THE UNIVERSITY OF IOWA HOSPITALS AND CLINICS

POLICY AND PROCEDURE MANUAL

SUBJECT: Protocol for Documentation of Informed Consent	POLICY NUMBER: V.07
SOURCE (DEVELOPED BY): Professional Practice Subcommittee	ONLINE REFERENCE: http://policies.uihc.uiowa.edu
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POLICY

Care is provided to patients of the University of Iowa Hospitals and Clinics based on the best judgment of the physician and the informed consent of the patient. Patients are entitled to information concerning the medical necessity, possible risks, and known alternatives prior to the initiation of care, unless the emergent nature of the patient's condition precludes such a discussion.

For certain diagnostic and therapeutic procedures, it is deemed prudent to document the patient's informed consent by securing the signature of the patient or the patient's legal representatives on a form approved by the Medical Records Subcommittee. In some cases, the consent of the patient's legal representative must be obtained, but the representative is not available to UIHC. In such cases, the physician can document informed consent through the mechanism of the monitored telephone call.

If the patient is unable to consent and there is no legal representative available, either in person or through a monitored telephone call, procedures may be performed only if the patient's condition is emergent and delay poses a threat to life or a significant body function. Two staff physicians must concur in the determination of the emergency and document their concurrence in the patient's medical record. In certain life-threatening situations, time may not permit contacting a legal representative or placing a phone call; emergency procedures may then be performed without consent.

Although any physician/dentist/physician assistant or advanced registered nurse practitioner may seek to document informed consent for any procedures they perform, they <u>are required to obtain the signature of the patient or patient's legal representative prior to performing the following categories of procedures</u>:

1) <u>Any procedure performed under general, spinal or epidural anesthesia</u>.

2) Elective procedures with significant potential for or actual cosmetic effects. (Procedures in this category include, but are not limited to scar revision, removal of lesions from the face involving incision, skin graft, dermabrasion, blepharoplasty, rhinoplasty.)

NOTE: Routine procedures not included in this category: acne surgery, superficial dermatologic electrodissection, and cryosurgery for warts.

3) Elective procedures with potential or actual functional significance. (Procedures in this category include, but are not limited to tendon repair, arthroscopic surgery, incision neuromas, lymph node dissection, procedure potentially affecting vision and hearing, dilation of the urethra.)

4) Major therapeutic and diagnostic interventions and procedures with known material risks. (Procedures in this category include but are not limited to: a) organ biopsies; b) bone marrow transplantation; c) laser therapy; d) brachytherapy; e) lithotripsy (gall bladder, biliary tree, kidney stone); and f) cardiovascular procedures including but not limited to cardiac catheterization, angiography, intra-aortic balloon counter-pulsation, angioplasty, valvuloplasty, central arterial lines, and central venous lines.)

NOTE: Intensive Care Units may establish policies defining certain procedures within this category as routine care within the unit. Documentation of informed consent for such procedures will not be required provided the unit has established a mechanism (e.g., brochures, videotapes) that provide adequate means for communicating effectively the risks and benefits of these intensive care procedures.

5) Procedures that enter a body cavity. (Procedures in this category include, but are not limited to lumbar puncture, bone marrow biopsy, paracentesis, amniocentesis or amnioscopy, laparoscopy, thoracentesis, pericardiocentesis, tracheostomy, bronchoscopy, chest tube placement.)

NOTE: Routine procedures not included in this category: peripheral intravenous and arterial lines, routine urinary catheter placement, arthrocentesis, joint, tendon sheath and bursa injections, and nasogastric tubes.

NOTE: Intensive Care Units may establish policies defining certain procedures within this category as routine care within the unit. Documentation of informed consent for such procedures will not be required provided the unit has established a mechanism (e.g., brochures, videotapes) that provide adequate means for communicating effectively the risks and benefits of these intensive care procedures.

6) Procedures with potential for perforation into a body cavity. (Procedures in this category include, but are not limited to upper gastrointestinal endoscopy, sigmoidoscopy, colonoscopy, biliary endoscopy, bronchoscopy, cystourethroscopy, renal endoscopy.)

7) Diagnostic or therapeutic procedures that include administration of diagnostic agents with risk of significant reaction. (Procedures in this category include but are not limited to angiography, myelography and hysterosalpingography.)

    NOTE: Routine procedures not included in this category: contrast gastrointestinal studies, intravenous pyelography, computerized tomography, magnetic resonance imaging and radiotracer studies.

8) Procedures related to reproductive system. (Procedures in this category include, but are not limited to amnioscopy, amniocentesis, IUD placement, tubal ligation or tubalplasty, abortion, vasectomy or ductal repair, artificial insemination, circumcision, prostatic or testicular surgery.)

    NOTE: Routine procedures not included in this category: routine urinary catheter placement, cultures, PAP smears and routine pelvic exams.