Clinical Trials: What You Need to Know

Clinical trials are an important way we improve how we treat cancer. You may hear about them as an option for you. This fact sheet will help explain:

- The benefits of clinical trials
- How clinical trials work
- Your rights and protections in a clinical trial

How Can Clinical Trials Help You?

Clinical trials are research studies to try out new treatments for diseases. Volunteers join in order to see how well they work. If a clinical trial works well, it can lead to new standards of care for those diseases. There are clinical trials to find better ways to diagnose, prevent and treat cancer.

Not every form of cancer or situation has a clinical trial available. Here are some questions to ask your doctors:

- Is there a clinical trial for my form of cancer?
- What kinds of tests and treatments are involved?
- What are the possible risks, side effects and benefits to the study?
- How long will the study last?
- How might this study affect my daily life?
- Who will pay for the treatment? Will the trial, or my insurance, cover all or part of it?

How Do Clinical Trials Work?

A clinical trial often hopes to improve on existing treatments. If the new treatment works better, then this will usually become the new standard of care.

Before any treatment is tested in a clinical trial, many scientists and physicians have studied how the drug or treatment works. They submit an application to the U.S. Food and Drug Administration (FDA). Scientists from the FDA review the procedure, technology or drug. They also review processes throughout the clinical trial.

Clinical trials are done in phases. Each phase has a different purpose, including drug safety, effectiveness, long term side effects and a comparison to the standard treatment. If a new drug or treatment does not seem promising in the early phases, the research can be stopped.

What Are Your Rights and Protections?

When you take part in a clinical trial, you have rights and protections to ensure your privacy and well-being. One of the most important protections is called 'informed consent.'

Informed consent makes sure that you understand all aspects of the study, including the risks and benefits. You will sign a written consent document. This states that you have entered the trial of your own free will. You should keep a copy for your files.

You always have the right to leave a trial at any time for any reason. All patients have the legal and ethical right to cancel their participation at any time. If it seems that the treatment is not working, the physician and patient may together decide to leave the trial.

You will be asked to sign another form called a HIPAA Authorization. The Health Insurance Portability and Accountability Act (HIPAA) allows doctors to use your health information as part of the report on the study without using your name or other personal details. Be sure to keep a copy for yourself.

Each clinical facility has a committee called an Institutional Review Board (IRB). An IRB includes doctors, nurses, lawyers and people affected by cancer. The IRB reviews each clinical trial on a regular basis to make sure it is safe, ethical and is carried out properly.

If you have concerns about any part of being in a clinical trial, speak with a patient representative. The name and contact information for this person are usually included on the informed consent document at the institution. If a patient representative is not listed, ask if there is someone else you can speak with, such as a nurse or social worker.