



Informed Consent

More and more, patients and their families are becoming responsible partners in their health care. When you go for medical care, you usually talk with the doctor to get his or her recommendations about the next step in your treatment. Most people follow these recommendations, but they are not required to do that. If you are an adult and you are able to make your own decisions, you are the only person who can choose which course of action to take.

All medical care requires the consent of the patient (or someone who is authorized to consent for the patient) before the care plan is carried out. In some cases, you approve the doctor's plan by simply getting a prescription filled, allowing blood to be drawn for lab tests, or seeing a specialist. This is called *simple consent*, and is OK for treatments that carry little risk for you. Often times, though, a more careful process called *informed consent* is required.

What is informed consent and what does it involve?

In cases where there are larger possible risks, you may be asked to agree in writing to the doctor's plan for your care. This is informed consent. It recognizes your need to know about a procedure, surgery, or treatment, before you decide whether or not to have it.

It is now common to go through this informed consent process before cancer treatment begins. If you are getting more than one type of treatment for cancer, you will likely need separate informed consents for surgery, chemotherapy, and radiation.

After your first talk with your doctor, you may have only a general idea of your doctor's treatment plan for you. You will likely want to know more so that you can think about the ways this plan may affect your health and your life. In order to freely decide whether the risks are worth the benefits you expect to get from the treatment plan, you must understand the risks and drawbacks of the plan. Most people find that they need to get some questions answered before they can decide on a treatment plan that carries some risk for them.

Informed consent is a process that includes all of these steps:

- You are told (or get information in some way) about the possible risks and benefits of the treatment.
- You are informed of the risks and benefits of other options, including not getting treatment.
- You have the chance to ask questions and get them answered to your satisfaction.
- You have had time (if needed) to discuss the plan with family or advisors.
- You are able to use the information to help make a decision that you think is in your own best interest.
- You share your decision with your doctor or treatment team.

If you have gone through these steps and decide to agree to the treatment or procedure, you are usually asked to sign a paper called a *consent form*. The completed and signed consent form is a legal document that lets your doctor continue with the treatment plan. The consent form names the procedure or treatment to be done. The rest of the consent form may be very general, stating only that you have been told about the risks of the treatment and other options that are available. Or it may be very specific, outlining in detail what the risks and other options are. Depending on how it is presented, you may sign for one certain procedure or treatment, or you may give blanket approval for any treatments and procedures that the health provider decides are necessary.

From the doctor's viewpoint, informed consent means that:

- A doctor or nurse must make every effort to be sure the patient understands the purpose, benefits, risks, and other options of the test or treatment. Then the doctor or nurse must get the patient's consent before starting. In some cases, even a simple blood test or an injection ("shot") requires written consent from the patient.
- As long as the adult patient is mentally able to make his or her own decisions, medical care cannot begin unless the patient gives informed consent.
- If the patient is a minor (under age), or has a serious mental disability, or cannot give consent, then the parent, legal guardian, or a person authorized by the court must give consent. This is usually a close family member who has reason to know what the patient would want. (See "Who besides the patient can give consent?" in the section "What are the legal requirements of informed consent?") As some very public court cases have shown, an elaborate legal system is in place to guide cases in which the patient is mentally or physically unable to give informed consent for treatment. Such cases may come up if the patient is in a coma (unconscious) or on life-support equipment.

Sometimes health care workers refer to the consent form itself as an "informed consent." This is not quite accurate. Informed consent is the process and actions that take place as you learn about and think about a treatment before you agree to it. Your signature on the form is taken to be evidence that this took place. If you decide that you do not want the

procedure or treatment, you would not sign the consent form. In this case, you may be asked to sign an *informed refusal* form or a form that states you are choosing not to follow medical advice. Your signature on this form implies that you know the risks of refusing, so be sure that you understand these risks and know your other options before you sign. (See the section below, "What if I don't want the treatment being offered?")

Why does the doctor need me to sign a consent form?

The main purpose of the informed consent process is to protect the patient. As mentioned earlier, a capable adult cannot be forced to take any type of medical treatment. In general, anything other than a life-threatening emergency in which the patient is unconscious requires consent before treatment. Even in that situation, consent may sometimes be required if the patient is known to have an advance directive. (See "Who besides the patient can give consent?" in the next section)

For simple diagnostic tests and situations in which consent is implied by your actions, a consent form is not needed. If you see your doctor and allow a blood sample to be taken for lab tests, your consent is assumed because you went to the doctor seeking care and allowed the blood to be drawn. At any point, you could change your mind and decide to refuse testing, leave the doctor's office, or seek care elsewhere. This is different from a treatment that puts you in a vulnerable position or can possibly cause serious harm. You need more information about more risky treatments so that you can weigh your options and consider your risks before making a decision.

Even when there are no other accepted medical treatment options, it is still your right as a competent adult to refuse a treatment that you do not want, or not to be in a study that you didn't choose. But once you sign the consent form, it is taken to be your formal, legal agreement that you are OK with the plan or procedure that is listed on the form unless you revoke (take back) your consent before treatment is given. The doctor or facility will usually give you a copy of the consent form, but they keep the original as a legal record that you agreed to the treatment.

What are the legal requirements of informed consent?

States have developed informed consent laws to govern certain types of communication between health providers and patients. These laws list the types of information that patients must be given so they can make an informed decision about having medical care, diagnostic studies, or treatment.

These laws apply to doctors and sometimes to nurses. They vary from state to state. Some states have very specific laws governing certain situations. For instance, some states dictate certain information be given on the issues of treatment for breast cancer or for clinical trials (scientific studies of promising new treatments). Another difference is that

some states call only for "reasonable" information; but others require "full and complete disclosure." (*Disclosure* means making information known.) If you want to check with your state to find out more about the laws where you live, see the section "How can I find out more?"

In general, informed consent assumes that you are legally able to make your own decisions. If you are not, the person who is legally allowed to make decisions for you goes through the same process on your behalf (see "Who besides the patient is allowed to consent?" below).

For informed consent to take place, the information that is given must be understood. This responsibility is shared by the patient, since the doctor won't know what you don't understand until you ask about it. The patient must have the chance to consider the information and ask questions.

And finally, informed consent assumes that when you make your decision, you are not pressured -- that you freely choose based on what you feel is best for you.

Informed consent for a clinical trial is usually required to be more detailed and thorough than consent for a standard medical procedure or treatment. This is because there is a bigger chance of unknown effects with new treatments, and it is even more important that you know about these possibilities. (See the section, "How is informed consent for a clinical trial or research study different from consent for standard treatment?")

Who besides the patient is allowed to consent?

For children or others who are unable to make the decision for themselves, the parent or legal guardian is legally responsible for getting the information, making the decision, and signing the consent form. But that does not mean that the child or patient who is not considered mentally competent is always left out of the process. Some facilities require the *assent* of older children before they go into a research study, even after the parents have agreed on the child's behalf. Assent means that, even though the parents sign the form, the child must also be OK with it before the facility will do the treatment.

Along the same lines, people who are unable to manage their daily affairs due to impaired thinking or emotional problems may still be able to understand the medical situation and make their wishes known. They should be given information in a way they can understand, and asked what they wish to do.

In the event that you become unable to take in information and make your wishes known, another person may be called upon to take part in the process of informed consent. There are several ways that person can be chosen. The only way you can choose the person to make those decisions for you is if you have set up a *durable power of attorney for health care* (also called a *health care power of attorney*). In this case, if you are unable to speak for yourself, the person you chose becomes legally responsible for making medical decisions on your behalf. This person is sometimes called your *proxy*, *agent*, or *surrogate*. A few states restrict the ability of your proxy to carry out certain requests. For

more on health care powers of attorney, see our information, *Advance Directives*. (It's available on our Web site at www.cancer.org, or you can call us for a copy.)

Another way is a *court-appointed* surrogate or proxy. This is someone a judge chooses to make medical decisions for you. If you become unable to make decisions for yourself, someone else -- such as the doctor, facility, friend, or even a family member -- may ask (petition) the court to appoint someone to do it for you. The process varies from state to state.

Many states have passed *family agency acts* that choose which family members (in a listed order of priority) may act on behalf of a person who cannot speak for her or himself. This way is likely to be used only if you do not have an advance directive or court-appointed proxy. Depending on your family situation and which state you are in, that person may be your legal guardian, spouse, parent, child, sibling, or other relative.

Are there times when the usual consent requirements do not apply?

In general, those who make decisions must be legally recognized as adults in the state where treatment is given. But there are a few times when an older teen (one who is self-supporting and doesn't live at home, is married, or in the military, for instance) does not need parental consent for procedures or treatments. There are also some situations where teens can consent for certain kinds of treatment even if they are underage. The rules and treatment situations vary from state to state.

There are also times when the decision from the parent or guardian of a child or an incompetent adult may be challenged by the doctor or facility. In these cases, the courts may overrule the usual decision-maker if they think the decision that was made would cause undue harm. But these instances are fairly rare.

In an emergency, if a person is unconscious and in danger of death or other serious outcome if medical care is not given right away, informed consent may not be required before treatment. If those who are giving treatment know that the patient has an advance directive refusing the care, the treatment may not be given. If those treating the person know that he or she has an advance directive that appoints someone else to make the patients' decisions, that person may be called for informed consent if there is time. But in general, emergency situations don't allow much time to check on advance directives.

How will I be given information for an informed consent?

The way in which information about the treatment must be given (for example, verbally or in writing) may be listed in your state's laws. Other methods may be used by your doctor or facility to make the information easier to understand, such as videos, audio files, interactive computer modules, booklets, fact sheets, etc. The most important thing is

that you understand and are allowed to get answers to your questions, so that you have all the information you need as you consider your decision.

Sometimes, a person other than the doctor who will be carrying out the treatment is asked to give you the information for your informed consent. If this person is unable to answer your questions to your satisfaction, you may want to wait to sign the consent form until you can talk to someone who can answer your questions more completely.

How much detail should I expect?

Material information: Informed consent requires disclosure of "material" (significant or important) information that will help the patient make an informed choice. The law defines *material information* in 2 ways.

- **The professional's point of view:** In this view, the health provider's responsibility is limited to telling you those things that a health professional who works in your community would tell you under the same or similar circumstances.
- **The patient's point of view:** A patient-oriented standard of disclosure is different. It means that the health provider is required to make known all the facts, risks, and alternatives that a reasonable person in the patient's situation would consider important in deciding whether to have a recommended treatment.

Some of the material information a patient wants may not be available. For example, the long-term risks of a new method of treatment may not be known. If this is the case, the spirit of the laws of informed consent require the health provider to give the best answer possible, which may be "we don't know that yet."

Limited knowledge shouldn't stop you from asking questions at whatever level of detail you want. Some people want to know as much as possible about their treatment or procedure before they agree to it, while others want very little. Again, the doctor may not have all the information you would like, but at least you can find out more about what is and isn't known.

What if I am having trouble understanding the information?

Informed consent is not only the health provider's responsibility. It is your duty to be sure that you understand the information you have been given, even if it means going over the information many times. Sometimes health care workers use words that are very hard to understand. Ask the doctor to define words and explain terms, and tell him or her what you understand and what you don't. Sometimes it helps to have a nurse, social worker, or patient advocate in the room. They may be able to re-phrase and explain things in ways that are clearer to you.

If you are facing an important health decision, it may be also helpful to bring a spouse, relative, or friend to your appointments. That way, there will be a second listener to help process the information and ask questions.

What questions should I ask during informed consent?

You will, of course, have your own questions, especially once the doctor starts sharing information. But some basic questions you might ask include:

- What is my diagnosis (the medical name for the illness I have) and what does that mean?
- How serious is my diagnosis?
- What treatments are recommended?
- Are there other treatment options? What are they?
- What benefits would you expect from the recommended treatments and other options?
- What are the risks or complications of the recommended treatment and the other treatment options?
- Are there problems or side effects that may be caused by the treatments?
- What methods will be used to prevent or relieve these problems or side effects?
- What are the side effects of the treatment -- immediate, short-term, and long-term?
- How will having treatment affect my normal functions and everyday activities?
- How would not having treatment affect my normal functions and everyday activities?
- How long will treatment last?
- How long will it be before I can go back to my normal activities?
- How much does the treatment cost?
- Will my insurance cover it?

It's a good idea to write down your questions and bring the list to your appointments, take notes on the responses, or bring a tape recorder to record the discussion. (You will want to check with the doctor before you record him or her.) Good health providers usually appreciate a patient's efforts to understand the challenges they face and to make informed decisions.

How long does the informed consent process take?

The entire informed consent process can take place in one short visit for a fairly simple procedure about which you have few questions. On the other hand, it may take 2 or more conversations for something more complex. For instance, if you are looking at more than one treatment option, a long course of treatment, or a clinical trial, it may take some time. In fact, even after you have signed up for a clinical trial and signed a consent form, the researchers conducting it should still keep you posted about new information that affects you as a volunteer. This is part of an ongoing informed consent process, which can sometimes extend past the clinical trial itself.

Can I change my mind after I've signed the consent?

You can change your mind at any time, even if you've already started the treatment. Most consent forms mention that you also have the right to stop treatment or withdraw from a study even after you have signed a consent form. Even if the form does not mention it, you still have this right. You would need to contact the doctor in charge of your treatment or of the clinical trial to make your wishes known. You may be asked to sign a form refusing further treatment so that the doctor or facility will have a legal record (see the next section, "What if I don't want the treatment that is being offered?").

What if I don't want the treatment that is being offered?

Part of the informed consent process includes letting you ask questions about other treatments that may help you or other options that you may prefer. You may choose other options, even if they are not as well proven as the one your doctor recommends. And, you may refuse a certain treatment, surgery, or procedure without refusing all care. For instance, you may choose to refuse surgery but still wish to be treated for infection or pain. Keep in mind that your doctor is not required to go along with your plan, though. It may be up to you to find someone who will treat you with such an approach, so you may need to seek care elsewhere -- with another doctor or facility.

As mentioned earlier, if you are competent to make your own medical decisions, you have the right to refuse any and all medical treatment and diagnostic procedures. Even if not treating the disease or condition means that the person will die, US courts have mostly affirmed the right of patients to reject treatment. If you have decided to refuse treatment or diagnostic tests, the health provider may inform you of the risks or likely outcomes of this choice so that you can make an informed refusal. The doctor or facility may ask you to sign a form that states you received this information, and that you still

choose not to be treated. If you do not wish to sign the form, the doctor may ask witnesses to sign that you were so informed.

How is informed consent for a clinical trial or research study different from consent for standard treatment?

Informed consent for a clinical trial or *investigational* drug or procedure (where new treatments are compared to the current standard treatment) usually includes more information than the consent for standard treatment. The informed consent process should tell you:

- What the clinical trial is set up to find out
- What is expected of you -- what will be done and how long you will take part
- Expected benefits
- What is known and not known about the new drug or procedure
- Any possible risks to you (if known)
- Whom you should contact with questions about or problems with the study
- Other possible treatment options
- That you can leave the study with no penalty and opt for standard medical care at any time
- How your personal information will be protected

The informed consent process is meant to give you ongoing explanations that will help you make educated decisions about whether to start or stay in a clinical trial. The most important part of this process is your everyday interaction and discussions with the research team and other medical staff before, during, and after the trial. The consent form can be a great tool to help get this conversation started.

This is all done so that you can make the best decision for yourself, and to be sure that you are able to choose freely whether to enroll in or stay in the study. Much of this information may be on the consent form itself, which also usually explains that you can withdraw from the study at any time without penalty. The doctor or nurse may encourage you to take extra time to think it over and come back with any questions. If you are giving consent for your child, both parents may be required to sign the form in order for your child to take part in the clinical trial.

Before you decide, the research team will talk with you about the clinical trial's purpose, procedures, risks, possible benefits, and your rights as a participant. If you decide to take part, the team will keep you up to date on any new information that may affect you and your situation. Before, during, and even after the clinical trial, you will have the chance to ask questions and talk about your concerns. Informed consent for clinical trials goes on for as long as the research lasts, and even afterward.

The process varies among different research institutions and clinical centers, but normally informed consent includes the following steps:

A first meeting. This is when you meet with a member of the research team who gives you the informed consent document and explains it to you. This discussion may also include your oncologist (cancer specialist), primary care doctor, and a nurse. Sometimes a social worker, patient representative, or staff psychologist may be there. You can bring along a family member or friend for support, and to help you keep track of the information. The information should be given in a way you can understand. It should also be given at a comfortable pace, with time allowed for you to think it over and ask questions. Some centers offer a video, audio recording, or even an interactive computer module to help you better understand the information in the consent form.

Time to take in the information. It can be hard to absorb this much new information in one sitting, especially at a time of emotional stress. You should be given a copy of the consent information so that you can take it home, review it as many times as you need, and talk it over with family, friends, clergy, counselors, therapists, patient representatives, or other trusted advisors.

A check of your understanding of the information. The research team should make every effort to be sure that you understand the information they give you. They can do this by having you fill out a questionnaire, asking you questions, or having you tell them about the clinical trial in your own words. You also should tell team members about anything you do not understand. If you find that the consent form or other information is written in words that are too technical for you, let them know. Otherwise they will likely assume that you understand when you really don't.

Chances to ask questions. During the first meeting and in later discussions, you should be given the chance to ask questions and raise concerns. Keep asking questions until you know enough to make your decision.

Continued updates on new information. As the clinical trial goes on, the research team may make new discoveries that could affect your health, well-being, or willingness to stay in the study. They will share this with you and may ask you to sign a new consent form. Of course, you are free to leave the study if this information leads you to have doubts about staying in it.

A contact person and phone number for more information should be given to you at the first meeting. While your doctor is likely to be a helpful source of information, only you can make the decision about being in a study. Not even the best medical experts can predict whether a treatment, screening, prevention, or supportive care method being studied in a clinical trial will work for you. The informed consent process is designed to help you weigh all of the pros and cons and make the best choice for you or your child.

Tips about clinical trials

- Keep a copy of the consent form. Ask for a copy if one isn't offered to you. You may also request a copy of the protocol (full study plan) that describes all the details of the clinical trial.
- According to US regulations, no informed consent document may say anything that asks or seems to ask you to give up (waive) any legal rights. It also may not include anything that releases or appears to release the investigator, doctor, sponsor, or facility from liability if they are negligent or careless.
- If you cannot understand the forms you are asked to sign, don't be afraid to let someone know that you are having trouble. Many people feel nervous about signing consent forms and talking with doctors. Take your time, and ask for help when you need it.

How is shared decision-making different from informed consent?

In shared decision-making and informed consent, you get information about treatment, and you get to make the final decision about whether you want treatment. But shared decision-making takes informed consent a step further, giving the patient more responsibility.

Shared decision-making is a newer way of talking about treatment and treatment decisions, and a few doctors are using it. It works like this: the doctor gives the patient information about the pros and cons of all the treatment options, including no treatment. This often involves "homework" for the patient, such as reading, looking at DVDs, or sifting through other types of information. The patient tells the doctor about factors (preferences, problems, home conditions, etc.) that might make each treatment option better or worse than the others. The patient and doctor then make the decision together about which treatment is best for the patient. Or they may decide on something else, such as waiting for further developments, before choosing a treatment.

This is quite different from just saying "yes" or "no" to the treatment the doctor offers you. It may mean that you must absorb more information, ask more questions, share more about yourself, and take more time to sort through your options together. This type of decision-making is especially helpful when there is no single "best" treatment option. For many people, the extra effort is worth it -- they can feel more certain that they made the best treatment choice for themselves. But for others, it may be too much or feel overwhelming (see the next section called "What if I want my doctor to make the decisions about my care...?").

It is OK to tell the doctor that you don't want a shared decision. But if you do want this kind of input into your medical decisions, let your doctor know that's what you're thinking. Be sure that you understand all the reasonable options for your situation, and go over them with your doctor. See the section called "What questions should I ask during

informed consent?" to get some ideas of what to ask about each treatment option. Keep in mind that your doctor may not have as much information about some treatments as others, and you may have to ask for a second opinion to get a more complete picture.

What if I want my doctor to make the decisions about my care, and I don't want more information?

Some people prefer not to know a great deal about their diagnosis or treatment. Just as you have a right to informed consent, you have a right to refuse information. Or you can ask for only minimal information and entrust the decisions about your care to your health provider. At the same time, informed consent laws do not allow a health provider to keep a diagnosis from the patient, even at the family's request. If you wish to refuse information in today's legal environment, a wise health provider will likely require you to put that in writing in the form of a waiver or other document.

How can I find out more?

If you need more information about informed consent, you can talk with your family lawyer. Or contact your American Cancer Society (1-800-227-2345 or www.cancer.org). Also check the "Additional resources" section for information on how to find local legal resources with help from the American Bar Association.

Additional resources

More information from your American Cancer Society

We have selected some related information that may also be helpful to you. These materials may be ordered from our toll-free number, 1-800-227-2345.

Advanced Directives

Clinical Trials: What You Need to Know (also available in Spanish)

Patient's Bill of Rights (also available in Spanish)

Surgery (also available in Spanish)

Understanding Chemotherapy: A Guide for Patients and Families (also available in Spanish)

Understanding Radiation Therapy: A Guide for Patients and Families (also available in Spanish)

National organizations and Web sites*

Along with the American Cancer Society, other sources of information include:

Your state or city **Bar Association**

Check your local phone book or find it online at the American Bar Association Web site:
www.abanet.org/barserv/stlobar.html

Your community's **Legal Aid Society**

If your income is limited, look in your phone book or check the online information at the American Bar Association Web site; click on your state and look for "Free Legal Help" at www.abanet.org/legalservices/findlegalhelp/home.cfm

Cancer Legal Resource Center

Toll-free number: 1-866-843-2572 (leave a message for call back -- it may take several days)

Web site: www.cancerlegalresourcecenter.org

Offers free, confidential information and resources on cancer-related legal issues

National Cancer Institute

Toll-free number: 1-800-4-CANCER (1-800-422-6237)

Web site: www.cancer.gov

Offers current information about cancer and cancer treatment, living with cancer, clinical trials and research

American Hospital Association

Web site: www.aha.org/aha/issues/Communicating-With-Patients/pt-care-partnership.html .

Read their "Patient Care Partnership" brochure online at the Web site above for more on patients' rights and responsibilities in the hospital. Also available in Spanish, Arabic, Chinese, Tagalog, Vietnamese, and Russian.

**Inclusion on this list does not imply endorsement by the American Cancer Society.*

No matter who you are, we can help. Contact us anytime, day or night, for information and support. Call us at **1-800-227-2345** or visit www.cancer.org.

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1 · 800 · ACS-2345 or www.cancer.org