# Patient Safety and Informed Consent [1]

**This section has been reviewed and approved by the Cancer.Net Editorial Board [2], 01/2016**

 *Watch the Cancer.Net Video: Clinical Trials and Safety with Eric Singer, MD, MA* [3], *adapted from this content.*

Patient safety is the top concern in clinical trials. That's why every research study must follow a rigorous review and oversight process.

## Regulation of clinical trials

Several committees and agencies watch over patient safety before, during, and after a clinical trial.

- **Institutional Review Board (IRB)**. An IRB is an independent committee that ensures a clinical trial is ethical. The committee also makes sure that researchers protect the rights and welfare of people in a study. An IRB can include:
    - Doctors
    - Statisticians, who expertly prepare and analyze statistics
    - Community advocates

    - Clergy
    - Lawyers

  By federal law, every clinical trial must have an IRB to:

    - Approve a clinical trial before it begins
    - Ensure the study's risks are as low as possible
    - Ensure potential benefits outweigh any risks
    - Ensure that the researchers are qualified to conduct the clinical trial
    - Ensure that potential patients are given adequate information to make an informed decision about their participation
    - Make sure patients know that they have the right to drop out of the trial at any time
    - Review the research periodically until it's done

- **Federal agencies.** These agencies include the U.S. Food and Drug Administration (FDA) and the National Institutes of Health (NIH). The FDA and the NIH:

    - Approve drugs
    - Monitor research
    - Enforce rules to make sure people in clinical trials are safe

- **Data Safety Monitoring Board (DSMB).** A DSMB is an independent group of people who monitor a clinical trial. The board makes sure the study is safe and scientifically relevant throughout the study period. The board can include:

- Doctors
- Medical ethicists
- Statisticians
- Other health professionals
- Patient advocates

A DSMB isn't part of an IRB. The IRB usually looks at a clinical trial before it starts. The DSMB looks at the study at regular intervals while it is underway. Then, it makes recommendations to the sponsor about stopping or continuing the study.

For example, a new treatment may cause many patients to leave the study because of severe side effects. In that case, the DSMB may recommend the sponsor stop the study. On the other hand, a new treatment may work really well. In that case, it's unethical to keep giving it to some patients and not others. The DSMB may suggest the study be stopped and the experimental drug be offered to everyone in the study.

A DSMB is very useful for large clinical trials that take place in many locations. That's because the board can look at all of the data gathered from all clinical trial sites.

## Informed consent

Federal law requires research institutions to get informed consent to participate from each person in a clinical trial. Informed consent helps patients understand the requirements and risks and benefits of participating in the specific trial.

### Participating in the informed consent process

Researchers obtain informed consent by discussing a particular clinical trial with potential volunteers. This process often involves discussions between the patient and:

- Trial investigators, who are the researchers running the clinical trial
- Research nurses or assistants

- The patient's doctor

During the informed consent process, the research team should:

- **Describe all of the patient's options.** That way the person knows about all of the treatment choices.
- **Explain the new treatment.** This includes how it’s different from standard treatment and why it is being studied.
- **List all of the potential risks and benefits, if any, of the new treatment.** These may or may not be different from the standard treatment’s risks and benefits.
- **Explain what each patient needs to do to join the clinical trial**. The patient will learn about the:
    - Number of doctor visits and tests
    - Treatment schedule
    - Right to leave the study at any time without penalty
    - Potential costs
    - Privacy protection
    - Whom to contact with questions or concerns

The research team will also review the written consent informed form with the patient and give him or her a signed copy.

**Signing the informed consent form**

After the research teams shares the trial information, it asks each patient to read and sign an informed consent form. The form gives the patient written details about the clinical trial. All patients have to sign the document before joining the study. You can ask for the consent form in

the language you're most comfortable reading and speaking.

Joining a clinical trial is an important decision. Ask the research team any questions [4] you have about the study before you volunteer. It's also a good idea to discuss the consent form with family members or friends. Talking about your options can help you feel more at ease with your decision.

If you decide to join the clinical trial, get a copy of the informed consent form. That way you can read it at any time. The informed consent process doesn't end after you sign the form. The process is an ongoing discussion with the researchers and your health care team that allows you to:

- Ask questions
- Get answers to your concerns
- Get any new information about the clinical trial or treatment

## Freedom to leave a clinical trial

Joining a clinical trial is always voluntary. You can leave the study for personal or medical reasons at any time:

- Before the study starts
- During the study
- During the follow-up period

Ask your doctor and the researchers about who will give you treatment and care:

- During the clinical trial
- After the clinical trial ends
- If you choose to leave the clinical trial before it ends

If you leave a clinical trial, you'll still get the standard medical care you need from your health care team.

## More Information

Video: What is Informed Consent with Carolyn Runowicz, MD [5]

Clinical Trials [6]

Finding a Clinical Trial [7]

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**Links**
[1] http://www.cancer.net/navigating-cancer-care/how-cancer-treated/clinical-trials/patient-safety-and-informed-consent
[2] http://www.cancer.net/about-us
[3] http://www.cancer.net/node/27076
[4] http://www.cancer.net/node/24881
[5] http://www.cancer.net/node/27081
[6] http://www.cancer.net/node/24863
[7] http://www.cancer.net/navigating-cancer-care/how-cancer-treated/clinical-trials/finding-clinical-trial