

Research Participant Information Sheet

The University of Pittsburgh Institutional Review Board (IRB) is dedicated to protecting the rights and welfare of those who take part in research studies. You are being invited to participate in a research study. Before you agree to be in a research study, you should understand all of the information presented in the attached consent form. If you do not understand the language or any word used in the study consent form, you can ask any member of the research staff to explain it to you.

Before agreeing to be in the study, you should understand that taking part in this study is your choice. You do not have to take part in this study. Before you make your decision, you should fully understand why the study is being done and how you may be affected if you participate. You should be given enough information to be able to answer the following questions as well as any additional questions that you may have:

- Why is this study being performed?
- What do I have to do if I participate in this study?
- If I take part in this study can I be harmed in anyway?
- Will the study help me in any way?
- Are there any other treatment options available for me?
- Who will know that I am in the study?
- How many other people are participating in this study?
- Who is paying for this study?
- Will I be paid for participating in this study?
- Who will make money from the results of this study?
- Will I be told the results of the study?
- If I am pregnant, can participating in this study harm my unborn baby?

After you have read the informed consent document and had all your questions answered, you can then decide whether or not you want to participate. If you decide that you would like to participate, then you must sign the informed consent document describing this study. You should be given a copy of the consent form that is yours to keep. In addition you should be given the name and phone number of a person from the research staff that you can contact at any time.

Before making your decision to participate, you should feel free to discuss your participation in this study with your family and your primary doctor. If your doctor is part of this research study, you may discuss your care with another doctor who is not part of this research study.

You may withdraw from the study at any time. Refusing to take part in the study or leaving the study will not harm your relations with your doctors or with the University of Pittsburgh Medical Center or the University of Pittsburgh.

The attached consent form contains detailed information about the study. However, it is not meant to replace the discussion that should occur between you and the research staff. Informed consent is an ongoing process. You are encouraged to ask as many questions as necessary before, during and after taking part in any research study.

The University of Pittsburgh IRB wants to ensure that the rights and welfare of research participants are protected. If you have any questions regarding your rights as a research participant, please contact the Human Subject Protection Advocate of the University of Pittsburgh IRB at 1-866-212-2668.