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## Informed Consent

Patients, their caregivers, and health care providers are partners in health care decisions. When you seek medical care, you usually get recommendations about needed treatment. Most people follow these recommendations, but some choose not to follow them. You do have the right to either accept or refuse a treatment. If you are an adult and you're able to make your own decisions, you are the only person who can choose whether to get treatment and which treatment to get. This is done through a process called **informed consent**.

All medical care requires consent (agreement) by the patient (or someone who is authorized to consent for the patient) before care is given. This includes treatments for illnesses such as cancer. In some cases, you approve or agree with the doctor's plan by simply getting a prescription filled, signing a form that allows blood to be drawn for lab tests, or saying yes to seeing a specialist. This is called **simple consent**, and is OK for treatments that carry little risk for you. Many times, though, the more careful process of **informed consent** is needed.

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  - [Informed Consent for a Clinical Trial](#)
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## What Is Informed Consent?

Informed consent is a process of communication between you and your health care provider that often leads to agreement or permission for care, treatment, or

services. Every patient has the right to get information and ask questions before procedures and treatments. If adult patients are mentally able to make their own decisions, medical care cannot begin unless they give informed consent.

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- [Can I change my mind after I've signed the consent?](#)
- [What if I don't want the treatment being offered?](#)
- [What is shared decision-making?](#)
- [What if I want the doctor to make the decisions about my care?](#)

The informed consent process makes sure that your health care provider has given you information about your condition along with testing and treatment options before you decide what to do.

This information can include:

- The name of your condition
- The name of the procedure or treatment that the health care provider recommends
- Risks and benefits of the treatment or procedure
- Risks and benefits of other options, including not getting the treatment or procedure

Signing informed consent means

- You have received all the information about your treatment options from your health care provider.
- You understand the information and you have had a chance to ask questions.
- You use this information to decide if you want to receive the recommended treatment option(s) that have been explained to you. Sometimes, you may choose to receive only part of the recommended care. Talk to your health care provider about your options.
- If you agree to receive all or some of the treatment options, you give your consent (agree) by signing a consent form. The completed and signed form is a legal document that lets your doctor go ahead with the treatment plan.

## **Why do I have to sign a consent form?**

The main purpose of the informed consent process is to protect the patient. A consent

form is a legal document that ensures an ongoing communication process between you and your health care provider. It implies that your health care provider has given you information about your condition and treatment options and that you have used this information to choose the option that you feel is right for you.

The way in which your treatment options must be given to you (for example, verbally or in writing) may be listed in your state's laws. Your health care provider works with you to figure out the best way to give you the information you need. The provider may choose to use methods other than a verbal discussion or a written document, such as videos, interactive computer modules, audio files or other methods to help you understand the information better. Be sure you understand all the information given, even if it means going over it many times or asking your provider to explain it in different ways.

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

Yes, you can change your mind at any time, even if you have already started treatment. Let your health care provider know of your wishes.

### **What if I don't want the treatment being offered?**

You have the right to refuse any and all treatment options. You may also choose other

decision-making, the health care provider and patient work together to choose tests, procedures, and treatments, and then to develop a plan of care. As described by the informed consent process, the provider gives the patient information about their condition and the pros and cons of all the treatment options. The patient then has a chance to ask questions and read more about the options. The patient also tells the health care provider what their preferences, personal values, opinions and such are about their condition and treatment options. The health care provider should always respect the patient's preferences and goals, and use them to help guide the patient's treatment recommendations. This type of decision-making is especially helpful when there is no single "best" treatment option.

## What if I want the doctor to make the decisions about my care?

Treatment cannot be given without your consent, Unless care and treatment are needed in an emergency and you are unable to give consent. However, you have the right to refuse information and treatment. Or, in advance, you can assign a person to make decisions for you through an advance directive or other legal document. You can also ask for minimal information and trust your health care provider to make decisions for you. At the same time, informed consent laws do not allow a health care provider to keep a diagnosis from the patient, even at the family's request.

## Hyperlinks

1. [www.cancer.org/cancer/managing-cancer/making-treatment-decisions/making-decisions.html](http://www.cancer.org/cancer/managing-cancer/making-treatment-decisions/making-decisions.html)
2. [www.americanbar.org/groups/law\\_aging/resources/health\\_care\\_decision\\_making](http://www.americanbar.org/groups/law_aging/resources/health_care_decision_making)
3. [www.aha.org/advocacy-issues/communicatingpts/pt-care-partnership.shtml](http://www.aha.org/advocacy-issues/communicatingpts/pt-care-partnership.shtml)
4. [www.cancer.gov/](http://www.cancer.gov/)

## References

Agency for Healthcare Research and Quality. *Strategy 61: Shared decisionmaking*. 2017. Accessed at <https://www.ahrq.gov/cahps/quality-improvement/improvement-guide/6-strategies-for-improving/communication/strategy6i-shared-decisionmaking.html>, on February 19, 2019.

Centers for Medicare & Medicaid Services (CMS). *Revisions to the hospital interpretive guidelines for informed consent*. 2007. Accessed at <https://www.cms.gov/Medicare/Provider-Enrollment-and->

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MedlinePlus. *Informed consent-adults*

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## National Cancer Institute

Toll-free number: 1-800-4-CANCER (1-800-422-6237) TTY: 1-800-332-8615

Website: [www.cancer.gov](http://www.cancer.gov)<sup>4</sup>

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

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

Last Revised: May 13, 2019

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# When Is Informed Consent Needed?

The informed consent process should begin before you start cancer treatment. If you are getting more than one treatment, you will probably need to sign separate informed consent forms. For example, if you are having surgery to remove cancer and then will have chemotherapy or radiation to treat it, you will need to give consent for both surgery and either the chemotherapy or radiation.

Some medical procedures that may require you to give written informed consent include:

- [Radiation](#)<sup>1</sup>
- [Chemotherapy](#)<sup>2</sup> (including targeted therapy and immunotherapy)
- [Surgery](#)<sup>3</sup>
- Some complex or advanced medical tests and procedures, such as a [biopsy](#)<sup>4</sup> (removing cells from a suspicious area so that they can be looked at in the lab to see if cancer cells are present)
- Some vaccines
- Some blood tests or other tests or procedures

Parts of informed consent are regulated by state and case law. In general, those who

make medical decisions must be recognized as adults in the state where the treatment

## Hyperlinks

1. [www.cancer.org/cancer/managing-cancer/treatment-types/radiation.html](http://www.cancer.org/cancer/managing-cancer/treatment-types/radiation.html)
2. [www.cancer.org/cancer/managing-cancer/treatment-types/chemotherapy.html](http://www.cancer.org/cancer/managing-cancer/treatment-types/chemotherapy.html)
3. [www.cancer.org/cancer/managing-cancer/treatment-types/surgery.html](http://www.cancer.org/cancer/managing-cancer/treatment-types/surgery.html)
4. [www.cancer.org/cancer/diagnosis-staging/tests/biopsy-and-cytology-tests/biopsy-types.html](http://www.cancer.org/cancer/diagnosis-staging/tests/biopsy-and-cytology-tests/biopsy-types.html)
5. [www.cancer.org/cancer/managing-cancer/making-treatment-decisions/advance-directives.html](http://www.cancer.org/cancer/managing-cancer/making-treatment-decisions/advance-directives.html)

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# Informed Consent for a Clinical Trial

- [Tips about clinical trials](#)

Informed consent for a clinical trial or study may include an investigational drug or procedure (where new treatments are compared to the current standard treatment). This process usually include more information than the consent forms for standard treatment. The informed consent process for clinical trials is meant to give you ongoing information to help you make an educated decision about whether to start or stay in a clinical trial.

A person who is thinking about being part of a clinical trial is called a potential **research subject**

Before signing the form be sure you understand all the information given to you and have had a chance to ask questions about what you don't understand. You can bring a family member or friend that you trust to help you keep track of your information. If you need extra time to review the information, you may ask your health care provider to give you a copy of the informed consent form so you can take it home and review it as many times as you need before making a decision.

If you take part in a clinical trial, during the study it's possible that the research team may make new discoveries that could affect your health, well-being, or willingness to stay in the clinical trial. They will share this with you and might ask you to sign a new consent form. Remember, you can leave the clinical trial if anything happens or any 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 where the informed consent forms are presented to you. While your health care team will likely 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 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 yourself

## 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 appears to not hold the investigator, doctor, sponsor, or facility accountable 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 health care providers. Take your time and ask for help when you need it.

We have more information that can help you understand clinical trials. Call us at 1-800-227-2345 or visit [Clinical Trials](#)<sup>1</sup> online to find information, worksheets, and videos that can help you decide if a clinical trial is right for you.

## Hyperlinks

1. [www.cancer.org/cancer/managing-cancer/making-treatment-decisions/clinical-trials.html](http://www.cancer.org/cancer/managing-cancer/making-treatment-decisions/clinical-trials.html)

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Last Revised: May 13, 2019

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