their scope of practice for which they have been granted privileges by the ASC.





Types of Consent

- Clinical Trials / Research / IRBs
- Studies subject to DHHS requirements (45 CFR 46.116)
- Studies subject to FDA requirements (21 CFR 50.20)
- Scheduled Medical Procedures [Surgery]
- Emergency Procedures



When Consent is Not Necessary

- Emergency Exception
 - Patient Cannot Consent [Implied]
 - A Reasonable Person would have Consented
 - Cannot Use the Emergency Exception if the Patient Refuses Care




When Consent is Not Necessary

- Consent by a Guardian or Parent
- Court Ordered Care
- Some Public Health Treatments




Documentation Requirements & Recommendations



Documentation Requirements & Recommendations


- Nature of procedure
- Risks
- Benefits
- Alternatives
- Any discussions with Patient-Family

*See State Medical Board also




Documentation
Requirements & Recommendations

- Ensure correct consent document is being utilized by those performing consent.
- Include new version number or date when making an Amendment to the consent.




Documentation
Requirements & Recommendations

- Track and document re-consent when necessary.
- Verify necessary signatures, initials and date.




Patient Safety Issues



Patient Safety Issues


Components of an Acceptable Informed Consent

- **Decision-Making Capacity**
- **Complete Disclosure**
- **Understanding**
- **Authorization**



Patient Safety Issues

- Informed Consent helps ensure the correct procedure is scheduled and performed
- Increased levels of institutional quality (e.g., compliance with law and accreditation standards)




Patient Safety Issues

- Potential time and money savings related to reduced litigation
- Greater patient satisfaction




Battery-Malpractice Concerns



Battery-Malpractice Concerns


Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent, commits an assault, for which they are liable in damages.

Schloendorff v. Society of New York Hospital, 105 N.E. 92 (N.Y. 1914)



Battery-Malpractice Concerns

- Battery is any intentional offensive touching without consent or lawful justification.
- The contact can be harmful & cause injury, or it can merely be offensive to the patient's personal dignity.
- It also results when a procedure is performed beyond the scope of consent [Wrong surgery, med, etc.].
- Patient consent may be revoked or withdrawn.



Battery-Malpractice Concerns

- The foundation for informed consent requirements in the United States grew from the common law action in battery (i.e., the right of an individual to be protected from nonconsensual touching).




Battery-Malpractice Concerns

Classic Intentional Tort

- Elements
 - Intent
 - Harmful or Offensive Touching
 - Damages
- Rejected if there is Consent
- Generally not Insured



What Can We Do to Improve




What Can We Do to Improve

1. Improve your written consent forms and related written educational materials
 - Readability (5th grade level)
 - Layout and Design
 - Language[s]




What Can We Do to Improve

2. Improve your informed consent process
 - Create the time for the process
 - Simplify the language
 - Allow time for questions
 - Make sure the patient understands
 - Plan for language assistance in advance of appointment



What Can We Do to Improve


3. Improve understanding of the informed consent process and the responsibilities and liabilities to health care organizations
 - Train support staff, nursing, administrators, interpreters, etc.



What Can We Do to Improve


4. Audit your records

- When looking at the document it should be clear when the patient was consented. The physician consents the patient and the witness will "witness" the signatures. Everyone is present together for a consent.
- It should be evident what date and time the patient was consented.



Closing Thoughts for Success

- Educate everyone involved in the process
- Follow requirements & regulations
- Document appropriately
- Ensuring patient safety
- Avoiding misunderstandings
- Collaborate with others





QUESTIONS?

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