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BEST PRACTICES

# RISK MANAGEMENT **RESOURCE**

This exclusive resource was developed and is maintained by NORCAL Group's risk management team and is made available to members of the American Society for Interventional Pain Physicians (ASIPP) by Tom Wierzbowski of Willow Risk Advisors.

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AMERICAN SOCIETY OF INTERVENTIONAL PAIN PHYSICIANS
ASIPP®

**INFORMED CONSENT AND REFUSAL**

BEST PRACTICES

## RISK MANAGEMENT RESOURCE

# INFORMED CONSENT AND REFUSAL

**ABOUT NORCAL GROUP**

The NORCAL Group of companies provide medical professional liability insurance, risk management solutions and provider wellness resources to physicians, healthcare extenders, medical groups, hospitals, community clinics, and allied healthcare facilities throughout the country. NORCAL Group includes NORCAL Mutual Insurance Company and its affiliated insurance companies. Please visit norcal-group.com/companies for more information.

## Informed Consent Process and Patients' Rights

There are two types of consent – simple and informed. A simple consent applies to common treatments or procedures with minimal or no risks, such as agreeing to a medical exam, withdrawing blood, treating the flu or getting an MRI. Simple consent is implied and based upon understanding, collaboration, and agreement. Alternatively, informed consent applies when a proposed treatment is invasive or carries more risk, such as surgery, complicated medical plans, prescribing high-alert medications, or research treatments. Informed means the person is given information and understanding as to what a reasonable person would need to know in order to make a decision.

Providing an adequate informed consent requires a physician to complete a four-part process. The process includes discussion, education, documentation and use of a consent form. The process is designed to give patients the information necessary to make a **voluntary and informed decision** about a proposed treatment or procedure –- even if that patient's ultimate decision is not what the physician believes to be in the patient's best interest. The concept of informed consent to medical treatment is based on the following premises:

- Patients are generally not knowledgeable in the medical sciences.
- Adults of sound mind have the right to determine whether or not to submit to medical treatment and decide what will happen to their own bodies.
- A patient's consent to treatment is always required and for some forms of treatment the physician must obtain an "informed consent."
- The physician must provide the patient with the information necessary to allow the patient to provide an "informed consent" when it is applicable.

Except in an emergency, a physician must obtain informed consent from the patient or a legal decision-maker before performing certain procedures. Depending on state law, procedures requiring informed consent may include surgical and invasive procedures, administering certain medications or contrast agents that could have severe or unknown outcomes to the patient, entering a patient in a research trial and in certain other circumstances.

Failure to obtain a patient's informed consent when required can result in a physician's liability-even if a procedure or treatment is indicated and is performed non-negligently.

## Medical Professional Liability Risks

Physicians may incur liability for consent issues even when their medical care met the standard of care. Consent issues are not usually the central focus of malpractice claims, but they often become important **associated issues or secondary allegations**. While a lack of informed consent or an insufficient disclosure may not necessarily have a causal connection to medical injuries in a malpractice case, those issues can and do discredit physicians at trial or during settlement discussions.

- The patient's right to determine what shall be done with his or her own body is reflected, in part, within the legal concept of **battery**. Battery is the intentional, nonconsensual touching of

another person. A **battery** claim by a patient, although specifically defined by state law, generally would include one or both of these elements:

1. There was no consent given for the examination or treatment.
2. The treatment provided constituted a substantially different form of care than that which was agreed upon by the patient and physician.

- A **negligence** claim by a patient would allege that the physician failed to disclose information that the patient should have had in order to make an informed decision about the treatment.

## Informed Consent Exceptions

There are generally two exceptions to informed consent standards. There may be other state-specific exceptions, so it is recommended to review your state's guidelines:

- **Emergency situations** — in an emergency situation, if the patient does not have the capacity to make decisions, there is no legally designated decision-maker or representative available, and all reasonable efforts have been made to contact the legal representative, then a patient will be presumed to have consented to necessary medical treatment. The emergency exception does not apply if the patient has already refused similar treatments in the past in writing (e.g., through an advance directive, durable power of attorney, or by signing a Do Not Resuscitate order).
- **Therapeutic privilege** — a very rare exception that arises when a physician can prove that disclosure of medical information would cause the patient such serious psychological distress that disclosure is contraindicated.

## Informed Refusal

A patient (or a person with decision-making authority for a patient), after being appropriately informed of risks, benefits and alternatives of a contemplated treatment, procedure or high-risk medication, has the right to refuse. Physicians should emphasize the importance of the treatment or procedure and the consequences of no treatment; the patient should be made aware of the ramifications of his or her decision. However, if the patient understands the risks of no treatment and still chooses to refuse, he or she has made an informed refusal decision that must be respected, regardless of how detrimental the physician or healthcare team members think the decision is. If, after receiving information about risks and benefits, a patient refuses a treatment or procedure, the patient's refusal should be documented in the medical record and the patient should be asked to sign a refusal of treatment form *(see Sample Refusal of Treatment Form).* The process related to the informed refusal (the main points of the discussions about risks, benefits and consequences of declining treatment) should also be documented.

## Obtaining Consent for Human Immunodeficiency Virus (HIV) Testing

Many states have laws and regulations associated with obtaining informed consent for testing for HIV. The Centers for Disease Control maintains a website that details testing laws in all 50 U.S. states, available at www.cdc.gov/hiv/policies/law/states (accessed 6/14/19).

## Obtaining Consent for Treatment of Patients Lacking Capacity

When an adult patient is competent, he or she has the right to obtain or to refuse healthcare. However, when a person lacks decision-making ability to understand the concepts associated with medical treatment, another person must help him or her to obtain care and must give the informed consent for the patient when the situation requires it. Examples of individuals that sometime fall into this category include elderly people who have reduced mental capabilities, intellectually disabled people, some mentally ill people, minors or accident victims who have lost the ability to reason effectively.

In some cases, a court may have adjudicated incompetency or there is a formal written arrangement that allows patients with diminished mental capacities to have a spokesperson make healthcare choices and help them get treatments. For instance, the patient may have pre-appointed a healthcare agent before his or her decline, or a parent or sibling may be the named guardian or conservator of a developmentally disabled individual. Sometimes, especially for elderly declining patients, the situation is handled less formally, with the patient's next of kin — a spouse, adult son or daughter, or a sibling — bringing the patient to medical appointments and assuming an increasing role in the person's living arrangements and overall care.

In general, there are several ways a surrogate may become responsible for making healthcare decisions for patients lacking capacity to make a decision. The surrogate decision-maker may be the patient's next of kin; the patient, when competent, may have designated the surrogate decision-maker as his or her healthcare power of attorney; or a court may have appointed the surrogate decision-maker when the patient was deemed incompetent. States' laws cover surrogate healthcare decision-making, including patients' designation of proxies and court appointment of decision-makers, so physicians should know and follow the rules in their states. The American Medical Association has an ethical opinion on surrogate decision-making available at www.ama-assn.org/sites/default/files/media-browser/code-of-medical-ethics-chapter-5.pdf (accessed 6/14/19).

Physicians, especially primary care, are in a position to play a role in helping patients prepare for future healthcare decisions. This can be done by encouraging them to make arrangements for an alternate healthcare decision-maker in the event they are no longer able to make sound independent choices. Physicians can educate patients about methods for preplanning, such as naming healthcare proxies and establishing living wills. They can inform patients that by establishing advance directives, this will ensure the patients' philosophies about healthcare are known and their needs are met.

## Consent for a Series of Treatments

There may be occasions where consent is necessary for a series of treatments (e.g. Botox injections, chemo or biotherapy treatments, immunotherapy injections, etc.). It is important that the consent reflect that this is a series of treatments and not one encounter. When discussing the treatment plan with patients, physicians should address the indication for the treatment/procedure, along with the risks, benefits, and alternatives, and if the treatment includes a specified number or schedule of treatments (e.g. one per week for four weeks, etc.) and should indicate a specified end date. The treatment series should be clear and specific and included in the informed consent discussion and form. A reconciliation process should occur at each patient visit, where the consent is reviewed and if anything has changed with the elements of the consent or the patient's condition, or understanding, then a new consent process should be started.

## Consent by Telephone, Email or Facsimile

At times, the person(s) having the legal authority to consent for the patient may not be available and physicians must obtain consent by telephone, email or facsimile. The responsible physician must, to the extent possible, provide the legal representative with the information needed to obtain consent for treatment or an informed consent for a procedure--just as if that person were present.

Excluding emergency situations, prior to obtaining consent by telephone, email or facsimile, it is important to have an established relationship with the patient. When obtaining consent by telephone:

- Verify the authenticity of the person legally authorized to consent for the patient by asking questions regarding DOB, address, phone numbers, etc. Verify the information provided is correct to ascertain you are speaking to the intended person.
- Have the call witnessed by a second responsible person.
- Follow standard consenting process, discussing the risks, benefits, and alternatives with the person authorized to consent as if he or she was present.
- Document in the patient's medical record that consent was obtained by phone, who consented, who obtained the consent, and who witnessed it.

After verifying the authenticity of the person authorized to consent by telephone and discussing the care and treatment, you may request that the person provide documentation of his or her consent by email or fax. Have the person giving consent send or affirm a message with words such as:

> "I have been informed by Dr. X of the risks, benefits and alternatives associated with the proposed treatment and grant permission for him/her to provide medical treatment [or a specific procedure or treatment] to [Patient's Name], their relationship to the patient."

Attach or scan a copy of the email or fax to the medical record. Whenever possible, original, signed consents should be obtained and filed or scanned into the medical record.

## Documentation of Informed Consent

Informed consent is a communication process in which a physician talks with a patient about the nature of his or her illness or condition, describes a procedure and its contemplated benefits, and discusses the risks and alternatives that a patient would require in order to make an informed decision about that procedure.

The physician performing the procedure, or ordering or providing the care, is responsible for obtaining the patient's informed consent prior to the provision of the care. Neither the hospital nor a referring physician is responsible for the consenting process. Physicians may not delegate to others the duty of informing patients about the treatment options, associated risks and material information needed by patients to make an informed decision. Physicians may delegate to a nurse or office staff member the task of getting a consent form signed, but the physician is ultimately responsible for the consent process and should be available to answer any questions the patient has prior to actually scheduling, ordering, or carrying out the procedure. Meeting this responsibility is considered best practice from a patient safety and risk management perspective.

It is also important to understand your own state-specific requirements in this area. For example, in Pennsylvania, per a PA Supreme Court ruling on June 20, 2017; physicians must personally obtain informed consent and must personally answer their patients' questions. Additionally, in Pennsylvania, communications between physicians' staff members and patients will no longer be admissible at trials as to the issue of whether a physician obtained informed consent from the patient. (For additional information and discussion about the PA Supreme Court ruling see the Pennsylvania Medical Society's website at www.pamedsoc.org/advocate/topics/medical-liability/InformedConsentBrief or the article *PA Supreme Court Ruling: Only Doctors Can Obtain Informed Consent* found at www.postschell.com/publications/1386-pa-supreme-court-ruling-only-doctors-can-obtain-informed-consent. Articles accessed 6/14/19.)

Documentation of the informed consent discussion is important. Having a patient sign a form is supportive evidence that the informed consent *process* took place. Also, a signed form cannot replace the elements documented in a patient's record summarizing the discussion and education provided in the informed consent process that took place. Additional notation in the patient's record about the details of the informed consent discussion, (e.g., questions answered, risks pointed out that were specific to that person, or educational elements reviewed); can be crucial in defending a lawsuit for an alleged failure to obtain the patient's informed consent. Informed consent litigation often pits the memory of the patient against the documentation of the physician. A doctor's best defense in these types of cases is the information contained in the medical record, including not only a consent form signed by the patient but a description of the content of the informed consent discussion in the progress notes. This type of evidence significantly reinforces the physician's testimony.

Physicians should develop informed consent forms that meet state and federal requirements. The consent form should include the same elements as the consent discussion and should be written in language that the patient can understand *(see sample informed consent forms and instructions for*

*developing an informed consent form that accompany this resource.)* The elements on the form should include the following:

- An explanation of the patient's problem and proposed procedure
- Disclosure of information that a reasonable person would regard as significant in deciding to accept or reject a recommended procedure, including the following:
    - Complications (e.g., bleeding, possibility of additional procedures)
    - Severity (e.g., death, paralysis and loss of function)
    - Incidence of risks (e.g., 1 in 1000 experience this complication), which helps the patient put the risk, including loss of life or limb, in perspective
    - Information about common side effects (e.g., swelling or pain)
    - Names of other physicians/clinicians who will be performing parts of the procedure, e.g. PA harvesting a leg vein for a CABG procedure.
- An explanation of the benefits of the procedure
- A discussion of alternative treatments
- A statement that there are no guarantees that the procedure will be 100% successful
- Information about potential outcomes if treatment is refused
- Encouragement of the patient to ask questions
- Acknowledgment that the patient can withdraw consent
- The offer of a second opinion, if applicable

## Barriers to the Informed Consent Process

Many factors, including a patient's limited literacy skills, fear, sensory issues, level of intimidation, degree of modesty, or expectation regarding a specific outcome can diminish the patient's ability to comprehend the consent process. Cultural and linguistic differences can also be barriers to a patient's understanding. Since the informed consent process relies on discussion and education so that a patient can make an informed choice, it is a process that is heavily dependent on clear communication.

Various groups have taken an interest in healthcare communications involving vulnerable populations, and studies have been conducted in an effort to better understand the issues, reduce barriers and improve comprehension. One such study published in 2006 in the *Journal of General Internal Medicine* examined the informed consent process and described how lower literacy and minority status (potential difficulty with the English language) limited understanding of consent information. This article suggests various strategies for modifying the consent process for patients who may have problems understanding consent information. Specific modifications that were shown to reduce barriers and improve the consent process include:

- Using a more readable consent form (written with plain language, large font, short paragraphs, a lot of white space)
- Arranging for consent forms to be read to patients in their native languages

- Using an iterative "teach to goal" strategy (asking patients to answer questions to show their comprehension of material)

The article is available at www.ncbi.nlm.nih.gov/pmc/articles/PMC1831581/ (accessed 6/14/19).

## Risk Management Recommendations

- Recognize that **informed consent is a process, not a form**. This process incorporates educating the patient through discussion, documenting the discussion in the medical record and using a form to record the discussion. **The consent form should never replace the discussion and education provided**.
- Some healthcare facilities have policies mandating that patient consents must be obtained (and consent forms signed) within certain time parameters (for example, no more than 30 days before a procedure at that facility). Physicians should determine which facilities have such policies and should comply. Even when no specific time policy is imposed by a facility, if a protracted period of time has elapsed since the physician obtained a patient's consent for a procedure, he or she should reassess the situation to ensure the underlying framework for the consent is still applicable by questioning the patient to find out if anything has changed (e.g., has the patient seen a new doctor, started a new prescription or over-the-counter medication, visited a hospital emergency department or started any other type of new treatment?).
- Develop a policy and procedure for the informed consent process that ensures that patients' rights are honored (see *Informed Consent: Sample Policy and Procedure*). The process should focus on four key elements: 1) informed consent discussion; 2) education; 3) documentation; and 4) consent form.

### Discussion

- Recognize that the clinician or practitioner performing the procedure or administering the treatment is responsible for having the informed consent discussion with the patient, and obtaining and documenting the patient's consent. This is the most important element of the informed consent process, as it strengthens the physician-patient relationship and provides the patient with the material facts the patient needs to make an informed decision.
- Recognize that the office setting is the best place for the discussion to occur and that the physician must tell his or her patient information that allows the patient to make a meaningful medical care decision.

### Education

- Use educational pamphlets, written handouts, pictures and pre-op/post-operative instructions to help patients understand what they need to know in order to make an informed decision. Using educational items allows patients to remember discussions and information reviewed regarding possible risks and complications involved in procedures. Without the physician's thorough educational effort, patients often do not understand that a less-than-optimal outcome may not be caused by substandard medical care. Document in the patient's record that the

patient received these materials, because referencing educational materials could be used as reminders of the discussion or if the consent is challenged at a later date. Even if no longer in use, educational materials can be a valuable defense tool in the event of litigation. Out-of-date educational materials should be archived and kept in storage or scanned, so that a practice can easily refer to them in the event of a claim.

## Documentation

- Document the informed consent discussion in the medical record. Include the following:
  - A notation in the progress notes that the informed consent discussion took place and the patient either consented or did not consent to the procedure. (A patient's refusal of any treatment should be documented in the medical record and the patient should be asked to sign a refusal of treatment form — see sample *Refusal of Treatment form*).
  - A notation regarding what items specific to that patient were discussed and any items that received special emphasis.
  - Questions and/or concerns patient had and how they were addressed.
  - A notation or copy of any written material given to the patient, including educational handouts, instructions, or information sheets.
  - The signed and dated consent form, if obtained.
  - A notation that the patient received a videotape, DVD, visual aids, etc.
  - A notation of the patient's language, if not English, and the name and relationship of the translator or other steps taken to facilitate communication, if applicable.

## The Consent Form

- Develop forms for procedures that require informed consent (See sample informed consent forms and instructions for developing an informed consent form).
- Allow space to insert factors unique to the individual patient, (e.g., the patient's comorbidities), that could affect the outcome, or a particular question or concern expressed by the patient and how it was addressed.
- Never replace the informed consent discussion with the consent form, which is simply a **record** of the discussion and agreement given.
- Include the elements of an informed consent form as listed above.
- Especially when a risk of refusal might cause significant harm to a patient, consider asking patients to sign a refusal of treatment form after completing and documenting the patient's refusal of treatment discussion and education provided. (See sample Refusal of Treatment form.)
- Give the patient a copy of the signed and dated consent (or refusal) form, and keep the original in the chart.

## Additional Resources

- Sudore RL, Landefeld CS, Williams BA, et al. Use of a modified informed consent process among vulnerable patients. *Journal of General Internal Medicine*. 2006; 21:867-873. Available at www.ncbi.nlm.nih.gov/pmc/articles/PMC1831581 (accessed 6/14/19).
- State HIV Laws. Available at www.cdc.gov/hiv/policies/law/states/ (accessed 6/14/19).
- AMA Code of Medical Ethics.
    - Chapter 2, Opinions on Consent, Communication and Decision Making. Available at www.ama-assn.org/sites/default/files/media-browser/code-of-medical-ethics-chapter-2.pdf (accessed 6/14/19).
    - Chapter 5, Opinions on Caring for Patients at the End of Life. Available at www.ama-assn.org/sites/default/files/media-browser/code-of-medical-ethics-chapter-5.pdf (accessed 6/14/19).

## Sample Forms

- Informed Consent for General Use – "About Your Procedure"
- Instructions for Developing a Procedure-Specific Informed Consent Form
- Consent for Office-Based Surgery
- Informed Consent for Anesthesia
- Refusal of Treatment

## Sample Policy and Procedure

- Informed Consent and Informed Refusal

# Appendix

The following table contains state-specific information related to informed consent for selected states. There may also be other laws/regulations not listed. Please refer to the cited regulations or consult with your attorney for more specific information.

**ALASKA**

http://www.touchngo.com/lglcntr/akstats/Statutes/Title09/Chapter55/Section556.htm (accessed 7/18/19).

**CALIFORNIA**

- California Medical Association (CMA) On-Call Documents, available at www.cmanet.org (accessed 7/19/19):
  - #3100: Informed Consent
  - #3101: Informed Consent Exceptions
  - #3103: Informed Consent: Inpatient Procedures
  - #3106: Format for Informed Consent Forms
  - #3116: Consent for HIV Test
- https://digitalcommons.lmu.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1122&context=llr **(accessed 7/19/19)**

**DELAWARE**

- **Informed Consent - see 18 Del. Code §6852, available at https://delcode.delaware.gov/title18/c068/sc06/index.shtml (accessed 7/19/19).**
- **Surrogate decision-making in Delaware – see 16 Del. C. §2501-2518, available at https://delcode.delaware.gov/title16/c025/ (accessed** 7/19/19**).**

**PENNSYLVANIA**

- In Pennsylvania, except in emergencies, physicians are required by law to get a patient's informed consent prior to conducting the following procedures: (40 P.S. § 1303.504)
  - Performing surgery, including the related administration of anesthesia
  - Administering radiation or chemotherapy
  - Administering a blood transfusion
  - Inserting a surgical device or appliance
  - Administering an experimental medication, using an experimental device, or using an approved medication/device in an experimental manner
- Per a Pennsylvania Supreme Court ruling on June 20, 2017, physicians must personally obtain informed consent and must personally answer their patients' questions. Communications between physicians' staff members and patients will no longer be admissible at trials as to the issue of whether a physician obtained informed consent from the patient. For additional information and discussion about the PA Supreme Court ruling see the following:
  - *PA Supreme Court Ruling: Only Doctors Can Obtain Informed Consent* found at www.postschell.com/publications/1386-pa-supreme-court-ruling-only-doctors-can-obtain-informed-consent (accessed 7/19/19)

**RHODE ISLAND**

- Rhode Island law provides that "[a]ny person of the age of sixteen (16) or over or married may consent to routine emergency medical or surgical care." (R.I.G.L. § 23-4.6-1)
- The concept of informed consent in this state is influenced by a landmark Rhode Island case, *Wilkinson v. Vesey*. This case set forth opinions that adults of sound mind have the right to decide whether or not to submit to treatment and that the physician has a duty to discuss with the patient the scope of treatment as well as its risks, alternatives and the risks linked to the alternatives. (*Wilkinson v. Vesey*, 295 A.2d 676 (R.I. 1972))

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# RISK MANAGEMENT RESOURCE

# SAMPLE FORM / TEMPLATE: INFORMED CONSENT

## Additional NORCAL Risk Management Resources:

- Informed Consent and Refusal
- Instructions for Developing a Procedure-Specific Informed Consent Form

For a modifiable template of this form, please contact NORCAL Risk Management at risksolutions@norcal-group.com or call 855-882-3412.

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# About Your Procedure

A [procedure name] can help us understand what might be causing your [insert symptoms]. With this information, we can make a plan that we hope will help you get better. This form has facts about the [procedure name] and a place for you to sign that you consent (agree) to having a [procedure name] performed.

## What is a [procedure name]?

- Doctors do a [procedure name] by looking at your [body part] with a [equipment name] [define equipment]. The doctor puts the [equipment name] [describe where the equipment is inserted]
- [Describe any modifications to the procedure, if applicable.]
- To help you relax, sleep lightly or to not feel as much pain, you may be given anesthesia (medicine that blocks pain or takes away feeling). Your doctor will tell you more about this if it is needed.

## Why does the doctor recommend that you have [procedure name]?

- Reason 1
- Reason 2
- Reason 3

*[Instructions: Use the following table as a checklist to cover pertinent risks, benefits, and alternatives to the procedure with the patient. Include additional risks unique for this patient, questions asked and your response to the questions. Add rows in each section as necessary.]*

| Physician Initials | Patient Initials | Benefits - How can this procedure help? |
|---|---|---|
| | | *List benefits to the procedure specific to the patient and their condition.*<br>1.<br>2.<br>3.<br>**Questions:** |
| **Physician Initials** | Patient Initials | **Risks – This procedure has some risks. We cannot list all of the risks. Here are risks that we think you would want to know about before you decide whether to consent. The list includes some problems that can happen most often or that, although less common, are the most serious.** |
| | | 1. *Description of common risk for procedure:*<br><br>**Additional Risk:** Based on patient's age, comorbidities, etc.<br><br>**Questions:** |
| | | 2. *Description of common risk for procedure:*<br><br>**Additional Risk**: Based on patient's age, comorbidities, etc.<br><br>**Questions:** |
| | | 3. *Description of common risk for procedure:*<br><br>**Additional Risk:** Based on patient's age, comorbidities, etc.<br><br>**Questions:** |

| Physician Initials | Patient Initials | Alternatives |
|---|---|---|
| | | What are your choices other than having this procedure? *List reasonable and appropriate alternatives to the procedure.*<br>1.<br>2.<br>3.<br>**Questions:** |
| | | What could happen if you do NOT consent to this procedure? *List consequences pertinent to patient.*<br>1.<br>2.<br>3.<br>**Questions:** |

## Do you agree to a [procedure name]?

Dr. _____ needs your consent (agreement) to do this [procedure name].

Your signature below means that:

- You understand what a [procedure name] is and why the doctor recommends that you have this procedure.
- You are aware of how a [procedure name] helps, problems a [procedure name] can cause, your choices and what could happen if you do NOT get a [procedure name].
- All of your questions have been answered.

**Choose One:**

❑ I agree to have a [procedure name].

❑ I do NOT agree to have a [procedure name].

_____

Patient's (or legal guardian's) signature Date/Time

_____ _____

Printed Name If not patient, indicate status

_____

Witness Signature

## Doctor's Statement

I talked to the patient about how this procedure can help, problems it may cause and choices. I believe the patient understands these. The patient has had the chance to ask questions and have them answered.

**Choose One:**

❑ The patient agrees to have a [procedure name].

❑ The patient does NOT agree to have a [procedure name].

_____

Physician's signature Date/Time

_____

Printed Name

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## RISK MANAGEMENT RESOURCE

# INSTRUCTIONS FOR DEVELOPING A PROCEDURE-SPECIFIC INFORMED CONSENT FORM

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An informed consent form does not replace the physician's face to face discussion with the patient. During that discussion, the clinical reasoning as to why a particular procedure or treatment is needed is explained to and with the patient. The discussion and education includes explaining significant elements of the procedure as well as associated risks, and also includes the benefits and alternatives. The patient should be given the opportunity to get answers to any questions they have about the procedure from the physician. Using plain language (consider a fifth-grade reading level), is often effective to help patients of all literacy levels understand the medical procedure. It is better to use simple language rather than legal or medical jargon that can intimidate or confuse a patient and not adequately support a collaborative physician/patient discussion and decision.

It is recommended that the practice identify those procedures deemed as requiring informed consent and develop informed consent templates specific to each of these procedures. That way, much of the information needed to obtain informed consent for that procedure can be incorporated as part of the form and does not require repeated re-writing. . In many cases, it may still be appropriate to reserve space on the form to hand write information that is specific to the patients' medical condition(s) and the procedure(s) that is being recommended.

Using pictures, videos, and educational materials in simple language to support the physician's discussion with the patient is encouraged and to supplement the form. Provide patients with a copy of this form to refer to later with other educational materials and/or instructions related to the procedure. Any pictures, videos or educational materials provided to the patient to facilitate the informed consent discussion should be documented in addition to any instructions related to the procedure.

## Developing Informed Consent Templates

These instructions accompany NORCAL's sample form/template *Informed Consent*. The template is designed so that the physician can insert specific information in each of the bracketed areas. Use layman's language and simple, factual declarative sentences, as in the examples below. Leave blank lines as needed to fill in risks, alternatives and possible outcomes specific to each patient's condition and presenting symptoms. The Centers for Disease Control and Prevention's (CDC's) National Center for Health Marketing has put together a *Plain Language Thesaurus.* This tool may be helpful for finding words in layman's language that might be more easily understood by patients. This document is available at www.plainlanguage.gov/populartopics/health_literacy/thesaurus_v-10.doc, accessed 6/18/19).

Below are several examples of language that can be used in the bracketed areas in the sample Informed consent form.

### Procedure name

- Fill in the procedure or test name in both medical terminology *and* layman's language (e.g., colonoscopy or examination of your bowels).
- Throughout the remainder of the form, insert only the medical terminology for the procedure name (e.g., colonoscopy).

### Body part

- For example: colon, large intestine, or bowel

### Equipment name/Define equipment

- For example: fiber-optic colonoscope / bendable light and camera

### Describe where equipment is inserted

- For example: rectum and large intestine

### Why does the doctor recommend that you have [procedure name]?

- For example: "The reason for the examination of your bowels is to find the cause of your bleeding when you have a bowel movement."
- State as many simple sentences as apply to the condition for this patient.

### Risks

- Simply state the common risks (e.g., bleeding from growth removal, tearing the bowel).

### What could happen if you do NOT consent to this procedure?

- Some possible examples include:
    - Your symptoms may remain the same or get worse.
    - Note other health problems that could happen, for example: "your cancer could spread," "your kidneys could fail," or "you could die."
    - It may keep us from making a treatment plan that can help you.

In addition, the accompanying sample form should be modified to best suit the needs of the physician's medical practice and to meet applicable state and federal requirements. It should support and facilitate documentation of the physician's face to face informed consent discussion with the patient. Giving the patient a copy of this form to refer to later with other educational materials and/or instructions related to the procedure helps to support the consent process.

## Additional Resource

- NORCAL's Risk Management Resource: Informed Consent and Refusal
- For more information on creating easy to understand materials for patients, see the CDC's guide *Simply Put*, available at https://www.cdc.gov/healthliteracy/pdf/simply_put.pdf (accessed 6/18/19).

## Sample Form

- Informed Consent – "About Your Procedure"

Revised: July 2019

# Consent for Office-Based Surgery

I, _____ authorize Dr. _____ to
(print patient/responsible party name) (print physician name)

perform _____
(print name of procedure)

on _____ under [local/general anesthesia or conscious sedation].
(print name of patient)

The above-named physician has explained to me the following alternatives to performing this procedure, among them doing nothing: _____

_____

_____

The above-named physician has explained to me the following benefits that are expected to be received by performing this procedure, including but not limited to: _____

_____

_____

I understand that any operation involves some risk of harm. The more common risks that occasionally occur with the above-named procedure include infection, bleeding, allergic reactions, and nerve injury. The above-named physician has explained the following additional risks to me as well: _____

_____

_____

IF YOU HAVE ANY QUESTIONS ABOUT THE RISKS, BENEFITS, ALTERNATIVES OR COMPLICATIONS OF THE PROPOSED PROCEDURE, OR ANY QUESTIONS CONCERNING THE PROPOSED PROCEDURE, ASK YOUR DOCTOR NOW BEFORE SIGNING THIS CONSENT FORM.

I have read the information above regarding alternatives, benefits and risks, and the above-named physician has discussed these subjects with me and answered all of my questions to my satisfaction.

_____
Patient's (or responsible party's) signature Date/Time

_____
If not patient, indicate relationship

## Physician Declaration:

I have discussed the alternatives, benefits and risks of the procedure as detailed above with the patient or the patient's authorized legal representative and answered all of the questions asked by the patient/representative. The patient/representative has agreed to the procedure.

_____
Physician's signature Date/Time

Revised: June 2019

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# Informed Consent for Anesthesia

*[NOTE: State law may require specific content to be added to this form.]*

**TO THE PATIENT:** It is your legal right to understand and consent to your medical care. Please read this form carefully and if you have any questions, ask your physician before you sign this form.

## PATIENT CONSENT

I have had the opportunity to read, or had read to me, the information on this form. I understand the general purpose and planned benefits, as well as the risks and possible problems of anesthesia care.

My anesthetic care will be provided by anesthesiologists, possibly in combination with certified registered nurse anesthetists (CRNAs) [or other anesthesia professionals] with hospital/surgicenter/facility privileges. Medical trainees who take part in my care will be supervised.

I understand the anesthetic plan may be changed during the procedure in response to changes in my condition, which may require a change in anesthetic method, additional monitoring, and/or treatment of medical problems occurring during the procedure, including but not limited to, receiving blood or life support.

I understand that anesthesia involves risks beyond those of the surgery itself (or other procedure for which anesthesia is necessary) and there may occur unexpected events and problems other than those listed and no promise is made to me about the results of anesthetic care.

I understand I will have the chance to have a complete discussion with my anesthesia professional about the risks and other choices with respect to anesthesia and that I can wait to sign this form until that talk takes place.

I consent to the administration of _____ *[Type of Anesthesia]* _____ anesthesia for my procedure, or an alternative type of anesthesia, if necessary, as deemed appropriate by the anesthesia professionals responsible for my care.

_____ _____

Patient's (or legal guardian's) signature Date/Time

_____ _____

Printed Name If not patient, indicate status

## RESPONSIBLE PHYSICIAN/ANESTHESIA PROVIDER ATTESTATION

I, _____, attest that this patient or patient's legal representative named above has been informed about the common foreseeable risks and benefits of undergoing the proposed anesthesia as well as its reasonable alternative(s), if any. Further questions with respect to this procedure have been answered to his/her apparent satisfaction. Should the patient or patient's legal representative seek further information pertaining to this matter, I will supply such information upon written or oral request.

_____ _____

Physician's/Anesthesia Professional's signature Date/Time

_____

Printed Name

Revised: May 2017

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The type of anesthesia (lack of pain) that you have is determined by many factors including your physical condition, the type of procedure, the preference of you and your physician. The type that has been recommended for you is checked below:

- ❑ **GENERAL ANESTHESIA** gives an unconscious state. This type of anesthesia is made by injecting medicine into the blood stream and by having the patient breathe other medicines. Frequently, the person who gives the anesthetic places a tube through the mouth or nose into the windpipe to aid in your breathing. You may also feel a sore throat, hoarseness, injury to teeth or airway, injury to blood vessels, awareness under anesthesia, minor pain or discomfort continuing after you leave the hospital. Strokes, brain damage, heart attacks, pneumonia, and death are very rare complications of general anesthesia.
- ❑ **SPINAL ANESTHESIA** is a medicine that is injected through a needle, which is put in the back into the spinal canal. The medicine causes a short-term loss of feeling and movement in the lower half of the body. Usually, a numbing medication is used to where the needle is inserted so that the entire procedure causes very little pain or discomfort. Sometimes this type of anesthesia is not satisfactory. When this happens, another type of anesthesia may be used. The more common problems of spinal anesthesia are headache, backache, and buzzing in the ears. Rare problems include heart attacks, infections, and the inability to move parts of the body.
- ❑ **REGIONAL (LOCAL) ANESTHESIA** is a medicine or mixture of medicines is injected around nerves so that the area to be operated on is without feeling for a few hours. The injection causes very little discomfort to the patient. Sometimes, the anesthesia does not work completely so that another type of anesthesia or the use of a different form of pain relief becomes necessary. Rare problems of regional anesthesia include infections and inability to move parts of the body.
- ❑ **INTRAVENOUS REGIONAL (LOCAL) ANESTHESIA** is a special type of local anesthesia given by injecting a medicine into the veins of an arm or leg to which a tourniquet (tight band) has been applied. A few patients complain of pain at the local anesthesia injection site after surgery. Rare complications of intravenous local anesthesia include infections and inability to move parts of the body.
- ❑ **INTRAVENOUS (IV) SEDATION** is an injection of a medicine into the veins of an arm or leg so that you will feel relaxed and somewhat sleepy. Sedation will also help relieve discomfort from the surgery. You may or may not remember what happened when surgery is over. Some of these medicines may irritate the vein through which they are injected. This irritation is usually short term. Some of these medicines may rarely produce unwanted effects such as difficult breathing, changes in heart action, and short term loss of memory.
- ❑ **EPIDURAL ANESTHESIA** is commonly used to relieve the pain of surgery or labor. The procedure involves placing a needle in the epidural space-located off the spinal column in the lower back. A thin plastic catheter is left in place and the needle is removed. Local anesthetics, narcotics, and/or other medicines are given through the catheter as needed. Usually, a local anesthetic is used to numb the skin where the needle is inserted so that the entire procedure produces very little discomfort. Sometimes the anesthesia does not work completely. When this happens, another type of anesthesia may be used. The more common problems are headache, backache, buzzing in the ears, low blood pressure, nausea, and vomiting. Rare problems include constant headache, infection, constant numbness, or weakness of lower body and legs, breakage of needle or catheter (possibly requiring surgery), blood clot (possibly requiring surgery), rapid absorption of local anesthesia causing dizziness and/or seizures, short-term total spinal anesthesia (requiring life support system), respiratory and/or cardiac arrest (requiring life support systems). Fetal distress during labor may result from one of the above problems.

Revised: May 2017

# Refusal of Treatment

I, _____, acknowledge that my physician, Dr. _____, has recommended that I undergo the following treatment, procedure, operation, or diagnostic test and has discussed with me the reasons for his/her recommendations. Further, my physician has explained the risks and benefits of (as well as alternatives to) this recommendation (or I have refused to have them explained to me). _____

_____

My physician has explained to me that if I refuse this treatment, procedure, operation, or diagnostic test, I may be at risk for serious or permanent injury, or even die as a result. My physician has explained the following risks, among others, that may occur if I refuse the treatment, procedure, operation, or diagnostic test:

_____

_____

_____

I refuse the recommended treatment, procedure, or diagnostic test. I assume the risks and consequences involved in my refusal.

_____

Signature Date

_____

Witness Date

**Physician's Statement**

I have explained the foregoing information to the patient

_____

Signature Date

**Revised: June 2019**

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## Subject: Informed Consent and Informed Refusal

**Effective Date:** **Revised Date:**

**Approved by:**

## Policy

The physician who will be performing a procedure or other treatment that requires informed consent is responsible for fully informing the patient about the risks and benefits of, as well as alternatives to, the planned treatment, procedure, operation or diagnostic test and for obtaining the patient's informed consent or informed refusal.

## Purpose

To establish proper procedures for obtaining informed consent to ensure that patients' rights are respected and liability risks are minimized.

## Procedure:

- Identify treatments and procedures that require informed consent.
- Describe who, besides the patient, may give informed consent.
- Describe the special circumstances in which a physician is not required to obtain fully informed consent.
- Describe the process to assess patient capacity to give informed consent.
- Describe who is responsible for having the informed consent discussion with the patient and obtaining informed consent.
- Describe who may obtain the patient's signature on the informed consent form.
- Describe who may provide the patient with additional education regarding the treatment or procedure.
- Describe the documentation process for informed consent.



**Revised: June 2019**