AHC Media

October 26, 2016

Informed Consent
Meeting CMS, TJC & DNV Requirements

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Speaker

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Objectives

- Describe the six minimum requirements that are now mandatory to be in the informed consent form for surgery performed at a hospital that receives Medicare funding.
- Explain why the CMS and accreditation standards applicable to your facility should be reflected in the hospital's policies and procedures.
- Explain new and revised standards, regulations, and laws put forth by CMS, DNV, TJC and the federal government.
- Evaluate compliance requirements and penalties.

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Introduction into Informed Consent

Consent Forms Missing in 66% of Surgeries

- OR is expected to work like clockwork
- Study found that consent forms were missing for 66% of surgeries
  - Problem if the timed antibiotics have been started
- This delayed 10% of all surgical procedures
- Cost of lost or misplaced consents cost average hospital $580,000 each year
- Study done by researchers at the prestigious Johns Hopkins University, Aug 2013

Consent Forms Missing in 66% of Surgeries


PSQH
PATIENT SAFETY & QUALITY HEALTHCARE
LUCIAN LEAPE INSTITUTE
6TH ANNUAL FORUM & GALA
New Research from Johns Hopkins – The Case of the Missing Consent Form
By Timothy Kelly, MS, MBA
The operating room is one place in a hospital where things are expected to run like clockwork – it is imperative that surgical procedures start on time. When delays occur, the impact can be significant: staff and equipment are underutilized, surgeons become frustrated, patients grow (more) anxious and optimum outcomes may be placed at risk, particularly if the prior administration of medications or antibiotics had been timed to the projected start of a procedure. It is thus alarming that a recent study in JAMA Surgery found that 10 percent of surgical procedures were delayed due to a missing piece of paper – the consent form.[1]
Researchers at the Johns Hopkins University School of Medicine found that consent forms were missing for 66% of surgical patients, which resulted in one out of ten cases being delayed. As a consequence, 43% obtain consent from a patient for whom the form was missing. Also of concern, only 47% of those residents reported that they felt comfortable obtaining consent for major procedures. The study also found that on average, residents spent less time obtaining consent from patients than did attending physicians and that disparity became more pronounced when residents obtained a patient's consent at the last minute.
Cost of Delays and Patient Dissatisfaction
The problem of lost or misplaced consents is both ubiquitous and extremely costly. It has been estimated that operating room delays resulting from these missing documents cost the average hospital $580,000 each year.[2] Fortunately, the application of technology can virtually eliminate this problem. Ten years ago the Department of Veterans Affairs (VA) implemented an automated informed consent software program that stores signed consent forms directly to the electronic health record – the VA reports that misplaced or lost consent forms have significantly decreased following their adoption of this electronic system.[3]
Inefficiency is only one consequence of a missing consent form. The Hopkins researchers noted that obtaining consent in the hurried environment of the preoperative area may

Which Informed Consent Provision?

- Need to know which standards and guidelines apply to you
- There are usually more than one that apply
- Hospitals that accept Medicare and Medicaid must follow the CMS Hospital CoPs
- There is a separate CoP for Critical Access Hospitals (CAH) and PPS Hospitals
  - Tag 304 and 320
- Every state has a specific state law

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Which Informed Consent Provision?

- Separate consent form is required for research that is conducted
- If facility is accredited by the Joint Commission (TJC) then need to follow that accreditation program's standard (no longer called JCAHO)
- Or other accreditation organization: DNV Healthcare, CIHQ (Center for Improvement in Healthcare Quality) and AOA Healthcare Facility Accreditation Program also have deemed status from CMS

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CMS Hospital CoP Deficiency Reports

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Access to Hospital Complaint Data

- CMS issued Survey and Certification memo on March 22, 2013 regarding access to hospital complaint data and quarterly since then
- Includes acute care and CAH hospitals
  - Does not include the plan of correction but can request
  - Questions to bettercare@cms.hhs.com
- This is the CMS 2567 deficiency data and lists the tag numbers
- Updates quarterly
  - Available under downloads on the hospital website at www.cms.gov

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Access to Hospital Complaint Data

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop: C2-21-16
Baltimore, Maryland 21244-1850

CMS

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 13-21- ALL

DATE: March 22, 2013

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Access to Statements of Deficiencies (CMS-2567) on the Web for Skilled Nursing Facilities, Nursing Facilities, Hospitals, & Critical Access Hospitals

Memorandum Summary

- ***Survey Findings Posted on http://www.cms.gov:*** In July 2012, the Centers for Medicare & Medicaid Services (CMS) began posting redacted Statements of Deficiencies (CMS-2567s) for skilled nursing facilities and nursing facilities on *Nursing Home Compare*. In March 2013, CMS began posting CMS-2567s for short-term acute care hospitals and critical access hospitals (CAHs) for surveys based on complaint investigations. This memorandum describes the contents and location of these files.
- ***Other Web-based Tools Based on These Data:*** At least two additional websites, provided by private parties (*ProPublica* and the Association for Health Care Journalists), publish information based on the CMS-2567 data. These websites are independent of CMS. CMS does not endorse or sponsor any particular private party application.
- ***Plans of Correction (POC):*** The posted CMS data do not contain any POC information. State Survey Agencies (SAs) and CMS Regional Offices (RO) may see an increase in requests for both the CMS-2567 and any associated POCs.
- ***Question & Answers:*** We plan to issue an update to this memorandum that will include an attachment of frequently asked questions in order to provide answers to other queries that may arise.

Background – Nursing Home Survey Findings

In July 2012, CMS began posting nursing home statements of deficiencies, derived from the Form

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Updated Deficiency Data Reports

www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/Hospitals.html

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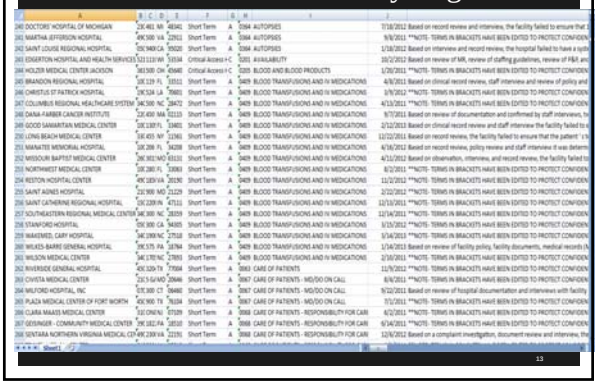
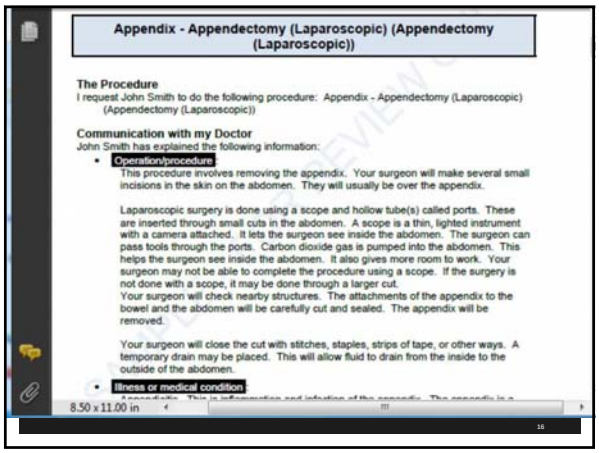
Can Count the Deficiencies by Tag Number



Informed Consent Deficiencies July 27, 2016

Tag Number	Section	Number of Deficiencies
131	Consent	208
466	Consent	52
955	Consent	44 Total 304

Introduction into the CMS Hospital CoPs



Informed Consent

- CMS has regulations that all hospitals must follow that accept Medicare reimbursement
- Must follow the hospital CoP for all patients and not just Medicare or Medicaid patients
- CMS takes the federal regulation and adds directions to the surveyors on how to survey
- Called the CMS Interpretive guidelines for the Conditions of Participation (CoPs)
- Has three sections on informed consent

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Informed Consent

- All are different so must read together
- Interpretive guidelines published more frequently now
- CMS PPS hospital manual has **three** sections on consent (Appendix A)
- CAH (25 bed hospital or less) has two section in Tag C-0304 and C-0320 (Appendix W)
- If CAH has a separate Rehab or Behavioral Health distinct unit and then follow the PPS Hospital CoPs (Appendix A)

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Informed Consent 3 Sections in CMS Manual

- **Informed decisions** (Tag A-131 Patient Rights)
- **Medical records** with minimum requirements for consent form (Tag A-465)
- **Surgical services** (Tag A-955)
  - Hospitals may want to have one person go out once a month and check for any updated manual
  - Also check for any new CMS survey memos
  - When issues survey memos, CMS reserves the right to tinker with the language, and when final publishes it in a transmittal and then updates the manual

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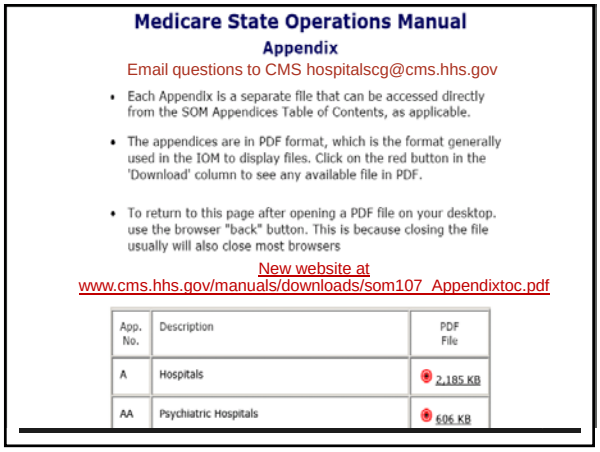


Medicare State Operations Manual

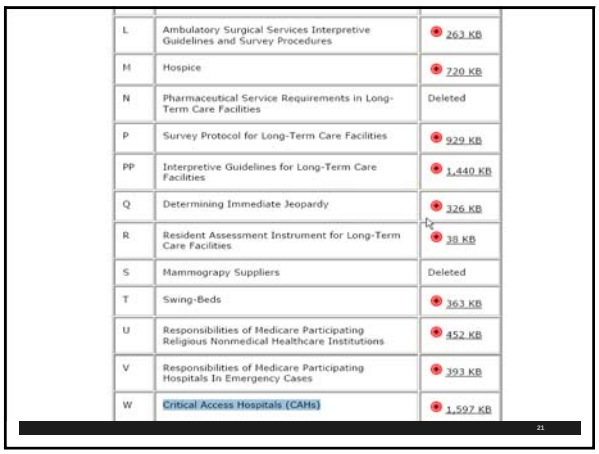
Appendix

Email questions to CMS hospitalscg@cms.hhs.gov

- Each Appendix is a separate file that can be accessed directly from the SOM Appendices Table of Contents, as applicable.
- The appendices are in PDF format, which is the format generally used in the IOM to display files. Click on the red button in the 'Download' column to see any available file in PDF.
- To return to this page after opening a PDF file on your desktop, use the browser "back" button. This is because closing the file usually will also close most browsers

New website at www.cms.hhs.gov/manuals/downloads/som107_Appendixtoc.pdf

App. No.	Description	PDF File
A	Hospitals	2,185 KB
AA	Psychiatric Hospitals	606 KB



L	Ambulatory Surgical Services Interpretive Guidelines and Survey Procedures	263 KB
M	Hospice	720 KB
N	Pharmaceutical Service Requirements in Long-Term Care Facilities	Deleted
P	Survey Protocol for Long-Term Care Facilities	929 KB
PP	Interpretive Guidelines for Long-Term Care Facilities	1,440 KB
Q	Determining Immediate Jeopardy	326 KB
R	Resident Assessment Instrument for Long-Term Care Facilities	38 KB
S	Mammograpy Suppliers	Deleted
T	Swing-Beds	363 KB
U	Responsibilities of Medicare Participating Religious Nonmedical Healthcare Institutions	452 KB
V	Responsibilities of Medicare Participating Hospitals In Emergency Cases	393 KB
W	Critical Access Hospitals (CAHs)	1,597 KB

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CoP Manual Also Called SOM

State Operations Manual
Appendix A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

Table of Contents
(Rev. 151, 11-20-15)

www.cms.hhs.gov/manuals/downloads/som107_Appendixtoc.p

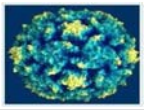
Transmittals for Appendix A

Survey Protocol

Introduction
- Task 1 - Off-Site Survey Preparation
- Task 2 - Entrance Activities
- Task 3 - Information Gathering/Investigation
- Task 4 - Preliminary Decision Making and Analysis of Findings
- Task 5 - Exit Conference
- Task 6 – Post-Survey Activities

Psychiatric Hospital Survey Module
Psychiatric Unit Survey Module
Rehabilitation Hospital Survey Module
Inpatient Rehabilitation Unit Survey Module
Hospital Swing-Bed Survey Module
Regulations and Interpretive Guidelines

Email questions **hospitalscg@cms.hhs.gov**



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CAH Appendix W

State Operations Manual
Appendix W - Survey Protocol, Regulations and Interpretive Guidelines for Critical Access Hospital (CAHs) and Swing-Beds in CAHs

(Rev. 149, 10-09-15)

Transmittals for Appendix W

INDEX

Survey Protocol

Introduction
Regulatory and Policy Reference
Tasks in the Survey Protocol
Survey Team
Task 1 - Off-Site Survey Preparation
Task 2 - Entrance Activities
Task 3 - Information Gathering/Investigation
Task 4 - Preliminary Decision Making and Analysis of Findings

www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107_Appendixtoc.pdf

271 Pages

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CMS Updated Website www.cms.gov

How to Keep Up with Changes

- First, periodically check to see you have the most current CoP manual[1]
- Once a month go out and check the survey and certification website [2]
- Once a month check the CMS transmittal page [3]
- Have one person in your facility who has this responsibility

- [1] http://www.cms.hhs.gov/manuals/downloads/som107_Appendicestoc.pdf
- 2 http://www.cms.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage
- 3 http://www.cms.gov/Transmittals

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CMS Survey and Certification Website

www.cms.gov/SurveyCertificationGenInfo/PMSR/list.asp#TopOfPage

Click on Policy & Memos to States

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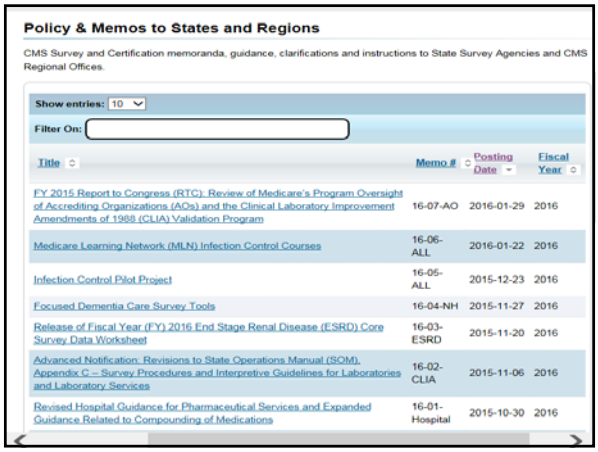
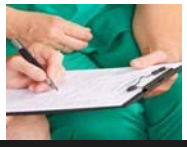


Transmittals

CMS Hospital CoPs

Informed Consent
Standards for Hospitals



Consent Informed Decisions 131

- **Standard:** The patients or their representatives has the right to make informed decisions regarding their care.
- This includes the right to be informed of their health status, be involved in the care planning, and can request or refuse treatment
- The right to make informed decisions means the patient is given information in order to be able to make this decision
- This is important to make sure informed consent is given

Informed Decision Making Tag 131

- The patient must be able to request or refuse treatment
- This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate
- Patient has right to delegate decision making to another person to the degree permitted by state law
- Patient has DPOA but it doesn't become effective until patient is mentally incompetent
- Competent patient can designate a decision maker (best to get in writing)

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Consent & Informed Decisions 131

- Competent patient asks someone to be their representative, orally or in writing, then person must be given information on informed decisions about patient care
  - So both the competent patient is given information along with the personal representative (PR) such as the patient advocate/support person (care partner)
  - This included getting informed consent from them when required including patient advocate
- CMS states "The hospital must **also** seek the written consent of the patient's representative when informed consent is required for a care decision."

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Consent of Patient and PR

- *When a patient who is not incapacitated has designated, either orally to hospital staff or in writing, another individual to be his/her representative, the hospital must provide the designated individual with the information required to make an informed decision about the patient's care. The hospital must also seek the written consent of the patient's representative when informed consent is required for a care decision. The explicit designation of a representative by the patient takes precedence over any non-designated relationship and continues throughout the patient's inpatient stay or outpatient visit, unless expressly withdrawn, either orally or in writing, by the patient.*

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Patient Rights

- Extends to the right to be informed in planning for discharge in post acute setting (home health, hospice, long term care)
- CMS requires that a written list be given to patient and documented in chart for LTC and HHC choices
  - Proposed changes will include 4 PACs
- Hospital must have P&P to assure right to request or refuse treatment
- Policies must address how patient request will be handled
- No obligation to medically unnecessary or inappropriate care

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Make Sure Hospital P&P Address:

- Right to make informed decisions and how to assure patient's ability to exercise this right
- Delegation of patient's right to representative
- How patients will be involved in their care planning and treatment
- Patient requests for treatment and circumstances in which request can be denied
- Policy must include any state laws on patient rights

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Advance Directives 132

- Patient has a right to formulate advance directives and to have hospital staff and practitioners follow these directives
- In advance directives can delegate decision making to another person
  - Can be DPOA or mental health care proxy who give **consent** if patient incapacitated
- Patient may also delegate support person to exercise visitation rights
  - Also referred to a the patient advocate/support person
- Designation in the AD takes precedence

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Medical Record Section on Informed Consent

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Medical Records 465 2cd Section

- Must have properly executed informed consent forms for procedures and treatments specified by the medical staff
  - or by Federal or State law if applicable, to require written patient consent
- Medical record must contain an informed consent for procedures and treatments specified as requiring one
- Medical staff by-laws should address this

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Medical Records Requirements

- Consider state laws requiring informed consent such as for invasive procedures
- Consider any federal laws such as informed consent for research
- The **list of procedures** should be the ones that physicians have privileges to do
- Add new ones to the list as physician request additional privileges
- Ones with risks should require a consent form

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List of Procedures

Procedure Name	Requires Informed Consent
Ablations	Yes
Amniocentesis	Yes
Angiogram	Yes
Angiography	Yes
Angioplasties	Yes
Arthrogram	Yes
Arterial Line insertion (performed alone)	Yes
Aspiration Cyst (simple/minor)	No
Aspiration Cyst (complex)	Yes
Blood Administration	Yes
Blood Patch	Yes
Bone Marrow Aspiration	Yes
Bone Marrow Biopsy	Yes
Bronchoscopy	Yes
Capsule Endoscopy	Yes
Catherizations, Cardiac & Vascular	Yes
Cardioversion	Yes

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Informed Consent Forms

- Need for **all** surgeries except in emergencies
- All inpatients and outpatients
- For all procedures specified
- Needs to reflect a process
- Form must follow policies
- Must include state or federal requirements
- Must contain 6 minimum requirements (mandatory)

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Minimum (Mandatory) Elements Required

- Name of the hospital where the procedure or other type of medical treatment is to take place
- Name of the specific procedure, or other type of medical treatment for which consent is being given
- Name of the responsible practitioner who is performing the procedure or administering the medical treatment

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Mandatory Elements Required

- Statement that the procedure or treatment, including the anticipated benefits, material risks, and alternative therapies, was explained to the patient or the patient's legal representative
- Same discussion of likelihood and severity
- Signature of patient or representative
- Date and time signed by patient
- Any applicable state law requirements

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CMS Well Designed Elements (Optional)

- Hospitals can adopt **optional** elements which CMS calls well designed elements
- Therefore, physicians and others practicing in the hospital need to review the hospital's policy to determine what other elements have been adopted
- Also be aware of any informed consent requirements in the medical staff bylaws or rules and regulations

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Optional Elements May Include:

- Name of the practitioner who conducted the informed consent discussion with the patient or the patient's representative
- Date, time, and signature of the person witnessing the patient or the patient's legal representative signing the consent form
- Indication or listing of the material risks of the procedure or treatment that were discussed with the patient or the patient's representative

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Optional Elements May Include:

- Statement, if applicable, that physicians other than the operating practitioner,
- Including but not limited to residents,
- That will be performing **important tasks** related to the surgery,
- In accordance with the hospital's policies and, in the case of residents,
- Is based on their skill set and under the supervision of the responsible practitioner

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Optional Elements May Include:

- Statement, if applicable, that QMP, who are not physicians,
- Who will perform important parts of the surgery or administration of anesthesia
- And who will perform only tasks that are within their scope of practice,
- As determined under State law and regulation, and for which they have been granted privileges by the hospital.

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Survey Procedure

- Verify hospital has assured MS has created a list of procedures and treatments that require consent
- Verify informed consent forms have elements listed as minimum elements
- Compare hospitals standard informed consent form to their policies to make sure consistent
- Make sure any state law requirements are there

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Survey Procedure

- These are directions to the surveyor
- Review six medical records for patient undergoing or who have had surgery or procedure or treatment that requires consent
- Verify each medical record has informed consent forms
- Verify each consent form has minimum elements required

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Informed Consent Surgery Section

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Surgical Services 3rd Section 955

- What does the regulation say?
- **Standard**: A properly executed informed consent form for the operation must be in the patient's chart before surgery, except in emergencies
  - Purpose of process is to ensure patient or representative is given information to evaluate a proposed surgery before agreeing to it
  - Discuss short and long term risks

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Surgical Services Guidelines

- Benefits to the proposed interventions
- The likelihood of each based on:
  - Clinical evidence
  - Practitioner's professional judgment
- Informed consent must be in the Medical Record prior to surgery
- Except in case of emergency surgery
- **"Surgery"** includes any procedure specified by the medical staff and that is listed as a surgery by ACS

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Surgical Services

- Hospital must assure practitioner responsible for surgery has obtained informed consent
- Must be in manner consistent with P&P
- Anesthesia consent went from requirement to recommendation but ASA recommends a consent
- Should mandate anesthesia consent for other invasive procedures and surgeries

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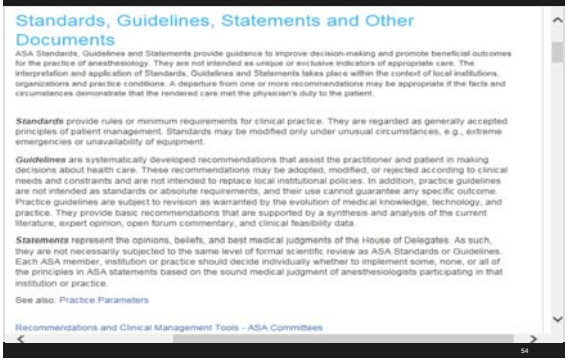
ASA Standards and Guidelines



Standards, Guidelines, Statements and Other Documents

ASA Standards, Guidelines and Statements provide guidance to improve decision-making and promote beneficial outcomes for the practice of anesthesiology. They are not intended as unique or exclusive indicators of appropriate care. The interpretation and application of Standards, Guidelines and Statements takes place within the context of local institutions, organizations and practice conditions. A departure from one or more recommendations may be appropriate if the facts and circumstances demonstrate that the rendered care met the physician's duty to the patient.

Standards provide rules or minimum requirements for clinical practice. They are regarded as generally accepted principles of patient management. Standards may be modified only under unusual circumstances, e.g., extreme emergencies or unavailability of equipment.

Guidelines are systematically developed recommendations that assist the practitioner and patient in making decisions about health care. These recommendations may be adopted, modified, or rejected according to clinical needs and constraints and are not intended to replace local institutional policies. In addition, practice guidelines are not intended as standards or absolute requirements, and their use cannot guarantee any specific outcome. Practice guidelines are subject to revision as warranted by the evolution of medical knowledge, technology, and practice. They provide basic recommendations that are supported by a synthesis and analysis of the current literature, expert opinion, open forum commentary, and clinical feasibility data.

Statements represent the opinions, beliefs, and best medical judgments of the House of Delegates. As such, they are not necessarily subjected to the same level of formal scientific review as ASA Standards or Guidelines. Each ASA member, institution or practice should decide individually whether to implement some, none, or all of the principles in ASA statements based on the sound medical judgment of anesthesiologists participating in that institution or practice.

See also: Practice Parameters

Recommendations and Clinical Management Tools - ASA Committees

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Hospital Surgical P&P Include:

- Who may obtain the patient's informed consent?
- Which procedures require informed consent?
  - Have a list approved by the Medical Staff
- The circumstances under which surgery is considered an emergency, and may be undertaken without an informed consent

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Hospital Surgical P&P Include

- The circumstances when a patient's representative, rather than the patient, may give informed consent for a surgery
  - Parent, guardian, support person (patient advocate, care partner) or DPOA
- The content of the informed consent form and instructions for completing it
- The process used to obtain informed consent, including how informed consent is to be documented in the medical record

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Hospital Surgical P&P Include

- Mechanisms that ensure that the informed consent form is properly executed and is in the patient's medical record prior to the surgery
- If the informed consent form is obtained **outside** the hospital, how the properly executed form is incorporated into the patient's medical record prior to the surgery
  - Fax, email, patient or physician can bring form in but remember HIPAA
- Any other state law requirements on consent

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Well Designed Elements (Optional)

- A description of the proposed surgery, including the anesthesia to be used
- Indications for the proposed surgery
- Material risks and benefits for the patient related to the surgery and anesthesia including the likelihood of each
  - Material risks are those with high degree of likelihood but low degree of severity and
  - Low degree of likelihood but high degree of severity

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Well Designed Elements (Optional)

- Treatment alternatives, including the material risks and benefits
- The probable consequences of declining recommended or alternative therapies
- Who will conduct the surgical intervention and administer the anesthesia
- Whether anyone else besides operating practitioner will be doing important tasks of surgery

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Important Surgical Tasks Include:

- Opening and closing
- Dissecting tissue
- Removing tissue
- Harvesting grafts
- Transplanting tissue
- Administering anesthesia
- Implanting devices and placing invasive lines

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Residents Doing Important Parts

Discussion is encouraged to include:

- Resident is doing part based on their availability and level of competence, (except when moonlighting)
- If it is decided at time of surgery which resident will participate
- Their level of participation
- Will be based on knowledge that surgeon has of resident's skill set
- Patient's condition

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Residents Doing Important Parts

Discussion is encouraged to include:

- If QMP will perform parts of surgery or anesthesia:
  - What types of tasks they will carry out
  - Must be within scope of privileges
- If a resident or QMP is doing important parts you still have to inform the patient but putting it in writing is optional for PPS hospitals

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Survey Procedures

- Verify hospital has assured that MS has specified what procedures are considered surgery when IC is needed
- Verify hospital's informed consent P&P address circumstances when surgery is an emergency
- Surveyor to review at least 6 medical records of surgical patients
- Surveyors look at patients about to go to surgery
- They interview 2 or 3 post surgical patients and see how satisfied they are with the informed consent discussion prior to surgery

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Resources

- A site for consent forms that list the risks, and complications, and alternatives of many procedures (Provided by the Queensland Government.)[1]
- They have forms for pediatrics, orthopedics, vascular, urology, surgical, renal, plastic surgery, psychiatry, ophthalmology, maxillofacial, medical imaging, neurosurgery, ear, nose and throat and many more.[2]

[1] http://www.health.qld.gov.au/informedconsent/ConsentForms/14025.pdf

[2] http://www.health.qld.gov.au/consent/html/for_clinicians.asp

http://www.health.qld.gov.au/consent/

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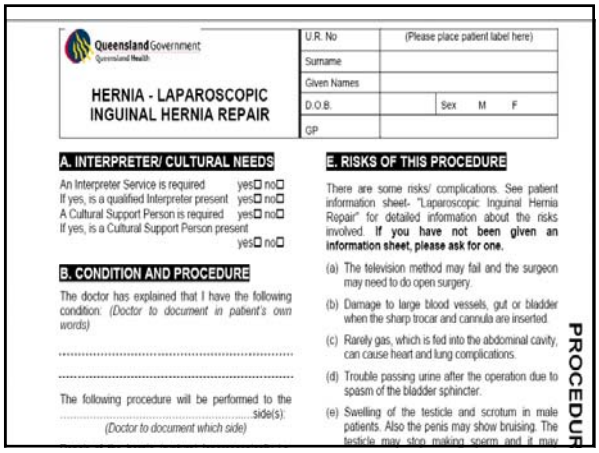

Queensland Government

HERNIA - LAPAROSCOPIC INGUINAL HERNIA REPAIR

U.R. No	(Please place patient label here)
Surname	
Given Names	
D.O.B.	Sex M F
GP	

A. INTERPRETER/ CULTURAL NEEDS

An Interpreter Service is required yes☐ no☐
If yes, is a qualified Interpreter present yes☐ no☐
A Cultural Support Person is required yes☐ no☐
If yes, is a Cultural Support Person present yes☐ no☐

B. CONDITION AND PROCEDURE

The doctor has explained that I have the following condition: *(Doctor to document in patient's own words)*

.....

.....

The following procedure will be performed to the .....side(s):

(Doctor to document which side)

E. RISKS OF THIS PROCEDURE

There are some risks/ complications. See patient information sheet- "Laparoscopic Inguinal Hernia Repair" for detailed information about the risks involved. **If you have not been given an information sheet, please ask for one.**

(a) The television method may fail and the surgeon may need to do open surgery.

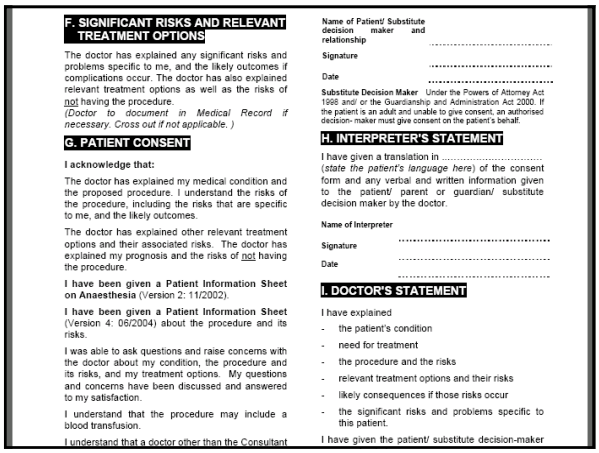
(b) Damage to large blood vessels, gut or bladder when the sharp trocar and cannula are inserted.

(c) Rarely gas, which is fed into the abdominal cavity, can cause heart and lung complications.

(d) Trouble passing urine after the operation due to spasm of the bladder sphincter.

(e) Swelling of the testicle and scrotum in male patients. Also the penis may show bruising. The testicle may stop making sperm and it may

PROCEDUR



F. SIGNIFICANT RISKS AND RELEVANT TREATMENT OPTIONS

The doctor has explained any significant risks and problems specific to me, and the likely outcomes if complications occur. The doctor has also explained relevant treatment options as well as the risks of not having the procedure.
(Doctor to document in Medical Record if necessary. Cross out if not applicable.)

G. PATIENT CONSENT

I acknowledge that:

The doctor has explained my medical condition and the proposed procedure. I understand the risks of the procedure, including the risks that are specific to me, and the likely outcomes.

The doctor has explained other relevant treatment options and their associated risks. The doctor has explained my prognosis and the risks of not having the procedure.

I have been given a Patient Information Sheet on Anaesthesia (Version 2: 11/2002).

I have been given a Patient Information Sheet (Version 4: 06/2004) about the procedure and its risks.

I was able to ask questions and raise concerns with the doctor about my condition, the procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.

I understand that the procedure may include a blood transfusion.

I understand that a doctor other than the Consultant

Name of Patient/ Substitute decision maker and relationship .....

Signature .....

Date .....

Substitute Decision Maker Under the Powers of Attorney Act 1998 and/ or the Guardianship and Administration Act 2000. If the patient is an adult and unable to give consent, an authorised decision- maker must give consent on the patient's behalf.

H. INTERPRETER'S STATEMENT

I have given a translation in .....
(*state the patient's language here*) of the consent form and any verbal and written information given to the patient/ parent or guardian/ substitute decision maker by the doctor.

Name of Interpreter

Signature .....

Date .....

I. DOCTOR'S STATEMENT

I have explained

- the patient's condition
- need for treatment
- the procedure and the risks
- relevant treatment options and their risks
- likely consequences if those risks occur
- the significant risks and problems specific to this patient.

I have given the patient/ substitute decision-maker

Issue of Low Health Literacy

- 90 million Americans have low health literacy
- One study 52% of patients did not understand the consent form
- Put it in a way patient can understand

www.mnpatientsafety.org/index.php?option=com_content&task=view&id=85&Itemid=6

68

Federal and Minnesota state regulations require additional documentation and consent for hysterectomy and sterilization. [2]

Hysterectomy - Department of Health and Human Services (DHHS) requires a hysterectomy acknowledgement statement (HAS). Below is a sample HAS. It is not mandatory for the provider to use this sample acknowledgment statement. Any document that the recipient, or her representative, has signed that shows the provider informed the recipient that she would be incapable of reproducing due to the hysterectomy is permissible

Sample Hysterectomy Acknowledgment Statement
My doctor informed me, both orally and with written materials, that the performance of a hysterectomy would make me sterile (not able to have children).

Signed_____ Date _____

Note: If the recipient signs the acknowledgment after the hysterectomy, the acknowledgment must show that the recipient was informed of the consequences of the hysterectomy before the procedure was performed.

Sterilizations - This requires exact language, and a DHHS approved form. This form is required by DHHS/CMS for Medicaid paid sterilizations and must be submitted with the bill. Any alternate form would have to be approved the Secretary of DHHS. The brochures with the specific federal consent form are available at:

[2] Requirements related to hysterectomy and sterilizations are under Title 42: Public Health Subpart F—Sterilizations § 441.258 Consent form requirements and § 441.256 Additional condition for Federal financial participation (FFP)

69

Consent for Sterilization

CONSENT FOR STERILIZATION

NOTICE: YOUR DECISION AT ANY TIME NOT TO BE STERILIZED WILL NOT RESULT IN THE WITHDRAWAL OR WITHHOLDING OF ANY BENEFITS PROVIDED BY PROGRAMS OR PROJECTS RECEIVING FEDERAL FUNDS.

■ CONSENT TO STERILIZATION ■

I have asked for and received information about sterilization from _____. When I first asked doctor or clinic

for the information, I was told that the decision to be sterilized is completely up to me. I was told that I could decide not to be sterilized. If I decide not to be sterilized, my decision will not affect my right to future care or treatment. I will not lose any help or benefits from programs receiving Federal Funds, such as A.F.D.C. or Medicaid that I am now getting or for which I may become eligible.

I UNDERSTAND THAT THE STERILIZATION MUST BE CONSIDERED PERMANENT AND NOT REVERSIBLE. I HAVE DECIDED THAT I DO NOT WANT TO BECOME PREGNANT, BEAR CHILDREN OR FATHER CHILDREN.

I was told about those temporary methods of birth control that are available and could be provided to me which will allow me to bear or father a child in the future. I have rejected these alternatives and chosen to be sterilized.

I understand that I will be sterilized by an operation known as a _____. The discomforts, risks and benefits associated with the operation have been explained to me. All my questions have been answered to my satisfaction.

I understand that the operation will not be done until at least thirty days after I sign this form. I understand that I can change my mind at any time and that my decision at any time not to be sterilized will not result in the withholding of any benefits or medical services provided by federally funded programs.

I am at least 21 years of age and was born on: _____ Month Day Year

I, _____, hereby consent of my own

■ STATEMENT OF PERSON OBTAINING CONSENT ■

Before _____ signed the name of individual

consent form, I explained to him/her the nature of sterilization operation _____ the fact that it is

intended to be a final and irreversible procedure and the discomforts, risks and benefits associated with it.

I counseled the individual to be sterilized that alternative methods of birth control are available which are temporary. I explained that sterilization is different because it is permanent.

I informed the individual to be sterilized that his/her consent can be withdrawn at any time and that he/she will not lose any health services or any benefits provided by Federal funds.

To the best of my knowledge and belief the individual to be sterilized is at least 21 years old and appears mentally competent. He/She knowingly and voluntarily requested to be sterilized and appears to understand the nature and consequences of the procedure.

_____ _____
Signature of person obtaining consent Date

_____
Facility

_____
Address

■ PHYSICIAN'S STATEMENT ■

Shortly before I performed a sterilization operation upon

_____ on _____
name of individual date of sterilization

I explained to him/her the nature of the sterilization operation

www.hhs.gov/forms/HHS-687.pdf

70

Critical Access Hospitals (CAH)

Informed Consent Sections
Two Separate CoP Sections

Critical Access Hospitals

- Has a separate manual
- Has two separate sections on informed consent
- Appendix W and very different that the consent provisions for non critical access hospitals
- Tag C-0150 to C 0408 and 1000-1002 and is in tag 304 and 320
- Interpretive guidelines updated more frequently now
- Manual available on-line[1]

[1] http://www.cms.hhs.gov/manuals/downloads/som107_Appendicestoc.pdf

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CAH Consent Provisions

- Page 16 under patient interviews tells surveyor to question a surgery patient about their knowledge of and consent for the procedure or surgery
- During document review the surveyor needs to review the medical record to make sure there is an informed consent form on the chart (page 16)

73

Informed Consent C 304

- Consent section in Tag 304 and 320, Appendix W
- Different from hospital CoPs
  - We need to get this changed so hospitals in systems may have different P&Ps
- Include evidence of properly executed informed consent forms for any procedures or surgical procedures
  - Specified by the medical staff
  - Required by Federal or State law

74

C-0304

§485.638(a)(4) For each patient receiving health care services, the CAH maintains a record that includes, as applicable--

(i) Identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;

Interpretive Guidelines §485.638(a)(4)(i)

The medical record must include evidence of properly executed informed consent forms for any procedures or surgical procedures specified by the medical staff, or by Federal or State law, if applicable, that require written patient consent.

Informed consent means the patient or patient representative is given the information, explanations, consequences, and options needed in order to consent to a procedure or treatment.

A properly executed consent form contains at least the following:

- Name of patient, and when appropriate, patient's legal guardian;
- Name of CAH;
- Name of procedure(s);
- Name of practitioner(s) performing the procedures(s);
- Signature of patient or legal guardian;
- Date and time consent is obtained;
- Statement that procedure was explained to patient or guardian;
- Signature of professional person witnessing the consent;
- Name/signature of person who explained the procedure to the patient or guardian.

75

Informed Consent 304

- CAH must maintain a record that has evidence of a properly executed informed consent form
- For any procedure or surgery specified by the MS, state or federal law
- Informed consent means the patient or patient representative is given the information, explanations, consequences, and options needed in order to consent to a procedure or treatment.

76

Informed Consent 304

A properly executed consent form contains at least the following:

- Name of patient, and when appropriate, patient's legal guardian
- Name of CAH
- Name of procedure
- Name of practitioner performing the procedure
- Signature of patient or legal guardian

77

Informed Consent 304

A properly executed consent form contains at least the following (continued):

- Date and **time** consent is obtained
- Statement that procedure was explained to patient or guardian
- Signature of professional person witnessing the consent
- Name/signature of person who explained the procedure to the patient or guardian

78

Informed Consent 304

- Surveyor is to verify that medical staff have specified which procedures and surgeries need a written informed consent
- Surveyor is to verify that there is a consent form on the chart for procedures required by the CAH policy
- Surveyor must verify consent forms are properly executed
- Must make sure all consent forms are signed and dated

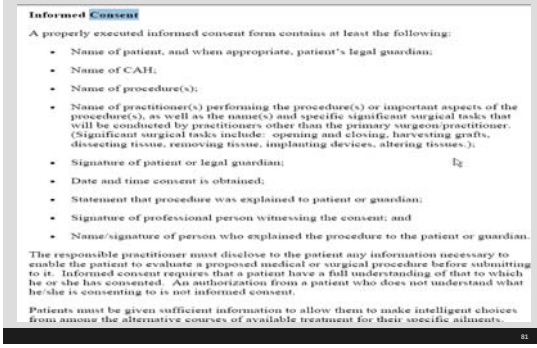
79

Informed Consent 320

- This includes all inpatients and outpatients
- Patient is informed of who will actually perform the surgery (no ghost surgery)
- Must inform patient if practitioner other than the primary surgeon will perform important parts of the surgical procedure
- EVEN if it is under the primary surgeon's supervision

80

Tag 320 CAH Manual



Informed Consent

A properly executed informed consent form contains at least the following:

- Name of patient, and when appropriate, patient's legal guardian;
- Name of CAH;
- Name of procedure(s);
- Name of practitioner(s) performing the procedure(s) or important aspects of the procedure(s), as well as the name(s) and specific significant surgical tasks that will be conducted by practitioners other than the primary surgeon/practitioner. (Significant surgical tasks include: -opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues.);
- Signature of patient or legal guardian;
- Date and time consent is obtained;
- Statement that procedure was explained to patient or guardian;
- Signature of professional person witnessing the consent; and
- Name/signature of person who explained the procedure to the patient or guardian.

The responsible practitioner must disclose to the patient any information necessary to enable the patient to evaluate a proposed medical or surgical procedure before submitting to it. Informed consent requires that a patient have a full understanding of that to which he or she has consented. An authorization from a patient who does not understand what he/she is consenting to is not informed consent.

Patients must be given sufficient information to allow them to make intelligent choices from among the alternative courses of available treatment for their specific ailments.

81

Informed Consent 320

Consent must include:

- Name of patient or their legal guardian
- Name of hospital (CAH)
- Name of specific procedure
- Name of person doing the procedure or important parts of the procedure other than primary surgeon
- Significant surgical tasks include: opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices and altering tissue

82

Informed Consent 320

- Nature and purpose of proposed treatment, Risks, consequences if no treatment is rendered, alternative procedures or treatments, probability that proposed procedure would be successful-discussed in text
- Signature of patient or guardian
- Date and time consent obtained
- Statement that procedure was explained to the patient or guardian
- Signature of professional person witnessing the consent
- Name of person who explained procedure

83

Informed Consent 320

- Must disclose information to patient necessary to make a decision
- It is a process and not a form
- Authorization form signed by a patient who does not understand what he is signing is not informed consent
- Given in language patient can understand
  - Remember issue of **low health literacy** and use **interpreter** when indicated and document

84

TJC Hospital Informed Consent Standards

TJC RI Informed Consent

- Remember CMS CoP provisions on informed consent discussed previously
- Remember your **state law** on informed consent and **AO** (accreditation organization) standards (DNV, AOA, CIHQ, and TJC)
- TJC has a standard on informed consent in the patient rights chapter or RI chapter
- **RI.01.03.01** and **RC.02.01.01**
  - Include all 3 sources in your consent policy

86

RC.02.01.01 TJC Consent

- **Standard:** The MR contains information that reflects the patient's care
- EP4 The medical record needs to contain the following:
- Any informed consent as required by the hospital policy
  - TJC added language at the request of CMS
  - Not called JCAHO anymore
  - See RI.01.03.01

87

RC.02.01.01 TJC Consent

- The consent form must be in the chart unless it is an emergency
- The consent form must be properly executed
- It must document the patient's mutual understanding and agreement for care
- Must have a written or electronic signature
- If patient unable them documentation of the verbal consent by the patient or surrogate decision maker

88

Record of Care RC.02.01.01

- A properly executed consent form must contain
  - Documentation of a patient's mutual understanding of and agreement
  - Through written signatures or electronic signature
  - Or when a patient is unable to provide a signature
  - There must be documentation of verbal agreement by the patient or surrogate decision maker

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TJC Informed Consent RI.01.03.01

- **Standard:** The hospital honors the patient's right to give or hold consent
- This section has a rationale
- Obtaining informed consent presents opportunity to establish a mutual understanding between the patient and the LIP
- It is a **process** is not merely a signed form

90

TJC Informed Consent RI.01.03.01

- It considers the patient's needs and preferences
- It considers compliance with laws and regulations and patient education
- Informed consent process helps patient to participate fully in decisions about their care
- It has 13 elements of performance
- EP 8 &10 do not apply to hospitals

91

TJC Informed Consent

- Informed consent is a discussion of:
  - What the procedure is to accomplish
  - Reasonable known risks
  - Alternatives
  - Benefits
  - Prognosis
  - What can happen if the surgery or treatment is refused

92

TJC Informed Consent RI.01.03.01

There are 13 Elements of Performance but only 11 apply to hospitals:

- EP1 - The hospital has a written policy on informed consent
- EP2 - The policy identifies specific care and treatment that requires an informed consent and this must be consistent with law and regulations
- EP3 - Policy describes exceptions to the rule
  - Such as emergencies then document in the chart

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TJC Informed Consent 01.03.01

- EP4 - Policy describes the process to be followed
- EP5 - Describe in policy how to document consent in the medical record
  - Consent form on the chart and document in the progress notes
- EP6 - Policy describes when a surrogate decision maker can give the informed consent (see RI.01.02.01 EP6)
  - If the patient is unable to make decisions about care, then it is made by surrogate decision maker

94

TJC Informed Consent 01.03.01

- EP 7 - Consent process includes a discussion about the patient's proposed care, treatment and services
- EP9 - Process includes a discussion about potential benefits, risks, and side effects, likelihood of achieving the patient's goals and any potential problems that might occur during recuperation
- EP11 - Process includes a discussion of the reasonable alternatives to the patient's proposed care, risks, benefits, and side effects of the alternatives
  - Includes the risks of not having the proposed treatment

95

TJC Informed Consent 01.03.01

- EP12 - Informed consent process includes a discussion about any circumstance under which information about the patient must be disclosed or reported **DELETED** July 1, 2016 since addressed by external requirements
- EP13 - Consent is obtained in accordance with the hospital policy and processes
  - RC.02.01.01 EP 4 requires the medical record to contain evidence of informed consent

96

RI.01.02.01 Surrogate Decision Maker

- EP 6 When a patient is unable to make decisions about his or her own care
- The hospital involves a surrogate decision maker in making these decisions
- An example would be a DPOA in a patient who is incapacitated or a legal guardian, a mental health proxy for a patient who is incapacitated on a behavioral health unit, or the parent of a five year child

97

RI.01.03.03 Consent for Photography

- TJC has a standard that requires the hospital to honor the patient's right to give or withhold informed consent
- To produce or use recordings, films, or other images of the patient
- For purposes other than his or her care
- There are 7 elements of performance
- RI.01.03.05 document research in consent form and 8 EPs

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Sample Consent Form for Photography

- The American Health Information Management Association (AHIMA)
- has a practice brief on Patient Photography, Videotaping and other Imaging[1]

[1] http://library.ahima.org/xpedio/groups/public/documents/ahima/bok2_000585.hcsp?dDocName=bok2_000585

99

Sample Consent for Photography/Videotaping (For Media or Educational Purposes)

Patient's Name: _____

Identification Number: _____

I hereby give my consent to have photographs, videotaped images, or other images made of myself or my family member and/or consent to interviews with a member of the news media or a representative of (name of organization). I understand and agree that these images may be used by the news media or by (name of organization) for the purpose outlined below:

Signature of Patient or Legal Representative Date Signature of Witness Date

NQF 34 Safe Practices

- National Quality Forum publishes 34 Safe Practices for Better Healthcare in 2010 with March 2011 update
- Safe Practice 5 addresses informed consent
- Need to make sure that patients understand the proposed treatment and complications
- Consent is an essential part of healthcare
  - Consent is a process
  - Need to have shared decision making

101

SAFE PRACTICE 5: INFORMED CONSENT

The Objective

Ensure that patients, and, when appropriate, families and legal guardians, understand the proposed treatment and its potential complications.

The Problem

Obtaining informed consent is an essential part of the healthcare process and is, in fact, a process rather than a single act or event. It is a process of communication between the patient and healthcare provider that results in the patient's agreement to undergo a specific medical intervention. Informed consent can be plainly described as the *learned* choice made by a patient. [Plawecki, 2009] The process may result in the execution of a written informed consent document. Informed consent is imperative before the undertaking of any major procedure, including, but not limited to, surgery and other invasive procedures. The primary

shown that more than two-thirds of patients in the United States do not receive any written information about their condition from their physicians. Other studies have shown that up to 75 percent of written consent forms are incomplete. [Shojania, 2001] Because an estimated 90 million adults in the United States have limited health literacy, [IOM, 2004] policies should be implemented to ensure the use of clear informed consent documents that most patients and their families can easily understand. [Denham, 2008a; Shaw, 2009]

Communication failures between patients and healthcare providers are at the root of systems failures and human errors that lead to harm. [Denham, 2008b; Levinson, 2008] but the severity of these failures is not known. Applicants may understand only 30 to 81 percent of information in standard consent forms. [Kripalani, 2008] Informed consent is a critical healthcare process, both clinically, to provide patients with vital information, and ethically, to preserve patient autonomy. A study in the *Archives of Surgery* examined 540 consent forms in 157 hospitals. Only 26 percent of them addressed the four key elements of informed consent: benefits of treatment, risks,

102

NQF 34 Safe Practices

- The frequency in which patients do not receive an appropriate consent is of great concern
- Studies have shown that more than 2/3 of patients do not receive any written information about their condition from their physician
- Studies show that up to 75% of written consents are incomplete (Shojania, 2001)
- 90 million Americans have low health literacy so make sure you use a clear consent form (Denham 2008, Shaw, 2009)

103

NQF 34 Safe Practices

- Patients only understand about 30 to 81% of information in a standard consent form (Kripalani, 2008)
- A study in the Archives of Surgery examined 540 consent forms in 157 hospitals
  - Only 26 percent of them addressed the four key elements of informed consent:
  - Benefits of treatment, risks, alternatives, and educational information. [Bottrell, 2000]
  - Use teach back

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DNV Healthcare

Consent Standards

DNV Healthcare

- Same as CMS CoPs
- Has deemed status with CMS for hospitals
- One of four accreditation organizations
- DNV Standards available on their website[1]
- Patient Rights or PR 4 on informed consent

[1] www.dnv.com

106

DNV Healthcare SR.3

- Must have a policy and procedure on consent
- Has a section under SS.4 on history and physicals
- SR.3 states you must have a properly executed informed consent for surgery
- It must be in the patient's medical record before surgery and surveyor is to verify this
- Except in an extreme medical emergency
- Must be signed by the patient or their representative
- If obtained outside how to get a copy in the MR

107

DNV Consent Form Must Include:

- Consent form must include:
  - Description of proposed surgery
  - Including anesthesia to be used
  - Risk and consequences of the procedure
  - Risk if no treatment is rendered
  - Probability that the proposed procedure will be successful
  - Alternative method of treatment and their risk and benefits
  - Who will actually be performing the surgery or procedure
  - Who else is doing important parts other than the primary surgeon

108

DNV P&P Must Include

- Hospital consent P&P must include:
  - Who can obtain the consent
  - Which procedures require consent
  - When is it an emergency
  - When does representative sign the consent form
  - Content of the form and instructions to complete
  - Process used to complete and documentation in the MR
  - Mechanism to make sure it is properly executed
  - Must be in the medical record before the surgery unless it is an emergency

109

Anesthesia Consent

- AS.3 Policies and Procedures
- The hospital must develop and implement P&P regarding the administration of post-anesthesia or sedation
- The P&P must include a consent for the administration of anesthesia or sedation
- This is consistent with the ASA standards for anesthesiologists

110

DNV Informed Consent

PR.4 INFORMED CONSENT

The organization shall obtain an informed written consent from each patient or authorized representative for the provision of medical and/or surgical care except in medical emergencies. The consent shall include an explanation of risks, benefits, and alternatives for high-risk procedures, sedation, and participation in research projects, as defined by the medical staff and State law.

Interpretive Guidelines:

All patients receiving either inpatient and outpatient care must complete an informed written consent form for all procedures and treatments specified by the hospital's medical staff, or State or Federal laws or regulations. In the event of a medical emergency, the hospital is not required to obtain a written consent, but timely efforts should be made to obtain an informed written consent from the patient's authorized representative.

The procedures/treatments which will require the hospital to obtain patient written consent will at least include: high-risk procedures (including blood transfusions); sedation; participation in research projects; and, filming or videotaping.

Definition elements: Informed consent means the patient or patient representative is given (in a language or means of communication he/she understands) the information, explanations of risks, benefits and alternatives, needed in order to consent to a procedure or treatment. Informed consent would include that the patient is informed as to who will actually perform planned surgical interventions.

111

DNV Informed Consent PR.4

- Standard: The hospital must ensure that there is a written consent form for the provision of medical or surgical care
  - Except in an emergency
- Must include explanation of risks, benefits, alternatives for high risk procedures, sedation, and research
- As defined by state law and the MS

112

DNV Informed Consent PR.4

- All patients must have a consent form for all procedures and treatments specified by MS or law
  - Including inpatients and outpatients
- Except in an emergency but timely efforts should be made to get consent from the patient representative
- Must get written consent for high-risk procedures, blood, sedation, research projects and filming and videotaping

113

DNV Informed Consent PR.4

- Given in language patient understands
  - Remember issues of using interpreter if patient does not speak fluent English
  - Remember issue of low health literacy so explain so patient can understand and use **repeat back or teach back**
- Must inform patient of who will be actually performing the surgical intervention
- If someone other than the surgeon is doing important parts of the surgical procedure, the patient must be informed
  - Including who they are and what they are doing

114

DNV Proper Consent Form Must Include:

- Name of patient
- Name of hospital
- Name of specific procedure or treatment
- Name of practitioner performing the procedure
- Material risks
- Alternative procedures, treatments or therapies

115

DNV Consent Form Must Include:

- Signature of the patient or representative
- Date and time consent form signed
- Signature of the witness
- Name of the person who explained the procedure to the patient or guardian
- Statement that the procedure or treatment was explained to the patient including benefits, risks, and alternatives

116

Surveyor Guidance Informed Consent

- Surveyor is to verify that MS specifies which procedures or treatments require consent
- Must verify that the medical records contain consent forms for all procedures required by P&P
- Surveyor is to review and validate that consent forms are properly executed
- MR.7 under Required Documentation requires a properly executed information consent for procedures as required by the MS or law
  - Must be signed by the patient or representative
  - Repeats element of consent; hospital name, signature, etc

117

Informed Consent Policy Must Include:

- Who may obtain the patient's informed consent
- Which procedures require informed consent
- The circumstances under which surgery is considered an emergency and may be undertaken without an informed consent
- The circumstances when a patient's representative, rather than the patient, may give informed consent for surgery

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Research

There may be additional regulations for facilities doing human subject research

Research

- US Dept of Health and Human Services (HHS) and several other federal agencies, such as Dept of Education, and the National Science Foundation
- Have regulations on research which are commonly referred to as the common rule
- To protect human subjects involved in research
- Institutional Review Boards (IRB) reviews research proposals even if informed consent is obtained, IRB can waive consent requirement
- See Title 46 Protection of Human Subjects at www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

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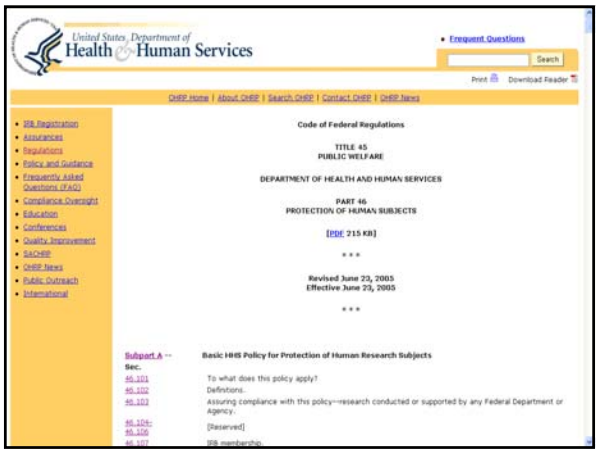
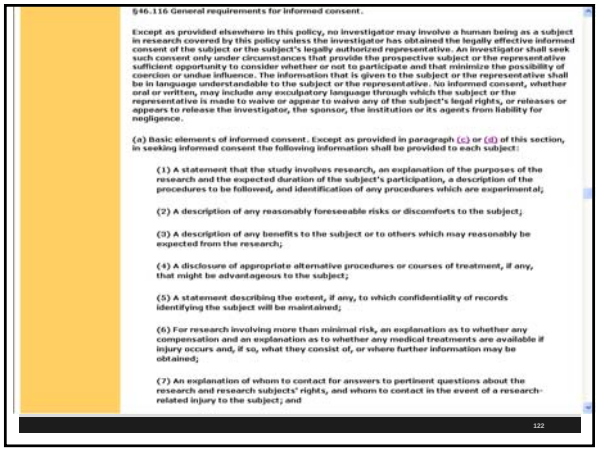

United States Department of Health & Human Services
Frequent Questions
Search
Print
Download Reader
OHRP Home | About OHRP | Search OHRP | Contact OHRP | OHRP News
IRB Registration
Assurances
Regulations
Policy and Guidance
Frequently Asked Questions (FAQ)
Compliance Oversight
Education
Conferences
Quality Improvement
SACHRP
OHRP News
Public Outreach
International
Code of Federal Regulations
TITLE 45
PUBLIC WELFARE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
PART 46
PROTECTION OF HUMAN SUBJECTS
[PDF 215 KB]
* * *
Revised June 23, 2005
Effective June 23, 2005
* * *
Subpart A -- Basic HHS Policy for Protection of Human Research Subjects
Sec.
46.101 To what does this policy apply?
46.102 Definitions.
46.103 Assuring compliance with this policy--research conducted or supported by any Federal Department or Agency.
46.104- [Reserved]
46.106
46.107 IRB membership.


§46.116 General requirements for informed consent.
Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.
(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:
(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
(2) A description of any reasonably foreseeable risks or discomforts to the subject;
(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;
(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
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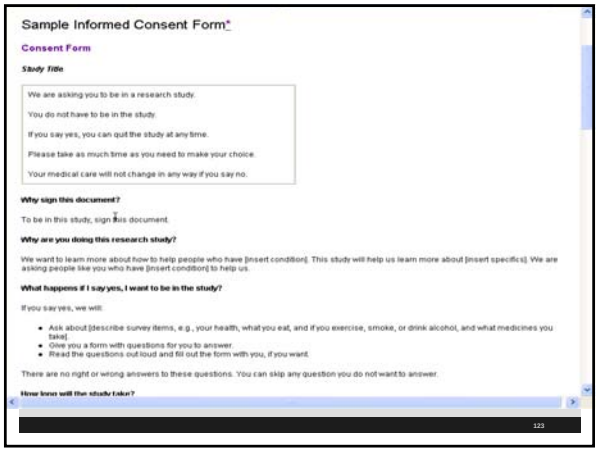
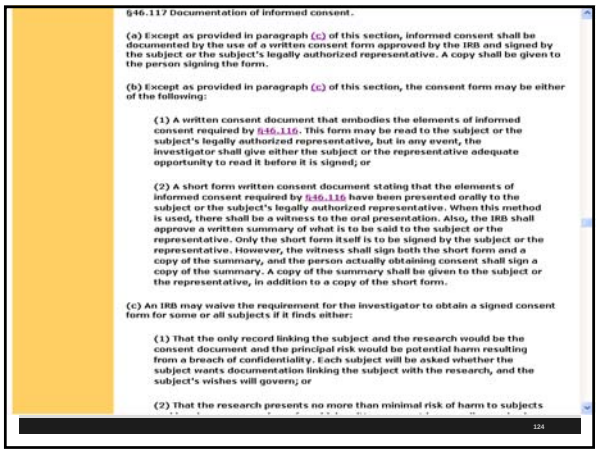

Sample Informed Consent Form*
Consent Form
Study Title
We are asking you to be in a research study.
You do not have to be in the study.
If you say yes, you can quit the study at any time.
Please take as much time as you need to make your choice.
Your medical care will not change in any way if you say no.
Why sign this document?
To be in this study, sign this document.
Why are you doing this research study?
We want to learn more about how to help people who have [insert condition]. This study will help us learn more about [insert specifics]. We are asking people like you who have [insert condition] to help us.
What happens if I say yes, I want to be in the study?
If you say yes, we will:
Ask about [describe survey items, e.g., your health, what you eat, and if you exercise, smoke, or drink alcohol, and what medicines you take]
Give you a form with questions for you to answer.
Read the questions out loud and fill out the form with you, if you want.
There are no right or wrong answers to these questions. You can skip any question you do not want to answer.
How long will the study take?
123



§46.117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A short form written consent document stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects

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Research Consent

- Research investigator needs informed consent from research subject
- Must be in plain language
- Must include a statement that the study involves research
- Explanation of the purpose of the research
- Expected duration of the subject's participation
- Description of procedures to be followed
- Identification of any procedure considered to be experimental

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Research Elements of Consent

- Description of any reasonable foreseeable risks or discomforts to the subject
- Disclosure of any benefits to the subject and others which may be expected
- Disclosure of appropriate alternative procedures or courses of treatment
- Statement to which confidentiality of records identifying the subject will be maintained

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Research Elements of Consent

- Contact information for answers to questions about the research
- Also to include information on patient's rights in case of a research related injury
- Statement that participation is voluntary and refusal to participate involves no penalty or loss of benefits
- Subject can discontinue participation at any time without penalty or loss of benefits

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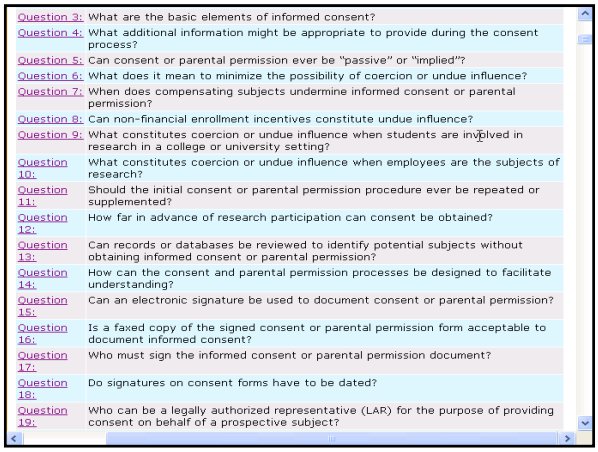
www.hhs.gov/ohrp/informconsfaq.html



AHRQ Toolkit to Facilitate Consent

- AHRQ toolkit to facilitate the process of obtaining informed consent
- Also information on the HIPAA authorization for potential research subjects
- Available at http://www.ahrq.gov/fund/informedconsent/
- Changes to HIPAA privacy, security, HITECH and GINA effective September 23, 2013

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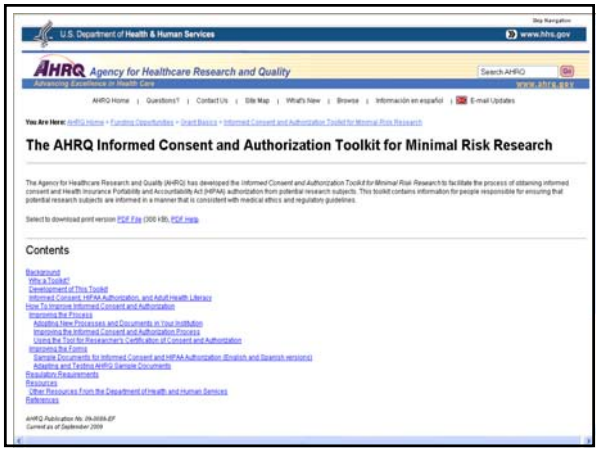

Q&A on Informed Consent Feb 2012

Guidance for Sponsors, Investigators, and Institutional Review Boards

Questions and Answers on Informed Consent Elements, 21 CFR § 50.25(c)

(Small Entity Compliance Guide)

www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm.

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Policy and Office of Good Clinical Practice
Office of the Commissioner

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Research References

- US Department of Health and Human Services. "Protection of Human Subjects." *Code of Federal Regulations*, 2002. 45 CFR, Part 46
- Office for Civil Rights. "Medical Privacy—National Standards to Protect the Privacy of Personal Health Information." Section "Research"[1]
- US Department of Health and Human Services. "Food and Drugs." *Code of Federal Regulations*, 2002. 21 CFR, Part 56, Section 102

[1] www.hhs.gov/ocr/hipaa/privacy.html

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Standards from Professional Organizations

Does your professional organization have any practice briefs or guidelines on informed consent?

Professional Organizations

- Sometimes have good samples, practice briefs or guidelines on informed consent
- This can be helpful to healthcare providers
- Most are now available on the Internet

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American Society of Anesthesiologists

Standards, Guidelines, Statements and Other Documents

ASA Standards, Guidelines and Statements provide guidance to improve decision-making and promote beneficial outcomes for the practice of anesthesiology. They are not intended as unique or exclusive indicators of appropriate care. The interpretation and application of Standards, Guidelines and Statements takes place within the context of local institutions, organizations and practice conditions. A departure from one or more recommendations may be appropriate if the facts and circumstances demonstrate that the rendered care met the physician's duty to the patient.

Standards provide rules or minimum requirements for clinical practice. They are regarded as generally accepted principles of patient management. Standards may be modified only under unusual circumstances, e.g., extreme emergencies or unavailability of equipment.

Guidelines are systematically developed recommendations that assist the practitioner and patient in making decisions about health care. These recommendations may be adopted, modified, or rejected according to clinical needs and constraints and are not intended to replace local institutional policies. In addition, practice guidelines are not intended as standards or absolute requirements, and their use cannot guarantee any specific outcome. Practice guidelines are subject to revision as warranted by the evolution of medical knowledge, technology, and practice. They provide basic recommendations that are supported by a synthesis and analysis of the current literature, expert opinion, open forum commentary, and clinical feasibility data.

Statements represent the opinions, beliefs, and best medical judgments of the House of Delegates. As such, they are not necessarily subjected to the same level of formal scientific review as ASA Standards or Guidelines. Each ASA member, institution or practice should decide individually whether to implement some, none, or all of the principles in ASA statements based on the sound medical judgment of anesthesiologists participating in that institution or practice.

See also: Practice Parameters

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ASA Standards www.asahq.org

- Anesthesia Care Team, The (2009)
- Anesthesia Consultation Program (2008)
- Avoidance of Medication Errors in Neuraxial Anesthesia, Statement on Standard Practice for (2010)
- Basic Anesthetic Monitoring, Standards for (Effective July 1, 2011)
- Clinical Privileges in Anesthesiology, Guidelines for Delineation of (2008)
- Conflict of Interest, Statement on (2008)
- Continuing Medical Education in Anesthesiology, Guidelines for Minimally Acceptable (2011)
- Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia (2009)
- Critical Care and Trauma Medical Services, Statement of Principles (2011)
- Critical Care by Anesthesiologists, Guidelines for the Practice of (2009)
- Distinguishing Monitored Anesthesia Care From Moderate Sedation/Analgesia (Conscious Sedation) (2009)
- Documentation of Anesthesia Care (2008)

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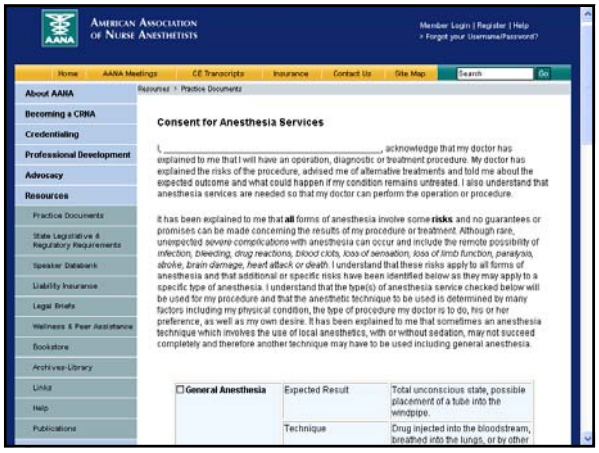
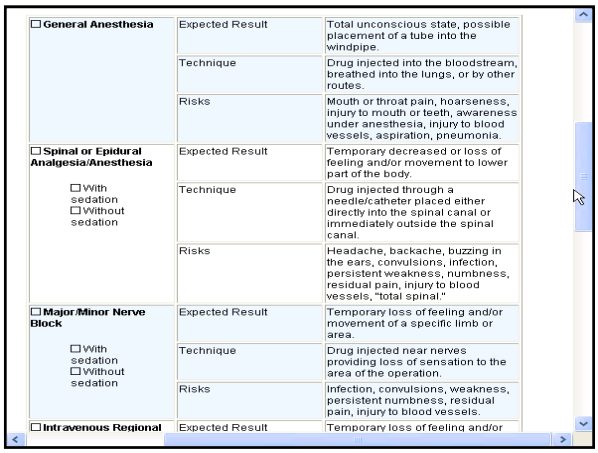
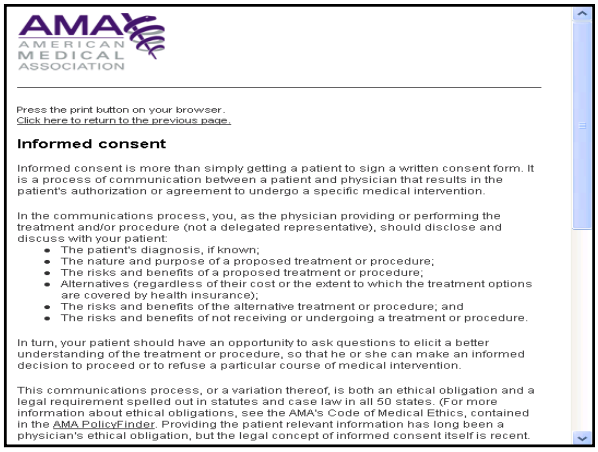




☐ **General Anesthesia**	Expected Result	Total unconscious state, possible placement of a tube into the windpipe.
	Technique	Drug injected into the bloodstream, breathed into the lungs, or by other routes.
	Risks	Mouth or throat pain, hoarseness, injury to mouth or teeth, awareness under anesthesia, injury to blood vessels, aspiration, pneumonia.
☐ **Spinal or Epidural Analgesia/Anesthesia** ☐ With sedation ☐ Without sedation	Expected Result	Temporary decreased or loss of feeling and/or movement to lower part of the body.
	Technique	Drug injected through a needle/catheter placed either directly into the spinal canal or immediately outside the spinal canal.
	Risks	Headache, backache, buzzing in the ears, convulsions, infection, persistent weakness, numbness, residual pain, injury to blood vessels, "total spinal."
☐ **Major/Minor Nerve Block** ☐ With sedation ☐ Without sedation	Expected Result	Temporary loss of feeling and/or movement of a specific limb or area.
	Technique	Drug injected near nerves providing loss of sensation to the area of the operation.
	Risks	Infection, convulsions, weakness, persistent numbness, residual pain, injury to blood vessels.
☐ **Intravenous Regional**	Expected Result	Temporary loss of feeling and/or



AMA AMERICAN MEDICAL ASSOCIATION

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Informed consent

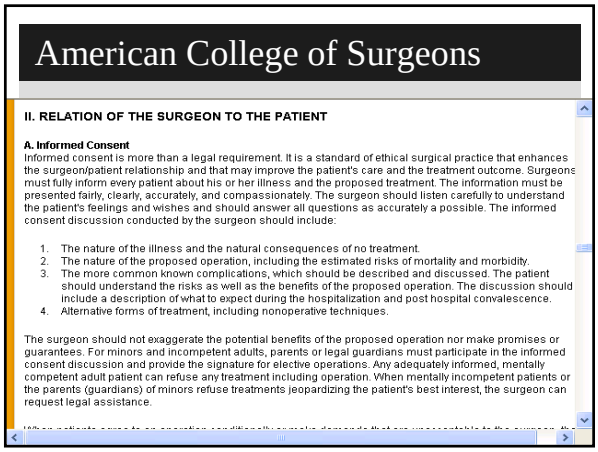
Informed consent is more than simply getting a patient to sign a written consent form. It is a process of communication between a patient and physician that results in the patient's authorization or agreement to undergo a specific medical intervention.

In the communications process, you, as the physician providing or performing the treatment and/or procedure (not a delegated representative), should disclose and discuss with your patient:

- The patient's diagnosis, if known;
- The nature and purpose of a proposed treatment or procedure;
- The risks and benefits of a proposed treatment or procedure;
- Alternatives (regardless of their cost or the extent to which the treatment options are covered by health insurance);
- The risks and benefits of the alternative treatment or procedure; and
- The risks and benefits of not receiving or undergoing a treatment or procedure.

In turn, your patient should have an opportunity to ask questions to elicit a better understanding of the treatment or procedure, so that he or she can make an informed decision to proceed or to refuse a particular course of medical intervention.

This communications process, or a variation thereof, is both an ethical obligation and a legal requirement spelled out in statutes and case law in all 50 states. (For more information about ethical obligations, see the AMA's Code of Medical Ethics, contained in the AMA PolicyFinder. Providing the patient relevant information has long been a physician's ethical obligation, but the legal concept of informed consent itself is recent.



American College of Surgeons

II. RELATION OF THE SURGEON TO THE PATIENT

A. Informed Consent

Informed consent is more than a legal requirement. It is a standard of ethical surgical practice that enhances the surgeon/patient relationship and that may improve the patient's care and the treatment outcome. Surgeons must fully inform every patient about his or her illness and the proposed treatment. The information must be presented fairly, clearly, accurately, and compassionately. The surgeon should listen carefully to understand the patient's feelings and wishes and should answer all questions as accurately a possible. The informed consent discussion conducted by the surgeon should include:

1. The nature of the illness and the natural consequences of no treatment.
2. The nature of the proposed operation, including the estimated risks of mortality and morbidity.
3. The more common known complications, which should be described and discussed. The patient should understand the risks as well as the benefits of the proposed operation. The discussion should include a description of what to expect during the hospitalization and post hospital convalescence.
4. Alternative forms of treatment, including nonoperative techniques.

The surgeon should not exaggerate the potential benefits of the proposed operation nor make promises or guarantees. For minors and incompetent adults, parents or legal guardians must participate in the informed consent discussion and provide the signature for elective operations. Any adequately informed, mentally competent adult patient can refuse any treatment including operation. When mentally incompetent patients or the parents (guardians) of minors refuse treatments jeopardizing the patient's best interest, the surgeon can request legal assistance.

Risk Calculators and Informed Consent

- A risk calculator that calculated the surgical complication risk based on age, weight, blood pressure, smoker, drug abuse history, diabetes etc.
- Initially used by heart surgeons
- Now being developed for other surgical specialties
- ACS introduced calculators for surgery of the colon and pancreas
- Now designing tools for 18 other procedures such as gastric bypass, hernia repair, and prostate surgery

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The Surgical Risk Calculator ACS NSQIP

- ACS has a surgical risk calculator to give physicians valuable information before scheduling elective surgeries
- Estimates the chance of an unfavorable outcome such as a complication or death
  - Risk percentages are only estimates
- Looks at up to 22 pre-op risk factors
- Estimates outcomes for more than 1,5000 procedures
  - Used data collected from nearly 400 hospitals and 1.4 million patients to develop the calculator

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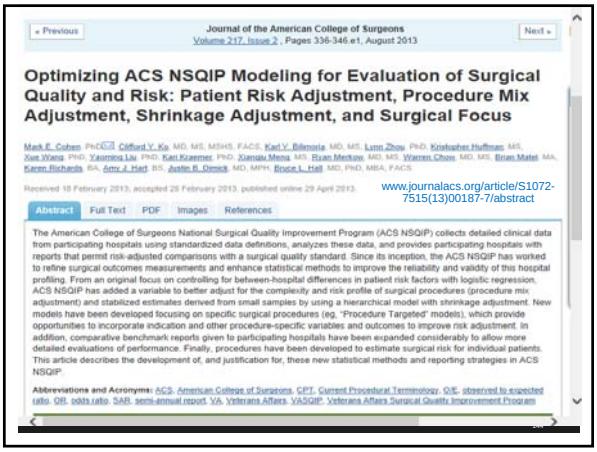
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Journal of the American College of Surgeons
Volume 217, Issue 2 , Pages 336-346.e1, August 2013

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Optimizing ACS NSQIP Modeling for Evaluation of Surgical Quality and Risk: Patient Risk Adjustment, Procedure Mix Adjustment, Shrinkage Adjustment, and Surgical Focus

Mark E. Cohen, PhD, Clifford Y. Ko, MD, MS, MSHS, FACS, Karl Y. Bilimoria, MD, MS, Lynn Zhou, PhD, Kristopher Huffman, MS, Xue Wang, PhD, Yaoming Liu, PhD, Kari Kraemer, PhD, Xiangju Meng, MS, Ryan Merkow, MD, MS, Warren Chow, MD, MS, Brian Matel, MA, Karen Richards, BA, Amy J. Hart, BS, Justin B. Dimick, MD, MPH, Bruce L. Hall, MD, PhD, MBA, FACS

Received 18 February 2013, accepted 25 February 2013, published online 29 April 2013.

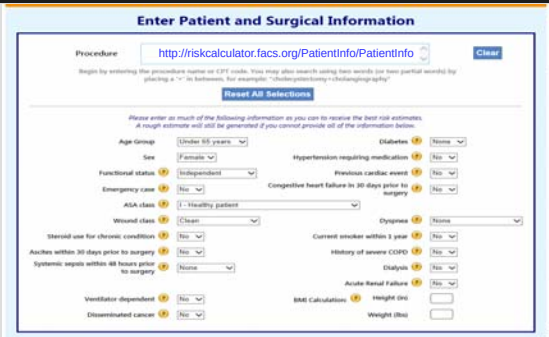
www.journalacs.org/article/S1072-7515(13)00187-7/abstract

Abstract | Full Text | PDF | Images | References

The American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) collects detailed clinical data from participating hospitals using standardized data definitions, analyzes these data, and provides participating hospitals with reports that permit risk-adjusted comparisons with a surgical quality standard. Since its inception, the ACS NSQIP has worked to refine surgical outcomes measurements and enhance statistical methods to improve the reliability and validity of this hospital profiling. From an original focus on controlling for between-hospital differences in patient risk factors with logistic regression, ACS NSQIP has added a variable to better adjust for the complexity and risk profile of surgical procedures (procedure mix adjustment) and stabilized estimates derived from small samples by using a hierarchical model with shrinkage adjustment. New models have been developed focusing on specific surgical procedures (eg, "Procedure Targeted" models), which provide opportunities to incorporate indication and other procedure-specific variables and outcomes to improve risk adjustment. In addition, comparative benchmark reports given to participating hospitals have been expanded considerably to allow more detailed evaluations of performance. Finally, procedures have been developed to estimate surgical risk for individual patients. This article describes the development of, and justification for, these new statistical methods and reporting strategies in ACS NSQIP.

Abbreviations and Acronyms: ACS, American College of Surgeons, CPT, Current Procedural Terminology, O/E, observed to expected ratio, OR, odds ratio, SAR, semi-annual report, VA, Veterans Affairs, VASQIP, Veterans Affairs Surgical Quality Improvement Program

The Surgical Risk Calculator ACS NSQIP



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Thanks for attending! Questions???

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- Call with questions, No emails

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