

Medical Research in our Community

The pharmaceutical pipeline is full of new promising therapies. The number of trials needed for these new products is growing. Medical research projects are more ambitious today than ever before. The large pharmaceutical companies that sponsor these trials are turning to smaller sites all over rural America just like we have within our community.

The news is encouraging. A recent survey done by CenterWatch, a clinical trial listing company, indicates that the majority of people that take part in clinical research today felt that it was a positive experience. Most felt like they benefited from the experience. The goal of the survey was to use the results to better the clinical trial experience. Over 80% rated their experience as very good to excellent. 77% would be involved in another clinical trial. The survey also indicated that people involved in the trial process desired feedback after the trial, wanted more education about their disease state and also felt that being part of a support group or receiving newsletters would be helpful. Being part of the trial process can also shape the future because you too will have a voice.

Many people have formed negative perceptions regarding medical research. Looking back in history, we find some heartbreaking accounts of human subjects used like a guinea pigs during times of war, taken from orphanages, the streets, from asylums, and other disadvantaged populations. It is no wonder that clinical research is still viewed with skepticism by some in the general public.

Clinical trials today focus on advancements in healthcare and the quality of lives. Studies are carefully designed, and they are supervised by a qualified physician investigator and other specially trained research professionals. I was not even eligible to take the national examination until I had worked with clinical research for four years, which was an indication that I was committed to this career choice. The eight hour examination evaluated my understanding of the clinical research process including my knowledge of all federal and

state regulations. I now understand the old motto “if you’re going to do it, do it right!”

The Food and Drug Administration carefully monitors all medical research involving human subjects. They insure compliance and high standards of conduct. Institutional Review Boards are made up of professionals who study trial protocol to ensure patient safety, product effectiveness and have established a code of ethics focusing on patient rights. Clinical investigators today give an oath to “do no harm” and actually enter into a contract with the F.D.A. to adhere to the code of regulations to protect subjects in research.

All professionals involved with clinical research today also adhere to Good Clinical Practice guidelines established by the F.D.A. These guidelines again emphasize the importance of safety, rights and the welfare of those involved in clinical trials

One should never be coerced into taking part in a clinical trial. This is why the informed consent process was established. The informed consent is written in a clear, easily understood language and outlines all information regarding the trial including risks, benefits, requirements and the fact that it is strictly voluntary.

Physicians can provide additional treatment options to their patients’ with chronic disease states, or to those that have not found a successful treatment. A clinical trial is a way of offering something new with real potential to effectively improve medical care. Patients’ with Aids sought help in clinical trials to gain access to investigational drugs that may have been their only hope. Those infected with HIV had access to a new classification of drugs called protease inhibitors, that proved effective in controlling the deadly virus. Many cancer patients routinely explore clinical research as part of their evaluation of treatment options available. People with inadequate health insurance coverage who might not otherwise be able to afford the expense of medication to treat their disease states gain access to treatment through research opportunities at no cost to them for the medical care and use of the investigational drug. Many of these trials extend into long term

studies over a period of many years, which represents a great deal of medical care and medication at no cost.

There are many phases of clinical trials. Phase 1 includes a small number of healthy volunteers for a short period of time in an overnight facility. This phase usually assesses drug safety. Phase 2 trials are used in the population for which treatment is intended. Usually less than one thousand subjects are involved with an emphasis on proof of effectiveness and again safety. Phase 3 trials involve thousands of volunteers recruited after the investigational drug shows good evidence of safety and effectiveness. Phase 4 trials are conducted following the FDA approval. These post-marketing studies continue to follow new drug therapies that are on the market.

The public needs to be informed about the value of local medical research and how to participate. Ask your physician for more information regarding clinical trials, watch your local health publications and news articles about research sites in your area and if you have internet access go to the clinicaltrial.gov web site as well as web sites for area medical facilities which have valuable information about participation in area research.

With today's major emphasis being on patient rights and safety, subjects are more secure about taking part in the testing and the collection of important data that is part of the clinical trial process. I believe that enrolling in local research can help worldwide advancement in medical science and being part of that is exciting!

[For more information on current studies, please click here.](#)