

Hi Dave,

I'm writing to provide you with some information on our Regional Cancer Center and our clinical research program. I realize that this is a lot of information. Perhaps you can pick and choose some key points for your Web site or together we could come up with a bulleted list of items for you to share with your friends. Additionally, I've mailed a few things to you at your work address.

Our Regional Cancer Center continues to be one of the three busiest cancer centers in Southeastern Wisconsin, caring for more than 1,500 new patients last year. Approximately 9 percent of new cases – compared to a national average of 2 percent – enrolled in clinical research trials, which are the newest and most promising treatments available anywhere in the country.

Three years ago, ProHealth Care's Regional Cancer Center (RCC) became the first American College of Surgeons (ACOS) network accredited center in the Midwest. The network accreditation is considered the "gold standard" in terms of measuring the quality of cancer programs across the country. For a network cancer program to be accredited by the ACOS Commission on Cancer, the network must hold multidisciplinary, patient-oriented treatment and planning conferences at least weekly. The goal of this requirement is to increase the number of cases that are reviewed while patient care can still be influenced. Multidisciplinary conferences are the best way to ensure that patients receive the best treatment options based on national guidelines.

Our RCC is now striving to become an "Outstanding Achievement" program; a new designation announced this year. The ACOS Commission on Cancer conducted their survey of our RCC recently. We do not yet have the results, but I'll let you know as soon as we do. If our RCC receives approval in this new "Outstanding Achievement" category, we would be one of the first (perhaps the first) in the country to be granted this level of approval.

Offering patients the opportunity to participate in potentially life-saving clinical research trials is a vital component for best outcomes. As a direct result of generous donations from community groups, individuals, and events such as **BarryShack/Cobberfest**, our RCC will remain able to extend opportunities to our patients that are not available elsewhere.

Cancer Clinical Trials

A clinical trial is a form of medical research that focuses on patients. These carefully planned, scientific studies help doctors select the safest, most effective approaches to cancer treatment. Most of the current techniques for treating cancer, and other major illnesses have been developed using clinical trials. The information gathered helps doctors determine what is the best medical treatment.

There are three phases of clinical trials in humans.

- **In Phase I** study, a new research treatment is given to a small number of patients. The researchers must find the best way to give a new treatment and how much of it can be given safely. They watch carefully for any harmful side effects. The research treatment has been well tested in laboratory and animal studies but no one knows how patients will react. Phase I studies are offered only to patients whose cancer has spread and who would not be helped by other known treatments. Phase I treatments may produce anticancer effects, and some patients have been helped by these treatments.

- **Phase II** studies determine the effect of a research treatment on various types of cancer. Each new phase of a clinical trial depends on and builds on information from an earlier phase. If a treatment has shown activity against cancer in Phase I, it moves to Phase II. Here it is compared with standard treatment to see which is more effective. Often researchers use standard therapy as the base to design new, and hopefully, better treatments.
- **Phase III** trials are randomized studies, meaning that patients are assigned to one or two or more treatments. Neither the physician nor the patient knows which treatment will be assigned. This is done to ensure scientific validity of the trial so that all patients treated are similar and no misleading information will result from the review of the trial. Phase III studies are the ones we do most often at the Regional Cancer Center at Waukesha Memorial Hospital.

What are the benefits of participating in a clinical trial?

Usually there are no economical benefits from participating in a clinical trial. The greatest benefit patients have is early accessibility to experimental drugs or new therapeutic approaches to treatment. This may be beneficial. In the case of Phase I trials, new treatments may occasionally have an effect on the course of the disease which was not considered possible with standard treatments. Excellent cancer care is available without participation in a clinical trial; however, some of the best care is now found as part of the diverse clinical trials.

What are the risks of undergoing treatment in a clinical trial?

Clinical trials are carefully designed to benefit the patients, while trying to answer scientific questions related to cancer care. These studies may only be conducted with the written consent of the participating patient. During the process of obtaining informed consent, all the risks related to the treatment are discussed. Other options are pointed out and participation is strictly voluntary. Also, if new information becomes available during the course of treatment study, the physician is responsible to notify the patient and change treatment accordingly. To assure these designs are followed and to protect the participants the department of Health and Human Services requires all federally funded institutions to have an Institutional Review Board to supervise and protect the rights of patients. Waukesha Memorial Hospital has an active Institutional Review Board, which is involved in all decisions related to clinical research.