Contact your on-site risk management designee when you have questions about clinical issues that are risk management related.

Shands at AGH..(352)733-0115 or 733-0111 x71113

Shands at Lake Shore.....(386) 754-8128

Shands at Live Oak.....(386) 362-0800

Shands at Starke.....(904) 368-2300

Shands at Vista/Rehab.....(352) 265-5491 x70022

Shands at the University of Florida (352)265-0002

Shands Jacksonville.....(904) 244-3477

Shands Clinics/Gainesville.....(352) 265-0002

Shands Clinics/Jacksonville.....(904) 244-3477

UF Clinics/Gainesville .....(352) 265-8067

UF Clinics/Jacksonville.....(904) 244-4094

UF Dental Clinics.....(352) 392-2911

Please refer patients with concerns to your facility Patient Representative.

Additional educational material can be obtained through the Gainesville UF Self-Insurance Program office.

- Basics in Risk Management
- Capacity to Consent
- Good Care, Bad Documentation
- Agency Reporting
- Practical Legal Knowledge
- Credentialing, Peer Review and Medical Staff Monitoring
- Retained Foreign Bodies
- Disclosure of Adverse Events and Accountability
- Pressure Ulcers Prevention
- Emergency Medical Treatment and Labor Act (EMTALA)

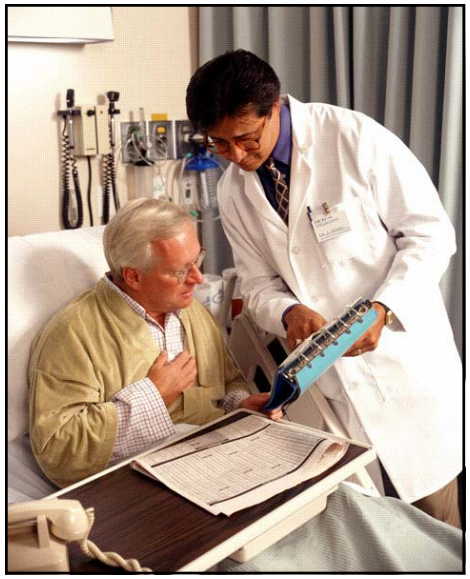
UF UNIVERSITY of FLORIDA

The Foundation for The Gator Nation

University of Florida
Self-Insurance Program
Risk Management and Loss Prevention
P. O. Box 112735
Gainesville, FL 32611
Phone: (352) 273-7006
Fax: (352) 273-7287
Website: www.sip.ufl.edu
e-mail: rmeduc@shands.ufl.edu

Basics in Consent

What Every Practitioner Needs to Know



04/06/09

WHAT IS INFORMED CONSENT?

It is consent given after being provided sufficient information with which to make a knowledgeable decision about care and in which there is opportunity to have questions asked and answered to the satisfaction of the patient.

FLORIDA MEDICAL CONSENT LAW §766.103, FLA. STATS.

There is no recovery under the law when consent is obtained in accordance with accepted medical practice, and it provides a reasonable person with these required elements:

- Enough information to formulate a general understanding of the procedure to be performed,
- The medically acceptable alternatives,
- An explanation of substantial risks and hazards, or
- The patient would have reasonably undergone the procedure had they been given that information.

CMS CONDITIONS OF PARTICIPATION FOR HOSPITALS, 42CFR482.51(b)(2)

Pertaining to perioperative services … "A properly executed informed consent form for the operation must be in the patient's chart before surgery except in emergencies."

ARE THERE EXCEPTIONS TO OBTAINING INFORMED CONSENT?

- Yes, pursuant to §401.445, Fla. Stats., "Emergency examination and treatment of incapacitated persons;" there are certain scenarios wherein deferring treatment to obtain consent would be detrimental to the patient.
- In emergency situations where an incapacitated patient has a life-threatening condition needing immediate treatment or prognosis for recovery will be severely effected and there is no surrogate or proxy to provide consent.
- It is important to document emergent nature of situation, patient incapacity, reasonable attempts made unsuccessfully to locate a surrogate or proxy.
- Such a situation and all pertinent information is then explained to the surrogate or proxy, when located, or to the patient as soon as capacity had been regained.

WHAT IS THE DEFINITION OF "RISKS & HAZARDS"?

Patients have always wanted to know the truth. The more likely and severe the "risks & hazards," the more they want to know. Although the law does not specifically define what ***substantial risks and hazards*** are, case law indicates that these include:

- Risks that occur frequently enough to be considered "known and recognized."
- Risks that result in significant deficit for the patient (such as paralysis, stroke, death) even if they occur infrequently.

WHO CAN OBTAIN CONSENT?

Based on §766.103, Fla. Stats., physicians, chiropractors, podiatrists, dentists, ARNPs and PAs can obtain consent. However, pursuant to 64B8-9.007(1), Florida Administrative Code, the Florida Board of Medicine views obtaining consent as a physician non-delegable duty irrespective of what other professional regulatory boards deem is appropriate for their own professionals**. Irrespective of what may be included on a standardized consent form, it is critical that the practitioner have a discussion with the patient and then confirm in his/her own mind that the patient understands.** Pursuant to §458.331(1)(w), Fla. Stats., delegating tasks to those not qualified by training, experience, or professional licensure to perform them is grounds for disciplinary action.

WHAT IS THE ROLE OF PHYSICIAN EXTENDERS AND HOSPITAL STAFF?

In all Shands facilities, they may assist in monitoring the process by performing administrative duties such as getting the consent form signed by the patient, witnessing the patient's signature on the form, and checking to see if the patient has any additional questions that need to be answered. If so, the physician should be notified.

DO PRACTITIONERS EVER GET SUED FOR MALPRACTICE OVER CONSENT ISSUES?

Yes, it happens all the time. Although that may not have been the initial allegation in the lawsuit, when complications of surgery are involved plaintiff attorneys will always examine the consent to see if it was complete. Failure to properly document the process makes it difficult to defend and can result in an insurance carrier settling a case that might have otherwise been defensible.

MUST I OBTAIN A "WRITTEN" INFORMED CONSENT?

Informed consent is a "process," that should always be documented in a progress note as well as on the facility's approved consent form. It is critical to obtain written informed consent (patient signature) when significant risks to the patient are associated with the procedure being performed. An incomplete form could be misinterpreted during litigation.

MUST I USE A STANDARD FORM?

No, but it is highly recommended. You are more likely to include all statutorily and Joint Commission required elements using a standardized form. Most facilities provide a template to assist in the process that can be "customized" for procedures that are performed often or are complicated and put the patient at significant risk for complication.

WHAT DOES THE JOINT COMMISSION REQUIRE?

Patient Rights—RI.2.30, RI.2.40, RI.2.60, RI.2.70, RI.2.100

- Nature of proposed treatment.
- Potential benefits and risks and side-effects.
- Potential problems with recuperation.
- Likelihood of success.
- Possible results of non-treatment.
- Significant alternatives and related benefits, risks and side-effects, including possible results of not receiving care.
- Name of physician responsible for primary care and name of physician performing treatment.
- Relationship to facility/physician and conflicts of interest.
- When indicated, any limitations on the confidentiality of information learned from or about the patient.
- Patients may refuse care. In these instances, the possible ramifications from such action must be relayed.
- Information shared in manner patient understands.

OTHER POTENTIAL IMPACT

- Licensure investigation by applicable regulatory board.
- Disciplinary action by the facility in which you practice with report to National Practitioner Data Bank.
- Claim outcome reported to Department of Insurance; posted on internet.
- Initiation of an assault/battery lawsuit.
- Loss of managed care contracts.
- Harm to professional reputation.