MOUNT SINAI HOSPITAL
Joseph and Wolf Lebovic Health Complex

CONSENT FORM (for parents/guardians)

Title of Project: **North American Wilms Tumor Study**

Investigators: Rayjean J. Hung, Ph.D., M.S. (1-416-586-4750)
Paul E. Grundy, M.D.

Funding Source: The funding of this research is from the Ontario Ministry of Health and Long-term Care, March of Dimes Foundation, Cancer Care Ontario, and the International Agency of Research on Cancer.

INTRODUCTION

You are being asked to participate in a research study. Please read this explanation about the study and its risks and benefits before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study doctor or study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish. Participation in this study is voluntary.

BACKGROUND AND PURPOSE

While we know that genetic and environmental factors have a role in cancer development, there is still very little known about the causes of cancer in infants and children. The purpose of this study is to obtain health and lifestyle information about healthy children who do not have cancer and their parents, and to compare this to information from children with cancer in order to identify the risk factors for childhood cancer. Although cancer in children is rare, research on childhood cancer could have an impact on the years and quality of life of affected children. This research study is being conducted by the Samuel Lunenfeld Research Institute of Mount Sinai Hospital, the Hospital for Sick Children and the International Agency for Research on Cancer, a research institute of the World Health Organization. The overall goal of this research is to find possible causes, including genetic or environmental factors and medical conditions that may increase the risk of Wilms tumor. Wilms tumor is a type of cancer in the kidney that occurs in very young children. By possible causes, we mean things in the environment, genetics, or certain medical conditions that may be related to the development of embryonal tumors.

Your participation would involve a telephone interview (with each parent/guardian separately). A total of 2200 families will be included in this research internationally. About 840 will come from North America.

STUDY VISITS AND PROCEDURES

If you decide to allow your child to participate in this study the following will occur:

1) An interviewer will administer a questionnaire to each parent/guardian on the phone at a time of their choice. The interviews will take about 1.5 hours each and they consist of questions related to lifestyle, environment and health history.
2) If you are willing to donate a saliva sample of your child, we will ask you to obtain some saliva sample of your child by following instructions on a self collection kit. If your child is too young to spit into the collection kit, you will follow the assisted procedure by using a small sponge or a soft bristle to brush from your child's mouth and placed into a small cup.
3) Any information obtained will only be used for the purposes of this study. Information which may identify you or your child will be destroyed within 5 years after the study is complete.

BIOLOGICAL SAMPLE ANALYSIS

The saliva samples from your child will be shipped to a laboratory at Mount Sinai Hospital for storage and analysis. These samples will be used for biochemical and genetic analysis in this study, and they will be tested for genetic and molecular characteristics that may be related to developing cancer or protecting against it. Any material not immediately used will continue to be stored to be used in the future to help scientists learn more about environment, genetic changes and health. By agreeing to participate in the biological sampling component of this study, you are granting consent now for future uses of these samples that relate to the purposes of this study. None of these samples will be tested for illegal drugs. All results will remain anonymous.

NOTIFICATION, COST AND COMPENSATION

The findings of the study will also be available to the public through publications in scientific journals. There will be no cost to you for participating in this study, other than your time. If you initially decide to give permission to have biologic samples stored for future research purposes, but later change your mind, whatever remains of your biologic samples will then be destroyed.

POTENTIAL DISCOMFORT AND RISK

During the saliva collection, your child may feel uneasy or bothered. No other physical discomfort is foreseen from the saliva collection.

POTENTIAL BENEFITS

You (your child) will not benefit directly from participating in this study. However, information learned from this study may help other children diagnosed with cancer and help to prevent the development of cancer in the future. Your participation is very important to the success of this scientific research**.**

ASSURANCE OF CONFIDENTIALITY

If you agree to join this study, the study doctor and his/her study team will look at your (or your child's) personal health information and collect only the information they need for the study. Personal health information is any information that could be used to identify you and includes your (your child's):

- name,
- address,
- date of birth,
- new or existing medical records, that includes types, dates and results of medical tests or procedures.

The information that is collected for the study will be kept in a locked and secure area by the study doctor for 5 years after the end of the study and last publication. Only the study team or the people or groups listed below will be allowed to look at your records.

The following people may come to the hospital to look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study followed proper laws and guidelines:

- Mount Sinai Hospital Research Ethics Board,

All information collected during this study, including your and your child's personal health information, will be kept confidential and will not be shared with anyone outside the study unless required by law. For example, the law could make us give information about you if a child has been abused or if the court orders us to give them the study papers. Any information about you or your child that is sent out of the hospital will have a code and will not show your name or address, or any information that directly identifies you or your child. You or your child will not be named in any reports, publications, or presentations that may come from this study.

If you decide to leave the study, the information about you and your child that was collected before you left the study will still be used. No new information will be collected without your permission.

REIMBURSEMENT

To thank you for your time and participation, you will be provided with a $25 USD gift card at the completion of the study.

VOLUNTARY PARTICIPATION

You and your child's participation in this study are voluntary. You may decide not to be in this study, or to be in the study now and then change your mind later. If your child is able to provide assent to participate, this will also be required from him/her. You and your child may leave the study at any time without affecting your care with your doctor. You may refuse to answer any question you do not want to answer.

We will give you new information that is learned during the study that might affect your decision to stay in the study.

IN CASE YOU ARE HARMED IN THE STUDY

As this is an observational study, it is very unlikely that there will be any harm or injury caused by study participation. However, as a standard policy, if you (your child) become ill, injured or harmed as a result of taking part in this study, you (your child) will receive care. The reasonable costs of such care will be covered for any injury, illness or harm that is directly a result of being in this study. In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities. You do not give up any of your legal rights by signing this consent form.

QUESTIONS ABOUT THE STUDY

If you have any questions, concerns or would like to speak to the study team for any reason, please contact the Research Assistant, Laura Adams at 416 586-4800 x8118 or adams@lunenfeld.ca or the Principal Investigator, Dr. Rayjean Hung at Rayjean.Hung@lunenfeld.ca.

If you have any questions about your rights as a research participant or have concerns about this study, call Ronald Heslegrave, Ph.D., Chair of the Mount Sinai Hospital Research Ethics Board (REB) or the Research Ethics office number at 1-416-586-4875. The REB is a group of people who oversee the ethical conduct of research studies. These people are not part of the study team. Everything that you discuss will be kept confidential.

CONFLICT OF INTEREST

The investigator for the study, Dr. Rayjean Hung, and the research team members have no conflicts of interest to declare.

CONSENT AND SIGNATURES

	Please initial boxes Yes	No
1. I agree that a saliva sample may be taken from my child. I understand that I will not be given the results of the saliva sample.		
2. I give permission to the research staff working on this project to contact me if questions arise, such as clarification of survey responses or additional biosamples are required. If yes, please provide daytime telephone number or e-mail address: _____.		
3. I am willing to be contacted for future research projects.		

Please provide the best phone number to reach you with: (____)_____ **AND/OR**

An email address as an alternate means of getting a hold of you:
_____

This study has been explained to me and any questions I had have been answered.
I know that I may leave the study at any time. I agree to take part in this study.

Print Study Participant's Name	Signature	Date

(You will be given a signed copy of this consent form)

My signature means that I have explained the study to the participant named above. I have answered all questions.

Print Name of Person Obtaining Consent	Signature	Date

Was the participant assisted during the consent process? ☐ **YES** ☐ **NO**

If **YES**, please check the relevant box and complete the signature space below:

☐ The person signing below acted as a translator for the participant during the consent process and attests that the study as set out in this form was accurately translated and has had any questions answered.

Print Name of Translator	Signature	Date

Relationship to Participant	Language

☐ The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to, and has had any questions answered.

Print Name of Witness	Signature	Date

Relationship to Participant