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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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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.

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 treatment options that have been presented to you by your health care provider, even if they are not as well proven as the one your health care provider recommends. You may also refuse part of the treatment options, without refusing all care.

For example, you may choose to refuse surgery, but still wish to be treated for pain. In this case, it may be up to you to find another health care provider or facility to treat you with such an approach if your health care provider is not comfortable with it.

If you have decided to refuse treatment or diagnostic tests, your health care provider may tell you about the risks or likely outcomes of this choice, so you can make an informed refusal (meaning, you understand what could happen to your health by refusing the recommended treatment but you still don't want the treatment). In this case, you might be asked to sign a form to state that you received this information and that you still chose not to be treated.

What is shared decision-making?

[Shared decision-making](#)¹ is actually part of the informed consent process and allows patients to play an active role in making decisions that affect their health. In shared 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/treatment/treatments-and-side-effects/planning-managing/making-decisions.html
2. www.americanbar.org/groups/law_aging/resources/health_care_decision_making
3. <http://www.aha.org/advocacy-issues/communicatingpts/pt-care-partnership.shtml>
4. [mail.google.com/mail/?view=cm&fs=1&tf=1&to=CLRC@drcenter.org](mailto:CLRC@drcenter.org)
5. <http://www.cancerlegalresources.org/>
6. <http://www.cancer.gov/>
7. www.americanbar.org/groups/law_aging/resources/health_care_decision_making
8. <http://www.aha.org/advocacy-issues/communicatingpts/pt-care-partnership.shtml>
9. [mail.google.com/mail/?view=cm&fs=1&tf=1&to=CLRC@drcenter.org](mailto:CLRC@drcenter.org)
10. <http://www.cancerlegalresources.org/>
11. <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/strategy61-shared-decisionmaking.html>, on February 19, 2019.

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Storm C, Casillas J, Grunwald H, Howard DS, McNiff K, Neuss MM. Informed consent for chemotherapy: ASCO member resources. *Journal of Oncology Practice*; 2008 (or 2016);6:289-295.

The Joint Commission, Division of Health Care Improvement. *Informed consent: More than getting a signature*. 2016. Accessed at https://www.jointcommission.org/assets/1/23/Quick_Safety_Issue_Twenty-One_February_2016.pdf on February 19, 2019.

Additional resources

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

American Bar Association Website: <https://www.americanbar.org/>
(www.americanbar.org/groups/law_aging/resources/health_care_decision_making)²

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 website; click on your state and look for Free Legal Help

Your state or city **Bar Association** Check your local phone book or find it online at the American Bar Association

American Hospital Association Website: www.aha.org (<http://www.aha.org/advocacy-issues/communicatingpts/pt-care-partnership.shtml>)³

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

Cancer Legal Resource Center

Toll-free number: 1-866-843-2572 Email: CLRC@drlcenter.org
([mail.google.com/mail/?view=cm&fs=1&tf=1&to=CLRC@drlcenter.org](mailto:CLRC@drlcenter.org))⁴ (please read email notice)

Website: www.cancerlegalresources.org (<http://www.cancerlegalresources.org/>)⁵

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) TTY: 1-800-332-8615 Website: www.cancer.gov (<http://www.cancer.gov/>)⁶

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.*

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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](#)¹
- [Chemotherapy](#)² (including targeted therapy and immunotherapy)

- [Surgery](#)³
- Some complex or advanced medical tests and procedures, such as a [biopsy](#)⁴ (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 is to be given. For children or others who are unable to make the decision for themselves, a parent or legal guardian is legally responsible for getting the information, making the decision, and signing the consent form. Some facilities require mentally competent older children who are being treated to give **assent** (willingness to participate) 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 okay with the plan before the facility will do the treatment.

There are times when the usual informed consent rules do not apply. This varies from state to state and may include:

- In an emergency, if a person is unconscious and in danger of death or other serious outcomes 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 that states the patient refuses the care, the treatment may not be given.
- When a decision made by the parent or guardian of a child or an incompetent adult may be challenged by the doctor or facility, the courts may evaluate the situation.
- An older teen (for example, one who is self-supporting and doesn't live at home, is married, pregnant, or in the military) does not need parental consent for treatments or procedures.

A patient may wish to delegate his/her right to make informed decisions to another person. (See [Advance Directives](#)⁵ for more detailed information on this process.) This choice should be made to the extent permitted by the law. Sometimes, the patient may be unconscious or unable to make an informed decision. In these cases, the hospital must check their records for the patient's advance directives, medical power of attorney or the patient's representative. As soon as the patient is able to be informed of his/her rights, the health care provider must give the patient that information.

Another option is a **court-appointed surrogate** or **proxy**. This is someone a judge chooses to make decisions for you if you become unable to make decisions for yourself. Some states have passed family agency acts that choose which family members (listed in order of priority) may act on behalf of a patient if the patient doesn't have an advance directive or medical power of attorney.

Hyperlinks

1. www.cancer.org/treatment/treatments-and-side-effects/treatment-types/radiation.html
2. www.cancer.org/treatment/treatments-and-side-effects/treatment-types/chemotherapy.html
3. www.cancer.org/treatment/treatments-and-side-effects/treatment-types/surgery.html
4. www.cancer.org/treatment/understanding-your-diagnosis/tests/testing-biopsy-and-cytology-specimens-for-cancer/biopsy-types.html
5. www.cancer.org/treatment/finding-and-paying-for-treatment/understanding-financial-and-legal-matters/advance-directives.html

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Informed Consent for a Clinical Trial

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**. If a person decides to be part in a clinical trial, this is referred to as enrolling or enrollment in the study. As a potential research subject, you must be given an opportunity to read the consent document fully, and to ask questions about anything you do not understand. The consent form for a clinical trial or research study should clarify the following information.

- The purpose of the research
- How long it is expected to take.
- A statement saying the study involves research.
- That research subject participation is voluntary and that refusing treatment will not result in not receiving the care that they need.
- All the procedures that will be completed during the enrollment into the clinical trial.
- Any possible benefits and risks that may be expected from the research.
- Any possible discomfort (e.g., injections, frequency of blood tests etc.)
- Any alternative procedures or treatment (if any) that might benefit the research subject.
- How the potential subject's information will be kept private during the clinical trial and that the FDA (Food and Drug Administration) may inspect the records at any time.
- Whether any compensation (payment) or medical treatments are available if injury occurs and where that information may be found.
- The research subject's rights; such as the right to refuse treatment or stop participation in the clinical trial at any time, without losing any treatment benefits.

- Contacts for answers to questions related to the clinical trial and to report any injuries that may occur.

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](#)¹ 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/treatment/treatments-and-side-effects/clinical-trials.html

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