Patient Safety and Informed Consent [1]

This section has been reviewed and approved by the Cancer.Net Editorial Board [2], 07/2013

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

Key Messages:

- Clinical trials are regulated and monitored by independent committees and federal agencies to ensure the study is safe and scientifically relevant.
- Informed consent is an ongoing process designed to protect the rights and safety of people participating in clinical trials.
- Volunteers may stop participating in a clinical trial at any time for any personal or medical reason, and they will continue to receive all necessary standard medical care.

Because patient safety is the highest priority in clinical trials, every research study must follow a rigorous review and oversight process.

Regulation of clinical trials

Various committees and agencies oversee patient safety before, during, and after a clinical trial.

Institutional Review Board (IRB). An IRB is an independent committee of doctors, statisticians (experts who prepare and analyze statistics), community advocates, clergy, lawyers, and others who ensure that a clinical trial is ethical and that the rights and welfare of study participants are protected. Every clinical trial in the United States must be approved and monitored by an IRB to make sure the risks are as low as possible and that any risks are outweighed by the potential benefits. All institutions that conduct or support medical research involving volunteers must, by federal regulation, have an IRB that approves the clinical trial before it begins and reviews the research periodically until it is completed.

Federal agencies. Federal agencies also approve and monitor clinical trials, including the U.S. Food and Drug Administration (FDA) and the National Institutes of Health (NIH). The FDA and the NIH are responsible for approving drugs and monitoring research. Both agencies make and enforce regulations to ensure the safety of clinical trial participants.

Data Safety Monitoring Board (DSMB). The DSMB is an independent group of doctors, medical ethicists, statisticians, and other health professionals that monitors a clinical trial for safety and scientific relevance throughout the study period. For example, if a new treatment is causing many patients to drop out of the study because of severe side effects, the DSMB may recommend stopping the study. Alternatively, sometimes a new treatment works so well that it is unethical to continue to give it to one group of patients and not the other. In this case, the DSMB may recommend stopping the standard treatment and offering the new treatment to all participants in the study. A DSMB is especially useful for large clinical trials that are taking place in many locations because they review all of the data accumulated from all clinical trial sites.

A DSMB is separate from an IRB. The IRB usually looks at the clinical trial before it starts. The DSMB reviews the study after it starts and makes recommendations to the IRB about stopping or continuing the study.

Informed consent

Research institutions are required to obtain informed consent from every person who decides to participate in a clinical trial. Informed consent is used to protect the safety and privacy of a person enrolled in a clinical trial.

Participating in the informed consent process

Researchers obtain informed consent by telling potential volunteers about the nature of a particular clinical trial. This typically involves one or more conversations between the research participant (the patient) and the trial investigators (the researchers conducting the clinical trial), research nurses or assistants, and the patient's doctor. It also includes a review of the written consent form with the patient.

During the ongoing informed consent process, the research team should list all of the patient's options so that the person understands all of the available treatment choices. The research team should also explain how the new treatment is different from the standard treatment. The research team must also list all of the potential risks and benefits (if any) of the new treatment, which may or may not be different from the risks and benefits of the standard treatment.

Finally, the research team must explain what will be required of each patient in order to participate in the clinical trial, including the number of doctor visits, tests, and the schedule of treatment, as well as the right to withdraw from the study at any time without penalty. Other topics covered during this discussion include potential costs, protection of privacy, and whom to contact with questions or concerns.

Signing the informed consent document

After receiving all of this information, the patient will be asked to read and sign an informed consent document. The informed consent document provides the patient with written information describing all aspects of the clinical trial, and all patients have to sign the document before participating in the study. If English is not your main language, you can ask for the consent document in a language you are more comfortable reading and speaking. Because joining a

clinical trial is an important decision, you should ask the research team any questions [4] you may have about the study before you make a decision.

It is also a good idea to take the consent document home and discuss it with family members or friends. Talking about your options can help you feel more comfortable with your decision.

If you decide to join the clinical trial, be sure to ask for a copy of the informed consent document so you can review it at any time. Also keep in mind that the informed consent process does not end after you sign the informed consent document. It is an ongoing conversation with the researchers and your health care team that allows you to ask questions, receive responses to your concerns, and keep up-to-date on any new information related to the clinical trial or treatment.

Freedom to withdraw from a clinical trial

Participating in research is always voluntary. You may stop participating in a clinical trial for any personal or medical reason at any time?before the study starts, during the study, or during the follow-up period. It is important to talk with your doctor and the researchers about who will be providing your treatment and care during the clinical trial, after the clinical trial ends, and/or if you decide to leave the clinical trial before it ends. If you decide to stop participating in a clinical trial, you will still be able to receive all necessary standard medical care 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]

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/node/24878