Informed Consent: Process

What's the Risk?

Informed consent remains an important issue in healthcare today. Viewed as a fundamental patient right, it is also an ethical obligation and a legal requirement that must be well understood and respected by those responsible for providing healthcare services to patients. It cannot guarantee that a claim will not be brought against a practitioner because of an adverse outcome, even if that outcome was presented to the patient as a possible result of the proposed therapy. Communication between patients, family, and practitioners is essential to the informed consent process. Coverys claims data identified inadequate informed consent for treatment options in nearly 6 percent of office/clinic-based closed claims from 2013 through 2017. Most informed consent cases to date have arisen from the following:

- Practitioner's failure (or alleged failure) to explain the proposed treatment/procedure in plain language the patient understands or to provide sufficient information about its risks, benefits, and consequences.
- Failure to document the discussion.
- Failure to obtain a written informed consent.
- Documentation of a lengthy informed consent form when the practitioner had a limited discussion with the patient.

Incomplete or nonexistent documentation of the informed consent process may result in the loss of a medical professional liability suit.

When Is This Risk an Issue?

Informed consent is a process, not just a form, and it involves two-way communication between the practitioner and the patient. It is a process that considers patient needs and preferences, patient education, and compliance with laws and regulations.

To fully understand when this risk is an issue, it is necessary to review the principle of informed consent, the legal basis of informed consent, implied versus express consent, decisional capacity, who may obtain consent, the elements of informed consent, which procedures and treatments need informed consent, and when to obtain consent.

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Principle of Informed Consent

The notion that physicians need to obtain patient consent prior to surgery dates back to the 1767 case *Slater v. Baker and Stapleton*.[1] This and other early American decisions looked to the law of battery, or nonconsensual touching, for the basis of their opinions. In the often cited 1914 case *Schloendorff v. Society of New York Hospital*, Judge Cardozo wrote, "Every human being of adult years and sound mind has the right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable for damages."[2] The term "informed consent" was introduced in the California case *Salgo v. Stanford* in 1957, in which the court stated:

> A physician violates his duty to his patient and subjects himself to liability if he withholds any facts that are necessary to form the basis of an intelligent consent by the patient to the proposed treatment . . . and that in discussing the element of risk a certain amount of discretion must be employed consistent with the full disclosure of facts necessary to an *informed consent.*"[3] [emphasis added]

These underlying policies have been reinforced in subsequent court decisions. They have been expanded to determine who may make a decision on behalf of a patient[4, 5] and to afford a patient the right to appoint a surrogate decision-maker when the patient is unable to make a decision regarding his or her care.[6]

Implied vs Express Consent

Informed consent comes in two basic varieties: *implied consent* and *express consent.* Implied consent may arise by conduct or operation of law. When, for example, a patient makes an appointment for a physical exam and willingly submits to various examinations and perhaps even a blood draw, the patient's own conduct implies consent. Consent is also implied when a patient requires emergency treatment to avoid death or serious bodily harm and is unable to provide verbal or written consent. Express consent occurs when the patient, or one who is able to speak on the patient's behalf, agrees to a specific provision of healthcare services and directly gives consent. A written consent is strongly recommended since there may be problems in proving the patient gave an oral consent.

Consent must be voluntary. To be legally effective, a written consent must also demonstrate that the procedure performed was the one for which the consent was given; that the person giving the consent understood the nature, risks, probable consequences, or outcome; the feasible treatment alternatives of the procedure; and the prognosis if the recommended procedure was not performed.

Decisional Capacity

Decisional capacity refers to the patient's ability to make a reasoned choice, taking into account the person's cognitive and affective functions, "including attention, intellect, memory, judgment, insight, language, emotion, and calculation."[7] Essential elements of appropriate decisional capacity are:

- The ability to receive information.
- The ability to process and understand information.
- The ability to deliberate.
- The ability to make and articulate a choice.[8]

The first step in the informed consent process is to assess a patient's decisional capacity.[9] This individualized approach can range from a relatively informal assessment gained from observing an obviously alert patient who demonstrates appropriate behaviors and judgment, to a more systematic and thorough examination using standardized tests to determine the decisional capacity of a patient who may be impaired in some way. Barriers to any of the four above-referenced essential elements may result in loss of decisional capacity and therefore the patient's capacity to provide informed consent. These barriers may be multifaceted, temporary, or permanent. Examples include dementia, intoxication, psychiatric conditions, language impairment, physical inability to communicate, severe pain, and various organic disease states.[10] Marco and Derse recommend the Stepwise Approach to Determination of Capacity:

1. Ensure the patient's ability to communicate.
2. Correct any reversible environmental, metabolic, mental, and physical challenges to capacity.
3. Utilize standardized tests of capacity, if indicated.
4. Assess patient goals and values using open-ended questions about choices (including risks and benefits), alternatives (including the option not to treat), and consequences.
5. Communicate with the patient and their healthcare advocates, if appropriate, about the decision and its ramifications.
6. Document essential elements of capacity or its impairment in the medical record.[11]

Additional pertinent cultural and linguistic specific information is available in the ***Cultural and Linguistic Competence*** chapter.

Who May Obtain Consent

The practitioner who will perform the procedure or treatment is best suited to explain the procedure or treatment and answer any patient questions. For this reason, this duty may not be delegated to one who is not able to respond to patient inquiries.

The Pennsylvania Supreme Court issued an opinion on June 20, 2017, in *Shinal v. Toms,* ruling that "the duty to obtain informed consent belongs solely to the physician and that it is non-delegable". The court further stated, "…we hold that a physician cannot rely upon a subordinate to disclose the information required to obtain informed consent. Without direct dialogue and a two-way exchange between the physician and patient, the physician cannot be confident the patient comprehends the risks, benefits, likelihood of success, and alternatives."[21]

Another healthcare practitioner who is not performing the procedure or treatment may:

- Ensure properly completed consent forms and appropriate medical record documentation.
- Witness the informed consent discussion.
- Act as a liaison.
- Convey information between the patient and the practitioner who will perform the procedure.
- Review the chart before the procedure begins to ensure that a documented informed consent is present.
- Refer any patient questions regarding the procedure to the practitioner who will perform it.
- Delay the signing of consent documentation until they are satisfied that all patient questions have been answered and that all elements of a valid consent are addressed in the medical record.

However, this practitioner should not obtain patient consent, as they may inadvertently omit vital information that is necessary to convey to the patient prior to consenting. Such a failure to convey pertinent information may result in unmet patient expectations and in allegations that the consent obtained was not truly informed consent.

Which Procedures and Treatments Need Informed Consent

At a minimum, obtain written consent for:

- All invasive procedures, including major or minor surgery involving an entry into the body, either through an incision or through a natural body opening.
- All procedures using anesthesia, other than a topical local.
- All high-risk therapies/drugs.
- Medical procedures that involve more than a slight risk of harm to the patient or may cause a change in the patient's body, e.g., chemotherapy, diagnostic procedures involving contrast or dyes, administration of drugs that carry very serious or irreversible side effects.

- All experimental procedures and clinical trials.
- All forms of radiology therapy.
- Electroconvulsive therapy.
- Blood and blood product use.
- Off-label medical device or medication use.
- Administration of anesthesia other than topical anesthesia.
- Any other procedure that the practitioner believes will require a specific explanation to the patient.

Elements of Informed Consent

It is important to understand that informed consent is a *process, rather than a form*. The form simply documents the process between the provider performing the procedure and the patient or the patient's representative, as circumstances may dictate.

Because informed consent is the direct communication between the practitioner performing the procedure and the patient concerning a proposed course of treatment, it must be based on a clear, concise, and factual explanation of proposed treatments, possible outcomes, and alternatives to therapy using plain language the patient understands. Since the term "informed consent" entered the medical-legal arena in the mid-1960s, courts have been developing a definition for the process and each of its elements. To establish its validity, the consent process in the medical record must include the following discussions:

- Diagnosis/nature of the illness being treated — Failure to disclose the diagnosis is rarely the basis for litigation since it is commonly discussed as a natural part of the practitioner-patient information exchange.
- Nature and purpose of the proposed treatment — Explain the treatment plan in lay terms that the patient can easily understand.
- Potential risks and benefits — Litigation involving the lack of informed consent may arise from the practitioner's alleged failure to provide enough information about the risks and benefits of the proposed treatment. Explain the procedure's risks and benefits in terms of the likelihood that they may occur, as supported by the available evidence. This will assist a patient in weighing the associated risks and benefits. For example, a certain percent chance of blood loss occurring with abdominal surgery is a risk. The fact that eight out of 10 patients with similar symptoms reported relief from or elimination of the symptoms is a benefit.
- Feasible Alternatives — Providing reasonable, available alternatives (and their risks and benefits) offers options and allows a patient to make a reasoned choice. Such alternatives may range from doing nothing to selecting a more conservative or more aggressive approach than the proposed procedure or treatment.

- Prognosis if the proposed procedure or treatment is refused — Another essential element of a patient's informed consent is an honest projection of what will likely happen if the procedure is not performed or the treatment is not undertaken. When available, provide supportive evidence.
- The name(s) of the provider(s) performing the procedure and of any residents, assistants, or providers who may perform a significant portion of the procedure or treatment.
- The name(s) of allied health professionals who may perform tasks related to the surgery.[12]
- The patient's opportunity to ask and receive sufficient answers to their questions.

When to Obtain Informed Consent

The main purpose of the informed consent process is to ensure that the patient or the patient representative receives the appropriate information to make an educated decision before consenting to a procedure or treatment. For this reason, allow sufficient time for the discussion and for the patient to ask questions. This discussion should not occur if the patient's ability to understand is compromised in any way, including being under the influence of alcohol or drugs.

Exceptions to Obtaining Informed Consent

Exceptions to the need to obtain informed consent are outlined below.

Emergencies

While specific definitions may vary from state to state, emergencies are recognized as exceptions to the need to obtain informed consent. In order to qualify as an emergency, three criteria must be present: (1) the patient must have a life-threatening illness or injury that presents an immediate risk of death, serious harm, or impairment; (2) the patient must be unable to give consent; and (3) there is no time to obtain consent from a surrogate decision-maker or next of kin.[13] When these circumstances exist, the law presumes that the patient would have consented to treatment.[14]

An important point to remember in providing emergency care without obtaining informed consent is that the documentation must support the reasons for not obtaining consent. A second element is that only the care that is medically necessary to alleviate the emergency situation is authorized under the emergency exception.

Therapeutic Privilege

Another exception to the requirement to obtain informed consent exists when the risk of disclosure may cause psychological harm to the patient. The therapeutic privilege is narrowly interpreted; it requires thorough documentation of the patient assessment, the anticipated harm, and any evidence the provider can cite that supports invoking the privilege. It may also be advisable to have an assessment by a psychologist or psychiatrist if time permits and if the practitioner has any question whether to invoke this privilege. This may be especially true when family members request that the practitioner not disclose certain facts to the patient.

The therapeutic privilege has been used far less frequently since the American Medical Association adopted the position that physicians "should sensitively and respectfully disclose all relevant medical information … tailored to meet the preferences of individual patients."[15] The information is not necessarily communicated all at once, but rather in easily understandable amounts and when the patient is fully capable of receiving it.

Repetitive Procedures/Treatments

When a patient undergoes repetitive treatment, such as renal dialysis or chemotherapy, it is not necessary to obtain consent before each treatment. It is sufficient that the initial informed consent process and documentation states the patient will undergo a series of treatments or procedures. In this situation, a new consent discussion and documentation would only be necessary if there is a change in the procedure or treatment that alters the risks, benefits, discomfort, or side effects originally disclosed to the patient.

Compulsory Procedure/Treatment

Yet another exception to informed consent is the compulsory treatment exception.[16] This includes treatment that is mandated by law, either by a judge's order or a legal statute, to protect the individual's well-being or the well-being of the community.[17] Compulsory treatment may be ordered when there is a threat of transmitting certain communicable diseases, such as tuberculosis. It may also be mandated to alleviate the symptoms of disabling mental illness. Even though patients may not be able to refuse treatment in certain circumstances, it is still recommended that the practitioner inform the patient about the treatment they are to receive.[18]

Patient's Refusal to Be Informed

A unique exception to the informed consent process occurs when a patient refuses to be informed about a proposed treatment or procedure. When a practitioner encounters this situation, they should try to determine why the patient is refusing to be informed and if the patient understands the implications of their consent to treatment without being fully informed. This discussion may prompt the patient to ask more questions. If the patient continues to refuse full disclosure, the practitioner must document the discussions and the reasons for the

practitioner's decision to proceed, along with any other actions taken or recommendations made.

Informed Refusal

The patient has the right to weigh all the information provided by the practitioner and to decide against a treatment or procedure. A practitioner may not agree with the patient's perception of the consequences of the proposed treatment or the patient's decision. However, it is imperative to abide by the patient's wishes once the patient has received information upon which to make an informed decision, understands the implications, and has had an opportunity to ask questions and have them answered.[19]

Withdrawal of Consent

The patient has the legal right to revoke or withdraw consent before or during treatment,[20] as long as they fully understand the risks and potential consequences of this decision. It is recommended that the withdrawal of consent be in writing. However, a patient may withdraw consent verbally. When this occurs, it is recommended that two caregivers serve as witnesses to the withdrawal, and the patient's stated reasons for withdrawal are documented. The primary healthcare provider and all consultants should be advised of the patient's decision.

Special Considerations

Minors

Adults of sound mind are generally deemed able to make their own decisions about consenting to or refusing care. Unless otherwise provided by state or federal law with regard to specific treatments or procedures, minors typically do not enjoy this right. The right to consent to or refuse medical care for minor children generally falls to their parents or legal guardian(s). Some exceptions apply for adolescent minors seeking contraception, an abortion, or treatment of sexually transmitted diseases or substance abuse (typically drugs and alcohol). Emancipated minors may be treated as adults for purposes of informed consent. Emancipation usually involves a demonstrated measure of independence from their parents, such as marriage, living on their own/financial independence, military service, pregnancy, or having children of their own. State laws outline the elements that constitute emancipation.

Lack of capacity to consent

Lack of competence may be permanent due to mental retardation, brain damage, dementia, or some other persistent state, or it may be temporary due to a physical or mental illness or impairment from drugs or alcohol. It is essential to determine whether the patient has sufficient mental ability to understand and make a rational decision about treatment. It is generally accepted by both the courts and the medical community that mental illness and/or civil commitment do not automatically render an individual incompetent to make treatment decisions. In some instances,

the patient has been formally judged incompetent and a substitute decision-maker has been legally appointed.

Patients with early dementias and otherwise failing memory may still have moments of lucidity and be able to make decisions on their own behalf. Those who do not have moments of lucidity must have a legal guardian or substitute responsible decision-maker give informed consent on their behalf.

Sight- and Hearing-Impaired
The Americans with Disabilities Act protects certain persons from discrimination. This protected class includes those whose sight and/or hearing are impaired.

Patient Education
Patient instruction in the informed consent process can be supplemented by the use of DVDs, sketches, and pamphlets that further explain a procedure or treatment. These tools can assist the practitioner in their verbal presentation, while providing the patient a springboard for additional questions and discussion. A patient who is educated on all aspects of their proposed care will be more compliant and less likely to file a complaint.

General Consent Form Versus Informed Consent Form
A general consent for care form that a patient typically signs at the time of the first office visit only authorizes a practitioner to provide routine care for the patient. The general consent form is not considered an informed consent form because it does not include the elements of informed consent, such as a discussion about potential risks, benefits, alternatives, or likely outcomes.

How Can I Reduce Risk?

Practitioners can limit the risk of a lack of informed consent claim by adhering to the following risk management recommendations: know when to obtain informed consent; know who may obtain informed consent; conduct an informed consent discussion; document the discussion; consider using a consent form; provide informed refusal when necessary; recognize issues related to minors; recognize the patient's right to withdraw consent; consider the patient's limitations and cultural sensitivities; and use telephone consent only when necessary. A detailed list of these recommendations appears below.

Know *When* to Obtain Informed Consent	
Obtain consent for certain procedures and treatments	• Obtain informed consent for the following procedures or treatments:

Know *When* to Obtain Informed Consent

- Invasive procedures, including major or minor surgery involving an entry into the body, either through an incision or through a natural body opening or those that pose more than a slight risk of harm.
- Procedures using anesthesia other than a topical local.
- High-risk therapies/drugs.
- Medical procedures that involve more than a slight risk of harm to the patient or which may cause a change in the patient's body, e.g., chemotherapy, diagnostic procedures involving contrast or dyes, administration of drugs that carry very serious or irreversible side effects.
- Experimental procedures and clinical trials.
- Procedures involving the use of cobalt and radiation therapy.
- Electroconvulsive therapy.
- Blood and blood product administration.
- Photographing or video recording the patient.
- Sterilization procedures such as tubal ligation or a vasectomy.
- Administration of chemotherapy, psychotropic medications, and contrast media.
- Medications with potentially serious side effects; e.g., Coumadin (warfarin sodium); long-term, high-dose steroids; and Ritalin® (hydrochloride methylphenidate hydrochloride).
- Off-label medical device or medication use.
- Any other procedure that the practitioner feels will require a specific explanation to the patient.

Know *When* to Obtain Informed Consent	
Obtain consent for hospital surgical procedures	• Obtain informed consent for hospital surgical procedures in the office. Discuss the following with the patient in terms and language they understand and document these discussions in the medical record: ○ Diagnosis/nature of the illness being treated. ○ Nature, purpose, and explanation of the procedure to be performed. ○ Potential risks and benefits. ○ Feasible alternatives. ○ Prognosis if the proposed procedure is not performed. ○ The name(s) of providers performing the procedure and any residents, assistants, or providers who may be performing a significant portion of the procedure or treatment. ○ The name(s) of advanced practice professionals who may be performing tasks related to the surgery. ○ The patient's opportunity to ask and receive sufficient answers to their questions.
Obtain consent when in doubt	• Obtain informed consent if there is any doubt as to whether consent is required.
Distinguish between general and informed consent	• Obtain the patient's general consent for routine care and informed consent when required for specific procedures, treatments, and medications.
Obtain consent for serial procedures	• Obtain one consent for serial procedures unless there are changes in the treatment or procedure used, in the level of risks or benefits, or in the anticipated discomfort and/or side effects initially disclosed to the patient.
Obtain consent for repeat procedures	• Obtain one consent if procedures are performed repeatedly over time (e.g., BOTOX® and steroid injections).

Know *When* to Obtain Informed Consent	
Renew periodically	• Renew consent periodically if treatment extends longer than anticipated.
Limit use of implied consent	• Use implied consent only in situations requiring emergency intervention or when an otherwise competent patient is unable to make a decision and a surrogate decision-maker is unavailable.

Know *Who* May Obtain Informed Consent	
Ensure practitioner obtains consent	• Ensure that the person performing the procedure obtains informed consent.
Delegate appropriately	• Understand those aspects of obtaining consent that may be delegated to those not performing the proposed treatment or procedure. For example, nurses may witness the patient's consent.

Conduct an Informed Consent Discussion	
Assess ability to understand	• Assess the patient's ability to understand and to process the information given before initiating an informed consent dialogue with the patient. Use lay terms.
Determine barriers	• Determine if there is a language barrier, presence of hearing or sight impairment, a question of mental competency, or a level of stress that may interfere with the patient's ability to fully understand or make decisions, for example, the patient who has just been given a cancer diagnosis. If you identify an issue, delay informed consent until an intermediary can be found or the issue is resolved.
Explain major risks	• Explain major risks and those most likely to occur that a reasonable patient would want to consider when deciding whether or not to consent to the procedure or treatment. Giving too much information can be as problematic as giving too little.

Conduct an Informed Consent Discussion	
Explain specific risks	• Explain the risks of a particular concern. In most instances, the patient needs to learn only of those risks that are common to the procedure. In some cases, however, a patient may need to be told about risks that have a more remote chance of occurrence. An example might be explaining a remote risk if a patient has a particular fear of the risk.
Carefully consider withholding information	• Disclose information necessary for the patient to make an informed decision. Refrain from withholding information solely because it may frighten the patient or because you fear they may decline the proposed treatment.
Let patient ask questions	• Give the patient the opportunity to ask questions about the proposed treatment, therapy, or procedure. Answer all questions fully, honestly, and to the patient's satisfaction.
Disclose facts	• Candidly share facts about the procedure, including statistics and your personal experience with the procedure. Refrain from trying to convince the patient if they appear reluctant to consent.
Document the Discussion	
Document consent process	• Ensure that the practitioner who obtains informed consent documents the consent process in the medical record.
Document rationale	• Document the rationale for all proposed treatment regimens and take extra care to document those that may be regarded as "unusual" or outside of standard practice procedures. Include any available supporting documentation to assist a reviewer in determining the practitioner's rationale in recommending a treatment option to the patient. This is important as treatment methods can vary among practitioners. It can also be critical in assisting the defense in the event of an adverse outcome.

Document the Discussion	
Document patient education	• Describe all patient education aspects. This includes written material given to the patient and any DVDs or other recorded media the patient watched as part of the informed consent process. Document the patient's response.

Consider Using a Consent Form	
Tailor consent form	• Tailor consent forms to the procedure for which they are intended, when possible. Include all the informed consent elements outlined in the paragraph, "Elements of Informed Consent." Review the following sample forms: ○ ***Consent for Anesthesia Services*** ○ ***Informed Consent for Minor Surgical Procedure*** ○ ***Informed Consent for Surgical and/or Invasive Procedures***
Conduct discussion first	• Ensure that the informed consent discussion occurs prior to the patient signing the consent form or informed refusal form.
Refrain from combining forms	• Ensure that the procedural or treatment consent is separate from the anesthesia consent. They may exist on the same document but should be visually separated and have separate signature lines for the practitioners providing the specific services.
Obtain signature	• Obtain the signature of the patient or the patient's advocate on the form. The practitioner who obtained the informed consent should sign the consent form.
Obtain attestation for electronic signature	• If you allow patients to sign informed consent forms electronically or if you offer patients the opportunity to electronically "sign" information posted on your website, obtain an attestation that the patient (or the patient's advocate) understands all the information presented.

Provide Informed Refusal When Necessary	
Obtain informed refusal	• Document informed refusal when a patient, patient advocate, or legal guardian refuses a specific treatment or procedure. When able, obtain the patient's signature or the patient's advocate's signature on a refusal of care form.
Discuss costs	• Discuss the known procedure costs, acknowledge whether a portion is paid by insurance, and help the patient investigate other options if they refuse a procedure due to financial reasons. Include available alternatives, along with their risks and benefits, as well as the likely result of no treatment.
Consider Refusal of Treatment Form	• See the sample ***Discussion and Refusal of Treatment*** form.

Recognize Issues Related to Minors	
Understand state laws	• Familiarize yourself with state laws regarding the treatment of minor patients.
Obtain parental consent	• Obtain the consent of a minor patient's parent or guardian before beginning an elective treatment or procedure on the minor. Parental consent is not required to treat a minor for substance abuse or a sexually transmitted disease in most states.
Reschedule if no parental consent	• Obtain the consent of a minor patient's parent or guardian before beginning an elective treatment or procedure on the minor. Parental consent is not required to treat a minor for substance abuse or a sexually transmitted disease in most states.
Contact attorney when necessary	• Consider contacting legal counsel when a parent or legal guardian refuses care or treatment that might save a minor's life.
Establish protocol	• Establish a written protocol addressing the management of situations in which a parent or legal guardian refuses routine minor care, such as vaccinations.

Recognize Issues Related to Minors	
Document refusal	• Document the refusal of routine care, such as vaccinations. Record the discussion with the parent or legal guardian and their decision.
Determine whether the minor is emancipated	• For more information on making this determination, see the section on emancipated minors.

Recognize the Patient's Right to Withdraw Consent	
Obtain in writing	• Obtain withdrawal of consent in writing and have the patient's signature revoking or withdrawing the consent witnessed by a healthcare professional. If the patient refuses to sign a form that revokes or withdraws consent, thoroughly document the discussion in the medical record. Obtain the signatures of any healthcare professionals or administrative staff members who were present during the discussion.
Document reasons	• Document the patient's reasons for withdrawal in the medical record.

Consider the Patient's Limitations and Cultural Sensitivities	
Recognize limited English proficiency (LEP) patients	• Provide an interpreter when the practitioner is seeking informed consent and the patient does not understand the English language. Provide an explanation (and form, if possible) in the patient's language. Document the translator's name on the appropriate consent forms and in the patient's chart.
Recognize literacy limitations	• Read the consent form to any patient who cannot read. Write consent forms at a fifth-grade reading level. Explain procedures and treatments in terms the patient can understand. Require at least two individuals to witness the consent if the patient signs the form with a mark rather than a full signature.

Consider the Patient's Limitations and Cultural Sensitivities	
Recognize sight- and hearing-impaired patients	• Read the written explanatory materials and consent form to any sight-impaired patient or provide Braille booklets and forms. Provide written materials and/or an interpreter to hearing-impaired patients. Document those instances when a hearing-impaired patient has asked for a translator, as well as the actions taken to provide one.
Recognize issues related to dementia	• Determine if the patient has moments of lucidity. Obtain the patient's consent if the patient is able to make a decision. Consider obtaining a formal evaluation of the patient's level of understanding by a provider trained in assessing dementia. Require that a witness be present for your informed consent conversations with the patient. Document the name of the witness in the medical record. Obtain consent from the patient's legal representative if the patient has no moments of lucidity.
Recognize cultural sensitivities	• Determine whether the patient's cultural or ethnic background may alter the typical informed consent process. For example, certain cultures forbid women to have discussions with a male about intimate body parts or require the presence of the woman's husband during these discussions.

Use Telephone Consent Only When Necessary	
Limit telephone consent	• Limit obtaining consent by telephone to those situations in which time and/or distance prevent a face-to-face discussion of the risks, benefits, alternatives, and expected results of the intervention.
Develop a policy	• Develop a policy to guide employees in conducting and documenting the telephone consent process.
Involve second professional	• Involve a second licensed healthcare professional as a witness whenever possible. Address who may serve as a witness in a policy.

Use Telephone Consent Only When Necessary	
Complete documentation	• Document the name of the individual contacted and their relationship to the patient; the rationale for obtaining the consent by telephone; the elements of the informed consent discussion, including questions asked and answered; and the signatures of the responsible practitioner and witness.
Include written confirmation	• Follow up telephone consent with written confirmation, either by fax transmission or by scanning and emailing the documents.

References:

1. Daniel W. Roslokken, "Two for the Show: Supreme Court advances informed consent and med mal law," *New Jersey Law Journal*, Dec. 6, 1999.
2. Schloendorff v Society of New York Hospital, 211 NY 125, 105 NE 92 (1914).
3. Salgo v Leland Stanford Jr. University Board of Trustees, 154 CalApp2d 560, 317 P2d 170 (1957).
4. Cruzan v. Director, Missouri Dep't of Health, 497 U.S. 261 (1990).
5. In re Quinlan, 70 N.J. 10, 355 A.2d 647 (NJ 1976).
6. The Patient Self-Determination Act of 1990.
7. Catherine A. Marco and Arthur R. Derse, "Informed Consent: Are You Up On the Basics," ED Legal Letter, Vol. 17, No. 5, May 2006, Pages 49-60. This information was originally published in ED Legal Letter. Reprinted with permission of Thompson American Health Consultants, PO Box 740056, Atlanta, GA 30374. For subscription information, contact customer service at (800) 688-2421.
8. Ibid.
9. Ibid.
10. Ibid.
11. Ibid.
12. U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), State Operations Manual - Appendix A, Survey Protocol, Regulations and Interpretive Guidelines for Hospitals, Rev. 116, 06/06/2014. (See §482.13(b)(2) and §482.24(c)(4)(v) and associated Interpretative Guidelines.)
13. Roberta Carroll (Series Ed.) and Sylvia Brown (Volume Ed.), Risk Management Handbook for Healthcare Organizations, Sixth Edition, Volume 2: Clinical Risks, John Wiley & Sons, Inc., San Francisco, CA, 2011, p. 85.
14. Ibid.
15. American Medical Association (AMA), "Opinion 8.08 - Informed Consent," Issued March, 1981, Updated November 2006, https://www.ama-assn.org/delivering-care/code-medical-ethics-consent-communication-decision-making 7/06/2018
16. Roberta Carroll (Series Ed.) and Sylvia Brown (Volume Ed.), p. 88.
17. Ibid.
18. Ibid.

19. Ibid, pp. 90-91.
20. Ibid, p. 91.
21. Coverys Risk Management Alert: Pennsylvania Supreme Court: Informed Consent is a Non-delegable Duty; August, 2017.