

# Doylestown Hospital Medical Research



*“Providing New Hope on the Horizon”*

“Doylestown Hospital views clinical research as a core component of our efforts to provide state of the art, clinically advanced, quality care for our community. Our participation in a number of trials (including NIH studies) helps assure that our culture is that of continued learning and growth, provides a mechanism for our physicians to remain current, and in addition becomes a powerful recruitment tool to motivate gifted physicians to practice in our community.”  
Scott Levy, M.D.

## Contact Information:

**Medical Research Office: 215-345-2119**

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## About Medical Research at Doylestown Hospital...

Americans are now living longer and healthier lives than ever before thanks to the biomedical discoveries made through collaborative medical research efforts. Doylestown Hospital is proud to be a part of this scientific movement. Doylestown Hospital has been involved in research for more than ten years beginning with the TIMI 9B Trial conducted by Dr. James Kmetzo, Cardiologist. The PAMI Trial (Primary Angioplasty in an Acute Myocardial Infarction) was instrumental in establishing the Doylestown Hospital Heart Institute which now stands as one of the finest cardiac care centers in the region.

We remain dedicated to bringing safer and more effective methods of treatment to various therapeutic areas such as cardiac and vascular disease, renal insufficiency, and bone disease. Our participation in clinical trials is based on sound scientific principles by adhering to the standards of Good Clinical Practice and the regulatory guidelines of accepted Institutional Review Boards and the Food and Drug Administration. Our goal is to bring proven, superior methods of treatment to our community, elevating patient outcomes, while maintaining the highest and most ethical standards of research.

## Understanding the Research Process:

Clinical trials must take place before new research treatments or devices can be made available to the public. It is imperative for these new treatment options to be brought to market with safety and efficacy upon which we can rely. Many currently available medical treatments have been analyzed through clinical trials, and carefully monitored under strict government regulations to ensure safety, reliability, and ethical concerns. These highly scrutinized and costly processes make it possible to improve the quality of life for patients who depend on such treatments. In order to successfully conduct research trials, we must rely on volunteers who meet inclusion criteria to participate in these studies. Studies vary widely in what they require of a volunteer, but their ultimate purpose is to gather knowledge that will help improve peoples' health and well-being. Participation in a study may benefit you directly, indirectly, or not at all, but the knowledge gained is important for furthering advances in diagnosis and treatment.

## Should I participate?

Choosing to participate in a clinical trial is an important personal decision which requires careful consideration. It is often helpful to talk to your physician or family members when deciding to join a trial. Certainly, participation as a volunteer in clinical research can be a rewarding experience. It can be very gratifying to know you are contributing to the advancement of medical science which promises benefits to present and future generations while taking an active role in your own health care. Many protections are in place for the research volunteer, by Doylestown Hospital, the sponsoring company, and at the Federal level. Your safety is paramount, and you should understand, and be comfortable, with your role in the research study.

Patient participation in research is completely voluntary and may be discontinued at any time. Eligible patients are never included without full disclosure and voluntary approval. If you choose not to participate or if you leave the study before its completion, you will **not** be penalized or lose any benefits to which you are otherwise entitled. This information should be made available to you in clearly written and understandable form. It is important that you ask any questions you may have by contacting the Medical Research Department at 215-345-2119.

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## What is “Informed Consent”?

Informed Consent is the process of learning the key facts about a clinical trial before deciding whether or not to participate. It is also a continuing process throughout the study to provide information to participants. To help someone decide whether or not to participate, the doctors and nurses involved in the trial explain the details of the study. If the participants' native language is not English, translation assistance can be provided. Then, the research team provides an [informed consent document](#) that includes details about the study and key contacts. Risks and benefits are also explained in the informed consent document. The participant then decides whether or not to sign the document.

**Informed consent is not a contract, and the participant may withdraw from the trial at any time.**

**The following questions might be helpful for the participant to discuss with the Medical Research health care team. Many of the answers to these questions are found in the Informed Consent Document.**

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

National Institute of Health 2006

***The clinical research process could not be conducted if not for the participation of people like you.***



Research & Clinical Trials

**Doylestown Hospital  
Institutional Review Board**  
*Protecting Human Subjects in Research*

Institution Review Boards are established to ensure the rights and welfare of people who choose to participate in clinical trials both before and during their trial participation. The primary function of an IRB is to guarantee adherence to all federal, state, local, and institutional regulations concerning the protection of all human subjects when testing investigational drugs or medical devices. These impartial review panels assess the risks and benefits of each study trial to minimize and fairly disclose risk to study participants.

The Doylestown Hospital IRB is free standing. That is, it is not regulated by any other group within the hospital. The Institutional Review Board of Doylestown Hospital is comprised of members from both scientific and non-scientific backgrounds. Membership consists of staff physicians in various areas of expertise, risk management specialists, and representatives of the local Doylestown community. Priority is placed on a membership of diversity to best serve the interests and safety of all study participants.

Doylestown Hospital and its IRB are committed to being a foremost clinical research center where standards of care are elevated both now and in the future!

**If you are interested in being considered for membership on this committee, please contact the Risk Management IRB Office at 215-345-2060.**