

Are Clinical Trials Safe?

It's natural to wonder whether clinical trials are safe—especially when you're already dealing with a serious medical condition. Required safeguards protect participants during every research study.

What is informed consent in research?

One safeguard is informed consent. Potential participants learn important information about the clinical trial during the informed consent process before deciding to join the study. This process of providing updated information continues throughout the trial.

Potential participants receive a document with information, such as:

- The purpose of the clinical trial
- The length of time the study will last
- Details about any required procedures or testing
- A list of contact information for the research team with instructions on who to contact for various reasons
- Potential **risks and benefits** of the trial
- An agreement that the clinical trial participant has the right to withdraw (leave) from the study at any time for any reason

Signing an additional document is required for children participating in clinical trials. Anyone younger than 18 must have consent from their legal guardians or parents.

In addition, children older than 7 years often must also give their own consent before joining a study. Research team members may explain the study to children using pictures and words that they can easily understand.



Who protects participants during clinical trials?

Many institutions, individuals, and/or government organizations monitor and review clinical trials to make sure participants are safe. These may include the following:



The clinical investigator:

This individual, also known as the principal investigator, is responsible for the entire clinical trial. If severe side effects occur during the trial, the clinical investigator must inform the institution sponsoring the trial immediately.



A Data and Safety Monitoring Board (DSMB):

A DSMB consists of subject matter experts and experienced researchers. They review clinical trial data, check for safety issues, and stop the study if harmful side effects occur.



An Institutional Review Board (IRB):

An IRB consists of doctors, statisticians, and community members who ensure that clinical trials follow a code of ethics to protect participant rights.



The National Cancer Institute (NCI):

If the NCI pays for any part of a clinical trial for leukemia treatments, the NCI must approve any study plans before the trial begins. The NCI checks the clinical trial site to ensure proper safety precautions are in place.



The Office for Human Research Protections (OHRP):

The OHRP is a part of the U.S. Department of Health and Human Services (HHS), which oversees any HHS-supported research. OHRP guides IRB review and analysis of study protocols.



The United States Food and Drug Administration (FDA):

This government organization oversees testing new medications or medical devices through clinical trials. The FDA thoroughly reviews applications at different stages of the research process to ensure participant safety. The FDA can shut down a clinical trial until these concerns are addressed if it considers any aspect of the clinical trial unsafe.

Remember that you have complete control over your treatment whenever you join a clinical trial. You can withdraw from the study at any time if you feel uncomfortable, your symptoms worsen, you don't see improvement, or for any other reason.

Find a clinical trial using our online search tool

The Leukemia Research Foundation's easy-to-use [online search tool](#) focuses solely on leukemia clinical trials. Use this tool to save time and effort looking for a trial to match your needs. The search tool uses your answers to specific questions to consider relevant details about your health situation.