

## Why Should I Participate in Phase I Rheumatoid Arthritis Studies?

by *Stanley B. Cohen, M.D.*



Over the last decade, the treatment of Rheumatoid Arthritis (RA) has dramatically improved. In the late 1980s, Tumor Necrosis Factor (TNF) and Interleukin 1 (IL-1) that are critically involved in the disease were discovered as a result

of basic scientific research. This resulted in the development of newer "targeted therapies" such as Enbrel®, Humira® and Remicade® which can block these proteins. The results have been dramatic and we now have the ability to well control the disease in nearly 60-70% of patients with Rheumatoid Arthritis, compared to the 1990s when we could only adequately control the disease in a third of patients. Additionally, these new therapies are effective at preventing joint damage, resulting in fewer patients with deformities and need for joint replacement.

*"...new therapies are effective at preventing joint damage"*

Rarely do we see patients developing disability from RA as we frequently observed in the past.

Unfortunately, we still have patients who either do not respond to the newer therapies or are intolerant of the treatments. Additionally, these treatments are expensive and we need to develop treatments that can be taken orally, that are as effective as the injections/infusions, to lower the cost.

We have been involved in developing new investigational RA treatments at MCRC for more than 20 years. We were one of the original research sites to work with Enbrel® in 1993 and have continued to participate in the development of newer investigational treatments. The physicians at MCRC have been involved not only with research

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## Did You Know?

More than 20 percent of U.S. adults have arthritis and more than a third of them have limited activity because of it.

*- The U.S. Centers for Disease Control and Prevention*

[www.mcrcdallas.com](http://www.mcrcdallas.com)

## Tenderness takes on a whole new meaning when you have **Early Rheumatoid Arthritis**



If you have been told less than one year ago that you have Rheumatoid Arthritis, you may be eligible to participate in an international 18-month research study of an investigational combination currently used for Rheumatoid Arthritis.

**For more information,  
call (214) 424-0407**



### Why Should I Participate in Phase I RA Studies? *(continued from page 1)*

study participation, but also in designing the trials and analysis of the data, and they have reported the results at both national and international scientific meetings.

Over the last year, the physicians at MCRC have become more involved in Phase I research. This early phase research is critical for determining the absorption and metabolism of new investigational therapies as well as establishing their potential future dose. Generally, in Phase I research, healthy volunteers are recruited for the studies but with newer RA therapies, individuals with well-con-

trolled or minimally active disease are recruited. Individuals generally receive a single dose of the study medication and, over the next hours and days, blood and urine samples are obtained to measure the levels of the study drug remaining in the body. Based on the information from these trials, doses are picked for the later stage studies which involve several hundred patients.

Thankfully, based on our better understanding of the dis-

*“...based on our better understanding of the disease process in Rheumatoid Arthritis, there are a number of new exciting molecules entering early phase studies.”*

ease process in Rheumatoid Arthritis, there are a number of new exciting molecules entering early phase studies. We are recruiting volunteers with RA who may be willing to participate in these studies. These studies do require a significant time commitment but compensation is available for participation. Without timely completion of these studies the whole process of evaluating these investigational therapies can be dramatically delayed. If you have interest in hearing more about these ongoing studies, please contact

**Chip Pemberton, (214) 424-0407,  
or Neha Cervantes, (214) 424-0405.**

### Research Begins with You Enroll in a Phase I study at MCRC

#### **Do you have Rheumatoid Arthritis (RA)?**

If you've been diagnosed with RA and have been on a stable dose of Methotrexate for four weeks or more, you may qualify.

#### **A clinical trial is under way for Systemic Lupus Erythematosus (SLE)**

If you have a diagnosis of Systemic Lupus Erythematosus, you may qualify for this Phase I study.

For further information about these studies, or to see if you may qualify for participation, please contact

**Chip Pemberton, (214) 424-0407,  
or Neha Cervantes, (214) 424-0405.**

## Phase I Studies and You

Participants in clinical trials can play a more active role in their own healthcare, gain access to potential new treatments, and help others by contributing to medical research. Phase I study participants work closely with a research team, which includes doctors and other healthcare professionals. They will assess your health at the beginning of the study, monitor you closely during the study, and follow up with you after the study is completed.

## Who Should Participate?

All clinical trials have guidelines about who can participate. These criteria are based on age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. Some research studies seek participants with medical conditions, while others need healthy participants. The trial guidelines help identify appropriate participants.

## Your Safety

The ethical and legal codes that govern medical practices also apply to clinical studies. To ensure participants' safety and well-being, clinical studies are heavily regulated by the government. In turn, the government empowers Institutional Review Boards (in North America) and Ethics Committees (in other countries) to monitor the study process and enforce regulations. Each trial follows a study plan which details what researchers will do.

## Your Consent

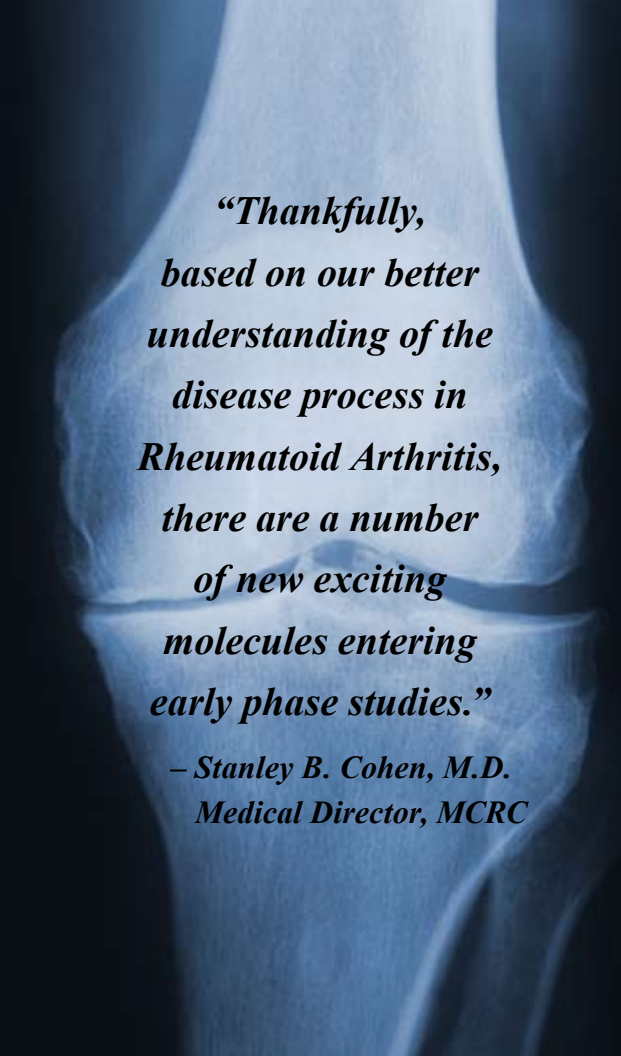
Informed consent ensures you know all the facts regarding the study, the investigational medication and your care in particular. The research team will detail the purpose and duration of the study, procedures, and any known benefits and risks associated with the investigational medication. If you decide to participate in the study, you will sign an informed consent document. This document is not a contract, and you may withdraw your participation at any time.



**DO YOU HAVE osteoarthritis?**  
**Got Knee Pain?**  
If you have experienced knee pain caused by Osteoarthritis for at least six months, you may qualify to participate in this clinical research study. Study participants are needed to test the safety and effectiveness of an investigational medication to see if it can provide pain relief. To qualify, you must be 40 years of age or older and currently taking medication on a regular basis for knee pain caused from Osteoarthritis.

**For more information, call (214) 424-0407**

**m c r c**  
**Metroplex**  
Clinical Research Center



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*– Stanley B. Cohen, M.D.  
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## Newsflash

Metroplex Clinical Research Center has made headline news lately with segments on Fox 4 News and WFAA-TV, Channel 8 about clinical trial opportunities for patients with arthritis. To view streaming video of John Hammarley’s Fox 4 report and Janet St. James’ and Brenda Teele’s WFAA segments, visit the following online links:

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### **ABC 8 Good Morning Texas. 7/18/08 and 8/8/08**

Log on to [www.wfaa.com](http://www.wfaa.com) and type in “Clinical Trials for Arthritis” in the search field. Upcoming Segment 10/13/08.

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### **ABC 8 Your Health Matters. 5/6/08**

Go to [www.wfaa.com](http://www.wfaa.com) and type in “Uncovered: find free medical care in clinical trials” in the search field.

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### **Fox 4 Marketplace. 5/5/08**

Visit [www.myfoxdfw.com](http://www.myfoxdfw.com) and type in “Clinical Trial Aims to Soothe Knee Arthritis” in the search field.

For more updates on current clinical trials at MCRC, visit **[www.mcrcdallas.com](http://www.mcrcdallas.com)**.

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For information about current research studies at MCRC, call Chip Pemberton at (214) 424-0407 or Neha Cervantes at (214) 424-0405. or visit [www.mcrcdallas.com](http://www.mcrcdallas.com).