

## Patient Information

Welcome to the Health Research of Hampton Roads web site. Our goal is to provide you with very basic information regarding participation in clinical research trials. We value your participation in research regard you as a partner in the pursuit of a common goal. The goal? A commitment to improving quality of life through the careful study of better medical treatments.

- ↓ What is a clinical trial?
- ↓ Who conducts clinical trials?
- ↓ Why should I participate?
- ↓ Who qualifies to be in a clinical trial?
- ↓ How do I obtain study information?
- ↓ What happens during a study?
- ↓ Are there risks involved in research participation?
- ↓ What can I expect after trial completion?
- ↓ Can I expect to be compensated for my participation in research?

### **What is a Clinical Trial?**

A clinical trial is a research study conducted to evaluate a potential medical treatment for a specific medical condition. The medical treatments under study are usually investigational medications or devices developed by pharmaceutical companies. Clinical trials are designed to answer important research questions about these investigational treatments and to determine if a medication is safe and effective in treating the medical condition being evaluated. Occasionally a pharmaceutical company performs a clinical trial that compares commercially available therapies for effectiveness and patient preferences. Other examples include, testing new antibiotics, cholesterol and asthma medications.

### **Who Conducts Clinical Trials?**

Pharmaceutical companies, research institutions, other health organizations, or even individual physicians may be a sponsor of a clinical trial. The sponsor is responsible for funding and designing its protocol. A protocol is a set of detailed guidelines that each investigator follows in order to conduct the same clinical trial. As a rule, pharmaceutical

company sponsored clinical trials are conducted at multiple locations nationally, and occasionally internationally.

### **Why Should I Participate?**

- ↓ Study related medical treatment at no charge
- ↓ Experienced, Board certified physicians
- ↓ Trained, experienced and professional Research Coordinators and Research Assistants.
- ↓ Convenient location
- ↓ Personal satisfaction from making a positive contribution to society
- ↓ To gain a better understanding of your medical condition
- ↓ Reimbursement for time and travel

### **Who Qualifies to be in a Trial?**

Because each trial is designed to answer some very specific research questions, not everyone is eligible to be a participant in a particular trial. The protocol of every clinical trial is designed to target a distinctive and specific medical condition. If the research trial is testing an investigational diabetes drug, then only patient volunteers with diabetes will qualify to be in the study. However every protocol is designed to exclude potential study participants who have coexisting medical problems or take certain medications that either put them at risk or cloud study results.

Once a potential participant has been identified, a brief medical evaluation that covers your general health, current medications, age and other factors, is performed. After this evaluation the research coordinators will be better able to discuss your eligibility for a particular study.

### **How Do I Obtain Study Information?**

Volunteers will receive complete information about the trial, in a written document referred to as the *informed consent form*. This document will include an honest discussion of the potential benefits and risks of the trial.

Contact HRHR at (757) 591-8100 for more information about participation in a research study.

### **Are There Risks Involved in Research Participation?**

Although researchers expect positive results, the fact that an investigational treatment is still being studied makes it impossible to rule out the potential for treatment side effects. All risks are explained in a document called the informed consent form. Be certain you understand the risks. The consent process is an opportunity for you to educate yourself about the nature of the study, obtain information about the goals of the research trial and to ask questions about anything that is unclear.

### **What Happens During a Study?**

Participating in a clinical trial is similar to a regular visit to your doctor. During your visits to HRHR you will initially meet with a research coordinator. The coordinator will discuss the study with you and explain in detail what to expect during the trial including your responsibilities. You will be presented facts about the study drug(s) and an *informed consent form* to read and sign. This is required by law to make sure you understand what is involved in a trial. Your medical history will be reviewed. If you qualify for study participation, you will be given a physical exam, blood and urine samples may be taken, and other specialized tests performed. The coordinator will also review your current medications. Depending on test results, which may not be known until after multiple visits, you will receive the investigational medication with detailed instructions on how to take it. As the study progresses you will meet with your study coordinator and physician at scheduled visits to discuss what has happened since your previous visit. This offers you the opportunity to ask questions and allow the coordinator to review your compliance with taking the medication and following the study requirements.

### **What Happens After the Trial?**

At the conclusion of a clinical trial, the HRHR staff will make sure that all participant questions are fully answered. Common questions center on the future availability of the study medications, additional available treatments, and the interpretation of any important health information revealed through lab work, other study related medical tests and your physical exams.

The HRHR staff and supervising physician strive to insure that volunteers leave each trial with a plan for continuing treatment by your family physician and/or a referral to a specialized health professional when warranted. Volunteers are treated professionally, with compassion and with the utmost attention to personal privacy. A recent survey of patients completing different studies at our office found that 92% report a very positive experience when working with HRHR.

The staff at Health Research of Hampton Roads views each trial volunteer as a partner. This partnership between volunteer patient and doctor centers on the pursuit of a common goal. The goal? A commitment to improving quality of life through the careful study of better medical treatments.

### **Can I Expect to be Paid for my Participation in Research?**

Goals for participation in research should reflect a desire to improve your or a loved ones health and to learn more about breakthrough treatments while helping society as a whole. The rewards should be secondary. No one should jeopardize his or her safety for financial gain. Every study is analyzed as to its benefits and inconveniences to the research participant and a decision is made as to the appropriate level of compensation. Consequently, the compensation should not encourage you to take unnecessary risks by being too large.

Reimbursement for your time and travel is provided by HRHR. The specific compensation may range from a small gift, to reimbursement of travel costs and meals. On occasion, larger rewards are offered if a significant investment of time is required.