

ASCO Expert Corner: Informed Consent



Clinical trials are research studies involving people, and they evaluate whether new treatments are safe, effective, and better than

the current standard of care. They may be used to evaluate all aspects of cancer, including prevention, diagnosis, treatment, and quality of life. A critical component of a clinical trial is informed consent; a patient agrees to participate with a full understanding of the implications. Here, Richard Schilsky, MD, helps Cancer.Net learn more about this process.

Q: In the context of clinical trials, what is informed consent and why is it important?

A: Researchers obtain informed consent by telling prospective research participants about the nature of a particular clinical trial. This typically involves one or more conversations between the research participant (the patient) and the principal investigator (the leader of the research team), research nurses or assistants, and the patient's doctor. It also includes a review of the written consent form with the patient. This communication is essential to protect the rights and ensure the safety and privacy of potential research participants.

Q: What information does the patient receive before giving informed consent?

A: The information includes a clear statement that the intervention being tested is for research purposes and an explanation of the type of treatment, potential risks and benefits (if any), available treatment alternatives, and the right to withdraw from participation in the study at any time without penalty. Other topics include potential costs, protection of privacy, and who to contact with questions or concerns about a perceived violation of patient rights. This information should be provided in a document written at an eighth-grade reading level in the patient's primary language. The informed consent process does not end after a patient signs the informed consent document; it is ongoing, allowing the patient to ask questions and stay up-to-date about new information related to the clinical trial.

Q: How is informed consent for a clinical trial different than consent for a standard medical procedure?

A: The primary difference is that a patient giving informed consent for a clinical trial is agreeing to receive treatments that may not yet have been proven to be effective or may have greater risk than standard treatments.

Q: What is an Institutional Review Board, and what is its role in the informed consent process?

A: The Institutional Review Board (IRB) is a group of individuals who review proposed research protocols (blueprints of a trial, outlining the purpose and detailed plan) and consent forms before patient enrollment begins. Its primary responsibility is to promote the safety and well-being of research participants. The IRB ensures that the potential risks to patients are clearly described in the clinical trial process and consent form and are justified by the patient's condition and the potential benefits to the patient. IRB members typically include doctors, scientists, clergy, lawyers, ethicists, and community members who have no direct involvement in the research study under consideration. Patient enrollment in a clinical trial may not begin until the protocol and consent form have been approved by the IRB. The IRB reviews the progress of each protocol yearly, including accrual (the number of participants in the clinical trial) and adverse events (side effects experienced by study participants), to ensure that the risk/benefit profile has not changed during the course of the study.

Q: Where can patients learn more about informed consent?

A: The best source of information about a specific clinical trial is the IRB at the facility conducting the research study. Contact information for the IRB is listed on the informed consent forms.

More information

[Clinical Trials](#) [1]

[Finding a Clinical Trial](#) [2]

[Clinical Trials Video: What is Informed Consent, with Carolyn Runowicz, MD](#) [3]

Additional Resources

National Cancer Institute: A Guide to Understanding Informed Consent [4]

Dr. Schilsky, a medical oncologist, is Professor of Medicine at the University of Chicago. He is a former Chair of Cancer and Leukemia Group B, a national research network that conducts clinical trials in cancer treatment, biology, prevention, and health outcomes. Dr. Schilsky's research focus is gastrointestinal cancers and cancer pharmacology and drug development, and his research has been continuously funded by the National Cancer Institute (NCI) since 1987. He was the president of ASCO from 2008 to 2009.

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Links:

[1] <http://www.cancer.net/node/24863>

[2] <http://www.cancer.net/node/24878>

[3] <http://www.cancer.net/node/27081>

[4] <http://www.cancer.gov/clinicaltrials/conducting/informed-consent-guide/page1>