Information & Consent Form
The BICE Study – Bicyclists' Injuries and the Cycling Environment

Study Personnel

Hospital Principal Investigator St. Michael's Hospital	Dr. Michael Cusimano, MD, Neurosurgery		416 864-6048
Toronto Study Coordinator University of Toronto	Lee Vernich	416 978.2966	lee.vernich@utoronto.ca
Study Principal Investigator University of British Columbia	Dr. Kay Teschke, PhD	604 822-2041	kay.teschke@ubc.ca

You are welcome to contact any of the above study personnel between 9 am and 5 pm EST (Toronto personnel), and between noon and 8 pm EST (Vancouver personnel).

Who is funding this study?

The Heart and Stroke Foundation of Canada & the Canadian Institutes of Health Research fund this study.

What is a Consent Form?

The purpose of a consent form is to give you information to help you decide whether or not to participate in a research study. Before agreeing to participate, it is important that you read and understand this consent form. It provides all the information we think you will need to decide whether or not you wish to participate in the study. If you have any questions after you read this form, please feel free to ask the study doctors or study personnel. You should not sign this form until you are sure you understand everything on it. You may also wish to discuss your participation in this study with your family doctor, a family member or close friend.

What is the purpose of this study?

We are asking you to participate in this study because you were injured while bicycling. We are studying 600 injured cyclists in Vancouver and Toronto to improve our understanding of which types of cycling routes are safest, with the aim of preventing cycling injuries in the future. This study is part of a program of research, called "Cycling in Cities". The website for the research program is www.cher.ubc.ca/cyclingincities. Information about the BICE Study can be found on the home page and on the "Injuries" page.

What are the study procedures?

To conduct this research, we will interview you about the route on which you sustained your injuries, the trip conditions, your bike and clothing, your cycling and driving experience, recent sleep, alcohol, medication or drug use, and some statistical information about you. You are free to decline to answer any question.

The interview will take less than an hour. It will be conducted at a time and place that is convenient to you. For example, you can choose to be interviewed at home, at the hospital or a nearby health unit, or at the University. We will not need your involvement after the interview.

After the interview, a research assistant will visit the site where you were injured and two other randomly selected sites on your route for that trip, to record information about the route characteristics. The focus of the study analysis is to compare the characteristics of the injury site to those of the other locations, to determine which characteristics are associated with increased or decreased risk of injury.

What are the potential harms?

This study involves an interview, which might be difficult if you are still suffering the effects of your injury. In the case that you feel emotionally distraught, you may stop the interview at any time. You can also be referred to cycling and cycling injury support groups if you would like. Additionally, the St. Michael's Hospital principal investigator is a physician and can make referrals to an appropriate health care practitioner if needed.

Another risk is that study information about you will be released. No system for protecting your confidentiality can be completely secure; however, this risk is extremely small. To protect your confidentiality, your interview and the observations of the sites along your route will be assigned an ID number. Our records of your name, address, and telephone number will not include this ID number, and will be stored separately from your interview and site observations. This system is designed to minimize the chance that information, such as the safety of your bike or any potential impairment from sleep deprivation, drug or alcohol use, will be sought or disclosed in any legal or insurance proceedings in which you may be involved. Please feel free to ask about this, if it is a concern to you. We can help clarify any risks.

What are the potential benefits?

There is no direct benefit to you for your participation in this study. There is no financial compensation. However, we hope the results of this study will provide information about how to make cycling routes safe. This may lead to improved cycling route design in the future.

Who will have access to the data?

All the measurements, observations and questionnaires will be kelp confidential. They will be coded with a number, not your name. We will keep a record of the number we assign to you, but will not release that record to anyone else. No one other than the study researchers and research assistants will have access to information about you, unless required by law. All information that identifies you will be kept in a password-protected electronic file on a secure university computer. All published reports or conference presentations will include only aggregate data and will not include your name or other identifying information. We expect to publish and present the results in 2011.

Is your participation voluntary?

Yes. You may choose not to be in this study or to participate in part of the study. You may withdraw from the study at any time, without penalty – just let one of the study personnel know. Participation in this study is not associated with treatment of your injuries, and declining to participate will not affect any further treatment you require.

How has this studied been reviewed?

The study procedures and consent form have been reviewed by the Research Ethics Boards at St. Michael's Hospital under the expedited review process and at the Universities of Toronto and British Columbia under the minimal risk review process. The members of the Board include scientists, medical staff, lawyers, ethicists, and community members. They consider the potential harms and benefits of the research to you and to society. The Board may review study procedures, and to do so, may contact you.

Who can you call?

If you have any questions or concerns about this study, please call or email one of the people listed on the front page of this consent form. If you have any questions about your rights or treatment as a research participant, you may contact the Chair of the Research Ethics Board, Dr. Julie Spence, at 416 864-6060 ext 2557, during business hours.

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Consent to participate:

This study has been explained to me. I have had a chance to ask questions and I have had enough time to make a decision about participation. I know I can ask the researchers later on if I have questions about the research or about my rights as described above. I understand that I can withdraw from this study at any time and that this study will not provide any direct benefits to me. I will receive a copy of this signed consent form for my records. **By signing this consent form, I voluntarily agree to take part in this study and authorize access by study personnel to the following information collected by the St. Michael's Emergency Department: my name, address, phone number, birth date, sex, whether I was transported to the hospital by ambulance, whether I was admitted to hospital, and the CTAS (Canadian Emergency Department Triage and Acuity Scale) number assigned to my injuries.**

☐ I would like to be informed of the results of this study.

Participant Name _____ Participant Signature _____ Date _____

I confirm that I have explained the study to _____ and have supplied him/her with a signed and dated copy of the consent form.

Name of Interviewer _____ Interviewer Signature _____ Date _____