

## Myths about Participating in Clinical Trials

**A clinical trial can do anything it wants; I am just a guinea pig.**

The health of participants is safeguarded through the study protocol. Clinical trials are also approved by an Institutional Review Board (IRB) before enrolling participants. An IRB performs critical oversight functions for research conducted on people to ensure that the trials are safe for the participants and scientifically sound. The IRB monitors and reviews the study through the entire duration of the study.

**Once I start a trial, I can't quit.**

Participants can drop out of a clinical trial at any time for any reason. If you do not like the trial, are not feeling well or the trial is not going like you think it should, you have the option to drop out.

**The blood samples that are collected during a clinical trial can be used for anything.**

Blood samples are usually drawn for laboratory tests to assess the progress of the study. They are not used for any purpose that is not explicitly stated in the consent form. Sometimes a patient may be asked to donate additional blood samples to help develop new lab tests for diagnosing and treating diseases. These research samples require a separate consent form, and are optional.

**If my doctor asks me to participate in a trial, I can't turn it down.**

Participating in a clinical trial is on a voluntary basis; your doctor will still be your doctor and treat you regardless of whether you participate or not.

**If I participate in a clinical trial, my insurance company might deny my coverage.**

Your insurance company cannot deny you any coverage if you participate in a trial. Insurance companies are not informed of your participation.



**You should always ask the following questions:**

- Who is doing the study?
- What is the study about?
- Will the study help to understand my condition?
- What do I have to do in the study?
- Are there any side effects to any medication?
- How much of my time is going to be involved?
- How often do I have to go to the participation site?
- How long will the visit be?

**Why should you volunteer?**

- People volunteer to participate in clinical trials for many reasons.
- They wish to benefit others and science
- They anticipate a personal benefit, a better treatment or outcome



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# Thurston Today

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DIVISION of RHEUMATOLOGY, ALLERGY and IMMUNOLOGY at the UNC SCHOOL of MEDICINE

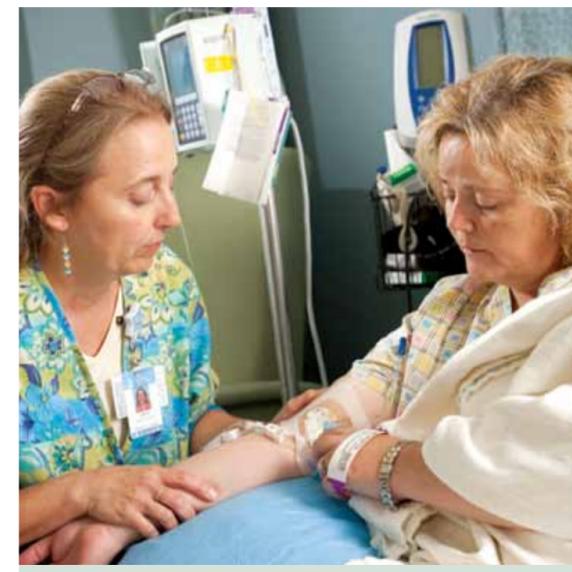
Spring 2010

## Clinical Trials

A clinical trial is a research study used to collect data about the safety and efficacy of a new drug or procedure. It takes place after researchers have tested new therapies or procedures in the laboratory and in animal studies. Consenting volunteers receive investigational treatments under the supervision of a medical or research professional.

Clinical trials are conducted in four phases. Each phase serves a different purpose and seeks to answer different questions.

- **Phase I** studies assess the safety of a drug or treatment in a small group of 20–80 for the first time. They are used to determine the effects of the treatment on humans, including how it is absorbed, metabolized, excreted, to determine safe dosage ranges and to find any side effects which may occur.
- **Phase II** studies assess the efficacy and safety of a drug or treatment in a larger group of 100–300. They are usually randomized trials where one group of participants receive the experimental treatment, while a second group receives a standard treatment or placebo. Phase II studies are also often “blinded” which means that neither the patients nor the researchers know who has received the experimental drug.
- **Phase III** studies take place in a large group of 1,000–3,000. They confirm a drug or treatment’s effectiveness, monitor side effects, compare the drug to commonly used treatments and collect information that will allow the drug or treatment to be used safely.
- **Phase IV** or postmarketing surveillance trials, provide additional information after a drug or treatment has been approved for consumer sale.



All clinical trials follow a study plan, or protocol, that safeguards the health of the participants. It explains what the study will do, how it will be carried out, and who may participate. It also includes a schedule of tests, procedures, medications and dosages and the length of the study. All doctors and research centers taking part in a specific trial use the same protocol. This ensures that all patients are treated the same.

All clinical trials taking place in the United States must receive approval by an Institutional Review Board (IRB) before the study can take place. The IRB ensures that the risks of the study are as low as possible and worth any potential risk. The IRB is an independent committee made of at least five qualified individuals with multidisciplinary backgrounds who evaluate the trials for scientific, legal, and ethical merit both before and during the course of the study.

## Join us for the 2010 Triangle Arthritis Walk

The Arthritis Walk is the Arthritis Foundation’s annual nationwide event that raises awareness about arthritis as well as money for arthritis research. This year’s walk will take place on Saturday, April 17 and will include the Bouncing Bulldogs jump rope team, a best pet trick competition, a VIP tent for non-walkers, and a tai chi demonstration. Walkers have the choice of participating in a 1- or 3-mile walk around the Imperial Center in Durham.

Last year, Thurston Arthritis Research Center’s Arthritis Walk team, The TARC Heels, was a visible presence at the Arthritis Foundation’s Triangle Arthritis Walk. Our team was the largest at the Walk and raised over \$2500.

This year we are hoping to have an even bigger team and raise more money for the Arthritis Foundation. You can help us reach our goal by joining or donating to our team. You can access our team page by visiting [www.trianglearthritiswalk.kintera.org](http://www.trianglearthritiswalk.kintera.org) and selecting TARC Heels from the list of teams on the right side of the page. You can also contact our team captains, Kathryn Martin ([kathryn.martin@unc.edu](mailto:kathryn.martin@unc.edu)) or Delesha Carpenter ([dmlmiller@email.unc.edu](mailto:dmlmiller@email.unc.edu)).

If you would like to start your own team or volunteer, visit the website listed above or contact Grace Danuck (919-303-8080, [gdanuck@gmail.com](mailto:gdanuck@gmail.com)).

**We hope to see you there!**



Thank you for supporting arthritis research!

The UNC Thurston Arthritis Research Center gratefully acknowledges the contributions of the individuals, corporations, foundations and organizations who provide vital support to our goal to find preventions, cures and treatments for arthritis, allergy and autoimmune diseases.

Private donations are essential to our operations and assist basic science research, population-based studies, faculty enhancements, fellowship support, professorships and other important initiatives.

Quite simply, the continued support and generosity of our donors enable us to serve as the arthritis center for the people of North Carolina.

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## Dear Friends,

Over the last year in the *Thurston Today* newsletter we have highlighted various research endeavors taking place at the Thurston Arthritis Research Center, ranging from basic science research to psychosocial research. One important area of clinical research that we think you should know about is our Clinical Trials Program. Clinical trials are research studies that test new and emerging medical treatments for arthritis, allergies, and autoimmune diseases. At this time, we have eleven trials being conducted, all bringing new, cutting-edge therapies to our patients.

In this issue of *Thurston Today*, you will find important information about clinical trials, ranging from what a clinical trial is to what procedures we use to protect research participants. We also highlight two of our best and brightest clinical trial researchers, Dr. Mary Anne Dooley and Dr. Beth Jonas. Each of them is nationally and internationally recognized for the work they do in bringing to our patients the best that medicine has to offer in exciting and ground-breaking clinical trials.

As spring approaches and the warmer weather begins to set in, faculty and staff here at Thurston join together to participate in the annual Arthritis Foundation Walk held in Raleigh, North Carolina. This year, Dr. Beth Jonas is Medical Co-chair of this wonderful event, one in which we can share with the community, as well as show our support and dedication to both arthritis research and our patients.

We once again hope you find the information in this edition of our newsletter informative and enjoyable. As always, we welcome your comments and suggestions, directed to [randy\\_mounce@med.unc.edu](mailto:randy_mounce@med.unc.edu).

Joanne M. Jordan, MD, MPH, Director



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trials being  
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## Interview with Mary Anne Dooley, MD

*When did you get started doing clinical trials?*

I started doing clinical trials immediately after my fellowship in 1991. Initially, the clinical trials were looking at a variety of drugs primarily for rheumatoid arthritis. My area of clinical and research interest is in lupus, but there has not been a drug approved for lupus since Plaquenil was approved in 1966. However, there are now two drugs that have shown benefits for lupus and are positioned to be considered for approval by the FDA.

*Did you participate in the clinical trials for either of those two drugs?*

Yes, one of the drugs will be called Benlysta and it was developed by Human Genome Sciences and GlaxoSmithKline.

*Why has it been so difficult to target lupus?*

One of the difficulties of targeting lupus is that there are not two patients with lupus that have the same exact manifestations of the disease. Lupus affects many of the organs in the body and so the symptoms can vary from person to person. It is difficult to find patients that meet the exact criteria for a clinical trial.

*What types of trials have you participated in?*

Most of the trials I have participated in have been unfunded trials to look at the natural history of the disease. I belong to an organization called Systemic Lupus International Cooperating Clinics (SLICC) which is a group of 30 rheumatologists from around the world at 27 different sites. We have a small amount of funding to provide for the organization of the group, but have still enrolled almost 15,000 patients who are in the first 18 months of their disease onset. We collect information and biological samples from these patients. This



has become a treasure trove of information that has been used in several studies to gain a better understanding of the disease.

*What has been your personal experience in dealing with lupus patients?*

Lupus has a huge impact on people's lives. Most people do not know what lupus is and since it has several symptoms, not a lot of doctors other than rheumatologists have much experience in dealing with it. Lupus patients are usually women, more frequently African American, and are usually affected at a younger age. As a physician, I have to not only treat my patients for their lupus but teach them how to understand their own disease and what they need from the medical system. Since this is a chronic condition, I will see patients for a very long time, so we get to know them and their families, which can be very rewarding.

- Lupus**
- Lupus is a chronic inflammatory autoimmune disease that can affect various parts of the body, especially the skin, joints, blood, and kidneys.
  - About 1.5 million Americans have lupus. Lupus typically affects women of childbearing age (15-44), though men, children and teenagers can develop lupus.
  - African American women have a three times higher incidence of lupus than white women. They tend to develop the disease at a younger age than white women and develop more serious complications. Nine times more women than men have lupus, and it is also more common in women of Hispanic, Asian, and Native American descent.
  - Lupus is a relapsing, remitting disease, characterized by periods of flares (the symptoms worsen and you feel ill) and remissions (the symptoms improve and you feel better).

## Interview with Beth Jonas, MD

*What is your area of interest in clinical trials?*

I have been doing clinical trials since I came to Thurston in 1998. I am primarily a clinician, so I do clinical work, clinical trials, and teach clinical medicine to fellows. My primary interest in clinical trials is inflammatory arthritis, focusing on rheumatoid arthritis, but I have also done clinical trials that focus on osteoarthritis.

*What benefits do you see in participating in a clinical trial?*

From a patient point of view, participating in a clinical trial gives them access to new drugs and treatments that they would not otherwise have access to. From a clinician's point of view, we gain experience with these new drugs, learn how to administer them, what the potential side effects are, and what the positive effects are, so that once the treatment is approved by the FDA we can effectively use it for our patients. Also, by participating in the clinical trial we add to the body of understanding of how these drugs and treatments work.

*What types of clinical trials have you participated in?*

Early on, I was involved in the Phase III trials for Cox-2 inhibitors looking at their efficacy for osteoarthritis. Most recently, we have participated in the Phase III trial for tocilizumab which was recently approved by the FDA for use in rheumatoid arthritis; it will be marketed as Actemra. When you do a Phase III trial, so much information, including the primary effects of the drug are well-known. It is different in a Phase I trial which basically looks at toxicity. In a Phase I trial, you have all the preclinical information, you have animal and in vitro studies, and some good ideas about what is going to happen in humans, but you don't really know if the drug will be as effective as anticipated.

I have done one Phase I trial. As a researcher, I found it to be most interesting, but as a clinician I have to look closely at these trials to see if there will be a benefit for my patients since there is more risk involved. I will not participate in a Phase I trial if I think that the risk will outweigh the benefits. Since Phase I trials are smaller with fewer patients involved than in a Phase II or III trials, the investigators have more input in the ongoing trial and planning for further trials.

*Do you participate in any registries?*

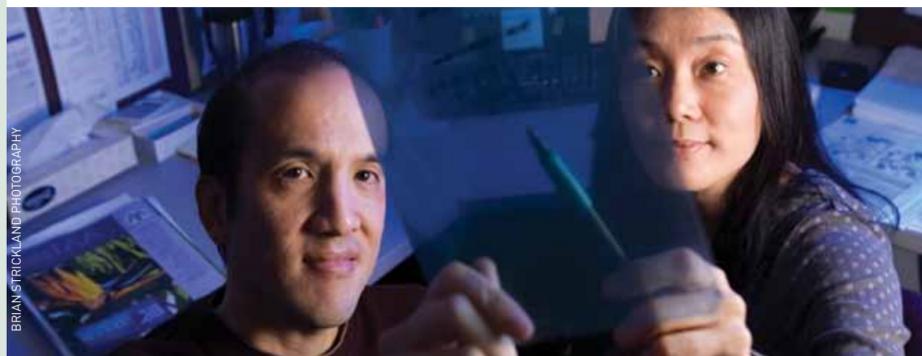
Yes, we have a large registry that is ongoing: the CLEAR Registry. This is different from a clinical trial, because it does not involve an intervention; patients are not asked to take medications. We use registries to help gain an understanding about the biology of a disease, which may involve questionnaires and collecting x-rays and blood samples.

The CLEAR Registry has a unique perspective because it looks at early rheumatoid arthritis in African Americans, who are often underrepresented in registries. Participants were followed for five years, collecting biological samples and clinical data. We will be enrolling 400 new participants. The 400 participants will also be enrolled in an even larger registry that is being developed by the American College of Rheumatology that will focus on all of rheumatologic conditions.



## Rheumatoid Arthritis

- Rheumatoid arthritis (RA) is a chronic autoimmune disease, mainly characterized by inflammation of the lining, or synovium, of the joints. It can lead to long-term joint damage, resulting in chronic pain, loss of function and disability.
- RA affects 2.1 million Americans. 75 percent of RA patients are women. RA typically occurs between the ages of 30 and 60; however, even children can develop RA.
- There is no single laboratory test or x-ray which can diagnose RA. A combination of test results, a clinical examination, and patient medical history can help determine a diagnosis of RA.



BRIAN STRICKLAND PHOTOGRAPHY