

## **National PF Research Program – The “IPFNet”**

The **IPFnet** is a clinical research network sponsored by the National Heart Lung and Blood Institute (NHLBI) of the National Institutes of Health (NIH). It was formed in 2005, after a national competitive peer review. The mission of the IPFnet is to develop and evaluate clinical treatment

### **IPFnet Recruiting Patients for Important Research Studies**

The IPFnet is a clinical research network sponsored by the National Heart, Lung and Blood Institute (NHLBI) of the National Institutes of Health (NIH). It was formed in 2005 after a national competitive peer review. The mission of the IPFnet is to develop and evaluate clinical treatment regimens for idiopathic pulmonary fibrosis (IPF).

**The broad objective** of the IPFnet is to conduct multiple randomized, controlled clinical trials to evaluate existing or new medications, combinations of medications, and defined management strategies for patients with IPF.

**The primary goal** of the IPFnet is to improve outcomes in the care of patients with IPF. The network develops protocols for all patients, including those in the early phase of IPF who have had minimal prior treatment and for those patients with a more advanced stage of the disease. The first of these protocols, Sildenafil Trial of Exercise Performance in Idiopathic Pulmonary Fibrosis (STEP-IPF), was recently presented at the annual meeting of the American Thoracic Society and published in the prestigious journal, the New England Journal of Medicine. This innovative study demonstrated that a therapeutic option can improve quality of life and decrease symptoms in IPF patients with more advanced disease. The IPFnet is also conducting a series of ancillary studies in which subjects who are enrolled in one of the clinical trials may also participate. These studies are investigating markers of disease activity, prognosis, and identification of potential new targets for future therapy.

“What we most need is additional information about the treatment of IPF. We don’t know whether what is considered standard therapy improves, worsens or has no effect on the disease. We don’t know whether early disease patients respond to existent therapies. We need to test the effects of available drugs in state-of-the-art therapeutic protocols. We will also need to train new investigators with clinical, epidemiologic, cell biology and genetics skills who are committed to the discovery of new therapeutic interventions. The Network is a great opportunity to accomplish all these tasks,” said acting IPFnet Steering Committee Chair Dr. Galen B. Toews. “The best treatment option for all patients with IPF at the present is to participate in an IPFnet trial. Physicians, scientist, nurses, study coordinators, the NIH and foundations funds all play crucial roles in discovery, but they cannot do this work without patients who agree to participate in therapeutic trials.”

The network is currently recruiting patients for two important studies:

- 1) The **PANTHER-IPF: Prednisone, Azathioprine, and N-Acetylcysteine: A Study That Evaluates Response in IPF** trial evaluates the effectiveness of N-acetyl cysteine (NAC) alone, and in combination with prednisone and azathioprine, at preventing the loss of lung function in people with IPF. This trial is available to all subjects with IPF diagnosed in the last 48 months between 35–85 years of age with moderate disease who meet study specific enrollment criteria.
- 2) The **ACE-IPF: Anticoagulant Effectiveness in Idiopathic Pulmonary Fibrosis** trial is investigating whether treatment with warfarin improves clinical outcome in subjects with IPF. This trial is available to all subjects with IPF between 35–80 years of age, regardless of time of diagnosis who meet study specific enrollment criteria.

*The participating IPFnet sites have a long history of excellence in IPF-related patient care and clinical research. Participating centers are listed below. If you or someone in your family would like to participate*

*in an IPFnet trial, please contact the appropriate center for you using the contact names and numbers listed.*

<b>State</b>	<b>Investigator</b>	<b>Institution</b>	<b>Contact Information</b>
Alabama	Joao de Andrade, MD	University of Alabama at Birmingham	Tonja Meadows 205.934.7630
California	Joseph Lynch, MD	University of California at Los Angeles	Eileen Callahan 310.794.8595
California	Talmadge King, MD	University of California at San Francisco	Renee Jeffrey 415.476.5034
Colorado	Kevin Brown, MD	National Jewish Health	Todd Dubois 303.398.1621
Connecticut	Danielle Antin-Ozerkis, MD	Yale University School of Medicine	Jean Estrom 203.785.7324
Florida	Marilyn Glassberg, MD	University of Miami, Miller School of Medicine	Emmanuelle Simonet 305.243.3728
Illinois	Imre Noth, MD	University of Chicago	Cathy Brown 773.834.7085
Kentucky	Jesse Roman, MD	University of Louisville	Tamra Perez 502.852.1358
Louisiana	Joseph Lasky, MD	Tulane University	Sandy Ditta 504.988.4040
Michigan	Fernando Martinez, MD	University of Michigan	Debra Dahlgren 734.936.8917
Minnesota	Jay Ryu, MD	Mayo Clinic	Susan Walsh 507.293.0367
Missouri	Neil Ettinger, MD	Saint Luke's Hospital	Sue Merli 314.576.4501
New York	Michael Kallay, MD	Highland Hospital/University of Rochester Medical Center	Elizabeth Lyda 585.233.4358
New York	Robert Kaner, MD	Weill Cornell Medical Center of Cornell University	Vanessa Monroy 646.962.5568
North Carolina	Lake Morrison, MD	Duke University Medical Center	Terri Haram 919.668.4562
Ohio	Jeffrey Chapman, MD	Cleveland Clinic Foundation	Susan Lubell 216.445.5872
Pennsylvania	Milton Rossman, MD	University of Pennsylvania	Susan Metzger

			215.662.3115
South Carolina	Steven Sahn, MD	Medical University of South Carolina	Kimberly Argabright 843.792.3168
Tennessee	James Loyd, MD	Vanderbilt University Medical Center	Wendi Mason 615.343.7068
Texas	John Fitzgerald, MD	University of Texas Southwestern Medical Center	Barbi Estes 214.648.6729
Utah	Mary Beth Scholand, MD	University of Utah Lung Health Research Center	Laurie Brewster 801.581.5811
Washington	Ganesh Raghu, MD	University of Washington	Carolyn Spada 206.598.4967

### **Su: This is the Clinical Trials segment**

#### **Clinical Trials Q&A:**

Source [www.clinicaltrials.gov](http://www.clinicaltrials.gov), a service of the National Institutes of Health (NIH); content shortened for space. Please see the NIH website for complete information.

#### **What is a clinical trial?**

Although there are many definitions of clinical trials, they are generally considered to be biomedical or health-related research studies in human beings that follow a pre-defined protocol. ClinicalTrials.gov includes both interventional and observational types of studies. Interventional studies are those in which the research subjects are assigned by the investigator to a treatment or other intervention, and their outcomes are measured. Observational studies are those in which individuals are observed and their outcomes are measured by the investigators.

#### **Why participate in a clinical trial?**

Participants in clinical trials can play a more active role in their own health care, gain access to new research treatments before they are widely available, and help others by contributing to medical research.

#### **Who can participate in a clinical trial?**

All clinical trials have guidelines about who can participate. Using [inclusion/exclusion criteria](#) is an important principle of medical research that helps to produce reliable results. The factors that allow someone to participate in a clinical trial are called "inclusion criteria" and those that disallow someone from participating are called "exclusion criteria". These criteria are based on such factors as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. Before joining a clinical trial, a participant must qualify for the study. Some research studies seek participants with illnesses or conditions to be studied in the clinical trial, while others need healthy participants. It is important to note that inclusion and exclusion criteria are not used to reject people personally. Instead,

the criteria are used to identify appropriate participants and keep them safe. The criteria help ensure that researchers will be able to answer the questions they plan to study.

### **What happens during a clinical trial?**

The clinical trial process depends on the kind of trial being conducted (See [What are the different types of clinical trials?](#)) The clinical trial team includes doctors and nurses as well as social workers and other health care professionals. They check the health of the participant at the beginning of the trial, give specific instructions for participating in the trial, monitor the participant carefully during the trial, and stay in touch after the trial is completed.

Some clinical trials involve more tests and doctor visits than the participant would normally have for an illness or condition. For all types of trials, the participant works with a research team. Clinical trial participation is most successful when the [protocol](#) is carefully followed and there is frequent contact with the research staff.

### **What are the benefits and risks of participating in a clinical trial?**

#### **Benefits**

Clinical trials that are well-designed and well-executed are the best approach for eligible participants to:

- Play an active role in their own health care.
- Gain access to new research treatments before they are widely available.
- Obtain expert medical care at leading health care facilities during the trial.
- Help others by contributing to medical research.

#### **Risks**

There are risks to clinical trials.

- There may be unpleasant, serious or even life-threatening side effects to experimental treatment.
- The experimental treatment may not be effective for the participant.
- The [protocol](#) may require more of their time and attention than would a non-protocol treatment, including trips to the study site, more treatments, hospital stays or complex dosage requirements.

### **What are side effects and adverse reactions?**

Side effects are any undesired actions or effects of the experimental drug or treatment. Negative or adverse effects may include headache, nausea, hair loss, skin irritation, or other physical problems. Experimental treatments must be evaluated for both immediate and long-term side effects.

### **How is the safety of the participant protected?**

The ethical and legal codes that govern medical practice also apply to clinical trials. In addition, most clinical research is federally regulated with built in safeguards to protect the participants. The trial follows a carefully controlled protocol, a study plan which details what researchers will do in the study. As a clinical trial progresses, researchers report the results of the trial at scientific meetings, to medical journals, and to various government agencies. Individual participants' names will remain secret and will not be mentioned in these reports (See [Confidentiality Regarding Trial Participants](#)).

## **What should people consider before participating in a trial?**

People should know as much as possible about the clinical trial and feel comfortable asking the members of the health care team questions about it, the care expected while in a trial, and the cost of the trial. The following questions might be helpful for the participant to discuss with the health care team. Some of the answers to these questions are found in the informed consent document.

- What is the purpose of the study?
- Who is going to be in the study?
- Why do researchers believe the experimental treatment being tested may be effective? Has it been tested before?
- What kinds of tests and experimental treatments are involved?
- How do the possible risks, side effects, and benefits in the study compare with my current treatment?
- How might this trial affect my daily life?
- How long will the trial last?
- Will hospitalization be required?
- Who will pay for the experimental treatment?
- Will I be reimbursed for other expenses?
- What type of long-term follow up care is part of this study?
- How will I know that the experimental treatment is working? Will results of the trials be provided to me?
- Who will be in charge of my care?

## **Does a participant continue to work with a primary health care provider while in a trial?**

Yes. Most clinical trials provide short-term treatments related to a designated illness or condition, but do not provide extended or complete primary health care. In addition, by having the health care provider work with the research team, the participant can ensure that other medications or treatments will not conflict with the [protocol](#).

## **Can a participant leave a clinical trial after it has begun?**

Yes. A participant can leave a clinical trial, at any time. When withdrawing from the trial, the participant should let the research team know about it, and the reasons for leaving the study.

## **What is a placebo?**

A placebo is an inactive pill, liquid, or powder that has no treatment value. In clinical trials, experimental treatments are often compared with placebos to assess the experimental treatment's effectiveness. In some studies, the participants in the [control group](#) will receive a placebo instead of an active drug or experimental treatment.

## **What is a control or control group?**

A control is the standard by which experimental observations are evaluated. In many clinical trials, one group of patients will be given an experimental drug or treatment, while the control group is given either a standard treatment for the illness or a placebo.

