

University of Illinois at Chicago
Consent/Authorization for Participation in Research
Protocol Title: Study of Bicycle Seat Effects on Male
Perineal Blood Flow

Principal Investigator: Craig Niederberger, M.D.
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STARTS APPROVAL EXPIRES

JUL 04 2008 TO JUL 03 2009

UNIVERSITY OF ILLINOIS AT CHICAGO
INSTITUTIONAL REVIEW BOARD

You are being asked to be a subject in a research study. The study will involve 2 steps to measure bicycle seat effects on blood flow to a man's perineum. The perineum is the region behind a man's scrotum, which is in contact with seats when a man sits down. Before you decide whether to participate, you should know what the study is about, the possible risks and benefits, and what you will have to do in this study.

Your participation in this study is voluntary. Your decision whether or not to participate will not affect your current or future relationship with the University. If you decide to participate, you are free to withdraw at any time without affecting that relationship. Please read this form and ask any questions you may have; if you decide to take part in the study, you will be asked to sign this form to verify that choice.

Who is doing the research, and why is it being done?

The research is being conducted by Dr. Craig Niederberger in the Department of Urology at the University of Illinois at Chicago (UIC). The purpose of the study is to determine if bicycle seats affect blood flow to the perineum. Bicycle riding places perineal pressure which in turn affects perineal blood flow which can potentially affect a man's ability to have an erection. Bicycle seat use has never adequately been tested for its effect on perineal blood flow. Each year, newer and "better" seats are released but what the true benefit to the rider has not been properly explained. The purpose of this study is to see if perineal blood flow can be adequately measured and what is the effect of a bicycle seat on this blood flow.

What procedures are involved?

There are 2 steps to determine perineal blood flow and how bicycle seats affect this flow. The first step will be to use doppler ultrasound to measure the perineal blood flow in the Ultrasound suite of University Illinois Chicago Medical Center. Ultrasound uses sound waves, which the patient cannot hear, to measure blood flow. At this ultrasound visit, patients will be asked to lie down on their back, with their legs in a frog-leg position on an exam table. This will allow access to the perineum. An ultrasound probe will be used to measure the flow through the perineal/cavernosal arteries which run through the perineum and ultimately supply blood for erections. By applying increasing pressure, the occlusion pressure will be measured along with blood flow at various applied perineal pressures. Also, we will stop the procedure if you feel any discomfort, although we do not anticipate any. This first study visit will take 30 minutes to complete.

The second step will involve a typical bicycle ride using the subjects own bicycle where perineal pressures will be measured. The investigators will not ride along side the subject. We use disposable sensors and a clear adhesive tape (tegaderm) to attach the sensors to the perineum. No shaving of the perineum will be required. The recording device is credit card size and will attach to the bicycle. The ride will take 30 minutes and will be on the Lake Shore Drive bike path where there is no rugged terrain and no extremes in altitude. The second study visit will take 45 minutes to complete. This will conclude your requirements.

What about the potential risks and discomforts, and benefits from this study?

There are minimal risks to you during participation in this study.

At no point will your medical record be accessed but there is a minimal risk of loss of confidentiality with regards to your name, date of birth, and contact info. This information will be placed on a password-protected computer, accessible only by Dr. Niederberger and the research staff, but there is a possible loss of confidentiality since absolute confidentiality cannot be guaranteed.

There is also the risk of riding a bicycle which has low probability of risk as you are an experienced rider. These potential risks involve, potential falls/accidents, weather related accidents (where the ride will be stopped). Should any trauma occur, we will stop the ride and you will receive medical attention immediately.

There is minimal risk related to the transducers, as they are insulated, have no electrical current in them, are tiny and pose no health risk to the subject.

You will not directly benefit by participating in this study, but others in the future may benefit from what we learn.

Will you be paid for your participation in this research?

There will be no compensation for your participation.

What about privacy and confidentiality?

Researchers will store information gathered about you on a password protected computer. Care will be taken to keep this information confidential, but there is a possible loss of confidentiality since absolute confidentiality cannot be guaranteed. You should know that in any research publications and scientific meetings coming from the research, you will not be identified individually.

There are University, state and federal agencies and officials who ensure the protection of human subjects in research, and they might access your research records in line with their official duties or as required by law.

Who should you contact if you have questions?

The researcher conducting this study is Dr. Craig Niederberger. You may ask any questions you have now. If you have questions later, you may contact the researcher at: 312-996-2779

What are your rights as a research subject?

If you feel you have not been treated according to the descriptions in this form, or you have any questions about your rights as a research subject, you may call the Office for the Protection of Research Subjects (OPRS) at 312-996-1711 (local) or 1-866-789-6215 (toil-free) or e-mail OPRS at uicirb@uic.edu.

Signature of Subject

You have read (or someone has read to you) the above information. You have discussed the procedures, risks and benefits of the study with the researchers. You have been given an opportunity to ask questions and your questions have been answered to your satisfaction. You agree to participate in this research. You will be given a copy of this signed form for your information and to keep for your records. The original copy will be stored in the research file.

Signature

Date

Printed Name

I have discussed the above research study, including the purpose, procedures, risks, and benefits, with the subject. I encouraged questions and answered all questions that were asked. The subject is aware that he/she does not have to participate in the research and may later withdraw their Authorization.

Signature of Person obtaining consent

Date
(Same as Subject's)

Printed Name